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Guidelines for Authors

THE PHILIPPINE JOURNAL OF OTOLARYNGOLOGY HEAD AND NECK SURGERY

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Abstract:
A 5-10 sentences abstract to precede article in case reports or a structured abstract that states the objectives, study design, setting, results and conclusions.

All manuscripts and other editorial matter should be addressed to Charlotte M. Chiong, MD, Editor-in-chief. The Philippine Journal of Otolaryngology-Head and Neck Surgery, PSO-HNS, 25th Floor, Medical Plaza Ortigas Condo, Ortigas, Pasig City

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EDITORIAL

STRESS & SANITY: SUPERMAN'S SECRET TO A SUCCESSFUL LIFE

As our predecessors used to say, life used to be quite simple and easy. There was much available land to till and cultivate, build your house in, trees to climb, and frontiers to conquer. There was food readily at hand and no need to buy most of what people required. (There were not much of them either then). Relaxation was forever assured and taken for granted and never sought nor fought for. Time was simply there in order for everything not to occur at the same time. Simply put, just a half century or so ago, people lived in a supposedly wonderful era and they had the luxury of time. As Gladys Knight sang, "Life was oh so simple then".

But times are no longer what they used to be nor has "time rewritten every line" Time has now become a luxury for the modern man. As people have progressed, so did the demands of modern life. They have to contend with all the hallmarks of life. There were no computers, cellphones, or even calculators then. Microwave ovens were unheard of but refrigerators were starting to make their appearance as a convenience but not as a necessity yet.

A decade or so ago, the Japanese discovered karoshi and people began falling dead even in the workplace. Karoshi is also known by some other terms like salaryman's disease, or the stress syndrome. The stress of everyday life combined with that posed by the economic realities of retrenchment, downsizing, job conversion to contractuals, or outright unemployment have of late placed the modern men into a very tight situation. Recent studies have shown that these economic realities per se have caused a significant increase in the death rate from heart attack or stroke. After all, man's reaction to stress, in whatever form, has always been either to fight or fly enabling him to be able to scale mountains, jump over fences and perform extraordinary feats ala Superman. But that is also the way that the body reacts to everyday causes of stress like noise, deadlines, heavy workloads etcetera. In short, life has turned against the modern man despite the presence of many user-friendly modern conveniences and a normal coping mechanism has turned deleterious against that very same body.

These very same stressors have also created havoc to the modern mind. Illegal drugs had allowed a means of escape from the rigors and realities of life. (And it is quite a thriving business worldwide). Flights of fancy have been as common a reaction to stress as the flight caused by the so-called adrenaline rush. With the increasing inability to cope would come anxiety, frustration, desperation and depression, the very things that brings into question the very sanity of the individual.

Is there a secret that will enable a person the capacity to cope with the worries of everyday life? Can we be like Superman and have the capacity to stop and even reverse the passage of time? What can we do to successfully hurdle the vagaries of life as we know it today? Fortunately for us, modern medicine has decided to step outside of its box and approach the problem in a holistic manner and include non-traditional ways of overcoming karoshi. It seems that a convergence of factors and practices have come to pass in order to give the modern man the necessary armamentarium to successfully handle stress and preserve one's sanity. In effect, it makes a superman out of each and every individual to be able to live in the supposedly modern times that we are in now.

A person can better cope with stress through what is called as the "relaxation response", a state of mental calm and characterized by a drop in blood pressure, slower pulse and respiratory rate and muscles become less tense. Studies have documented that this results in better grades, work habits and cooperation among those who have learned this practice. This can be elicited by three simple practices namely meditation, paced respiration and repetitive activities. On the other hand, mindfulness teaches people to step back from pain and the worries of life again with meditation as the keystone. Hypnosis, though much maligned in yesteryears, is actually a way of increasing one's control, of teaching people how to control aspects of their bodily functions and sensation. Even prayer is now being advocated in certain so-called scientific quarters as part of combination therapy to promote not only a healthy body but also a healthy mind especially in a diseased body. In plain terms, this had been fully amplified by Paul Simon before with the catch phrase "Slow down, You're moving too fast!"

Is this now what we call progress or forward movement in the management of the ever present stress? Or is this merely a recognition of the greater sensitivity of the past that not everything can be explained by science alone and that what is referred to as mysticism has in fact a scientific basis all along! If that is so can Superman be a human being after all?

JOSELITO C. JAMIR, MD
Editor-in-Chief (1991-1998)

ACKNOWLEDGEMENT

The editorial staff of the Philippine Journal of Otolaryngology-Head and Neck Surgery appreciates the full and unconditional support and assistance given by Mr. Marcus P.M. Wondergem and Solvay Pharma Philippines, Inc. without which this could not have been possible and Ms. Lruzel S. Carillo for facilitating everything.

PHILIPPINE SOCIETY OF OTOLARYNGOLOGY – HEAD AND NECK SURGERY CODE OF ETHICS

PREAMBLE

The following Statement of Principles and Code of Ethics express the principles of conduct that are considered appropriate and acceptable by the Philippine Society of Otolaryngology-Head and Neck Surgery (PSO-HNS). The statements and principles found herein are not laws, but rather guidelines for honorable and acceptable behavior. However, we believe that these ethical principles should be aspired to by all Fellows of the Society. They should serve to define and clarify areas where confusion might occur in the course of current Otolaryngology practice. Compliance to these principles should help Otolaryngologists to conduct themselves honorably and professionally toward their patients.

PRINCIPLES

1. The best welfare of the patient must be the foremost concern of the physician in all circumstances.
2. The patient must be treated with competence, respect, dignity and honesty. Confidences shall be kept except as required by law.
3. The physician must maintain proficiency and competence through continuing study and be diligent in the administration of patient care.
4. Fees must be commensurate with the service provided.
5. The impaired physician must withdraw from that part of the practice that is affected by the impairment.
6. Members should aid fellow members in adhering to these principles.

THE PHYSICIAN-PATIENT RELATIONSHIP

Each patient must be treated with respect, dignity, compassion, and honesty. The patient's right to participate in the treatment process must be recognized and promulgated by the otolaryngologist. The otolaryngologist shall be free to choose whom to serve, however discrimination against a patient on the basis of race, color, gender, age, sexual orientation, socioeconomic status, religion or national origin is not acceptable. Confidentiality of patient information is to be kept, within the constraints of the law and the duty to protect the interest of the individual and the community. The otolaryngologist is duty bound to establish and maintain correct relational boundaries, avoiding exploitation of patient vulnerability and specifically avoiding sexual misconduct with patients.

The otolaryngologist must disclose actual or potential conflicts of interest to patients, including but not limited to, fee arrangements and professionally related commercial interests. If a conflict of interest cannot be resolved, the otolaryngologist should withdraw from the relationship in a timely, appropriate manner. After having accepted a patient for care, the otolaryngologist may not neglect that patient.

COLLEAGUE INTERACTIONS

Colleagues interaction should be established on mutual respect and a desire to improve patient care. Otolaryngologists must know their own professional limitations and expertise. Consultation and referral must be sought when appropriate. Communication with colleagues must be truthful and straightforward. Disparagement in any form is to be discouraged.

COMMERCIAL INTERESTS

This Code of Ethics does not seek to limit legal trade practices. However, a physician's commercial or financial interests should never be put ahead of the interests and welfare of patients. Conflicts of interest weaken the trust and confidence that patients place in their physician. For this reason, physicians should work hard to avoid any business interest that poses a conflict of interest between personal financial concerns and the best interests of the patient. Conflicts that arise between a physician's financial interests and the physician's responsibilities to the patient should be resolved to the benefit of the patient.

REFERRAL PRACTICES

All decisions regarding patient referral should be founded primarily upon consideration of the needs and best welfare of the patient. A physician's referral practice should never give rise to exploitation of patients. Referral to a health facility in which a physician has a financial stake is not in itself unethical. However, such referrals are appropriate when the referring physician will be directly involved in providing care to the patient at the facility.

PRESCRIBING PRACTICES

The financial stake that the physician might have in the company supplying the product should not influence a physician in the prescribing of drugs, devices, appliances, or treatments. Neither should a physician's referral or admission patterns be intended so as to enhance the physician's financial interests in any health facility. Physicians should not accept gifts from industries that would influence their prescribing patterns or practices.

PATENTS

Physicians should be allowed and encouraged to innovate and patent devices, but the use of these devices must be in accordance with the patient's best medical interests, without regard to the physician's financial interests. Medical and surgical procedures contribute to a whole body of medical knowledge. Unlimited access to that knowledge is one of the defining attributes of the medical and surgical profession. Enforcing patent restrictions on medical and surgical procedures restricts access to medical knowledge, denies potential benefit to patients, and thus is unethical. Physicians should be permitted to charge a reasonable fee for instructional courses that describe and teach techniques and procedures to other physicians.

ADVERTISING

It is not unethical for Otolaryngologists to advertise their services. Advertisement must be truthful and not misleading. An Otolaryngologist should not misrepresent his/her qualifications and/or training, and should not exaggerate the effectiveness or the uniqueness of treatments rendered. Advertisements should also adhere to established legal requirements with regard to format and content.

RESEARCH

Otolaryngologists – Head & Neck Surgeons must conduct biomedical research based on ethical, moral, medical, and legal principles. All research should honor the dignity and sanctity of human life. The objective of research should be the advancement of mankind, the relief of suffering, and most importantly the improvement of medical practice. Research that knowingly and unnecessarily compromises the health, safety, or longevity of human subjects is unethical.

Biomedical research projects should be approved by institutional animal research boards or institutional ethics review board for human subjects when applicable. When possible, animal studies should precede the use of new and experimental techniques in humans. All human research subjects should be fully informed of the benefits and risks of the research being conducted and should give their informed consent prior to their participation subjects in any prospective trial. Further, any subject should be allowed to withdraw from a research protocol at any time without prejudice. Research study protocols should not be constructed in a manner such that the research subject would receive a treatment that knowingly provides less benefit than the currently accepted standard of care.

The patient's right to privacy must be observed. Communications to the public must not convey false, untrue, deceptive, or misleading information. In addition, these communications should not misrepresent a surgeon's credentials, training, experience, or ability. Otolaryngologists should seek to avoid conflicts of interest in research. When unavoidable, such conflicts should be publicly disclosed.
Credit should be accorded to all investigators who contribute in a material way to a project. Conversely, coauthorship should not be rendered to individuals who do not participate in the project.

CHARACTER ISSUES

Patients and society at large place a high level of confidence and trust in physicians. Physicians are regarded with the highest moral standards in the community. This level of trust is based on an supposition that the physician maintains a high degree of personal integrity and strictly observes a professional code of ethics. Physicians are required to be truthful and honest. Otolaryngologists should conduct themselves morally and ethically so as to earn the trust and respect placed in them. Anything that detracts from the ability of an Otolaryngologist to conduct himself or herself in such manner should be avoided. Otolaryngologists have the responsibility to call the attention of their colleagues in order that they can avoid or eliminate any behavior that is not conducive to maintaining personal integrity.

DISABILITY

Physician disability or impairment represents a potential danger to patients and to the affected physician. Otolaryngologists should make every effort to recognize the signs of physician impairment in themselves and in their colleagues. The Otolaryngologist who suspects impairment in a colleague has an

ethical responsibility to the impaired physician and his/her patients. Self-referral for appropriate treatment should be advised and encouraged. The physician should withdraw from any component of practice that adequate assessment deems impaired. Appropriate management, including counseling, should follow. Should a physician refuse to self-refer when presented with evidence of impairment, Otolaryngologists have a responsibility to report the physician concerned to their supervisor this society or Professional Regulations Commission (PRC), particularly if the impairment is a threat to safe patient care. Confidentiality should be observed for physicians undergoing evaluation and treatment for impairment. Physicians who have completed rehabilitation for impairment should not be restricted from practice provided that proper post-rehabilitation monitoring shows no evidence of relapse.

ILLEGAL ACTIVITY

Otolaryngologists should recognize that they are subject to all civil and criminal laws of the Philippines. They are further subject to rules and regulations vested in the PRC. Illegal activity by an otolaryngologist jeopardizes his or her own personal integrity, and deprecates the medical profession at large. Otolaryngologists who knowingly engage in illegal or fraudulent behavior should be reported to the appropriate local authorities.

FEES

Fees must be in accordance with the service(s) rendered. It is unethical for a physician to charge an illegal or exorbitant fee. Illegal fee arrangements include charges for services not provided, fee splitting in exchange for referrals, and repeated upcoding (i.e, submitting claims with higher codes than is appropriate for the services rendered). Fee collection efforts should take into consideration the ability of the patient to pay.

Physicians should not withhold vital and emergent treatment to a patient because of their inability to pay. Physicians should not abandon a patient in a post-operative period because of that patient's inability to pay.

COMMUNITY RELATIONS

Physicians have been conferred by society with trust and respect that no other profession can claim. Physicians in turn have a duty to their communities that goes far and above that of other commercial enterprises. This may involve participation in health education programs. It also may involve the physician assuming a protective role when the health and safety of a community is threatened. PSO-HNS members should refuse to cooperate in policies that violate the patient's interests and should become advocates for the sick whenever economics, organizations, or regulations threaten the good and welfare of our patients. Physicians may be enlisted to act in other roles as civic leaders within the community. Each physician must respond within the scope of his or her abilities. Activities that advance the health and well being of the community in a cost-effective way should be supported.

Otolaryngologists should not neglect the underprivileged segments of our society and should be encouraged to devote some time in caring for patients who are unable to pay.

Otolaryngologists should preserve to maintain their good reputation within the community, and should avoid activities that undermine the trust and high regard society places in them.

DISCIPLINARY ACTIONS

Otolaryngologists have an ethical duty to report colleagues first to the PSO-HNS through the ethics committee provided that documentary evidence exists of illegal activity and is submitted accordingly. The Philippine Society of Otolaryngology – Head and Neck Surgery will not act as an enforcement agency but as an educational vehicle regarding acceptable physician behavior.

IMPLEMENTING GUIDELINES: CODE OF ETHICS

Approved by the Execom under BR 04-03-01during the meeting held on March 9, 2004.

1. All members of the Society shall be subject to the provisions of this Code of Ethics.
2. Specific violation/s of the Code of Ethics may be filed with the PSO-HNS by any individual by filing verified and sworn statements with supporting documents.
3. The statements will be endorsed to the Ethics Committee and the Membership Committee which as a body shall conduct an investigation on the complaint.
4. Within a period of ten (10) calendar days from receipt of the complaint from the investigating panel, the member against whom the complaint was filed shall submit a written explanation and in the

event that no explanation was received, the member will be considered to have waived his right to due process.

5. All cases concerning ethical, moral, and criminal violations by the member being investigated by a private and/or government entity tasked to investigate such anomaly (i.e. Philippine Judicial Courts, Professional Regulations Commission, Philippine Medical Association, Philippine College of Surgeons and other Specialty Medical Organizations, etc.) may be investigated by the panel.
6. The findings and recommendations of the investigation panel will be submitted to the Board of Directors for ratification and implementation.
7. This Code of Ethics shall be published in the Journal of the Philippine Society of Otolaryngology–Head and Neck Surgery.
8. These Implementing Guidelines shall have the force of the Code until revoked or superseded by new guidelines.
9. The Code and its Implementing Guidelines shall take effect 15 days after its publication in the Philippine Journal of Otolaryngology-Head and Neck Surgery.

SANCTIONS

1. Violations of the provisions of the Code shall constitute unethical and unprofessional conduct and shall be grounds for reprimand, suspension or expulsion from the society as recommended by the Ethics Committee after due process and approved by the Board of Trustees.
2. Should the violation be sufficiently grievous, the Board of Trustees may, on the basis of the violation, endorse the case to the Professional Regulation Commission (PRC) for possible revocation of registration.

Prepared by: The Ethics Committee - PSO-HNS, Inc.

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Special recognition to: Ma. Fita P. Guzman, MD - Resource person

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THE ACCURACY AND VALIDITY OF THE HAND HELD METAL DETECTOR IN LOCALIZING INGESTED COINS IN THE ESOPHAGUS*

MARIA MINNIE U. YAO, MD**
GIL M. VICENTE, MD, FPSO-HNS***
ANTONIO H. CHUA, MD, FPSO-HNS***

ABSTRACT

GENERAL OBJECTIVE: To demonstrate the reliability of hand held metal detectors (HHMD) in confirming the presence of ingested coins in the esophagus.

SPECIFIC OBJECTIVES:

1. To determine the accuracy of hand held metal detectors as compared to chest radiographs (CXR) in localizing ingested coins in the esophagus.
2. To determine the sensitivity, specificity and positive predictive value of HHMDs using intraoperative esophagoscopic findings as the gold standard.

STUDY DESIGN: Cross-Sectional Study

SETTING: Tertiary Government Hospital

PATIENTS AND METHODS: In the first phase of the study, patients with history of coin ingestion were scanned with a HHMD at the emergency room and later confirmed by CXR. The accuracy rate was then determined. In the second phase of the study, the patients were scanned with a HHMD just prior to esophagoscopy. Sensitivity, specificity and positive predictive values were then determined.

RESULTS:There were 59 patients in the first phase of the study comparing the findings of HHMD with that of CXR. The accuracy rate was 96.6%, the sensitivity was 100% and specificity was 90.5%, the positive and negative predictive values were 95% and 100% respectively. Thirty-eight patients eventually were admitted at the ENT-HNS ward (21 patients were transferred to Surgery Department due to the passage of the coin beyond the esophagus). In the second phase, only 15 out of the admitted 38 patients were scanned with HHMD prior to esophagoscopy. The sensitivity, and positive predictive value was found to be 100% and 93.3% respectively.

CONCLUSION: Hand held metal detector scanning is an accurate, portable, radiation-free screening tool that may be used to localize the position of ingested coins prior to esophagoscopy in lieu of repeat radiographs.

INTRODUCTION

Foreign body ingestion accounts for a significant number of emergency room visits.[1-13] Although exact figures are unavailable, nearly 75,000 ingestions by patients 19 years and younger were reported to 67 American Poison Control Centers in 1996.[14] In the 10 year study made by a tertiary government hospital, there were 632 patients admitted due to foreign body ingestion[9]. Four hundred forty(93%) patients had coin ingestion[9]. In foreign literature, the most commonly ingested foreign bodies among pediatric groups were also coins.[1-8] Since clinical signs and symptoms are unreliable predictors of foreign body impaction, a routine radiographic evaluation is recommended to localize the ingested metallic objects.[2,4] Radiographs are necessary in all patients with history of foreign body ingestion.[3,4] The initial radiographic studies yield valuable information: presence or absence of a radiopaque foreign body; presence of multiple foreign bodies; size, shape, orientation of the foreign body ; and mediastinal or thoracic

*First Place, PSO-HNS Analytical Research Contest, 47th PSO-HNS Annual Convention, December 1, 2003, Westin Philippine Plaza Hotel, Manila

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complication resulting from esophageal perforation.[3]

Most of the coins can pass uneventfully towards the stomach and eventually pass out with the stools. However some coins can impact into the esophagus and warrant an emergency procedure to prevent the onset of complications such as esophageal ulceration and perforation, tracheoesophageal fistula, tracheal compression and aortoesophageal fistula formation.[2,5,6,7,8] However according to Dee et al,[4] and Binder[15], round metallic objects cause little or no damage once below the gastroesophageal junction. Coins in the esophagus can be observed for up to 12 - 24 hours to allow for spontaneous passage before removal is attempted.[3,4,15] Hodge et al[4] reported that 40% of his patients with confirmed esophageal foreign bodies passed spontaneously after 1 to 5 hours, Schunk et al[19] reported that 6 out of 9 asymptomatic and 2 out of 21 symptomatic patients passed spontaneously towards the stomach in 4 hours.

Previous studies have shown HHMDs to be accurate screening tools for patients with suspected metallic foreign bodies. Use of HHMD for following the progression of coins through the gastrointestinal tract was first described by Lewis in 1980.[20] Kessler in 1990, reported a case in which HHMD accurately localized an esophageal razor blade that went undetected by plain films and fluoroscopic swallow. Arena and Baker[21] recorded no false positive or false negative results when HHMD was compared to plain radiographs as a gold standard. Sacchetti et al reported 94% sensitivity and 100% specificity in detecting 15 out of 16 radiopaque foreign bodies (11 coins, a button battery, a medallion, a token and leaded glass marble). The undetected foreign body was a sewing needle barely perceptible on plain radiograph. Ros and Cetta[12] studied the use of HHMDs in localizing ingested coins using simulated scans of metallic foreign bodies through soft tissues. Distance between scanner and foreign body were taken from measurements from the anterior chest to gastroesophageal junction on computed tomographic images. Authors reported accuracy of 100% in 40 positive cases and 10 negative cases at distances of 6.1 to 7.9 cms (2.4" –3.1"). In a subsequent clinical study, they[1] reported sensitivity of 91 % and specificity of 100% in 14 children. The sole failure of Garrett scan was noted in one patient with foreign body in the rectum in whom management was not likely to be affected. In the study of Seikel,[2] the 3 experienced investigators demonstrated sensitivity of 100%, specificity of 92.4%, positive predictive value(PPV) of 90.0%, negative predictive value(NPV) 100%. The inexperienced investigators demonstrated sensitivity of 95.7% specificity of 81% PPV of 77% and NPV of 96.6%. Using Mc Nemar test demonstrated no significant difference between experienced and inexperienced hands but they feel it is of clinical relevance that inexperienced investigators performed 3 false negative scans.[2]

OBJECTIVES

This paper aims to demonstrate the reliability of hand held metal detectors (HHMD) in confirming the presence of ingested coins in the esophagus.

Specifically, it aims:

1. To determine the accuracy of hand held metal detectors as compared to chest radiographs (CXR) in localizing ingested coins in the esophagus.
2. To determine the sensitivity, specificity and positive and negative predictive values of HHMDs using intraoperative esophagoscopic findings as the gold standard.

MATERIALS AND METHODS

The Super Scanner Garrett (Figure 1) measures 15.5" (L) x2.6" (W) x1.25" (H). It detects medium sized pistols from a distance of 9" away on low sensitivity and 11" on high sensitivity. Large pocket knives can be detected from up to 6" away on low sensitivity and 8 "on high sensitivity. Razor blades , handcuff keys, foil wrapped drugs, tiny jewelry, hatpins and coins can be detected at 2" away on low sensitivity and 4 " on high sensitivity .[10] It has a large scanning surface about 360^0. This unit features a Reduced Sensitivity mode for scanning near rebar floors or if ambient metal causes interference. The housing is made of polycarbonate fiber reinforced materials.[10] It uses surface mount electronic component technology. A 9-volt alkaline or rechargeable battery powers it. On full use the battery can last up to 80 hours.[10]

Prior to the study, the authors tried to verify if the HHMD is sensitive enough to detect a coin by taping it at the back of a mannequin by an assistant. The mannequin was placed in a spacious area away from walls and fixtures. The investigators were blinded as to the location, presence or absence of the coin. The HHMD was slowly run down vertically from chin to subdiaphragmatic area and horizontally at the abdominal area. The HHMD sensitivity was switched to high or low by pressing the button at

the side of the appliance. A sensitivity rate of 100% and a specificity rate of 100% was noted.

Another experiment was done by the investigators to know the range of sensitivity of HHMD in coin detection. The assistant raised the coin in one hand, and the HHMD was placed near the coin. Once the audio and visual indicator was on, the distance between HHMD was measured anteriorly, posteriorly, superiorly and inferiorly. The

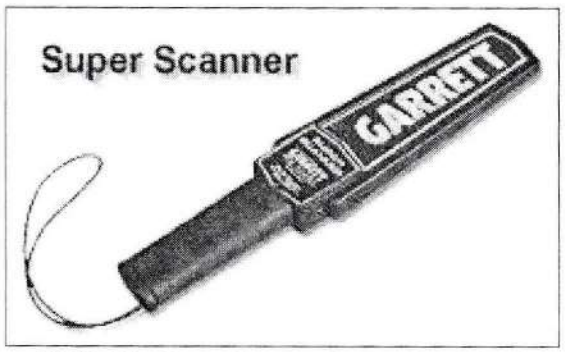

FIGURE 1. Super Scanner Garrett Hand Metal detector (Measures 15.5"L x2.6"W x1.25"H)

sensitivity from the coin to the HHMD anteriorly and posteriorly were both 3" on high sensitivity and 1" on low sensitivity. The superior and inferior distance of the coin to HHMD were both 0.5" on low sensitivity and 1.5 " on high sensitivity.

FIRST PHASE OF THE STUDY

From April 1, 2003 through October 1, 2003, patients with history of coin ingestion were seen at the emergency room of the Department of Otorhinolaryngology at a tertiary government hospital. Patients at the emergency room were subjected to thorough history and physical examination. Pertinent data included time of ingestion and symptomatology. Procedures were explained to the guardians and informed consent was secured. The HHMD was borrowed from the guard on duty. A Super Scanner Metal Detector (Garrett Security System Inc, Garland Texas) (Figure 1) was used to detect whether the foreign body was located in the cervical (inferior border of chin to clavicle), upper thoracic (from clavicle to the level of nipple), lower thoracic (from nipple area to xiphoid level), subdiaphragmatic (from xiphoid to epigastric level), abdominal (below epigastric area) (Figure 2). The distance of the HHMD should not be more than 2 inches above the skin. The sensitivity button can be pressed to reduce to range of area covered by the HHMD. All patients were positioned away from possible interfering objects such as beds, walls, and fixtures. Pockets were cleared of contents and clothes removed if it had metallic buttons or zippers. Patients were scanned vertically from under the chin to the xiphoid, then horizontally from xiphoid up to the pelvis. A positive scan was defined as a strong audio and light signal on the indicator of the metal detector (Figure 2).

All patients, after establishing the presence or absence and location of the suspected foreign body HHMD underwent a conventional radiographic study (chest X-ray posteroanterior or anteroposterior -lateral view).

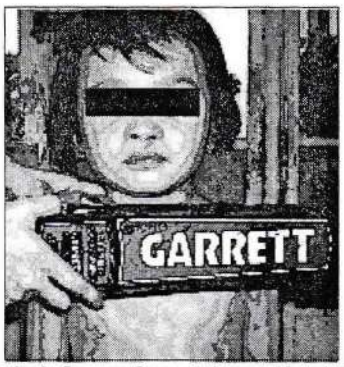

FIGURE 2. A Super Garrett Hand Metal Detector was used to screen patient with history of coin ingestion

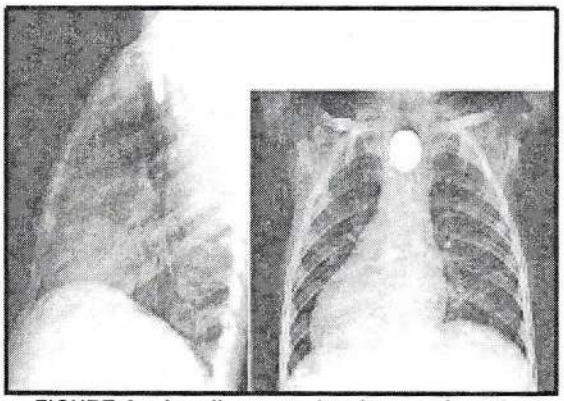

FIGURE 3. A radiopaque density noted on the esophagus in plain chest radiograph

Patients with disease (+ sign) were defined as metallic foreign body visualized in the esophagus on plain radiograph (Figure 2). Radiographs demonstrating the coin below the diaphragm or no foreign body (- sign) were considered free of disease.

The findings using HHMD and conventional radiographs were compared. Accuracy rate, sensitivity, specificity, positive and negative predictive values were determined.

SECOND PHASE OF THE STUDY

The second phase (diagram 2) of study, included patients admitted in the ward with foreign body in the esophagus as confirmed by radiographs. Patients were scanned with HHMD

few minutes prior to esophagoscopy (enroute to OR). The sensitivity of HHMD was further confirmed by intraoperative findings (gold standard).

RESULTS

A total of 86 patients were seen at the emergency room of the Department of Otorhinolaryngology for evaluation of suspected coin ingestion from April 1, 2003 to October 1, 2003. Patients at the emergency room were first screened with HHMD followed by a CXR. Twenty-seven patients were not scanned with HHMD due to unavailability of the gadget and thus were excluded from the study.

FIRST PHASE OF THE STUDY (DIAGRAM 1)

There were 59 patients enrolled in the initial phase of the study, forty-one were boys and 18 were girls, with an age range of 5 months to 9 years (median age 45 months). The average time from foreign body ingestion to time of consultation was 1 to 48 hours (average 9 hours). The following are locations of foreign body as detected by the HHMD: 31 cervical, 5 upper thoracic, 2 lower thoracic, 20 subdiaphragmatic area, 1 abdomen. (See Table 1). Radiographic studies were done and the findings were compared to that of HHMD (Table 1). Twenty-one patients were classified disease free by radiographs due to coins located below the subdiaphragmatic area. These patients were referred to Department of Surgery for further evaluation and management.

The difference between the findings of HHMD and radiographs were noted in a 6-month-old girl with the coin localized by HHMD at upper thoracic area but on radiograph the foreign body was noted at the C6-7 level. However, the findings were not significant since both were categorically still in the esophagus. There were 2 patients, a 5-month-old and a 7-month-old boy with coins which were localized by HHMD to be at lower thoracic level but on radiographs the coins were located below the subdiaphragmatic area. The accuracy rate in the first phase of study was 96.6%. The sensitivity was 100% and specificity was 90.5%, positive and negative predictive value were 95% and 100% respectively. (See Table II).

SECOND PHASE OF THE STUDY (DIAGRAM 2)

Out of the 59 patients seen at the emergency room, 38 patients were subsequently admitted due to presence of foreign body in the esophagus. Our subjects had an observed delay time of 3- 19 hours (average of 10 hours) in the ward prior to esophagoscopy. The reasons for delayed esophagoscopy varied from full stomach to competition for OR room and time. The HHMD was used to confirm the location of the coin few minutes prior to rigid esophagoscopy. On the course of scanning, coins in 8 patients were noted to be below the subdiaphragmatic level. Repeat radiographs were done to confirm the passage of coin to the stomach. The sensitivity and negative predictive value were both 100% and 93.3% respectively (Table IV). There were 15 patients excluded from the study due to the unavailability of HHMD prior to esophagoscopy. The 15 patients who were scanned preoperatively with HHMD underwent esophagoscopy. Out of the 15, one patient was positive for HHMD but no foreign body was noted on esophagoscopic finding. The patient was a 13-month-old male with initial findings of coin in the upper thoracic and T1-2 level on HHMD and radiograph respectively. Few minutes prior to OR, a repeat scan using a HHMD revealed positive signal on lower thoracic level however no foreign body was found intraoperatively. The sensitivity and positive predictive value were 100% and 93.3% respectively (Table III).

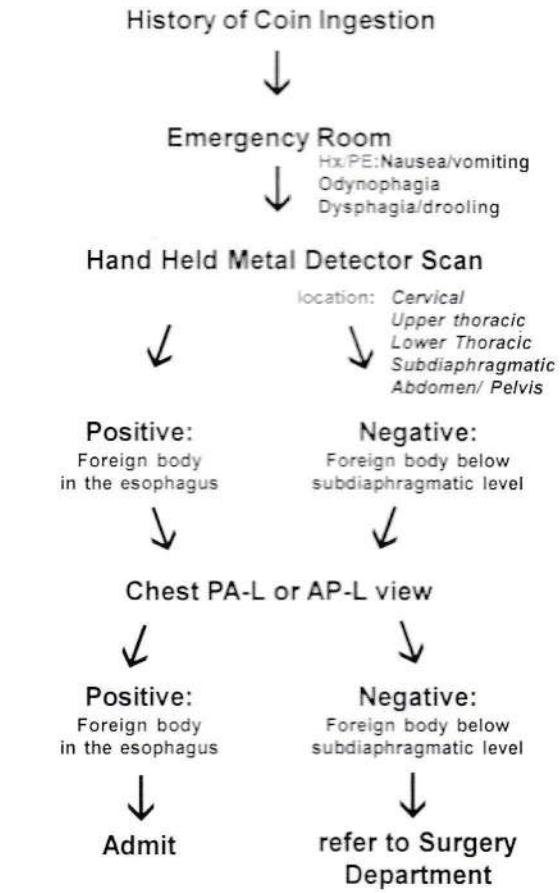

Diagram 1 : First Phase of the Study (Emergency Room)

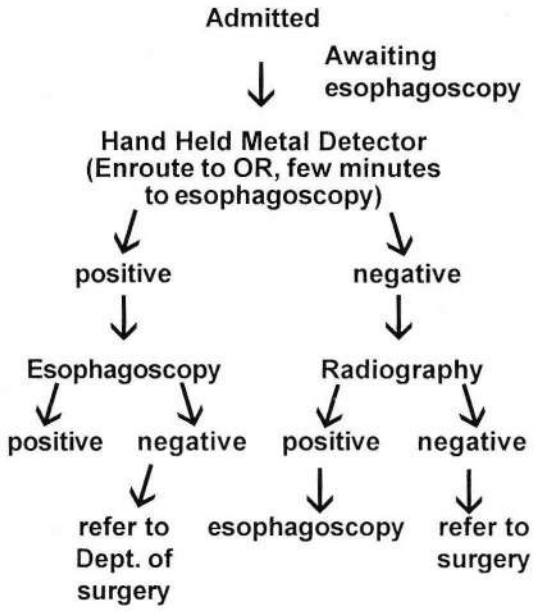

Diagram 2 : Second Phase of the Study (Ward)

TABLE 1. Location of Coin using Hand Held Metal Detector (HHMD) and Chest Radiographs(CXR)

LOCATION	HHMD	CXR
PA-L		
Cervical		
(below chin to clavicle)		
CXR: C5-C7	31	32
Upper Thoracic		
(clavicle to nipple area)		
CXR:T1-T4	5	4
Lower Thoracic		
(below nipple to below Xiphoid)		
CXR: T5-T7	4	2
Subdiaphragmatic		
(below xiphoid to epigastric level)		
CXR: area of stomach	18	20
Abdomen		
(below epigastric level)		
CXR: area of small and large intestines	1	1
Total	**59**	**59**

TABLE II. Comparison of Hand Held Metal Detector (HHMD) with Chest Radiograph (CXR) n=59

		CXR : +	CXR (-)	Total
HAND METAL DETECTOR	POSITIVE	a= Number of individual diseased and truly positive 38	b= Number of individuals disease free &revealed positive 2	40
	NEGATIVE	c= Number of individual diseased and negative 0	d= Number of individual disease free and revealed negative 19	19
TOTAL		38	21	59

Total no. of diseased
= a+c
= 38+0
= 38

Total no. of disease free
=b+d
=2+19
=21

ACCURARY = (a+d)/(a+b+c+d)
= (38+19)/(38+2+0+19)
= **96.6%**

Sensitivity =a/(a+c)
=38/38+0
=100%

Specificity =d/(b+d)
=19/(2+19)
=90.5%

Positive Predictive Value(+PV) = a/a+b
=38/38+2
=95%

NegativePredictive Value (-PV) =d/c+d
= 19/0+19
=100%

TABLE III. Comparison of Hand Held Medical Detector (HHMD) findings with Intraoperative esophagoscopic findings: n=15

		Esophagoscopy(+)	Esophagoscopy(-)	
HAND METAL DETECTOR	POSITIVE	a= Number of individual diseased and truly positive 14	b= Number of individuals disease free &revealed positive 1	15
	NEGATIVE	c= Number of individual diseased and negative 0	d= Number of individual disease free and revealed negative 0	0
TOTAL		14	1	15

Total no. of diseased
= a+c
= 14+0
= 14

Total no. of diseased free
= b+d
= 1+0
= 1

Sensitvity
= a/(a+c)
= 14/ 14
=100%

Negative Predictive Value (+PV)
= a/a+b
= 14/14+1
=93.3%

TABLE IV. Comparison of Chest Xray findings with Intraoperative esophagoscopic findings: N=15

		Esophagoscopy(+)	Esophagoscopy(-)	Total
CHEST XRAY	POSITIVE	a= Number of individual diseased and truly positive 14	b= Number of individuals disease free &revealed positive 1	15
	NEGATIVE	c= Number of individual diseased and negative 0	d= Number of individual disease free and revealed negative 0	0
TOTAL		0	8	8

Sensitivity
= a / (a+c)
= 14 / 14+0
= 100%

Positive Predictive Value (+PV)
= a /a+b
= 14 / 14 +1
= 93.3%

TABLE V. Comparison of Repeat Hand Held Medical Detector (HHMD vs Chest Radiographs (CXR) in Patients with Negative Disease

		Esophagoscopy(+)	Esophagoscopy(-)	Total
HAND METAL DETECTOR	POSITIVE	a= Number of individual diseased and truly positive 0	b= Number of individuals disease free &revealed positive 0	0
	NEGATIVE	c= Number of individual diseased and negative 0	d= Number of individual disease free and revealed negative 8	8
TOTAL		0	8	8

Total no. of diseased
= 0+0
= 0
= 100%

Total no. of diseased free
= b+d
= 0+8
= 8

Specificity
= d/ (b+d)
=8/ 0+8
=100%

Negative Predictive Value (+PV)
d/c+d
=8/0+8
=100%

DISCUSSION

Hand held metal detectors (HHMDs) are used to detect metal objects in malls, restaurants, hospitals, airports, school, courthouses, banks, manufacturing plants, law enforcement agencies, companies and different establishments. Law enforcers and security officers commonly use this gadget, mainly to check for dangerous metal weapons. There was more use to metal detectors than stated. HHMDs can also be used to detect metal foreign body esophagus.[20,21]

Most of the time, several hours may elapse before definitive treatment can be done. This delay may cause displacement of the coin to the stomach. In our setting, delayed esophagoscopies were due to full stomach on admission or competition with other surgical department for OR room and time. About 6-7 % revealed no foreign body intraoperatively. These necessitate repeat radiographs to confirm the location of the coin ingested. The repeat radiographs would entail additional expense to an already financially constrained family, additional radiation exposure to the child and additional time and effort for the hospital staff to perform the radiologic test. In an institution that caters for indigent patients such as ours, the added cost, effort and time make repeat radiography hard to perform.

In the first phase of our study (diagram 1), HHMD compared to conventional radiograph yielded an accuracy of 96.6%, sensitivity of 100%, specificity of 90.5%, positive of 95% and negative predictive value of 100% . The definition of positive and negative for disease means the coin is located within the esophagus or stomach (subdiaphragmatic area), respectively. The level of the esophagus was further anatomically divided into cervical, upper and lower thoracic, subdiaphragmatic level, abdominal and pelvic. The first three were categorically in the esophagus, and the last three belongs to the stomach and distal to it. There were 3 patients in whom HHMD scans did not match radiographic findings. In a 6-month-old girl, the coin was localized by HHMD at upper thoracic area, but on radiograph the foreign body was noted at the C6-7 level. The findings were not significant since both were categorically in the esophagus. Two patients revealed false positive result. Coins in a 5-month-old and a 7-month-old boy were localized by HHMD to be at lower thoracic level but on radiographs the coins were located at the subdiaphragmatic area (stomach). These variations can be due to the small body frame of the child using the 2.6" width of HHMD that covers a significant surface in a small child's body. The sensitivity range of HHMD can detect foreign body 1" above and below the long edge of the lateral side HHMD, making adjacent levels hard to decipher as to which level the coin belongs to.

In the second phase of the study sensitivity and positive predictive value were found to be 100% and 93.3% when esophagoscopy was used as a gold standard. The difference was noted in one 13-month-old male scanned by HHMD enroute to operating room to be positive at the lower thoracic area, however the coin was not found intraoperatively. The possible reasons might be due to the delay of about one hour from time of HHMD scan to the operation proper and the induction of general anesthesia might have caused the sphincter of the esophagus to relax, resulting in the coin moving distally towards the stomach.

Coin and non-coin foreign bodies such as aluminum pull tab, battery, bullet, camera film, can opener gear, earrings, fishing weight, game token, nail, paper clip, ring, spring, screw, razor blade have been successfully identified [1,16,17,18]. The false–negative radiograph of aluminum is consistent in several reports of authors regarding "invisibility " of aluminum on radiograph films because of very low radiodensity of metal.[1,16,17,18] It is likely that the HHMD is more sensitive than plain radiography for evaluation of ingested aluminum foreign bodies.[1,16] In our own institution, it has yet to be verified since we had no patient with aluminum tab ingestion. The varied metallic foreign bodies that HHMD can identify are quite encouraging and large samples will be needed in our institution to prove the analysis.

This study does not aim to replace the initial radiographic examination because HHMD cannot identify the exact location of lodgment and the numbers of coins ingested. However, it aims to obviate the need for repeated radiographic studies prior to removal by esophagoscopy. The results were encouraging to advocate the use of HHMD in locating coins in esophagus prior to contemplated rigid esophagoscopy.

Limitation of the study includes: The study needed an adequate sample size to obtain sufficient power. Ethical issues will come to play if one proceeds with esophagoscopy, when HHMD and repeat radiograph revealed passage of coin distal to the esophagus. The authors are still pursuing the study to get adequate sample size and applying HHMD in non-coin metals. Repeat radiographic studies would be a better gold standard in lieu of intraoperative esophagoscopy to establish good statistical analysis. A better design would have been doing esophagoscopy on all patients to better compare between HHMD and CXRas a diagnostic screening tool.

CONCLUSION

Hand held metal detector scanning is an accurate, portable, radiation-free screening tool and may be used for evaluation on patients presenting to the ER with a history of coin ingestion. It is a handy tool in lieu of repeat radiographs prior to rigid esophagoscopy, thus preventing unnecessary exposure to anesthetic agents and surgery. It does not replace the role of the initial radiographs in locating the exact lodgment of coin in the esophagus and the number ingested or assesses other pathologic chest findings .

RECOMMENDATION

The hand held metal detector can act as screening tool for presence or absence of metallic foreign body. In trained hands, it can even accurately localize the coin in older children where body frames are larger. In infants, the width of the HHMD can encompass the entire neck, chest and abdomen, making localization of foreign body difficult. Practice is needed to increase the accuracy of HHMD in locating metallic foreign bodies. HHMD can also be tried in other non-coin metallic foreign bodies such as aluminum where radiography is not helpful.

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UNILATERAL VERSUS BILATERAL EAR LOBE CREASE AS AN ASSOCIATED FACTOR OF CARDIOVASCULAR RISK: A COMPARATIVE STUDY*

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ABSTRACT

The presence of a diagonal ear lobe crease has been recognized as a sign of cardiovascular disease. Through the years, it has been utilized as a physical finding that may help document coronary artery disease. In this study, 300 patients admitted at a tertiary hospital were interviewed for cardiovascular risk using Grisanti's index classifying them into high or low risk groups. Thereafter, they were examined for the presence of a diagonal ear lobe crease (DELC). Based on the data gathered, the patients were divided into three groups: Combined, Unilateral and Bilateral DELC. Sensitivity, Specificity, Positive and Negative Predictive Values, Overall Accuracy and odds ratio were determined which showed that patients with bilateral DELC have higher correlation with heart disease than those with unilateral DELC. Therefore, the presence of a bilateral ear lobe crease is a more reliable associated factor than unilateral DELC in assessing the development of cardiovascular disease.
Key Words: DELC - Diagonal Ear Lobe Crease; Grisanti's Index

INTRODUCTION

For the past 30 years, Coronary Artery Disease (CAD), has been the leading preventable cause of morbidity and death in the Philippines. In fact, 1 out of 5 Filipino was reported to have manifested any of these cardiovascular symptoms such as: chest pain and heaviness, difficulty of breathing, body weakness, numbness of extremities and nape pain once they reach the age of 40.[1]

There are several risk factors attributed to the development of cardiovascular disease. It is classified as intrinsic or extrinsic. Intrinsic factors are those that are inherent to the individual such as: family history of cardiovascular disease, personal history of myocardial infarct, hypertension, diabetes mellitus, thyroid disorders and renal diseases. On the other hand, extrinsic factors or the modifiable risks are: obesity, history of stress, high fat diet, sedentary lifestyle, alcohol intake, use of prohibited drugs and oral contraceptives.[2]

In continuing the search for other risk factors, several researches were pioneered by Frank in 1973. Thus, the inclusion of diagonal ear lobe crease (DELC) as a pertinent physical finding in patients with cardiovascular risk was proposed. In his study, 4 main hypotheses were presented: Hypothesis 1: DELC is a coronary risk factor or a marker of coronary disease. Hypothesis 2: DELC is a genetic marker of atherosclerotic coronary disease. Hypothesis 3: DELC is in fact the result of aging and the relationship with atherosclerotic coronary disease is mere coincidence. Hypothesis 4: DELC is an anatomic peculiarity of the ear lobe. Among these, he was able to prove hypotheses 1 and 2 saying that since the ear lobe is richly vascularized, a decrease in blood flow over an extended period of time is believed to result in collapse of the vascular bed. This leads to a diagonal crease. Thus, he proved the relationship between DELC and heart disease.[3]

Moreover, the data reported by Petrakis in 1980 mentioned the presence of this sign in some of the Greco-Roman cultures in the museums of Rome. The most famous of which is the Bust of Hadrian, the great Roman Emperor. He had a chance to compare Hadrian's sculpture with other Roman nobles which depicted him to have a prominent bilateral DELC while others do

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not. Thus, he assumed that it represented a physical trait. Historical information further hypothesized that Hadrian probably died from hypertensive and coronary atherosclerotic disease because of recurrent epistaxis and edema suggestive of an underlying hypertension which progressed to congestive heart failure.[4]

After almost 3 decades, many reports proving Diagonal ear-lobe crease (DELC) as a coronary risk factor followed. Based on the report of Grisanti in 1996, he recommended the finding of DELC as a cardiovascular marker and be included as part of routine physical evaluation.[5] Furthermore, T.Ishi in 1990, published his report on the association between ear-lobe crease and coronary atherosclerosis in 100 autopsied men with age ranging form 50-79 years. Earlobe crease was graded and defined as groups 1, 2 and 3 according to the length and length in both ears. Grade 1, was described as crease occupying one third (1/3) of the ear lobe. Grade 2 is a visible crease approximating two-thirds (2/3) of the lobe and Grade 3 when the crease is seen on the whole part of the lobe. He concluded that the higher the depth and length of DELC, the greater is the risk of atherosclerosis.[6] Despite several follow-up studies on the phenomenon, the DELC remains largely underutilized in clinical practice as a screening tool and few realized the importance of the DELC to an otorhinolaryngologist in close tie-up with an internist.

This study was therefore undertaken to compare unilateral and bilateral DELC as a factor of cardiovascular risk in terms of sensitivity, specificity and positive and negative predictive values, overall accuracy and odds ratio.

MATERIALS AND METHODS

A hospital based study was conducted for 6 months from March 2002 to October 2002.About 300 patients admitted at the Medicine ward and ICU with cardiovascular symptoms were seen and examined. After obtaining consent, a thorough history was taken in the form of a questionnaire using Grisanti's index [7] which is seen below:

Grisanti's Index (Scoring System)

1. Family History of Cardiovascular Disease (2)
2. Myocardial Infarction, Pulmonary Artery Disease, Coronary Artery Disease (2)
3. Obesity (1)
4. Diabetes (1)
5. Hypertension (2)
6. Thyroid Disoders (1)
7. Stress (1)
8. Chronic illness (1)
9. High Fat diet (1)
10. Sedentary Lifestyle (1)
11. Alcohol/ Prohibited Drug intake (1)
12. Oral Contraceptive Use (1)
13. Hormonal imbalance (1)
14. Post-menopause (1)
15. Renal disorders (1)
16. Earlobe crease (1)

- > or = 12 – HIGH RISK FOR CARDIOVASCULAR DISEASE
- < 12 – LOW RISK FOR CARDIOVASCULAR DISEASE

Each of the patients was asked thoroughly. Points for each index were given. Any score above twelve is considered as high-risk and those whose scores were below 12 were labeled as low-risk population. After getting the Grisanti's index, patients were examined for the presence or absence of DELC either unilateral or bilateral. When found positive, they were graded accordingly.

Tabulations were done separately for Combined, Unilateral and Bilateral DELC. Using Grisanti's index, the true positive and negative, false positive and negative data were obtained. From this, the sensitivity, specificity and positive and negative predictive values and overall accuracy and odds ratio were derived.

RESULTS

Of the 300 patients seen and evaluated by Grisanti's index, 207 (69%) were females and 93 (31%) were males. Ages range from 42–79 years. A total of 232 patients obtained a score of = or > 12 thus categorizing them as high risk population group, whereas 68 patients had an index below 12 clustering them as low risk individuals.

Among the high- risk population group, (n=232) 155 were females (66%) and 77 were males (34%). A total of 104 patients (44%) were examined to have unilateral diagonal earlobe crease while 123 patients (53%) were evaluated to have bilateral DELC. Only 5 patients (3%) of the high- risk group were devoid of any earlobe crease.

TABLE 1.1. Demographic data

Age	
Mean	59
Median	61
Mode	55
Age Range	42-79

This table shows that the age range of subjects is between 42-79 years. The mean age is 59 years and median age of 61 for both male and female subjects.

TABLE 1.2. Sex distribution of patients recruited

GENDER	FREQUENCY	%
Female	207	69
Male	93	31
Total	300	100

This table shows that 207 of 300 (69%) were females whereas 93 of 300 (31%) were males.

In comparison, those who belonged to low risk population group (N=68: F= 52, M =16) revealed a total of 62 patients (91%) without DELC; 4 patients (6%) have unilateral DELC and 2 subjects (3%) showed bilateral DELC

TABLE 2.1. Distribution of cardiovascular risk according to presence or absence of combined crease.

	(+) crease	(-) crease	Total
> or = 12 (High Risk)	227	5	232
< 12 (Low Risk)	6	62	68
	233	67	300

Sensitivity = 227 / 232 = 97.8% + predictive value = 227 / 233 = 97.4%
Specificity = 62/68 = 91.2% - predictive value = 62 / 67 = 92.5%
OA = 227 + 62 / 300 = 96.33%

TABLE 2.2. Distribution of cardiovascular risk according to presence or absence of unilateral crease.

	(+) unilateral crease	(-) crease	
> or =12	104	5	109
< 12	4	62	66
	108	67	175

Sensitivity = 104/109 = 95.4% + predictive value=104/108=96.3%
Specificity = 62/66 = 93.9% - predictive value= 62/67= 92.5%
OA = 104 + 62/ 175= 94.90%

TABLE 2.3 Distribution of cardiovascular risk according to presence or absence of bilateral crease

	(+) bilateral crease	(-) crease	
> or =12	123	5	128
< 12	2	62	64
	125	67	192

Sensitivity = 123/128 = 96.10% pV+ = 123 / 125 = 98.4%
Specificity = 62/64 = 96.9% p V - = 62 / 67 = 92.5%
OA = 123 + 62/192 = 96.4%

TABLE 2.4 Summary

	Combined	Unilateral	Bilateral
Sensitivity	97.8%	95.4%	96.1%
Specificity	91.2%	93.9%	96.9%
Positive predictive value	97.4%	96.3%	98.4%
Negative predictive value	92.5%	92.5%	92.5%
Overall Accuracy	96.33%	94.9%	96.4%

TABLE 3. Distribution of cardiovascular risk according to Bilateral and Unilateral Creases.

	Bilateral	Unilateral	Total
> or +12	123	104	227
< 12	2	4	6
	125	108	233

Mantel-Haensel Common Odds Ratio=
123 x 4 / 2 x 104 = 492 / 208 = 2.4 = point estimate

Table 1 and 2 show that among the 232 patients who belonged to the high-risk cardiac population group(by Grisanti's Index), 155 patients(69%) were females with a mean age of 61 and 77 patients(31%) were males with a mean age of 56. From these data, it is important to note that the onset of cardiovascular symptoms were much earlier in males than females.

The high incidence of cardiovascular risk in females can be explained by the gradual decline in the level of progesterone during menopausal period. Progesterone is an essential hormone that lowers the production of cholesterol, a known predisposing factor in the pathophysiology of cardiovascular diseases. For the male patients, smoking and alcohol intake were found to be significant and contributory to the development of cardiovascular symptoms.[8]

Of the 68 low-risk cardiac population group, 52(76%) were females with a mean age of 64 and 16(24%) were males with a mean age of 59. In comparison, it can be deduced that the age of onset of cardiovascular symptoms in this group appears much later in life in the low-risk group than the high-risk population group.

Based on table 2.4 which summarizes the outcome of statistical data for unilateral DELC, bilateral DELC and the combined group, the one with the highest sensitivity percentage belonging to the combined group with a value of 97.8%.

In terms of specificity, positive predictive value and overall accuracy, the Bilateral DELC garnered the highest percentage with values of 96.9%, 98.4%, and 96.4% respectively. Negative

predictive score for the 3 groups were the same at 92.5%.Odd's ratio revealed a value of 2.4 interpreted as a two-fold increase in developing cardiovascular complications for patients found to have cardiovascular symptoms and at the same time with a physical finding of either a unilateral or bilateral DELC.

DISCUSSION

Cardiovàscular disease claims as many lives as the next eight leading causes of death combined, including cancer, accidents and AIDS. No other modern illness comes close to reaping such a grim toll on human life: an average of about 2600 deaths each day and the number one cause of mortality in the Philippines today. Thus, a review of the medical research strongly documents the need for all individuals suspect of having a heart disease to be thoroughly evaluated.

It was in the mid 60's that the first report suggesting a scientific association between the DELC and Coronary Artery Disease (CAD) was made. Frank studied 20 patients with the crease in terms of personal and family history of premature cardiovascular disease and known risk factors. He observed that 19 out of 20 patients with the crease had at least one of the known risk factors for CAD. The results are so striking; therefore, he suggested that the DELC is associated with premature cardiovascular disease.

Since Frank's description, published reports on the issue describing its association with CAD flourished. In fact, DELC is now mentioned prominently in the textbook of Cardiology as a risk factor for CAD.[9]

There have been studies linking DELC with acute myocardial infarction. Four authors found a correlation between AMI and the DELC. The largest of this was done by Shoenfeld et al in Israel where a statistically significant correlation between the DELC and AMI was found in 421 patients. The crease was deemed independent of age because the analysis demonstrated a statistically significant increase in the frequency of the DELC among patients with AMI in each group regardless of age.[10]

Undoubtedly, although all the mentioned reports showed some significant correlation between the DELC and CAD, however, no study has ever been proven comparing a unilateral with a bilateral DELC among Filipino patients and no attempt has been done to determine the value of the phenomenon as a predictor of cardiovascular risk.

Since the correlation between DELC and CAD has already been established, the etiology of what predisposes an individual to have either a unilateral or a bilateral DELC remains to be uncovered. Another question that arises is whether they have the same value or they have a difference in predicting future cardiovascular risks.

As in the outcome of this study, 232 out of 300 had positive cardiovascular symptoms, with 123 accounting for bilateral DELC and 104 patients have unilateral DELC. From these data, there is an increased incidence of bilateral DELC than unilateral DELC observed

Moreover, the computed specificity, positive predictive value and overall accuracy affirmed the hypothesis that the presence of a bilateral DELC has a higher correlation than a unilateral DELC making this physical finding a more reliable predictor of cardiovascular risks.

CONCLUSION

This study indicates that the diagonal ear lobe crease could identify patients who are at risk of coronary artery disease and its attendant complications. Statistically, the combined group, unilateral DELC a bilateral DELC showed significant results. However, bilateral DELC has a higher specificity, positive predictive value and overall computed accuracy which makes it the most reliable cardiovascular marker among the 3 groups.

The integration of this "physical marker' or risk factor into the coronary risk profile for the presence and severity of coronary artery disease and therefore remind the internist or cardiologist to introduce preventive measures such as control of the modifiable factors. Furthermore, close monitoring of patients who have the crease may help to detect the disease and thus prevent any future cardiovascular complications.

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COMPARISON OF THE SOUND ATTENUATION OF EARPLUG, EARMUFF AND EARPLUG-EARMUFF COMBINATION IN NORMAL HEARING FILIPINOS USING REAL-EAR MEASUREMENTS*

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ABSTRACT

GENERAL OBJECTIVES: To determine which hearing protective device would give the most sound attenuation per frequency to normal hearing Filipinos using Real-Ear Measurements
SPECIFIC OBJECTIVES:

1) To determine the amount of sound attenuation per frequency using different hearing protective devices on normal hearing Filipinos using Real-Ear Measurements

2) To compare the sound pressure levels perceived by the same normal subjects when using earplugs and without using any hearing protective device, using an earmuff and without using any hearing protective device, using an earplug-earmuff combination and without using any hearing protective device

3) To compute if the mean difference between these values are significant

4) To compute if each hearing protective device has a significant difference in sound attenuation per frequency level

DESIGN: Experimental
SETTING: Tertiary Medical Center
PATIENTS: 25 Normal hearing Medical Students
RESULTS: The results of the study showed that the earplug-earmuff combination was shown to give the highest computed mean difference in sound attenuation among the three types of hearing protective devices used. It was also observed that the earplug-earmuff combination gave the most attenuation in all frequencies with the lowest sound pressure level noted also at 1000 Hz
CONCLUSION: We conclude that different hearing protective devices give different levels of attenuation per frequency. The earplug was shown to attenuate noise the least and the earplug-earmuff combination gave the most attenuation per frequency in normal hearing Filipinos. Each type of hearing protective device has different efficiency per frequency levels.

INTRODUCTION

In developing countries, occupational noise and urban, environmental noise are increasing risk factors for hearing impairment. This is partly due to the increasing number of machineries and factories in the advent of rapid urbanization. In the Philippines, 23.63% of the workforce is comprised of factory workers and laborers. Almost seven out of 10 Filipinos working in "traditionally noisy workplaces" are hearing impaired or suffering from various degrees of hearing loss.[1]

Noise-induced hearing loss is the most common cause of acquired hearing loss and is totally preventable. The surest method of preventing occupational deafness is to reduce noise at the source by engineering methods.[2] However, in certain workplace conditions, there is very little or nothing one can do to reduce noise at the source. In such workplaces, workers wear hearing protectors as a temporary solution.

A worker is noise-exposed if he is exposed regularly to sound levels greater than an 8-hour time-weighted average (TWA) of 85 A-weighted decibels (dBA).[3] Hearing protectors should be worn when the noise or sound level at the workplace exceeds 85 dBA, or generate 120 dB peak sound level or greater.[4] The Canadian Standards Association recommends the use of

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different hearing protectors depending on the Time-Weighted Average Noise Exposure of a person (Table 1).

Hearing protective devices (HPDs) are devices designed to reduce the level of sound reaching the eardrum. Different types of HPDs are commercially available: insert type earplugs, earmuffs, ear canal caps (also called semi-inserts) and helmets. The HPD should provide the desired noise reduction. If the noise exposure is intermittent, earmuffs are more desirable, since it may be inconvenient to remove and reinsert earplugs.

No guidelines for the use of HPDs in the Philippines exist at present. Workers are allowed to wear any type of HPDs regardless of the amount of noise exposure and sound attenuation of the HPD being used. This results in the increasing incidence of work-related hearing loss in the country. The growing concern for occupational deafness instigated this study.

The main objective of this study is to determine which hearing protective device would give the most sound attenuation per frequency to normal hearing Filipinos using Real-Ear Measurements. Its specific objectives are: 1) To determine the amount of sound attenuation per frequency using different hearing protective devices on normal hearing Filipinos using Real-Ear Measurements, 2) To compare the sound pressure levels perceived by the same normal subjects when using an earplugs and without using any hearing protective device, 3) To compare the sound pressure levels perceived by the same normal subjects when using earmuff and without using any hearing protective device, 4) To compare the sound pressure levels perceived by the same normal subjects when using an earplug-earmuff combination and without using any hearing protective device, 5) To compute if the mean difference between these values are significant, 6) To compute if each hearing protective device has a significant difference in different frequency levels.

In comparing the different types of hearing protective devices, this study will attempt to give a baseline recommendation on the best type of hearing protective device the Filipino workforce can use.

MATERIALS AND METHODS

Subjects

The investigation was a within subjects, uncontrolled trial involving persons who underwent real-ear measurements without using any hearing protective device, then using earmuffs, then using earplugs, then using a combination of earplug-earmuff hearing protective devices. This experiment was done at the Ear Unit of a tertiary medical center from January 2003 to February 2003.

Inclusion Criteria:

1. Subject's age should be from 18-25 years
2. Subjects should have normal otoscopic findings (absence of discharge, impacted cerumen, perforation; no abnormalities in the ear canal)
3. The tympanic membrane should be mobile on Siegel's Pneumatoscopy
4. Subject should not have nasal discharge
5. Subject should not have any history of recurring bouts of nasal allergies, ear problems (otitis media) nor any ear operations
6. Subjects should have a normal hearing acuity based on puretone audiometry

Exclusion Criteria:

1. Subject's age is less than 18 or more than 25 years
2. Subject has a clinical finding of otitis externa, otitis media, impacted cerumen, immobile eardrum
3. The subject has an acute nasal infection at the time of examination
4. Subject has an abnormal hearing acuity based on puretone audiometry

The subjects for this study were randomly selected from a list of fourth year medical students from a Tertiary Medical Center College of Medicine. All subjects who satisfied the above criteria and have consented with the procedure were included in the study. If a subject failed to be included, another was drawn from the list of fourth year medical students. The sample size was computed based on the formula on analytic studies comparing two means from different populations.

A complete history was taken from each subject and a complete otolaryngologic examination was performed on each of them. All subjects underwent Pure Tone Audiometry testing which was administered by a single audiometrician.

The study utilized the Ear Unit's Audiometer and the RASTRONICS Real-Ear Measurement Apparatus. The earplug used in the study was the Howard Leight expandable pre-shaped foam type of earplug (NRR 33) and the EM 44 Earmuff, both of which were purchased at the

hardware store of nearby shopping mall.

The following parameters were observed to control biases: 1) only the same brand of earplug and earmuff were used, 2) each earplug and earmuff were inspected prior to every test, 3) the audiometer and real-ear measuring apparatus were precalibrated, 4) only one audiometrician performed puretone audiometry on every subject, and 5) only one audiologist performed the real-ear measurement on every subject.

PROCEDURE

Each subject was seated with his/her head positioned forty-five degrees from the sound source. A flexible probe was inserted into the better hearing ear canal. The tip of the probe tube was placed approximately 6 mm from the eardrum and the external marking of the probe was placed just on the outer rim of the ear canal.

The real-ear measurement instrument was started. The sound pressure level (SPL) produced by the machine was recorded in all frequencies. This served as the measurement of the baseline variable or the control group (without HPDs).(Figures 1,2)

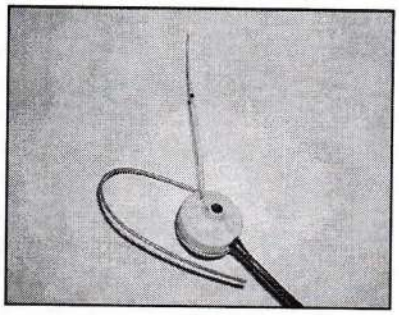

Figure 1: Probe Tube

Figure 2: Earmuff

With the probe tube still in place, the earmuff was placed making sure that the probe microphone was not covered and that the probe was not misplaced. Real-ear measurements were taken and results recorded. These measurements represented the first experimental group [earmuff alone (EM group)]. (Figure 3,5)

The earmuff was removed and an earplug

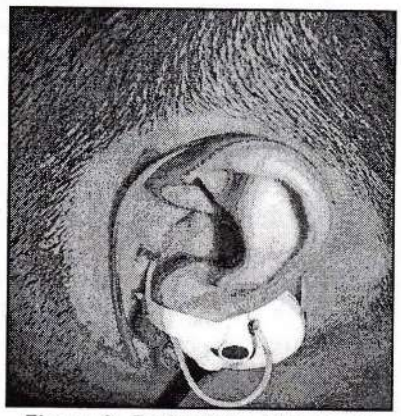

Figure 3: Probe Tube Placement

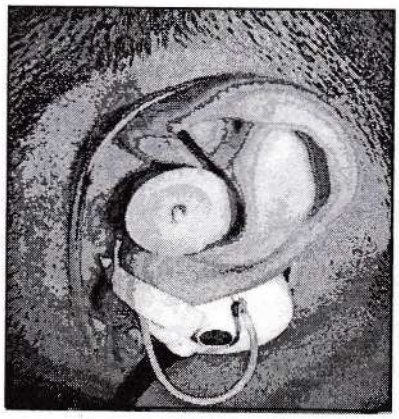

Figure 4: Earplug Alone

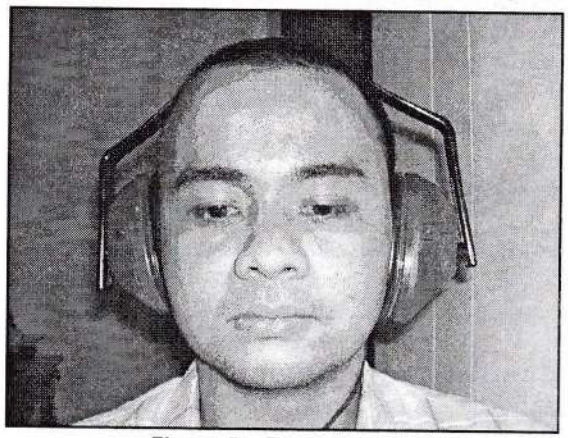

Figure 5: Earmuff Alone

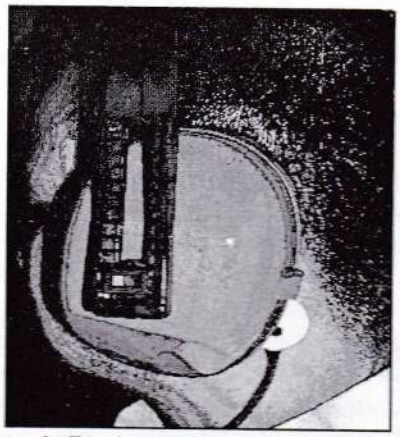

Figure 6: Earplug and Earmuff Combination

was then inserted into the ear canal making sure that the probe was not displaced. Real-ear measurements for all frequencies were then taken and recorded. These measurements represented the second experimental group [earplug alone (EP group)]. (Figure 4)

The earmuff was then carefully placed covering the earplug while again making sure that the microphone was not covered. Real-ear measurements were again taken and recorded. These measurements represented the third experimental group [earplug-earmuff combination (EP-EM group)].(Figure 6)

Initial results were recorded and later tabulated. The analysis of the results consisted primarily of computation of the indicators of the outcome, namely mean and standard deviation for each frequency involving two groups (no HPD vs. HPD). It included comparison of the values before and after the intervention noting the differences in mean between frequencies of each group. The statistical analysis of observed differences between SPLs per frequency when wearing each type of hearing protective device versus the SPLs without any hearing protective device was done using the paired T test. Also included is the statistical analysis of observed differences between SPLs per frequency when the earplug was worn alone, earmuff was worn alone, earplug-earmuff combination was worn and without any hearing protective device using the one-way ANOVA test.

RESULTS

A total of 25 subjects were included in the study consisting of 13 males (52%) and 12 females (48%). Their age ranged from 21 to 25 years, with a mean age of 23.8 years.

All measurements were recorded, tabulated (Tables 2-5) and graphed noting the sound pressure levels per frequency without wearing, and then wearing the hearing protective devices (earmuff alone, earplug alone, earplug-earmuff combination). The tables also included the identification of the subject, age and sex.

With the sound pressure level emitted by the loudspeakers of the test boxed at 90 dB SPL, there is a noticeable increase in sound pressure level at frequency octaves 2000-4000 Hz with a peak pressure at 3000 Hz. This was seen in all test subjects not wearing the hearing protective devices.

The mean sound pressure level per frequency of subjects not wearing any hearing protective device and the mean sound pressure level per frequency when wearing earplug, earmuff and earplug-earmuff combination were computed and tabulated (Table 6). There is a noticeable decrease in the sound pressure level in all frequencies for the three types of hearing protective devices used with the highest attenuation range noted at frequency range 2000-4000 Hz with the peak attenuation at 3000Hz.

The mean difference in attenuation between the without HPD and the with HPD was also computed. The mean difference in attenuation between the without HPD and the EP group was not computed since there was no noted difference in the sound pressure level at the 250 Hz between the without HPD group and the EP group. The highest mean difference in attenuation between the without HPD and the EP group was also observed at the 3000 Hz (Table 7). The same was true for the without HPD vs. EM group (Table) and the without HPD vs. EP-EM group (Tables 8-9). The earplug-earmuff combination was shown to give the highest computed mean difference among the three types of hearing protective devices used.

Significant difference at $p<0.05$ was shown between the sound pressure levels per frequency when the subjects did not wear any hearing protective device and when they wore the hearing protective devices using the paired t-test (Table 10).

Attenuation was observed with the use of the earplug, earmuff and earplug-earmuff combination in all frequencies except at the 250 Hz using an earplug. It was shown that the highest attenuation for all types of hearing protective devices in this study was seen at the 1000Hz frequency level. It was also observed that the earplug-earmuff combination gave the most attenuation in all frequencies with the lowest sound pressure level noted also at 1000 Hz. Significant difference at $p<0.05$ among the three types of hearing protective device in the different frequency levels was noted using the one-way ANOVA test (Table 11).

DISCUSSION

Work-related hearing loss continues to be a critical workplace safety and health issue. The National Institute for Occupational Safety and Health (NIOSH) and the occupational safety and health community named hearing loss one of the 21 priority areas for research in the next century.

Developing countries often lack both effective legislation against noise and program to prevent noise-induced hearing loss. Hearing loss due to occupational noise exposure is one of the most prevalent health issues today. This problem is totally preventable. However, symptoms are not visible and gradually worsen over time making

it very easy to ignore. Noise-induced hearing loss once acquired is permanent and irreversible.

The most effective way to prevent noise-induced hearing loss is to remove the noise from the workplace or to remove the worker from the noise. Reducing noise exposures to safe levels using engineering controls is the preferred method. However, this would entail a lot of expenses for the employer. In instances where engineering controls are not feasible, hearing protective devices should be used by workers.

Different hearing protective devices (earplugs, semi-insert earplugs and earmuffs) are commercially available. The amount of attenuation a hearing protector gives depends on its characteristics and how the worker wears it. The Canadian Standards Association recommends the use of different hearing protectors depending on the Time-Weighted Average Noise Exposure of a person (Table 1). The earplug used in the study was the Howard Leight expandable pre-shaped foam type of earplug (NRR 33) and the EM 44 Earmuff.

With the sound output of 90 dB, the subjects without HPDs were noted have an increase in intensity between frequencies 2000-4000 Hz with a peak increase noted at 3000 Hz. With the use of each type of hearing protectors (EP, EM, EP-EM), attenuation of sound in all frequencies was observed. The earplug gave minimal attenuation (<10 dB) at the low (500-1000 Hz) and high frequencies (6000-8000 Hz). At the 2000-3000 Hz, the earplug gave an overall attenuation of about 20 dB. The earmuff gave overall attenuation of about 10 dB at the extreme low (250 Hz) and extreme high frequency (8000 Hz), 30 dB at 500-1000 and 4000 Hz, 40 dB at the 2000-3000 Hz. The EP-EM combination gave overall attenuation of about 20 dB at the extreme low (250 Hz) and extreme high (8000 Hz) frequencies, 30 dB at 6000 Hz, 40 dB at 500-1000 and 4000 Hz, 50 dB at 2000 Hz and 60 dB at 3000Hz. All HPDs were noted to give the best attenuation at the 3000Hz. EP-EM combination EP-EM combination was shown to give the most attenuation among the three types of hearing protectors.

CONCLUSION

The importance of legislation and programs to prevent noise-induced hearing loss secondary to noise exposure in the workplace cannot be stressed enough. In the Philippines, workers are allowed to wear any type of hearing protector regardless of the amount of noise exposure.

We conclude that different hearing protective devices give different levels of attenuation per frequency. The earplug was shown to attenuate noise the least and the earplug-earmuff combination gave the most attenuation per frequency in normal hearing Filipinos. Each type of hearing protective device has different efficiency per frequency levels.

RECOMMENDATIONS

We recommend that a study be performed using the other hearing protective devices commercially available in the market.

We recommend that a study on field adjusted (real-world) Noise Reduction Ratio of each type of hearing protective device for normal hearing Filipinos be done.

We recommend that a study be conducted on the protected time weighted average of each type of hearing protective device for the different hypothetical noise levels on normal hearing Filipinos.

APPENDIX A

TABLES

Table 1: Selection of Hearing Protectors

TIME-WEIGHTED AVERAGE (TWA) Noise Exposure (expressed in dBA)	Recommended Class of Hearing Protection
TWA less than 85 Dba	Hearing protection not required
TWA up to 89 dBA	Class C Hearing Protector
TWA up to 95 dBA	Class B Hearing Protector
TWA up to 105 dBA	Class A Hearing Protector
TWA up to 110 dBA	Class A earplug + Class A or B earmuff
TWA greater than 110 dBA	Class A earplug + Class A or B earmuff and limited exposure

Classification of hearing protectors as Class A, B, C is based on the minimum noise attenuation at various assigned frequencies. Class A provides the highest level of attenuation across the test frequencies. Class B provides the next higher level of attenuation and Class C provides the least attenuation (virtually no attenuation below 500 Hz).

It must be stressed that there is no dividing line whereby regular noise exposure below a TWA of 85 dBA is considered "safe" and above this level is "unsafe". The majority of individuals who are regularly exposed to noise levels between 80-95 dBA will not experience noise-induced hearing loss but there may be some susceptible individuals who will experience this loss. This possibility should be discussed with any individual whose TWA is between 80-85 dBA and appropriate hearing protection should be provided on request.

Courtesy: The Canadian Standards Association Standard Z94.2-M1984

Table 2: Sound Pressure Level per Frequency of Subjects not wearing Hearing Protective Devices

Name	Age	Sex	Frequency (Hz)							
			250	500	1000	2000	3000	4000	6000	8000
J.B.	24	M	90	90	90	98	118	100	90	80
W.B.	24	F	90	90	90	100	118	100	95	80
J.G.	24	M	90	90	90	105	120	105	100	100
D.L.	24	F	90	90	90	100	115	100	95	95
J.M.	25	M	90	90	90	105	115	103	95	88
D.N.	24	M	90	90	85	100	105	100	95	95
R.M.	25	M	90	90	90	105	117	100	95	87
C.O.	22	F	90	90	90	100	108	100	95	95
J.C.	23	F	90	90	90	105	110	100	95	95
R.S.	24	M	90	90	90	100	105	95	90	90
C.C.	24	F	90	90	90	100	115	95	90	85
C.CS.	24	F	90	90	90	100	115	100	95	95
F.B.	25	M	90	90	90	100	110	100	90	80
R.B.	24	M	90	90	90	100	110	90	90	90
A.M.	23	F	90	90	90	100	105	100	100	95
J.V.	24	M	90	90	90	100	110	100	90	90
M.U.	21	F	90	90	90	100	115	100	95	90
R.Y.	24	F	90	90	90	100	105	95	90	90
M.D.	24	F	90	90	90	100	110	100	95	90
C.D.	24	M	90	90	90	100	110	100	90	90
T.P.	24	M	90	90	90	95	110	105	100	95
T.M.	22	M	90	90	90	100	115	100	90	90
K.S.	25	F	90	90	90	100	110	100	95	90
A.S.	24	M	90	90	90	100	110	100	95	90
A.D.	24	F	90	90	90	95	110	100	100	100

Table 3: Sound Pressure Level per Frequency of Subjects wearing Earplugs

Name	Age	Sex	Frequency (Hz)							
			250	500	1000	2000	3000	4000	6000	8000
J.B.	24	M	90	90	90	90	93	90	87	80
W.B.	24	F	90	80	80	80	95	85	83	80
J.G.	24	M	90	85	80	85	85	85	85	88
D.L.	24	F	90	90	90	95	105	90	90	90
J.M.	25	M	90	90	80	85	95	85	85	88
D.N.	24	M	90	80	85	95	90	88	93	98
R.M.	25	M	90	85	75	80	90	85	85	85
C.O.	22	F	90	90	75	85	90	80	83	85
J.C.	23	F	90	90	90	100	95	90	95	95
R.S.	24	M	90	80	80	85	85	80	85	90
C.C.	24	F	90	90	90	90	90	85	85	85
C.CS.	24	F	90	90	80	90	95	85	85	85
F.B.	25	M	90	90	80	80	85	80	80	80
R.B.	24	M	90	90	75	90	80	75	80	90
A.M.	23	F	90	90	85	85	85	85	85	90
J.V.	24	M	90	90	80	80	80	80	90	85
M.U.	21	F	90	90	75	75	85	90	90	80
R.Y.	24	F	90	90	80	80	85	80	80	85
M.D.	24	F	90	90	80	85	90	90	90	80
C.D.	24	M	90	90	80	80	95	85	90	80
T.P.	24	M	90	90	90	90	90	100	80	90
T.M.	22	M	90	90	80	80	85	80	85	70
K.S.	25	F	90	90	90	90	90	90	90	75
A.S.	24	M	90	90	90	90	90	90	90	75
A.D.	24	F	90	90	80	85	90	80	85	85

Table 4: Sound Pressure Level per Frequency of Subjects wearing Earmuffs

Name	Age	Sex	Frequency (Hz)							
			250	500	1000	2000	3000	4000	6000	8000
J.B.	24	M	80	69	58	60	62	70	75	80
W.B.	24	F	75	68	63	65	75	80	80	80
J.G.	24	M	90	70	65	68	70	70	75	75
D.L.	24	F	75	65	60	60	80	60	70	75
J.M.	25	M	85	70	58	70	75	70	75	75
D.N.	24	M	80	60	50	55	75	60	65	75
R.M.	25	M	75	55	50	50	65	50	55	60
C.O.	22	F	75	60	75	70	75	70	73	75
J.C.	23	F	50	40	40	40	40	55	55	60
R.S.	24	M	75	60	55	65	65	60	65	70
C.C.	24	F	80	70	60	60	75	60	65	70
C.CS.	24	F	75	60	55	60	70	60	70	80
F.B.	25	M	80	65	60	70	65	65	70	80
R.B.	24	M	80	60	50	65	60	65	65	65
A.M.	23	F	85	70	55	70	75	75	75	85
J.V.	24	M	80	70	50	65	65	65	70	75
M.U.	21	F	85	70	60	60	75	70	90	80
R.Y.	24	F	80	65	60	75	75	70	78	85
M.D.	24	F	80	65	60	60	75	70	70	80
C.D.	24	M	80	65	55	70	65	75	80	80
T.P.	24	M	85	70	55	70	80	80	80	90
T.M.	22	M	80	65	60	60	80	70	80	70
K.S.	25	F	75	60	55	75	75	60	75	75
A.S.	24	M	80	65	60	75	75	75	75	75
A.D.	24	F	80	70	60	60	65	85	85	85

Table 5: Sound Pressure Level per Frequency of Subjects wearing Earplug-Earmuff Combination

Name	Age	Sex	Frequency (Hz)							
			250	500	1000	2000	3000	4000	6000	8000
J.B.	24	M	70	40	40	40	45	50	52	60
W.B.	24	F	70	52	55	45	50	60	65	70
J.G.	24	M	70	40	40	40	40	40	55	60
D.L.	24	F	55	40	40	40	45	45	55	60
J.M.	25	M	80	65	45	55	63	65	65	65
D.N.	24	M	50	40	40	40	40	40	50	55
R.M.	25	M	50	40	40	40	45	50	55	60
C.O.	22	F	73	45	50	55	65	60	65	75
J.C.	23	F	50	40	40	40	40	40	55	60
R.S.	24	M	50	40	40	40	40	40	50	60
C.C.	24	F	80	70	55	55	60	60	70	75
C.CS.	24	F	55	40	40	40	40	50	55	60
F.B.	25	M	80	55	45	65	60	65	65	65
R.B.	24	M	75	55	50	65	50	65	65	70
A.M.	23	F	85	70	55	60	60	60	75	75
J.V.	24	M	80	66	55	60	60	70	75	80
M.U.	21	F	80	60	60	60	60	65	78	85
R.Y.	24	F	75	50	60	65	60	60	75	80
M.D.	24	F	80	55	60	70	60	70	60	70
C.D.	24	M	75	50	55	60	50	70	80	80
T.P.	24	M	55	40	40	40	50	45	55	60
T.M.	22	M	75	45	60	60	65	70	75	65
K.S.	25	F	80	65	55	55	65	65	75	75
A.S.	24	M	80	60	65	70	70	70	70	65
A.D.	24	F	80	65	55	60	65	70	75	70

Table 6: Mean SPL per frequency of subjects without HPD, with EP, with EM, with EP-EM

Freq (Hz)	Without HPDs	Std. Dev.	EP* Group	Std. Dev.	EM* Group	Std. Dev.	EP-EM* Group	Std. Dev.
250	90.000	0.0000	90.000	0.0000	78.500	7.14473	78.120	12.0910
500	90.000	0.0000	88.400	3.4521	54.280	6.73000	51.280	10.7297
1000	89.800	1.0000	82.400	5.4237	57.160	6.50944	49.600	8.52940
2000	100.32	2.5120	86.000	5.9512	63.920	8.11134	52.800	11.0000
3000	111.64	4.3958	89.520	5.5085	70.280	8.62090	53.920	9.91600
4000	99.520	3.0838	85.320	5.3285	57.500	8.30666	57.800	11.0943
6000	94.000	3.5355	86.240	4.1461	72.540	8.22254	64.500	9.75530
8000	90.200	5.8166	88.160	4.2689	76.000	7.35598	68.000	8.29160

*earplug (EP), earmuff (EM), earplug-earmuff (EP-EM)

Table 7: Mean Difference in Sound Pressure Level (SPL) between groups without HPD and with EP

Frequency	Mean Difference	Standard Deviation
250		
500	1.600	3.4521
1000	7.4	5.6125
2000	14.32	6.4143
3000	22.12	5.8167
4000	14.2	4.3397
6000	7.76	5.2858
8000	2.44	4.1239

Table 8: Mean Difference in SPL between groups without HPD and with EM

Frequency	Mean Difference	Standard Deviation
250	11.4	7.1473
500	25.72	6.73
1000	32.64	6.3501
2000	36.4	9.1606
3000	41.36	9.4907
4000	31.92	8.0152
6000	21.36	8.2203
8000	14.6	8.7655

Table 9: Mean Difference in SPL between groups without HPD and with EP-EM

Frequency	Mean Difference	Standard Deviation
250	19.88	12.0910
500	38.48	10.9967
1000	40.2	8.3516
2000	47.52	11.7442
3000	57.72	11.5921
4000	41.32	11.5207
6000	29.4	10.8474
8000	22.6	10.4363

Table 10: Computations for Significant Difference using paired t-test analysis of related samples

Pair	Without HPD	EP	95% Confidence Interval Difference		t	Sig (2-tailed)
			Lower	Upper		
1	250	250	0	0	0	0
2	500	500	0.1751	3.0249	2.317	.029
3	1000	1000	5.0833	9.7167	6.592	.000
4	2000	2000	11.6723	16.9677	11.163	.000
5	3000	3000	19.7004	24.5396	18.868	.000
6	4000	4000	12.4086	15.9914	16.360	.000
7	6000	6000	5.5781	9.9419	7.340	.000
8	8000	8000	0.7377	4.1423	2.958	.007

Table 11: Computations for Significant Difference using paired t-test analysis of related samples

Pair	Without HPD	EP	95% Confidence Interval Difference		t	Sig (2-tailed)
			Lower	Upper		
1	250	250	8.4498	14.3502	7.975	.000
2	500	500	22.9420	28.4980	19.106	.000
3	1000	1000	30.0188	35.2612	25.701	.000
4	2000	2000	32.6187	40.1813	19.868	.000
5	3000	3000	37.4424	45.2776	21.790	.000
6	4000	4000	28.6115	35.2285	19.912	.000
7	6000	6000	17.9668	24.7532	12.992	.000
8	8000	8000	10.9818	18.2182	8.328	.000

Table 12: Computations for Significant Difference using paired t-test analysis of related samples

Pair	Without HPD	EP	95% Confidence Interval Difference		t	Sig (2-taile
			Lower	Upper		
1	250	250	14.8891	24.8709	8.221	.000
2	500	500	33.9408	43.0192	14.496	.000
3	1000	1000	36.7526	43.6474	24.067	.000
4	2000	2000	42.6722	52.3678	20.231	.000
5	3000	3000	52.9350	62.5050	24.896	.000
6	4000	4000	36.5645	46.0755	17.933	.000
7	6000	6000	24.9224	33.8776	13.552	.000
8	8000	8000	18.2921	26.9079	10.828	.000

Table 13: Mean Difference of Sound Attenuation of each Hearing protective Device per Frequency Level

		Mean	Std. Deviation	95% Confidence Interval Difference	
				Lower	Upper
250	Without HPD	90	0	90	90
	EP	90	0	90	90
	EM	78.6	7.1473	75.6498	81.5502
	EP-EM	70.12	12.0910	65.1291	75.1109
500	Without HPD	90	0	90	90
	EP	88.4	3.4521	86.9751	89.8249
	EM	64.28	6.73	61.5020	67.0580
	EP-EM	51.52	10.9967	46.9808	56.0592
1000	Without HPD	89.80	1	89.3872	90.2128
	EP	82.4	5.4237	80.1612	84.6388
	EM	57.16	6.5044	54.4751	59.8449
	EP-EM	49.6	8.5294	46.0793	53.1207
2000	Without HPD	100.32	2.5120	99.2831	101.3569
	EP	86	5.9512	83.5435	88.4565
	EM	63.92	8.1134	60.5710	67.2690
	EP-EM	52.80	11	48.3594	57.3406
3000	Without HPD	111.64	4.3958	109.8255	113.4545
	EP	89.52	5.5085	87.2462	91.7938
	EM	70.28	8.6290	66.7181	73.8419
	EP-EM	53.92	9.9160	49.8269	58.0131
4000	Without HPD	99.52	3.0838	98.2471	100.7929
	EP	85.32	5.3285	83.1205	87.5195
	EM	67.60	8.3066	64.1712	71.0288
	EP-EM	57.80	11.0943	53.2205	62.3795
6000	Without HPD	94.0	3.5355	92.5406	95.4594
	EP	86.24	4.1416	84.5286	87.9514
	EM	72.64	8.2254	69.4447	76.0353
	EP-EM	64.60	9.7553	60.5732	68.6268
8000	Without HPD	90.60	5.4160	88.3644	92.8356
	EP	88.16	4.2689	86.3979	89.9221
	EM	76.0	7.3598	72.9620	79.0380
	EP-EM	68.0	8.2916	64.5774	71.4226

Table 14: ANOVA of Sound Attenuation of Hearing Protective Devices per Frequency Level

Frequency (Hz)		Sum of Squares	Mean Square	F	Sig
250	Between Groups	7014.12	2328.04	47.406	.000
	Within Groups	4734.64	49.319		
500	Between Groups	26559.47	8853.157	198.795	.000
	Within Groups	4275.28	44.534		
1000	Between Groups	28163.88	9387.96	258.136	.000
	Within Groups	3491.36	36.368		
2000	Between Groups	34384.96	11461.653	200.595	.000
	Within Groups	5485.28	57.138		
3000	Between Groups	46479.56	15493.187	278.588	.000
	Within Groups	5338.88	55.613		
4000	Between Groups	25802.96	8600.987	149.591	.000
	Within Groups	5519.68	57.497		
6000	Between Groups	13116.99	4372.33	90.847	.000
	Within Groups	4620.32	48.128		
8000	Between Groups	8426.03	2808.677	65.903	.000
	Within Groups	4091.36	42.618		

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QUALITY OF LIFE AMONG HEAD AND NECK CANCER PATIENTS AT THE PHILIPPINE GENERAL HOSPITAL: A PRELIMINARY REPORT*

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ABSTRACT

OBJECTIVES: To determine the quality of life of head and neck cancer patients at a tertiary institution and identify and correlate factors affecting it. Methods: Forty post-treatment head and neck cancer patients seen at the outpatient section (ENT) were asked to complete a self-administered questionnaire (Head and Neck Quality of Life Instrument) covering 6 domains, namely, eating, speech, emotions, pain, global bother and response to treatment. Chart review was done to determine variables like age, sex, diagnosis, surgery, neck dissection, staging, radiotherapy, and presence of tracheotomy. Data Analysis: ANOVA and simple linear regression analysis were employed to determine significant differences among groups and associations of QOL scores with above factors. Multiple linear regression analysis was done to determine the effect of staging on quality of life scores, considering other factors. Results and Conclusion: Mean QOL scores for each domain parallels findings of previous studies (eating=70.16, speech=60.85, emotion=62.95, pain=62.17, global bother=55.63, response to treatment=45.63). Factors significantly associated with QOL scores include age (speech), sex (emotion and global bother), neck dissection (eating), tumors in the nasopharynx and oropharynx (pain and response to treatment). Staging can reduce the QOL scores, but not statistically significant. Other factors cannot be determined because of the small sample size. Large-scale prospective studies are needed to further improve head and neck quality of life questionnaire for Filipinos, and to evaluate impact of both illness and treatment to their quality of life.

Key words: quality of life, head and neck quality of life

INTRODUCTION

As in any form of malignancy, head and neck cancers carry a very grave predicament for afflicted individuals. The quality of care, as assessed by survival, mortality and morbidity rates, have not improved that much (20). The scientific community evaluates treatment outcome using these so-called "easy, objective, and scientific" measures. But recently, health care givers have been questioning the value of these measures. There is an increased realization among medical practitioners and patients that these "do not capture the essence of clinical practice and human illness"(2) — that, it is also important to involve the patients in decision-making regarding treatment options as well as its evaluation in terms of their perspective based on real concerns. Thus, over the last few years, many researchers in head and neck cancer have focused their efforts in identifying the quality of life of patients with these disorders.

The most common goal of quality of life studies is to assess the effect of the treatment or therapy among patients. Initially, it was meant to determine the ability of social programs to enhance the patients' quality of existence (21). Among cancer patients, as the disease progresses, the quality of life generally declines. Introduction of treatment regimens, such as surgery, radiotherapy and chemotherapy produce adverse effects and diminishes the quality of life, even as the patient's survival is extended. Hence, it is necessary for health providers to weigh the

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effects of control of the malignancy against the complications resulting from treatment. Thus, quality of life studies establish limits within which cancer care occurs (20). According to Campbell (4), clinicians should determine the balance between an optimal therapeutic effect on patient survival, and an acceptable quality of life outcome.

At the Department of Otorhinolaryngology of the Philippine General Hospital, admitted head and neck cases occupy from 15 -20 beds at any one time. In 1998, there were at least 15 new cases of head and neck cancer seen every month at the Outpatient Department and subsequently given surgery, radiotherapy, chemotherapy or a combination of these. Cases include different types of head and neck cancer involving the oral cavity, oropharynx, nasopharynx, hypopharynx, larynx, paranasal sinuses, skin, parotid, mandibular and temporal bones. Most patients seen are already in an advanced stage (usually in stage III or IV), with poor prognosis, and where only palliative treatment can be offered. Yet, the determination of the patients to seek consult for removal or, if not possible, for relief of morbidity and inconvenience (such as pain) make the clinicians lean towards an approach combining surgery and radiotherapy, even if the consequences are grave. Surgery involves removing the entire mass and reconstruction, when necessary. This often results in severe disfiguring and disabling defects for the patients, especially for very large tumors. Radiotherapy, on the other hand, also has a multitude of deleterious effects — oral dryness, cataract formation, bone necrosis, to name a few.

The participation of the patients in determining which type of treatment is necessary and acceptable for their illness is very important. The course of the disease is usually pre-determined. There is not much to be done in delaying its progression, except in a few cases. The consequences of any treatment must be assessed, to determine its overall effect, not only in terms of patient survival, but also in its ability to make the patient's life as fulfilling as possible.

There are no studies yet in the Philippines regarding the quality of life of head and neck cancer patients. Likewise, survival studies are wanting. The volume and diversity of patients seen at PGH and more so the severity of their illness makes it necessary to conduct a quality of life study in conjunction with survival. The ultimate goal of this is to be able to plan out effective and acceptable treatment regimens that will be meaningful, either in prolonging the life of a patient and/or maintaining the level of function in all aspects of life.

This study aims to determine the quality of life of post-treatment head and neck cancer patients at the Philippine General Hospital, in particular, (1) to determine the head and neck cancer-specific quality of life among patients at PGH using the Head and Neck Quality of Life questionnaire (Appendix), (2) to identify factors that may affect the quality of life of head and neck cancer patients, (3) to correlate quality of life scores with the stage of the disease, and (4) to predict effect of clinical stage of head and neck cancer, considering other factors, to the quality of life scores.

REVIEW OF LITERATURE

According to Bailey (1), in the United States, approximately 78,000 new cases of head and neck cancer are diagnosed annually, where the case fatality rate is 33%. Overall 5-year survival was reported to be about 50-60% for local disease and 30% with regional involvement. In the United Kingdom (9), the incidence rate of head and neck cancers is approximately 88 cases per million, with 2500 deaths in 1 year with poor survival rates. In the Philippines, there has been no large-scale study on the epidemiology of head and neck cancers, but according to experts; survival rate despite treatment has not significantly increased. Goals of management for head and neck cancers, especially for early lesions, include full control and cure of local and regional disease, but this is not usually the case. Many of these patients, already in an advanced stage, are merely provided palliative measures, because prognosis is inherently poor. Thus, important goals to be considered would be to provide maximal oropharyngeal function and an acceptable cosmetic restoration.

Head and neck cancers affect a wide range of population, occurring mostly in the elderly with significant history of smoking and heavy alcoholic drinking. Other risk factors are radiation exposure for thyroid and salivary glands; leather, chromium and nickel for nose and paranasal sinuses, Epstein-Barr virus types 2 and 3 for nasopharyngeal carcinoma and sun exposure for melanomas. Almost 82% of these cancers occur in the oral cavity, oropharynx and larynx. Other sites include the nasopharynx, major salivary gland, nose and paranasal sinuses, thyroid, skin melanoma, and connective tissues. More than 80% are squamous cell carcinomas.

Tumor aggressiveness, management options and prognosis are related to the clinical staging for each type of cancer. Pre-cancerous, stage I and II usually have relatively high cure rates of 80-100% using only a single modality of treatment (either surgery or radiotherapy). For advanced cases (stage III-IV) with or without

regional metastases, there is an increased risk for local and regional failure of treatment as evidenced by recurrences. Usually, these patients are physically debilitated by the illness and treatment, especially where multiple modalities are employed (i.e., combination of surgery and radiotherapy). This subset of patients is of concern to the head and neck surgeon, not only because of their poor prognosis for recovery and cure, but also the grave and debilitating consequences of treatment. Functional morbidity, especially with surgery (where large areas of normal tissue are resected), includes disturbances in respiration, phonation, deglutition, mastication, audition and vision. Late effects of radiation therapy, on the other hand, include xerostomia, damage to teeth, fibrosis, soft tissue necrosis, bone necrosis, cartilage necrosis, cataracts, and sensorineural hearing loss.

Due to this bleak situation, over the last 50 years, there have been several researches that put emphasis on the utilization of patient outcome in head and neck cancer management. Schipper et al (24) defined quality of life as representing the functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient, and overall effect covers four domains namely, physical and occupational function, psychological state, social interaction and somatic sensation. Although there is still no consensus among experts as to what would be included in the quality of life, this definition more or less sends the real message. There are many uses of quality of life studies (24). For head and neck malignancies, evaluation of treatment effects and relating it to survival is the most relevant. The ability to determine factors contributing to a lower quality of life will assist health caregivers in their decision-making regarding the treatment plan for each patient.

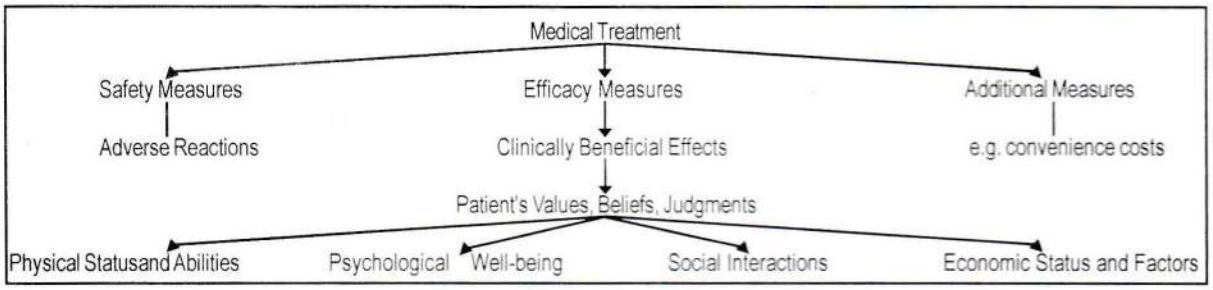
Morton (20) reviewed head and neck quality of life studies from 1950 to 1994. He noted the evolution of QOL studies from descriptive cross-sectional studies focusing on single type of surgery (mostly laryngectomy) and one domain (physical status, sexuality or psychological status) to correlational cross-sectional studies where QOL was correlated with treatment modalities and presence of pre-operative counseling. There are many quality of life for head and neck cancer researches that have sprouted during the last ten years, these include some prospective studies. He listed longitudinal studies that assessed the association of specific factors with QOL. The trend for QOL studies now is to formulate a model of quality of life in association with survival outcome, to have a better perspective of head and neck cancer management.

There are a lot of researches, completed and ongoing, which address the quality of life of patients with head and neck cancer. The development, and validation of QOL scales have also been the focus of much research. Measurements of quality of life, must be reliable and valid. This is pertinent because of the realization of clinicians, particularly head and neck surgeons, that patient-related outcomes are very important in contemplating the management of patients. The basic tenet for cancer treatment is to cure the disease if at all possible, but probably not at any cost (20). Survival outcome of these patients have not been very good. Thus, the belief that it is better to live a short, full life than a life prolonged with misery, has a valid reason.

The quality of life, is very difficult to measure. QOL measures using self-administered questionnaires may raise questions of content validity. Nevertheless, wanting of other measuring tools, majority of scientists have accepted the practice. At present, there are many measuring tools of quality of life and only a few have been tested for validity and reliability. Among these questionnaires is the Head and Neck Quality of Life (HNQOL) Instrument by Dr. Jeffrey Terrell et al (23) of the University of Michigan, Department of Otolaryngology. The HNQOL is applicable because of its multi-dimensional analysis of quality of life, simplicity, reliability and validity.

Quality of life is affected by many factors. Since most of the tools are self-administered questionnaires, factors affecting it relate to patients' perceived net benefit and risks. Spilker 1990 (24) developed a conceptual framework of quality of life and showing the possible factors

Figure 1. Conceptual Framework on Quality of Life.



that can affect it.

Thus, in conducting quality of life studies, it is necessary to take into account these factors and determine if there are strong associations with quality of life. Programs for these patients can now be planned and instituted.

METHODOLOGY

Study Design

This is a cross-sectional study. A head and neck cancer-specific questionnaire was administered to post-treatment head and neck cancer patients on follow-up at the Department of Otorhinolaryngology-Cancer Institute Outpatient Section, from October 18-29, 1999.

Sampling Design

All head and neck cancer patients seen at the Department of Otorhinolaryngology - Cancer Institute Outpatient Section from October 1999 onwards where a sample of 40 patients was identified for this preliminary study.

Study Population

The target population for this study is Filipino post-treatment head and neck cancer patients. The sampling population will be those patients seen at the Philippine General Hospital - Department of Otorhinolaryngology - Cancer Institute Outpatient Section (CIOPS) patients from October 1999 onwards, on the assumption that majority of head and neck cancer patients consult or are referred here (see pretesting). Since there are also head and neck cancer services in other areas, it is also recommended that a multi-center study be commenced in the future.

Study Variables

The following variables were measured: Sociodemographic factors (age,gender, educational attainment, occupation, illness/ disease, geographic location), TNM stage, which is related to prognosis, and treatment (any procedure or set of procedures that is applied on the patient for purposes of stopping the progression and/or eliminating the disease and may include the following: none, surgery – operative procedure within the head and neck, with or without neck dissection - any manipulation of the structures within the neck during the operative procedure to remove partly or wholly the lymphatic system, number of operations done, radiotherapy - a form of treatment regimen that uses external beam, radiation to suppress and/or kill cancer cells, chemotherapy, and/or in combination), and complications – any discomfort and/or disability following a surgical procedure, Gastrostomy tube insertion, Tracheotomy tube insertion, and HNQOL scores (see Appendix).

Data Collection

Post-operative head and neck cancer patients were identified at the Department of Otorhinolaryngology Outpatient Sections at the Cancer Institute. Patients were advised of the study and informed consents were obtained. Conditions of confidentiality and autonomy were explained. Data from the patient's charts were gathered, and these patients were administered the HNQOL questionnaires.

The study employed the Head and Neck Quality of Life questionnaire, a head and neck cancer-specific questionnaire, adapted from the University of Michigan Head and Neck Quality of Life (HNQOL) instrument (23).

Preliminary Procedures on Questionnaire Development

1. Review of literature on the quality of life of head and neck cancer patients were done to determine the range of important questions to be included. There were at least 4 head and neck-specific quality of life questionnaires noted from the literature worldwide. The most commonly used are the following: the Functional Assessment of Cancer Therapy-general (FACT-G); Functional Assessment of Cancer Therapy- Head and Neck; Performance Status Scales for Head and Neck Cancer with three subscales (Eating in public, understandability of speech, normalcy of diet); European Organization for Research on the Treatment of Cancer (EORTC) core questionnaire, where each has its own advantage (3, 6, 9, 12). There is no head and neck cancer-specific quality of life scale in the Philippines. The University of Michigan Head and Neck Quality of Life Scale was chosen because of its relative simplicity, reliability, validity and consideration of the multiple domains of quality of life of head and neck cancer patients. Domains identified are the following with the following reliability and validity tests:

Domain	Cronbach alpha value	Intraclass coefficient score	Pearson Product relation Score
Communication	0.93	0.73	0.81
Eating	0.87	0.89	0.89
Emotion	0.88	0.92	0.92
Pain	0.79	0.81	0.82

According to Terrell (23), there was strong reliability between two time points for each domain with test-retest reliability. Correlation for each question was noted to be between 0.53 to 0.93.

2. Personal communication with experts was done to determine the important variables to be considered for head and neck cancer patients.

3. Informal interviews were done on patients admitted at the PGH for head and neck cancer to determine their responses and possible concerns. These included general questions on health, their concerns and specific problems related to their illness. Their responses were compared with those already in the questionnaire.

4. Additional information needed (factors - patient-related, illness-related and service-related) was included in a separate abstraction form.

Modification in the format of the adapted HNQOL scale was done, utilizing the same format as the University of the Philippines-Department of Health Quality of Life, which was already validated at the Philippine General Hospital.

Tools

Data Abstraction Form - data form where variables from the chart of the patients will be placed and consists of the illness, duration of hospitalization, type of procedure, number of procedures undergone, and complications.

Head and Neck Quality of Life (HNQOL) - developed by the University of Michigan, is a multiple domain, concise, reliable, valid and relatively comprehensive instrument for the assessment of disease-specific quality of life in head and neck cancer. It has the following domains: communication (4 items), head and neck pain (4 items), eating and swallowing (6 items), and head and neck emotional (6 items), with five choice, Likert scale response options for each item or question (Appendix). This was then translated to Filipino. Consultation with experts and back-translation were done to obtain content validity.

Pretesting

A sample of 32 head and neck cancer patients presently admitted at the ENT ward during the months of September and October 1999 were included in the pretesting.

Patients were asked to answer the translated HNQOL questionnaire, with informed consent, and conditions of confidentiality and autonomy. Responses were assessed for reliability and validity. Results show that majority of the respondents were in the 17-45 age group (12, 38.71%), with females predominating (58.06%). Seventy-nine percent finished elementary and high school, and 41.94% were unemployed prior to and 96.77% after the diagnosis of their illness. Almost all regions in the Philippines were represented where the highest are the following: Region 4 (19.35%), Region 3 (16.13), Region 8 and NCR (12.9%).

Reliability

Test-retest reliability was not done due to time limitations. Internal consistency was determined using item-total correlation and Cronbach alpha reliability (see table 3).

Table 3. Head and Neck Quality of Life Domain Reliability: Domain Testing

Domain	Cronbach alpha value	Intraclass coefficient score	Pearson Product relation Score
Communication	0.3222	0.3351	0.2428
Eating	0.8938	0.7872	0.8142
Emotion	0.8964	0.5964	0.7546
Pain	0.6797	0.3742	0.4807

There is relatively a homogenous response across the domains, and average correlation within domains especially for pain and communication. Correlation of all items were low for communication, but still >0.20. The relatively low number of oral cavity and laryngeal cancer patients during this time may explain this low correlation, nevertheless, the items were still included because of its clinical significance. Further studies, with larger samples may give strength in assessing item correlation.

Data Processing

Data from the abstraction form and HNQOL were encoded separately using the Excel file and analyzed using the STATA statistical software.

Data Analysis

Descriptive univariate analysis was done to describe the population of head and neck cancer patients. Patients were categorized into important variables. Means, standard deviations and proportions were used.

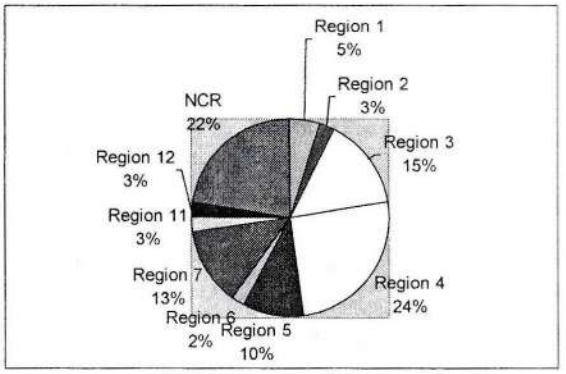
Inferential bivariate and multivariate analyses were done using correlation coefficients and multiple coefficient of determination for two variables. Linear regression was employed to explain the association of clinical staging with quality of life, considering other factors.

RESULTS

There were 40 patients who completed the questionnaire with region of origin shown in Figure 1. Sixty five percent of the patients are more than 45 years old, predominantly male (55%) and married (57.5%). Majority (52.5%) attained secondary education.

Scores for head and neck cancer-specific domains shown below, are noted to be similar to the values obtained in several other studies (15, 23, 4). As shown, mean score in the response to treatment domain is generally lower than for other

FIGURE 1. Distribution of Patients According to Region,PGH, 1999



domains, indicating that patients feel that they are not improving despite treatment given.

Head and neck cancer-specific quality of life scores were analyzed using analysis of variance (ANOVA) to determine differences between and among different groups. Patients who are more than 45 years old, male and with stage IV disease, and who underwent neck dissection and tracheotomy, have significantly lower scores for eating. On the other hand, patients who were given cobalt therapy have significantly higher scores for eating. Neck dissection and tracheotomy appears to be significant factors in the speech domain. Tracheotomy among patients seems to be a factor in lower scores for emotion. No patient underwent chemotherapy, excluding it in the analysis.

TABLE 1. Mean Quality of Life Scores for Head and Neck Cancer-Specific Domains, Philippine General Hospital, 1999.

Domain	Mean QOL Score (0-100)	Standard Deviation	Minimum Value	Maximum Value
Eating	70.76	28.23	0	100
Speech	60.85	33.46	0	100
Emotion	62.36	28.03	0	100
Pain	62.17	25.32	12.5	100
Global Bother	55.63	36.90	0	100
Response toTreatment	45.63	27.67	0	100

TABLE 2. Distribution of Patients and Mean Quality of Life Scores According to Several Factors, Philippine General Hospital, 1999.

Variable	No. (%)	Head and Neck Cancer-Specific QOL Score (0-100)					
		Eating	Speech	Emotion	Pain	Global Bother	Treatment response
Age							
<45	14(35)	**79.0***	82.6	76.6	69.9	35.7	50.0
>45	26(65)	**65.4***	49.1	55.6	58.0	66.3	43.3
*significant at p=0.05(ANOVA)							
Sex							
Male	22(55)	**64.1***	53.5	60.4	56.5	55.7	51.4
Female	18(45)	**77.6***	69.9	66.1	69.2	55.6	38.9
*significant at p=0.05(ANOVA)							
Diagnosis/Site							
Oral cavity	2(5)	81.5	84.5	81.5	81.5	37.5	37.5
Oro-Pharynx	8(20)	40.7	32.9	42.1	39.2	66.6	50.0
Larynx	8(20)	65.1	29	44.2	51.6	75.0	40.6
Nose/PNS	5(12.5)	79.2	72.6	78.4	65.0	30.0	50.0
Skin	1(2.5)	96.0	75	38.0	75.0	0	50.0
Naso-Pharynx	9(22.5)	77.0	82.7	74.1	71.1	44.4	41.7
SalivaryGlands1(2.5)	58.0	44	58.0	56.0	75.0	0	
Others	6(15.0)	93.1	90.7	84.6	83.5	66.7	58.3
Clinical Staging							
I-II	8(20)	**89.6***	79.1	73.0	78.1	53.1	50.0
III-IV	32(80)	**65.3***	56.3	60.4	58.2	56.3	44.5
*significant at p=0.05(ANOVA)							
Surgery							
With	31(77.5)	68.2	54.5	59.7	59.6	44.4	41.7
Without	9(22.5)	77.0	82.7	74.1	71.1	58.9	46.8
Neck Dissection							
With	14(35)	**59.0***	**37.1***	50.4	46.6	66.1	42.9
Without	26(65)	**76.1***	**73.7***	69.7	70.6	50.0	47.1
*significant at p=0.05(ANOVA)							
Radiotherapy							
Yes	13(32.5)	**72.2***	71.7	71.8	68.1	50.0	42.3
No	27(67.5)	**69.2***	55.6	58.7	59.3	58.3	47.2
*significant at p=0.05(ANOVA)							

Tracheotomy							
With	12(30)	**48.7***	**21.9***	**39.2***	41.3	64.6	43.7
Without	28(70)	**79.4***	**77.5***	**73.1***	71.1	57.8	46.4

*significant at p=0.05(ANOVA)

Linear regression analyses were performed to determine strength and direction of association between quality of life scores for each specific domain and each of the different factors, namely: age, sex, diagnosis/site, clinical staging, surgery, neck dissection, radiotherapy, and tracheotomy. Tracheotomy, site and staging seem to be significant factors in the eating domain; tracheotomy, site, age and neck dissection for speech, emotion (excluding site) and pain (excluding age). Staging and neck dissection are significantly associated with the general global bother domain. There seems to be no association between sex and response to treatment, rather site of the disease is significantly correlated.

TABLE 3. Association of Head and Neck Cancer QOL Scores and Factors Related to QOL, Philippine General Hospital, 1999.

Variable	Multiple Coefficient of Determination (R2)					
	Eating	Speech	Emotion	Pain	Global Bother	Treatment
Age	**0.098***	**0.286***	**0.130***	0.050	0.044	0.029
Sex	0.059	0.061	0.01	0.065	0.001	**0.000***
Site	**0.207***	**0.315***	0.188	**0.207***	0.198	**0.277***
Staging	**0.122***	0.075	0.033	0.016	**0.095***	0.038
Surgery	0.017	**0.127***	0.047	**0.104***	0.015	0.059
Neck Dissection	**0.087****	**0.278***	**0.112***	**0.209***	**0.108***	0.0138
RadioTherapy	0.003	0.052	0.050	0.026	0.013	0.033
Tracheo-Tomy	**0.255***	**0.594***	0.314	**0.299***	0.132	0.003

***significant at p=0.05**
**** marginally significant p=0.065**

For each specific domain, almost all the factors in the model were noted to be confounding the relationship of QOL scores and clinical staging. Only age (eating, pain, global bother and response to treatment), sex (emotion) and diagnosis (global bother), were not confounders. From Table 4, it can be shown that the model can fairly explain the variability of QOL scores in the different domains, except for general global bother and response to treatment. The presence of a tracheotomy appears to be a consistently significant factor in all the domains.

TABLE 4. Linear Regression Analysis of Head and Neck Cancer-Specific Quality of Life Domains, Philippine General Hospital, 1999.
Model: B0 + B1staging + B2diagnosis + B3surgery + B4neckdissection + B5tracheotomy + B6radiotherapy + B7age + B8sex + E

Domains	R2	Adjusted R2	Root MSE	Significant Factors
Eating	0.6520	0.4779	20.372	Neck dissection Tracheotomy
Speech	0.8109	0.7163	17.824	Age Tracheotomy
Emotion	0.6514	0.4771	20.249	Sex Tracheotomy
Pain	0.5697	0.3546	20.353	OropharynxNasopharynx Tracheotomy
Global Bother	0.4253	0.1380	34.262	Sex
Response to Treatment	0.3485	0.0228	27.353	Oropharynx Nose/PNS Nasopharynx

Model(eating): 135 + (-13.4)staging +(-17.5)oropharynx + (32.1)larynx + (32.3)nose/pns + (46.4)skin + (1.6)nasopharynx + (8.9)salivary glands + (44.3)others + (-31.3)neckdissection + (39.9)tracheotomy + (-22.6)radiotherapy + (-13.6)age + (-9)sex + E

Model(speech): 73.9 + (-9.0)staging +(-31.4)oropharynx + (-12.7)larynx + (-5.8)nose/pns + (-1.9)skin + (-8.5)nasopharynx + (-33.1)salivary glands + (11.3)others + (-14.5)neckdissection + (50.0)tracheotomy + (-5.0)radiotherapy + (-17.1)age + (-7.3)sex + E

Model(emotion): 144.7 + (-7.2)staging +(-14.7)oropharynx + (13.3)larynx + (45.2)nose/pns + (5.4)skin + (-0.4)nasopharynx + (26.3)salivary glands + (48.7)others + (-28.1)neckdissection + (34.1)tracheotomy + (-26.9)radiotherapy + (-13.3)age + (-18.5)sex + E

Model(pain): 71.7 + (-8.7)staging +(-44.3)oropharynx + (-16.9)larynx + (-38.6)nose/pns + (-34.5)skin + (-44.3)nasopharynx + (-53.2)salivary glands + (-20.5)others + (10.0)neckdissection + (26.0)tracheotomy + (18.4)radiotherapy + (1.6)age + (4.2)sex + E

Model(bother): 194.7 + (-31.4)staging + (-9.7)oropharynx + (13.0)larynx + (56.2)nose/pns + (20.4)skin + (12.8)nasopharynx + (20.4)salivary glands + (56.5)others + (-16.9)neckdissection + (17.1)tracheotomy + (-22.1)radiotherapy + (-7.8)age + (-37.2)sex + E

Model(response to treatment): 50.6 + (-6.2)staging + (65.7)oropharynx + (-47.1)larynx + (-81.0)nose/pns + (-55.0)skin + (-74.9)nasopharynx + (-55.0)salivary glands + (-80.2)others + (13.0)neckdissection + (10.0)tracheotomy + (2.9)radiotherapy + (13.2)age + (3.8)sex + E

Patients who are older than 45 years have decreased QOL by 17.13 in the speech domain; males have lower scores by 18.48 and 37.18 in the emotion and global bother domains, respectively. Those who underwent neck dissection have lower QOL in the eating domain by 31.28. Tumors involving the nasopharynx have decreased scores in pain and response to treatment, (44.33 and 74.87). Likewise, tumors of the oropharynx resulted in a similar decrease in both domains (44.28 and 65.66). Lower scores were also achieved with tumors in the nose and/or paranasal sinuses with 81.05.

DISCUSSION

During the last 50 years, many studies have been done about the quality of life of different subsets of patients. Among head and neck cancer patients, numerous studies have focused in different areas of quality of life studies, such as measuring tools, quantifying the concept of QOL, and determining the factors that are related to poor quality of life. Presently, there are a lot of questionnaires addressing head and neck cancer-specific quality of life, but there is no consensus among experts as to what to use, as long as these are valid and reliable. QOL have already been quantified in head and neck cancer patients, and several subsets of patients. The trend now is to formulate prospective studies that would determine associations of specific factors for each subset of H&N cancer patients.

This study shows that quality of life among Filipino head and neck cancer patients are similar to those reported in other countries. This can be due to the fact that management principles are more or less the same — i.e. more aggressive forms of treatment for stage III and IV cases. Most affected in these types of patients are their speech, eating, pain, and emotion because of the disabling and disfiguring consequences. The challenge for head and neck surgeons is how to use these quality of life data in such patients.

Preliminary findings using ANOVA and simple linear regression analysis show that in general, factors identified to be determinants of lower quality of life are age, sex, site, clinical staging, neck dissection and presence of tracheotomy. The other variables measured, for this study, may not have significantly different QOL scores, due to a small sample size. As shown in Table 2, there are differences among categories of each variable under study. Thus, patients tend to have lower QOL scores with age>45, male, oropharyngeal and laryngeal tumors, stage III-IV, with surgery, neck dissection and tracheotomy. Radiotherapy was noted to have higher QOL scores, maybe due to the fact that these patients did not undergo any surgery, and they may be at an earlier stage of the disease.

Forced model for linear regression analysis, with QOL scores as outcome and clinical staging, show that there are still other unidentified factors that explain the variability of the outcome. Significant factors that correlate well with the association of QOL and clinical stage, are tracheotomy, neck dissection, oropharyngeal, nasopharyngeal tumors, age and sex. Staging is important because it implies aggressiveness of the tumor, outlines the management (whether conservative or not) and predicts the possible functional morbidities in a patient. In this study, it was not found to be statistically significant. But due to the small sample size, significant association cannot be ruled out.

In spite of the results of the study, valid generalizations can be more elucidated with large-scale prospective studies. The design may have introduced selection bias (excluding patients who did not follow-up at the clinic, and may have a different QOL from the present sample population). Further validity (criterion and construct) by comparing it with Filipino-validated general QOL questionnaires (such as the University of the Philippines-Department of Health Quality of Life Form) and reliability analysis on the head and neck quality of life instrument can be done with a larger population to improve its capacity to measure head and neck specific quality of life for Filipinos. There is also a need to include other factors that may affect QOL such as support groups, type of surgery (i.e. with reconstruction), the duration of last treatment (i.e. surgery or radiotherapy) general quality of life, and functional status. QOL studies would be helpful in deciding between two treatments with similar endpoints (survival rate), but varying level of QOL. And lastly, correlating quality of life with survival studies would be most valuable in determining the best possible treatment option for the patient.

CONCLUSION

Preliminary results show that Filipino head and neck cancer patients have similar quality of life with regards to specific domains as speech, eating, emotion, pain, and general global bother. Factors identified and significantly correlated with QOL include age (eating and speech), sex (global bother), site (pain and response to treatment), neck dissection (eating) and presence of tracheotomy (eating, speech, emotion, pain). Other factors cannot be adequately determined due to a small sample size.

RECOMMENDATIONS

Realizing the importance of quality of life of studies among head and neck cancer, this study, despite its limitations may provide avenues towards more focused research on the topic. Therefore, to have a better perspective of this topic, large-scale prospective, if not randomized trials, probably multi-center studies, be done to: (1) further improve and validate this head and neck specific cancer questionnaire, (2) determine effect of specific treatment on the quality of life of specific patients, (3) evaluate management protocols for different stages of a disease, (4) incorporate survival data with QOL data to obtain a good estimate of a patient's benefits and risks from disease and treatment.

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APPENDIX

INSTRUCTIONS: *This survey is designed to assess how much you are bothered by your Head and Neck condition and/or treatment. Please answer every question by marking one box. If you are unsure about how to answer, please give the best answer you can.*

1. As a result of your head and neck condition or treatment, over the past FOUR WEEKS how much have you been BOTHERED by your...

	Not at all	Slightly	Moderately	A lot	Extremely
A. Ability to talk to other people					
B. Ability to talk on the phone					

2. As a result of your head and neck condition or treatment, over the past FOUR WEEKS how much have you been BOTHERED by problems with...

	Not at all	Slightly	Moderately	A lot	Extremely
A. Volume of your voice					
B. Clarity of your voice					
C. Difficulty opening your mouth					
D. Dryness in your mouth while eating					

2. As a result of your head and neck condition or treatment, over the past FOUR WEEKS how much have you been BOTHERED by problems with...

	Not at all	Slightly	Moderately	A lot	Extremely
E. Chewing food (For example, pain, difficulty opening or closing your mouth, moving food in your mouth, or teeth or denture problems)					
F. Swallowing liquids					
G. Swallowing soft foods and/or solids H Your ability to taste food (For example, loss of taste, and/or loss of appetite due to poor taste)					
I. Pain, burning, and/or discomfort in your mouth, jaw, or throat					
J. Shoulder or neck pain					

3. Over the past FOUR WEEKS, how often did you take pain medication?...

Never	Rarely	Sometimes	Frequently	Always

4. Over the past FOUR WEEKS how much have you been bothered by ...

	Not at all	Slightly	Moderately	A lot	Extremely
A. Concerns or worries about your appearance related to your head and neck condition or treatment					
B. Emotional problems related to your head and neck condition or treatment					
C. Embarrassment about your symptoms					
D. Frustration about your condition					
E. Financial worries due to medical problems					
F. Worries that your condition will get worse					
G. Physical problems related to your head and neck condition					

5. Were you working (employed) prior to being diagnosed with cancer? Yes No
If no, go to question 6 (next page)

5A. If yes, did your doctor declare you unable to work due to your head and neck condition or treatment? Yes No

6. Have there been other problems related to your head and neck condition that were not mentioned. If so please write them in the spaces below and tell us how much this problem has bothered you. (For instance, if your treatment included surgical transfer of tissue from a donor site to the head and neck, does the donor site bother you)

	Not at all	Slightly	Moderately	A lot	Extremely
A._____					
B._____					
C._____					

7. For the past FOUR WEEKS, please rate your OVERALL amount of disturbance or BOTHER as a result of your head and neck cancer condition?

8. Overall how satisfied are you with your Head and Neck cancer care at this hospital?

9. Overall how would you rate your response to treatment?

Poor	Fair	Good	Very Good	Excellent

10. Approximately how long did it take you to answer this questionnaire? _____Minutes

11. How difficult was it to complete this questionnaire?

Not at all	Slightly	Moderately	A lot	Extremely

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ESOPHAGEAL AND TRACHEOBRONCHIAL FOREIGN BODIES: A TEN-YEAR RETROSPECTIVE STUDY*

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ABSTRACT

OBJECTIVES: To review the clinical profile of foreign body ingestion and aspiration.
To assess predisposing conditions.
To evaluate esophagoscopy and bronchoscopy as management
To determine outcome and complications.

STUDY DESIGN: Cross-sectional Study

SETTING: Government Tertiary Medical Center

METHODS AND PATIENTS: Using the medical record registry, a retrospective analysis of all patients admitted at the Department of Otorhinolaryngology for foreign body ingestion and aspiration from April 1993 to April 2003 was done.

RESULTS: Of 648 patients, 632 (98%) were cases of foreign body ingestion and 16(2%) cases were foreign body aspiration. 484 (75%) were pediatric patients (<20 years old) and 164 (25%) were adults. Majority of the cases seen (460 patients or 71%) were males, yielding a male to female ratio of 2.4:1. 81% of the pediatric patients belong to the <7 age group and accidental swallowing/aspiration of the foreign body while playing was always the cause given. Hasty eating (49%) was the most common cause given by the adult group. 471 (97%) cases of foreign body ingestion belong to the pediatric group. Coins and dentures were the most commonly ingested foreign bodies in the pediatric and adult group respectively. Dysphagia and/or foreign body sensation in the throat was the most common symptom of the foreign body ingestion cases above 7 years of age. In all cases, chest radiograph was requested. A contrast study (modified barium or modified Meglumine swallow) were requested in 88/632 (14%) patients. In 466/648 (72%) cases, the foreign body was located at the level of the 5th cervical vertebrae (C5) up to the 1st thoracic vertebrae (T1). 620 (98%) cases were successfully managed by esophagoscopy. Most of the foreign bodies were located at the cricopharyngeal level in all age group. Esophageal mucosal abrasions were detected intraoperatively in 145/484 (30%) of pediatric cases and 68/164 (42%) of adult cases. One patient died of post-operative sepsis secondary to mediastinitis after undergoing diagnostic esophagoscopy. Ten patients had post-operative mediastinitis that was treated medically. About 621 (98%) of the patients were discharged improved after 3 post-operative days comprise 13/16 (81%). The pediatric age group (< 20 years old). Seeds were the most commonly aspirated foreign body in the pediatric age group while 2 cases of denture aspiration were reported in the adult age group. About 14/16 (88%) of the patients presented with cough. Chest radiograph were requested in all cases but only 7/16 (44%) of the foreign bodies were seen radiographically. About 13/16 (81%) cases were successfully removed by bronchoscopy tracheal mucosal abrasion was noted in one case. Complications post-operatively included pneumonia (3 patients) and atelectasis (2 patients). About 9/16 (56%) of the patients were discharged improved after 3 post-operative days.

CONCLUSION: The clinical profile of 648 cases of esophageal and tracheobronchial foreign bodies for the past 10 years was described. Majority of the patients belong to the pediatric age group, similar to those reported in literature. Diagnoses were established based on history and symptomatology and supported by radiographic examination. Predisposing conditions were mostly due to carelessness in pediatric care and carelessness in eating for the adult age group. Almost all of the cases were successfully treated with esophagoscopy and bronchoscopy. There were cases of intraoperative and postoperative complications that were treated medically. 97% of the patients were discharged improved after 3 postoperative days.

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INTRODUCTION:

Foreign body ingestion and aspiration still account for a significant number of emergency room visits. Ayed[1] et al reported 206 cases of foreign body aspiration from 1993-1997 in a hospital in Kuwait. Similarly, Ciriza et al[7] reported 122 cases of foreign body ingestion from 1995-1997 attended to at a hospital in Spain. In 1999, it is estimated that there were more than 182,000 cases of foreign body ingestion in children and adolescents less than 20 years of age in the United States[23]. Despite these repeated documentation, it remains to be a diagnostic and therapeutic challenge to clinicians. In fact, cases of misdiagnosis[17] and complications[14,22] are still being reported.

As the population continues to increase, the number of cases is expected to rise. As such it should interest the clinician, especially the otolaryngologists, to review the clinical profile, predisposing conditions, management, outcome and complications of this problem.

OBJECTIVES

The objectives of this study are:

1. To review the clinical profile of foreign body ingestion and aspiration.
2. To assess predisposing conditions.
3. To evaluate esophagoscopy and bron choscopy as management.
4. To determine outcome and complications.

METHODOLOGY

This was a cross-sectional study done at the Department of Otorhinolaryngology at a tertiary government hospital. A total of 648 cases of foreign body ingestion and aspiration admitted from April 1993 to April 2003 were identified using the hospital's medical record registry. The charts were reviewed to determine the age and sex distribution, the nature of ingested or aspirated foreign body, the predisposing factors, duration of time between ingestion or aspiration to extraction, diagnostic modalities requested, management done, and complications, if any. The data were then analyzed using percentages, means, medians and standard deviations.

RESULTS

Age and Sex Distribution

Of the 648 patients admitted, there were 460 males (71%) and 188 females (29%), with a 2.4:1 male to female ratio. Four hundred eighty four (75%) were pediatric patients (≤ 20 y.o.) and 164 (25%) were adults. See Table 1

TABLE 1. Age and Sex Distribution of ForeignBodies in the Esophagus and Airway

	Male Frequency (Percentage)	Female Frequency (Percentage)	Total
Pediatric Patient	339	145	**484(75%)**
Adult Patient	121	43	**164(25%)**
Total	460(71%)	188(29%)	**648(100%)**

The age ranged from 4 months to 72 years. In the pediatric age group, the mean age was 5.55 years (median = 5.3 years) with a standard deviation of 3.84 years. In the adult group, the mean age was 25.46 years (median=33.5 years) with a standard deviation of 14 years. See Appendices A and B.

Nature of Foreign body

Of the 648 foreign bodies, 632 (98%) were lodged in the esophagus and 16 (2%) in the airway. See Table 2.

TABLE 2. Distribution of Foreign Bodies in the Esophagus and Airway

	Foreign Bodies in the Esophagus	Foreign Bodies in the Airway	Total
Pediatric patients	471(75%)	13 (81%)	484 (75%)
Adult patients	161(25%)	3(19%)	164(25%)
Total	632(98%)	16(2%)	**648(100)**

Foreign Bodies in the Esophagus.

Among the pediatric age group, coin was the foreign body seen in 440 cases (93%). The most common type of coin was the one-peso (59%) and 25-centavo coins (26%). The other less common foreign bodies encountered were dentures (n=14), thumbtacks (n=4), and meat bone (n=2). See Table 3.

TABLE 3. Foreign Bodies in the Esophagus in the Pediatric Age Group

Esophageal Foreign Bodies in Pediatric Child	Frequency (Percentage)
Coin	**440(93%)**
10 centavos	3 (1%)
25 centavos	114 (25%)
50 centavos	45 (10%)
1 Peso	260 (59%)
2 Peso	7 (2%)
5 Peso	11 (3%)
Denture	
14(3%) Others	
17(4%)	
	thumb tacks (4), fish spine (3), meat bone (2), earring (1), santol seed (1), meat bolus (1), metal fastener (1), aluminum bottle cap (1), watch battery (1), key-chain ring (1), wristwatch cap (1)
Total	**471(100%)**

Among adults, the most common foreign bodies are the denture (44%), balut white (28%), and meat bone or bolus (22%). (Table 4)

TABLE 4. Foreign Bodies in the Esophagus in Adults

Esophageal Foreign Bodies in the Adult	Frequency (Percentage)
Denture	**70 (44%)**
Balut White	**45 (28%)**
Meat Bone or Bolus	**36 (22%)**
Others	**10 (6%)** Fish spine (3), santol seed (3), metal (1), glass (1), stone (1), pin (1)
Total	**161 (100%)**

Foreign Bodies in the Airway. Of the foreign bodies in the airway, 13 occurred in the pediatric age group and 3 in the adult. The foreign bodies were pin, seeds, coin, eggshell, ballpen tip, hairclip, plastic whistle, spring, fastener tip, dentures, and fractured tracheostomy tube. (Table 5.)

TABLE 5. Foreign Bodies in the Airway

Foreign Bodies in the Airway	Frequency (Percentage)
Pediatric group	**13 (81%)** pin (1), chico seed (1), camachile seed (1), atis seed (1), coin (1), egg shell (1), ballpen tip (2), fastener tip (1), hairclip (1), plastic whistle (1), spring (1), fractured tracheo stomy tube (1).
Adult	**3 (19%)** dentures (2), fractured tracheostomy tube (1)
Total	**16 (100%)**

Predisposing factors

Pediatric Age Group. All of the patients under 7 years of age allegedly accidentally ingested/aspirated the foreign body while playing. Other reasons include eating (n=9), trauma (n=1) and psychiatric disorder (n=1).

Adult. Hasty eating was the most common cause given by the adult group accounting for 81 (50%) of cases. Other reasons include accidental swallowing of ill-fitting dentures, sleeping, drinking and senile dementia. (Table 6).

TABLE 6. Factors Predisposing to Foreign Body Ingestion or Aspiration in Adults

	Frequency (Percentage) Hasty
eating	**82 (50%)**
Ill-fitting dentures	**70 (43%)**
Sleeping	**3 (2%)**
Drinking	**3 (2%)**
Alcoholic intoxication	**3 (2%)**
Senile dementia	**1 (0.5%**
Total	**164 (100%)**

Symptomatology

Ninety eight percent of pediatric patients under 7 years of age who had foreign body ingestion were brought to the emergency room on the asymptomatic stage. Those above 7 years including the adult group complained of dysphagia and/or foreign body sensation in the throat. Chest pain was also elicited from 140/161(87%) of the adult cases.

Cough was the most common manifestation of the cases of tracheobronchial aspiration (14/16 or 88%). Temperature elevation to at least 38°C was recorded in 5 patients. Dyspnea was seen in 7/16 (43%).

Diagnostic Modality

Chest radiographs were requested in all the cases of foreign body ingestion. A contrast study (modified Barium or modified Meglumine swallow) was requested in 466/648 (72%) cases. In 466/648 (72%) cases, the foreign body was located at the level of the 5th cervical vertebrae (C5) up to the 1st thoracic vertebrae (T1). In 11 cases (2%), the foreign body was seen at the T7 to T9 vertebrae. (Table 7).

TABLE 7. Level of Foreign Body Preoperatively

Level	Pediatric Age Group	Adult	Total
C5-C6	89	27	**116 (18%)**
C6-C7	154	27	**181 (28%)**
C7-T1	138	32	**170 (26%)**
T1-T2	75	26	**101 16%)**
T3-T4	20	37	**57 (9%)**
T5-T6	6	6	**12 (1.7%)**
T7-T8	2	7	**9 (1%)**
T8-T9	0	2	**2 (0.3%)**
Total	484	164	**647 (100%)**

Chest radiographs were also requested in all the cases of foreign body aspiration but only 7/16 (44%) of the foreign bodies were seen radiographically.

Duration from Admission to Surgical Intervention

About 50% of patients underwent esophagoscopy or bronchoscopy within the first 12 hours of admission. On the 24th hour of admission, about 90% of endoscopy have already been done. (Table 8).

TABLE 8. Duration from Admission to Surgical Intervention

Duration	Pediatric Age Group	Adult	Total 0-12
hours	229 (50%)	109 (58%)	335 (52%)
13-24 hours	179 (39%)	53 (28%)	232 (36%)
25-36 hours	31 (7%)	20 (11%)	51 (8%)
37-48 hours	19 (3%)	3 (2%)	22 (3%)
48-60 hours	3 (1%)	2 (1%)	5 (1%)
Total	461 (100%)	187 (100%)	646 (100%)

Results of Endoscopy

All cases of foreign body ingestion underwent rigid esophagoscopy. In 621 cases (95%), the foreign body was removed successfully. Most of the foreign bodies were seen at the cricopharyngeal level in all age group (Table 9). In 27 (5%) of the cases, no foreign body was seen. 1 case (pin) was eventually passed out through natural passages.

Thirteen cases of foreign body aspiration were successfully removed by bronchoscopy. 6 (43%) of the foreign bodies were seen on the left main bronchus (Table 10). 2 cases (hairclip and dentures) were removed by direct laryngoscopy only as it was protruding out of the glottis. Two of the patients (camachile seed and metal fastener tip) coughed out the aspirated foreign body.

TABLE 9. Level of Foreign Body in the esophagus intraoperatively

Age	Distance from the Upper Central Incisors	Frequency
<1 y/o	**7-11 cm (cricopharyngeus level)**	**9 (52%)**
	12 cm (aortic level)	0
	13-16 cm (left main bronchus level)	1 (5%)
	17 cm (hiatus level)	2 (12%)
	>18 cm (stomach level)	5 (30%)
1-2	**9-13cm(cricopharyngeus level)**	**98 (72%)**
	14 cm(aortic level)	6 (5%)
	15-17 cm (left main bronchus level)	23 (17%)
	18 cm(hiatus level)	2 (1%)
	>19 cm (stomach level)	6 (5%)
3-5	**(cricopharyngeus level)**	**173 (80%)**
	15 cm(aortic level)	24 (11%)
	16-20cm (left main bronchus)	12 (5.5%)
	21 cm(hiatus level)	1 (0.5%)
	>22cm (stomach level)	6 (3%)
6-9	**11-15 cm (cricopharyngeus level)**	**59 (70%)**
	16-17 cm (aortic level)	14 (17%)
	18-23 cm (left main bronchus level)	5 (6%)
	24 cm (hiatus level)	1 (1%)
	>25 cm (stomach level)	5 (6%)
10-13	**12-16cm (cricopharyngeus level)**	**9 (82%)**
	17-19 cm (aortic level)	0
	20-25 cm (left main bronchus level)	0
	26 cm (hiatus level)	0
	>27 cm (stomach level)	2 (8%)
14-18	**14-20 cm (cricopharyngeus level)**	**18 (76%)**
	21-23 cm (aortic level)	2 (8%)
	24-32cm (left main bronchus level)	2 (8%)
	33cm (hiatus level)	0
	>34 cm (stomach level)	2 (8%)
>18	**16-22 cm(cricopharyngeus level)**	**119 (74%)**
	23-26 cm (aortic level)	22 (14%)
	27-37 cm (left main bronchus level)	12 (8%)
	38-39 cm (hiatus level)	0
	>40 cm (stomach level)	7 (4%)

Note: The classification into the different esophageal levels is based on Chevalier Jackson's Measurements

TABLE 10. Levels of Foreign body in the tracheobronchial tree intraoperatively

Location	Frequency (Percentage)
Left Main Bronchus	6 (43%)
Right Main Bronchus	1 (7%)
Subglottis	2 (14%)
Trachea	4 (29%)
Secondary Bronchus	1 (7%)
Total	14 (100%)

Complications

Esophageal mucosal abrasions were detected intraoperatively in 145/484 (30%) of pediatric cases and 68/164 (42%) of adult cases. Esophageal mucosal edema was noted in 5 cases. 10/648 (2%) of the cases also had postoperative mediastinitis but resolved after medical treatment. One adult male who allegedly ingested a santol seed (although no foreign body was seen intraoperatively) developed mediastinitis after 24 hours and eventually succumbed to sepsis.

There was one tracheal mucosal abrasion noted and this was after extraction of the ball pen tip. 3 patients had pneumonia preoperatively and 2 others were also found to have atelectasis. They were medically treated.

Postoperative course

Of the 632 cases of foreign body ingestion, 621 (98%) were discharged improved after 3 post-operative days. Three cases who developed mediastinitis were transferred to the thoracovascular surgery service, 1patient died and the other 7 (1%) stayed for 5 – 7 postoperative days.

There were 9/16 (56%) of the cases of foreign body aspiration were discharged improved after 3 post-operative days. The other 3 who had pneumonia and the 2 with atelectasis were treated medically and were discharged improved after 7 post-operative days.

DISCUSSION

Age and Sex Distribution

Ingestion and aspiration of foreign bodies is primarily a pediatric problem with approximately 80% of cases occurring in childhood and the majority of cases presenting in children between 6 and 36 months of age (Wahbeh, 2002)[23]. Crysdale (1991)[8] mentioned the incidence of foreign body in 76% of his study regarding esophageal foreign bodies in children. In a local study, Caparas (1989)[6] reported a 57% incidence of foreign body ingestion in children. Ayed et al[1] reported 206 cases of foreign body aspiration in children in a span of 4 years. In this study, a total of 395 (61%) belong to the pediatric age of less than 7 years.

There is a male predominance in both age groups in this study which is similar to that reported by Villarta et al [21] where 95% of their cases were males. Crysdale[8] reported that the male population was involved more often in foreign body ingestion.

Nature of Foreign Body

The first recorded pediatric foreign body ingestion was in 1692 by Frederick the Great, at the time crown prince of Bradenburg, who swallowed a shoe buckle at the age of 4 that passed without incident[23]. Since then, the reported type of foreign body ingested varied. In North America and Europe, coins are the most common foreign body ingested in childhood.[23]. Ong (1978)[18] reported 2, 934 foreign body ingestions in China, 84% of which were fish bones. Binder (1984) reported that coin was the most commonly ingested foreign body in his study of 125 patients. Similarly, in a local study conducted at UP-PGH (1982)[21], there were 45 cases (53%) involving children who ingested coin. In this study, coin also was the most common foreign body ingested in the pediatric age group accounting for 440 (93%) cases. In Table 3, 7 % of the pediatric population ingested objects other than coins. In the study done by Binder in 1984[5], there was a 10% incidence of ingested material other than coin, which included thumbtacks, batteries and watch glass. In the adult subjects, 70 (44%) cases were denture ingestion. This is similar to the study by Villarta et al (1982) where dentures were most common in the entire adult series. In contrast, foreign authors have reported meat as the most common in the adult group (Giordano, 1981[10] and Baraka, 1975[4]).

For the cases of tracheobronchial foreign bodies, seeds are the most commonly aspirated (3/13 or 23%) in children, similar to the study of Zaytoun. For the adults, the reported types of foreign body aspirated were varied. In this study, there were 2 cases of denture aspiration and one case of fractured tracheostomy tube. Gupta (1996) who also reported a similar case mentioned that various factors contibute to the possible fracture of a tracheostomy tube such as alkaline tracheobronchial secretions, long duration of usage, mechanical stress and fatigue caused by repeated removal cleaning and insertion.

Predisposing factors

The propensity for small children to put whatever comes into their grasp into their mouth accounts for majority of the pediatric cases of foreign body ingestion and aspiration. This can also be attributed to carelessness in child's care, like allowing children to play while eating, giving food such as peanuts or hard candies to children who do not have the proper molar teeth, and improper supervision of small children playing in the vicinity of infants[17]. All of the pediatric patients under 7 years of age in our study were allegedly playing when they accidentally swallowed or aspirated the foreign bodies.

For the adult group, Villarta, et al. (1982), in their local study on esophageal foreign bodies, noted several causes of swallowed foreign bodies, similar to those seen in the studies of Jackson (1957) and Hollinger (1962). The most common of which is ill-fitting denture. In our study, hasty eating accounted for 81 (50%) of the ingestion and aspiration cases. Martinez attributed such cases to improper preparation of food, incomplete dentition and talking with food in the mouth.

Symptomatology

Foreign bodies in the tracheobronchial tree and esophagus may simulate signs and symptoms of relatively common respiratory diseases especially in children under three years of age [17]. Respiratory symptoms can be caused by direct tracheal impingement by the foreign body or from swelling of the tracheal or paraesophageal soft tissue following prolonged retention (Mcpherson, 1996). Upon ingestion of the esophageal foreign body, there may be a brief period of coughing and choking but the initial symptoms soon subside and are followed by relatively symptomless interval (Smith, 1974). Dysphagia and/or foreign body sensation in the throat was the most common symptom of foreign body ingestion elicited in this study (236/631or 37%), similar to Villarta's study.

In this study, cough was the most common manifestation of the cases of tracheobronchial aspiration (14/16 or 88%). This is similar to a study by Kula, et al. (1998) of 25 cases of foreign body aspiration where 96% of the patients complained of cough[15]. Coarse breathing, dyspnea, fever and chest pain were the other presenting symptoms noted. These were also elicited from our patients.

Diagnostic modality

The diagnosis of foreign bodies in the esophagus is usually straight forward based on the history and symptoms. Since a high proportion of foreign bodies are opaque, diagnosis is readily made with a plain x-ray while Barium or Meglumine swallow is sufficient for others. Hodge (1985) recommended that all children presenting with a history of coin ingestion should receive a chest radiograph that include the cervical esophagus and a lateral view of the chest[12]. In this study, chest radiograph was requested in all cases. Preoperative levels were based from these.

In contrast, only ten to fifteen percent of tracheobronchial foreign bodies are visualized radiographically[17]. Therefore, indirect signs must be sought on x-ray such as atelectasis, pneumonia or obstructive emphysema. In this study, two patients showed atelectasis (chico seed and ball pen tip), three patients revealed pneumonia (egg shell, 0.25 centavo coin and atis seed), and five patients showed no radiologic evidence of the above-mentioned findings. These findings were also present in more than 50% of the study by Lemberg (1996)[3].

Duration from admission to surgical intervention

A foreign body, which has become arrested in the esophagus, should be removed as soon as the diagnosis is made. This is because (1) once an object is impacted in the esophagus, the chance of spontaneous passage is small; (2) edema from local trauma tends to grip the object more firmly making later manipulation increasingly difficult; and (3) perforation of the esophagus is much more serious and dangerous than perforation of any part of the gastrointestinal tract [18]. Villarta, et al., however mentioned that esophageal foreign body, in general, should only be regarded as true emergencies when the airway is embarrassed or there is imminent danger of perforation or if it is felt that the foreign body may migrate to a more dangerous position.

Tracheobronchial foreign bodies should always be regarded as emergency cases[16] In this study, 50% of patients underwent esophagoscopy or bronchoscopy within the first 12 hours of admission and almost all within 24 hours.

Results of Endoscopy

Kussmaul, who used a rigid urethroscope to examine the esophagus of a sword-swallower, reported the first case of esophagoscopy in 1868. It was not until the early part of the 20th century, however, that Chevalier Jackson designed modern end-illuminated esophagoscopes and pioneered the use of these instruments in esophageal foreign body removal[23]. To this day, these esophagoscopes are the workhorse in management of foreign body ingestions.[5]

In this study, all cases of foreign body ingestion underwent rigid esophagoscopy and were successful in 621(95%) cases. In a retrospective review by Bacon, et al., (1991) of open tube esophagoscopies, they reported a success rate of 98%. Villarta, et al., also reported similar success rate of 95%.

Similarly, the definitive treatment of tracheobronchial foreign body aspiration is bronchoscopy. As early as 1897, Killian described removal of foreign body with a rigid esophagoscope. In 1904, Chevalier Jackson designed the first bronchoscope with a light at its distal end. He also developed grasping forceps that made removal of foreign bodies easier. 13 of our cases (81%) underwent bronchoscopy under general anesthesia and the foreign bodies were successfully removed from their lodgment. Zaytoun et al (2000) reported a 96% success rate of bronchoscopy in his study in Lebanon.[25]

Complications

Although foreign body ingestions cause little or no morbidity, some lead to tracheal aspiration and gastrointestinal perforation and obstruction (Paul, 1992). Complications of endoscopy may be due to inexperience in the introduction of the esophagoscope or traction on the presenting part of the foreign body without first determining the possible results of such traction[21] .In the cases reviewed, there were 10 cases of post-operative mediastinitis that resolved after medical treatment. Esophageal mucosal abrasions and edema were also reported although it was not specified if it were caused by the foreign body impaction or the instrumentation.

Zaytoun, et al divided complications of foreign body aspiration into intraoperative and postoperative. They reported complications like respiratory distress necessitating tracheotomy, bronchial pneumonia, pneumothorax, bradycardia and cardiac arrest[25]. In this study, pneumonia and atelectasis were reported although these were already noted pre-operatively.

Postoperative Course

The postoperative care of patients consist of careful observation for one or two days if the procedure was associated with no trauma or minimal abrasions, and for three to five days if there is nonperforating trauma. If the postoperative course is uneventful, the patient is started on oral feedings and discharged after a day or two [21]. In this study, 95% of the cases were discharged on the 3rd post-operative day and the other 5% stayed for 5 – 7 postoperative days.

CONCLUSION

The clinical profile of 648 cases of esophageal and tracheobronchial foreign bodies for the past 10 years was described. Majority of the patients belong to the pediatric age group, similar to those reported in literature. Diagnoses were established based on history and symptomatology and supported by radiographic examination. Predisposing conditions were mostly due to carelessness in pediatric care and carelessness in eating for the adult age group. Almost all of the

cases were successfully treated with esophagoscopy and bronchoscopy. There were cases of intraoperative and postoperative complications that were treated medically with 97% of the patients discharged improved after 3 postoperative days.

Recommendation :

There should be a heightened awareness on the part of parents, adults, primary health physicians and ENT specialists regarding foreign body ingestion and aspiration.

Pediatric care, proper eating manners for adults and dental care should be evaluated and given focus to prevent these cases.

Primary healthcare givers should be informed that specialists can manage these cases successfully and thus once identified, prompt referral should be done.

ENT specialists, on the other hand, should always be knowledgeable and updated on the diagnostic and therapeutic management of these cases.

Appendix A

AGE DISTRIBUTION OF PEDIATRIC PATIENTS

Class (y/o)	Frequency (Relative)	Cumulative frequency
0-3	210 (48%)	43%
4-7	185 (38%)	81%
8-11	42 (9%)	90%
12-15	27 (6%)	96%
16-18	20 (4%)	100%
Total	**484 (100%)**	

Mean = 5.55 years
Median = 5.3 years
Mode = 2 years
Standard Deviation = 3.84 years

Appendix B

AGE DISTRIBUTION OF ADULT PATIENTS

Class (y/o)	Frequency (Relative)	Cumulative frequency
19-28	74 (45%)	45%
29-38	39 (24%)	69%
39-48	22 (13%)	82%
49-58	16 (10%)	92%
59-68	12(7%)	99%
69-78	1 (1%)	100%
Total	**164 (100%)**	

Mean = 25.46 years $\pm$ 14 years
Standard Deviation = 14 years

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MIDDLE EAR EFFUSION AMONG PATIENTS WITH NASOPHARYNGEAL CARCINOMA: CURRENT CLINICAL PRACTICES OF FILIPINO OTOLARYNGOLOGISTS*

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ABSTRACT

OBJECTIVES: To determine the current clinical practices of Filipino otolaryngologists in the management of middle ear effusion among patients with nasopharyngeal carcinoma
STUDY DESIGN AND SETTING: This study represents the results of a national survey of diplomates of the Philippine Society of Otolaryngology – Head and Neck Surgery and trainees of accredited training institutions of the society.
RESULTS: Of the 250 self-administered questionnaires distributed, 135 completed questionnaires were retrieved from the respondents (54% response rate). Results show that 79.3% (n=107) of the otolaryngologists surveyed will treat middle ear effusion in patients with nasopharyngeal carcinoma with myringotomy and ventilation tube insertion, while 9.6% (n=13) will perform myringotomy alone. Eleven percent (n=15) would opt to observe or perform other treatment modalities.
CONCLUSION: Majority of Filipino otolaryngologists would treat middle ear effusion in patients with nasopharyngeal carcinoma with myringotomy with ventilation tube insertion. Given the reported complications of ventilation tube insertion and the lack of a well-designed outcome study of treatment options, a prospective randomized study is needed to address the issue.

INTRODUCTION

Nasopharyngeal carcinoma (NPC) is more prevalent in Orientals, especially among the Chinese, than in the white race. It has traditionally been treated with radiotherapy, with surgery reserved for very limited tumors and for management of the positive neck when the primary nasopharyngeal tumor has been controlled. NPC has been known to cause hearing loss and middle ear effusion (MEE) due to mechanical or functional obstruction of the eustachian tube caused either by the tumor or as a side effect of radiotherapy (1). This can be in the form of atresia of the tubal opening, adherence of mucus to the lateral wall of the nasopharynx, or fibrosis around the levator veli palatini. Both tubal and inflammatory factors contribute to MEE in patients who undergo radiation for NPC.

Myringotomy and the insertion of ventilation tubes will theoretically overcome the tubal dysfunction, and this has been advocated as the standard treatment (2). Improvement in hearing and decrease in tinnitus has been documented after insertion of ventilation tubes. However, there are significant complications, which are higher if the patients had received radiation therapy prior to the surgery (3, 4). While ventilation tubes can relieve the mechanical obstruction, it can also aggravate the inflammatory process. Patients develop otorrhea, sometimes purulent, which in some cases result in a persistent tympanic membrane perforation. Some studies suggest insertion of tubes prior to radiotherapy, while others advocate the use of myringotomy alone, plus local treatment with antibiotic otic drops, in these patients (5).

There are no local prospective controlled trials regarding the benefits and complications of the various treatments available for the management of middle ear effusion in patients with NPC, whether before or after radiation. It is desirable that a baseline evaluation is made of the current practices of Filipino otolaryngologists and their experience of the complications reported in foreign literature, prior to embarking on a full-scale study of the effects of myringotomy with ventilation tube insertion (M with

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VT), myringotomy alone or other treatment modalities which may come to light during this survey.

Subjects and Methods

Otolaryngologists and resident trainees in accredited otolaryngology training programs from various areas in the Philippines were surveyed. These physicians are usually the ones consulted for nasopharyngeal tumors and for the hearing loss or ear pain with which these tumors sometimes present. Our aim was to determine the current practices of these otolaryngologists regarding middle ear effusion in patients with NPC.

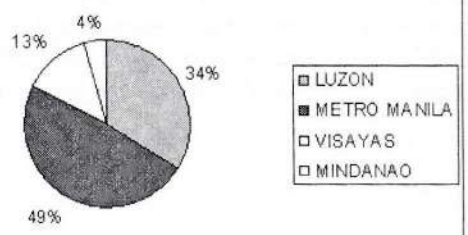
Data collection was carried out using a self-administered, structured questionnaire with a combination of closed- and open-ended questions. This was initially validated at our institution, then distributed in its final form (see Appendix) during two consecutive conventions of the Philippine Society of Otolaryngology – Head and Neck Surgery in 2002 and 2003. Contact numbers were provided in case respondents needed clarifications. Only responses with answers to all the questions were included in the study.

RESULTS

Of the 250 questionnaires distributed, 136 questionnaires were returned, of which one was excluded due to incompleteness (54% response rate). Of the respondents, 66 were already diplomates of the Society, while 39 were still in residency training. This comprises about 18% of the 365 diplomates of the PSO-HNS and 23% of the 170 resident trainees of accredited otolaryngology training programs. Thirty (30) did not indicate whether they were diplomates or resident trainees.

Age ranged from 23 to 59 years old, with a mean of 36.6 years. Years in practice of the diplomates ranged from 1 to 40 years, with a mean of 9.1 years. Practice location was concentrated in Metro Manila (Makati, Mandaluyong, Manila, Metro Manila, Quezon City), with 45 of the 92 respondents who indicated practice location coming from this area (48.9 %). Figure 1 shows the geographic distribution of responses.

Figure 1. Geographic Distribution of Responses



Responses were initially analyzed collectively, and then separated into replies from diplomates and those from resident trainees. Most responses from the residents reflected those of the diplomates, with major differences only in that a smaller percentage of residents (76.9 vs. 81.8%) would perform M with VT insertion, and they (81.2%) favored self-fabricated tubes more than the diplomates (50.9%). (Tables 1 and 2)

TABLE 1. Primary Preferred Treatment

Treatment Option	Percentage of Otolaryngologists		
	Overall	Graduates	Residents
Myringotomy with ventilation tube insertion	79.3	81.8	76.9
Myringotomy alone	9.6	6.1	17.9
Observation	6.7	9.1	—
Other treatment options	4.4	3.0	5.1

TABLE 2. Type of Ventilation Tube Used

Treatment Option	Percentage of Otolaryngologists		
	Overall	Graduates	Residents
Self-fabricated*	58.2	50.9	81.2
Commercially-produced, Short-duration	17.3	25.4	9.4
Commercially-produced, Long-duration	24.5	23.6	9.4

Only 15.6% of otolaryngologists surveyed were aware of internationally accepted guidelines or treatment protocols for the management of MEE in patients with NPC. Of these, 5 were still in residency training, while the 8 diplomates averaged 7 years in practice. Eight (8) of the respondents did not identify themselves as residents or diplomates.

Table 1 summarizes the responses concerning the primary treatment option for the management of MEE in patients with NPC preferred by otolaryngologists. Majority (79.3%) preferred myringotomy with ventilation tube insertion. Of these, 58.2% used self-fabricated ventilation tubes (Table 2). Most respondents (70.9%) encountered persistent or recurrent otorrhea in their patients after surgery, with 29.1% not encountering this problem. In contrast, only 57.1% of those who performed myringotomy alone encountered this problem, with 42.9% not encountering this problem. However, the sample for the latter group is much smaller than the first, so results may not be comparable (Table 3).

Only 20% of the respondents would change their management if the patient with NPC developed MEE after the commencement or

completion of the definitive treatment for the tumor (radiation therapy).

TABLE 3. Incidence of Otorrhea

Incidence of otorrhea	Percentage of Otolaryngologists		
	Overall	Graduates	Residents
AFTER MYRINGOTOMY WITH VENTILATION TUBE INSERTION			
Less than 25% of the time	45.4	47.3	59.4
25-50% of the time	19.1	16.4	9.4
More than 50% of the time	6.4	3.6	3.1
Problem not encountered	29.1	32.7	16.4
AFTER MYRINGOTOMY ALONE			
Less than 25% of the time	33.3	25.0	42.8
25-50% of the time	14.3	—	—
More than 50% of the time	9.5	25.0	—
Problem not encountered	42.8	50.0	57.1

DISCUSSION

Myringotomy with ventilation tube insertion has historically been the standard treatment for middle ear effusion in patients with nasopharyngeal carcinoma (2). In recent years, this has become controversial due to the significant rate of complications in spite of its reported benefits, especially when compared to myringotomy alone. Complications include chronic otorrhea, infection and persistent eardrum perforation (3, 4, 5, 7). In this study, we performed a survey to determine the current clinical practices of Filipino otolaryngologists for this group of patients.

This survey documents that majority of otolaryngologists in the Philippines still perform myringotomy with ventilation tube insertion for middle ear effusion in patients with nasopharyngeal carcinoma. This management plan may not be evidence-based, as only a minority are aware of internationally-accepted treatment protocols on this topic.

Majority of respondents use self-fabricated ventilation tubes, which may be reflective of the inavailability of commercially available tubes, either due to actual scarcity or due to their patients' financial incapacity.

Persistent or recurrent otorrhea, sometimes purulent, have been reported in patients with ventilation tubes. These occasionally result in permanent tympanic membrane perforation. Incidence of otorrhea was reported to be 34.8% in patients who underwent M with VT insertion (3). A study by Young et al (5, 6) reported persistent otorrhea 5 years after RT in 78% of patients who underwent M with VT insertion prior to the RT, compared to 44.5% of those who underwent myringotomy alone. Another study reported otorrhea in 49% of patients with MEE related to NPC who underwent M with VT insertion (4). Comparison was made with patients who underwent the same procedure in the same setting for MEE not related to NPC to confirm that the high incidence was not related to artifacts such as contamination or surgical technique. Otorrhea in the latter group was only 20%. Similarly, persistent perforation was reported to be higher in patients with NPC (25%) than those without (9%).

In this survey, majority of respondents who performed M with VT insertion encountered persistent otorrhea in their patients less than 25% of the time. However, this problem also developed in a much smaller proportion of patients who underwent myringotomy alone. This data appears to be slightly lower than that reported in international literature, but this is only a rough estimate and based purely on recall. A factor which may contribute to the lower rate of otorrhea in patients with ventilation tubes in this survey may be the kind of tubes which the respondents favor. Self-fabricated tubes may be extruded faster than the commercially-produced ones which are specially designed to remain in the tympanic membrane for a specific duration. Complication rates would then approximate myringotomy alone, as the time self-fabricated tubes remain in place may be a mere fraction of the 3 to 18 months other tubes do (3, 7). Further studies may delve further into specific rates of persistent otorrhea, time ventilation tubes remain in place and time frame when otorrhea starts and resolves.

Although current literature reports that complications increase when M with VT insertion is done after commencement of radiotherapy, majority of respondents would not change their management of the effusion. Most respondents may be unaware of the increased complication rate. Wei et al reported that 44% of patients who underwent M with VT insertion after radiation developed persistent otorrhea, which occurred in only 23.8% of patients who underwent the procedure before radiation was started (3).

This study may be subject to all of the flaws and biases associated with any survey, which include dependence on respondents' memory, their desire to come up with politically correct answers, limited participation and flaws inherent in the questionnaire itself. Despite this, it is hoped that this survey will ultimately reflect the spectrum of management options currently

in practice and prompt further study into this controversial issue.

CONCLUSION

This survey was designed to document the trend in clinical practices of Filipino otolaryngologists regarding middle ear effusion in patients with nasopharyngeal carcinoma and determine whether these conform to practices recommended in current literature. The results of our survey indicate that majority of these patients will undergo myringotomy with ventilation tube insertion, in spite of the higher incidence of otorrhea with this procedure. Given the current literature, it is unlikely that such management is evidence-based. However, these trends are subject to a large variety of biases and flaws associated with any survey. Nonetheless, we hope that the documentation of such practices and the unfavorable comparison with international literature will encourage re-evaluation of the management of middle ear effusion in patients with nasopharyngeal carcinoma.

RECOMMENDATIONS

Further surveys may delve further into specific rates of persistent otorrhea, time ventilation tubes remain in place and time frame when otorrhea starts and resolves. With this information, accurate comparison may be made with reported complication rates.

Given the reported complications of ventilation tube insertion and the lack of a well-designed outcome study of treatment options, a prospective randomized study should be undertaken to determine the benefits and complications of the various treatment options available for the management of middle ear effusion in patients with nasopharyngeal carcinoma.

If these studies confirm that current clinical practice of local otolaryngologists do not conform with internationally-accepted practices, or that these practices continue in spite of unacceptable complication rates, steps must be taken to re-educate Filipino otolaryngologists in the proper management of middle ear effusion in patients with nasopharyngeal carcinoma.

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APPENDIX: Survey Questionnaire

Dear Colleague:

Mabuhay! We are conducting a survey to determine the current management practices of Filipino otolaryngologists regarding the treatment of MIDDLE EAR EFFUSION in patients who have been diagnosed to have NASOPHARYNGEAL CARCINOMA.

We hope that the results of this survey will help to advance our knowledge regarding the proper management of patients suffering from this condition.

Thank you for your time and for sharing with us your experience.

The Research Committee

The following case is presented only as an example of the TYPICAL situation in which the pertinent clinical decision-making process may apply. The questions that follow should be answered based on your current management practice for the clinical situation IN GENERAL. **Please read all the questions through and encircle your answer.**

CASE SUMMARY: A middle-aged gentleman consults you for a unilateral hearing loss of a month's duration. Examination reveals the presence of a unilateral middle ear effusion with audiometric findings of a conductive hearing loss. Examination also reveals the presence of an ipsilateral nasopharyngeal mass, which on biopsy is shown to be consistent with nasopharyngeal carcinoma. PRIOR to definitive management of the nasopharyngeal neoplasm, the patient inquires about the management of the hearing loss.

Question #1: What form of management do you currently advise patients with untreated nasopharyngeal carcinoma complaining of hearing loss secondary to a concomitant middle ear effusion? PLEASE CHOOSE ONLY YOUR PRIMARY PREFERRED TREATMENT OPTION **FOR THE MIDDLE EAR EFFUSION** FROM THE LIST BELOW.
A. Myringotomy with ventilation tube insertion
B. Myringotomy alone (single or serial)
C. Observation
D. Other treatment modality (Please specify)

Question #2: If your primary preferred treatment is MYRINGOTOMY WITH VENTILATION TUBE INSERTION, what type of ventilation tube do you commonly use? **If this is not your primary treatment option, please answer D.**
A. Self-fabricated ventilation tube
B. Commercially-produced short-duration tube (Armstrong type/Reuter bobbin/etc.)
c. Commercially-produced long-duration tube (Paparella-type/T-tube/etc.)
D. This is not my primary treatment option/I do not perform this procedure

Question #3: Have you encountered persistent or recurrent otorrhea after performing a MYRINGOTOMY WITH VENTILATION TUBE INSERTION in these patients? **If this is not your primary treatment option, please answer E.**
A. Yes, less than 25% of the time
B. Yes, 25-50% of the time
C. Yes, more than 50% of the time
D. No, I do not encounter this problem
E. This is not my primary treatment option/I do not perform this procedure

Question #4: If your primary preferred treatment option is MYRINGOTOMY ALONE, then have you encountered persistent or recurrent otorrhea after MYRINGOTOMY ALONE on such patients? **If this is not your primary treatment option, please answer E.**
A. Yes, less than 25% of the time
B. Yes, 25-50% of the time
C. Yes, more than 50% of the time
D. No, I do not encounter this problem
E. This is not my primary treatment option/I do not perform this procedure

Question #5: Would your PRIMARY TREATMENT OPTION remain the same if the patient with nasopharyngeal carcinoma develops a middle ear effusion and hearing loss AFTER the commencement or the completion of definitive treatment for the nasopharyngeal tumor?
A. Yes, I would treat them in a similar fashion
B. No, my treatment preference would differ
If your treatment differs, what would it be? (Please specify)

Question #6: Are you aware of any internationally accepted guideline or treatment protocol for the management of middle ear effusion secondary to nasopharyngeal carcinoma?
A. Yes
B. No

Thank you for completing this survey!
In order to achieve a high rate of response, we request that you provide us with the information listed below. The respondent list is based on the current ROSTER OF FELLOWS of the Philippine Society of Otolaryngology - Head and Neck Surgery. The confidentiality of your responses will be strictly enforced.
Last Name:
First Name:
Age:
Years in Practice (if a diplomate):
Years in Training (if still a resident):
Practice/Training Location (City, Province):

If you have any questions about this survey, then please do not hesitate to contact us at the following numbers:

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VESTIBULAR EVOKED MYOGENIC POTENTIAL (VEMP) FINDINGS IN THE DIFFERENTIAL DIAGNOSIS OF VERTIGO – A PILOT STUDY*

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ABSTRACT

OBJECTIVE: This pilot study aims to describe the VEMP findings in patients presenting with dizziness and to correlate with other diagnostic tests in the differential diagnosis of patients complaining of dizziness
METHODS:The charts of a consecutive series of 14 patients from June 2002 to January 2003 undergoing VEMP at the Hearing and Vestibular Sciences Laboratory of a tertiary hospital were reviewed.
PATIENTS: The study population consists of 14 patients with dizziness as chief complaint. The patient population comprises ten females and four males with a mean age of 45.35 years. Majority of these patients had a vestibular origin of dizziness with diagnosis ranging from Meniere's disease (four), unilateral acoustic neuroma (one), bilateral acoustic neuroma (one), superior semicircular canal dehiscence syndrome (two), labyrinthitis (one), benign paroxysmal positional vertigo (three), two had accompanying cervical problems, and the remaining two had purely cervicogenic source of dizziness. VEMP recording was performed with a two channel Nihon Koden Neuropak Evoked Response Machine. EMG electrodes were applied to the anterior neck muscles and forehead. Because the examination was done on both ears, recordings on each tested ear generated an ipsilateral neck EMG tracing and a contralateral neck EMG tracing. Hence, testing each ear would generate four EMG tracings for each subject.
RESULTS: In 14 patients with vertigo, 12 were presumed to have a vestibular origin. Almost all of these patients exhibited an amplitude asymmetry on the affected ear. The VEMP tracing on these patients when compared with the various studies done by numerous authors for the differential diagnosis of vertigo were almost the same. VEMP were requested in all of our patients, only 2 had normal result. There were five patients diagnosed with Meniere's disease and VEMP findings were normal in 2, while the remaining 3 showed marked asymmetric response on the affected ear. One patient diagnosed solely with cervicogenic vertigo showed normal VEMP. The 2 patients diagnosed with BPPV elicited a contrasting response in relation to the VEMP findings, only 1 showed slightly weak response on the affected ear. Patients with acoustic neuroma and superior semicircular canal dehiscence consistently elicited amplitude asymmetry on the diseased ear.
CONCLUSION: VEMP recording is simple, inexpensive, rapid, and was well tolerated by patients. We found a good correlation of VEMP and the other vestibular tests employed to diagnose patients with vertigo. In general, VEMP can be used as a screening examination for patients complaining primarily with vertigo of peripheral origin and sudden hearing loss. Based on our preliminary experience, VEMP is an added armamentarium for clinicians to further help in the diagnosis of patients debilitated by vertigo and provides early appropriate treatment. Clinical usefulness of this potential is its ability to identify right and left vestibular end-organ response asymmetry, particularly those end organs supplied by the inferior vestibular nerve specifically the saccule and the posterior semicircular canals.

INTRODUCTION

Evaluation of patients with vertigo can be challenging, and the availability of examinations that evaluate each component of the vestibular apparatus would facilitate a more comprehensive evaluation. The vestibular organs include 3 semicircular canals and 2 otolithic organs. The

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otolith organs provide information for the control of posture and ocular stability. The incidence of the dysfunction of this area of the vestibular labyrinth is probably much higher than appreciated since there is a lack of a simple, reliable clinical test to evaluate otolith function. Routine clinical vestibular tests (ENG, Calorics, Dix-Hallpike) evaluate the horizontal SCC and the posterior SCC and fail to evaluate the remaining 3 vestibular organs.

The vestibular evoked myogenic potential (VEMP) has been considered as a new clinical test of the vestibular system, specifically the sacculo-collic pathway. A 100% specificity and 59% sensitivity has been reported be Heide et al[1]. This is done by stimulating the ears with loud sound and acquiring potentials from tonically contracted neck muscles. VEMP testing can reflect inner ear function other than the cochlea and semicircular canal. This increases the test for clinicians to explore saccular disease, adding a potential usefulness to the saccular sternocleidomastoid myogenic reflex, which starts from the saccule, towards the inferior vestibular nerve, vestibular nuclei, traverses the vestibulospinal tract and goes to the motor nucleus of the SCM and thus affecting the contractions of the SCM muscle (Fig 1).

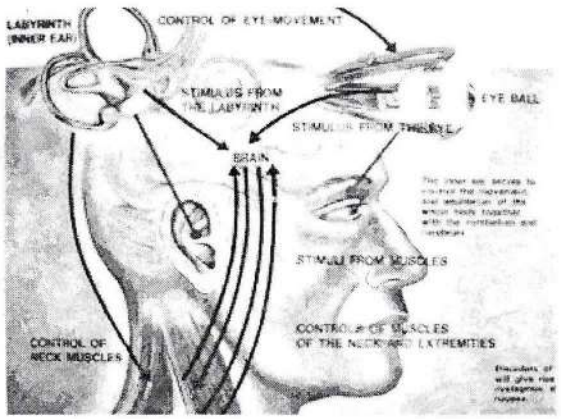

FIGURE 1. Sacculo-collic Pathway

Clinically, the VEMP test has been applied to patients with disorders such as vestibular neuritis, acoustic neuroma, and Meniere's disease to investigate its route. In particular, patients with acoustic neuroma have been reported to present with absent or decreased VEMP responses. A study by Wu et al [3] revealed an intriguing finding that the VEMP response, despite being stimulated by loud clicks, existed in cases of profound sensorineural hearing loss, which proves the non-cochlear origin of the VEMP. VEMP has also been used in documenting abnormally low thresholds in persons with the "Tullio" effect (transient vertigo or osccilopsia elicited by a loud sound), which largely occurs in persons with fistula or Superior Canal Dehiscence Syndrome[4]. Ochi and associates [5] reported the use of VEMP to diagnose vestibular neuritis involving the inferior division of the vestibular nerve. Since VEMP evaluates this nerve, VEMP should be absent in inferior vestibular nerve pathology.

In Meniere's disease, it has been reported that low amplitude of VEMP may be found in the affected ear. It has recently been proposed that VEMP, which increases on glycerol loading or furosemide injection, are suggestive of Meniere's disease. VEMP, like other evoked potential tests, can also be abnormal in patients with CNS demyelinating diseases such as multiple sclerosis and brainstem lesions [7].

Thus this new clinical test which has been included in routine vestibular testing in dizziness centers overseas offers a number of potential applications and here we describe our initial experience and how it helped in the diagnosis of dizzy patients. This is the first local investigation of this novel test and establishment of the normative values for Filipinos are ongoing.

OBJECTIVE

This pilot study was done at the Hearing and Vestibular Sciences Laboratory of a tertiary hospital and aims:

1. To describe the VEMP findings in patients presenting with dizziness
2. To describe VEMP in correlations with other diagnostic tests in the differential diagnosis of patients complaining of dizziness.

METHODOLOGY

Patients' selection and clinical evaluation

The charts of a consecutive series of 14 patients from June 2002 to January 2003 undergoing VEMP at the Hearing and Vestibular Sciences Laboratory were reviewed. The study population consisting of 14 patients were referred to an ENT clinic with dizziness as their chief complaint. Based on the clinical examination, a vestibular origin of vertigo was presumed. The patient population of ten females and four males have ages ranging from 22 to 79 with a mean age of 45.35 years. Majority of these patients had a vestibular origin of dizziness with diagnosis ranging from Meniere's disease (four), unilateral acoustic neuroma (one), bilateral acoustic neuroma (one), superior semicircular canal dehiscence syndrome (two), labyrinthitis (one), benign paroxysmal positional vertigo (three), two had accompanying cervical problems, and the remaining two had purely cervicogenic source of

dizziness (Table 1.).

All patients were selected from the clinic of one neurotologist. Patients were assessed by a dizziness questionnaire and by clinical vestibular examination. Audio-vestibular laboratory examination included an audiogram, tympanogram, electronystagmography, auditory brain evoked response, electrocochleography, and vestibular evoked myogenic potential. Additional radiological studies such as cervical APO, computed tomography or magnetic resonance imaging were likewise requested when indicated.

Vestibular Evoked Potential Recording

VEMP recording was performed with a two channel Nihon Koden Neuropak Evoked Response Machine. EMG electrodes were applied to the anterior neck muscles with the sternum or thyroid notch as a reference and the forehead as a ground. Patients were laid supine with their head up unsupported using the anterior neck muscles for 45 seconds. Loud clicks ranging from 75, 95, and 105 dB HL rarefraction clicks were repeatedly delivered to each ear at 7 pps at 50 msec intervals. No adjustments were made in relation to individual hearing loss. The EMG activity was recorded using a band pass of 30-3000Hz and averaged for at least 100 presentations. Because the examination was done on both ears, recordings on each tested ear generated an ipsilateral neck EMG tracing and a contralateral neck EMG tracing. Hence, testing each ear would generate four EMG tracings for each subject. The prominent components occur at approximately 13msec (positive deflection) and 23 msec (negative deflection). The response would give off a "positive-negative" deflection, and will be labelled, p13 for positive deflection and n23 for the negative deflection (Fig. 2). These responses were thought to be generated by the activitation of the vestibular afferents from the saccule and transmitted via the oligosynaptic pathway to the anterior neck muscles (sternocleidomastoid).

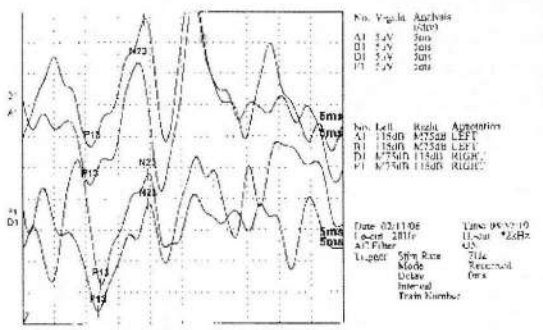

FIGURE 2. VEMP wave pattern

RESULTS

Twelve out of the 14 subjects examined were diagnosed with peripheral vestibular disorder, and 1 of which was noted to be bilateral. These patients with vestibular lesion were diagnosed with the characteristic clinical picture of vertigo, tinnitus, and / or hearing loss. Out of the 12 with peripheral vertigo, 2 were reported to be multifactorial and had an associated cervical problem. The remaining 2 were reported to be diagnosed with purely cervicogenic vertigo.

A. Hearing Sensitivity in relation with VEMP findings

Even though the main complaint of these patients was dizziness, only 11 complained with hearing loss while 4 experienced tinnitus. All patients were required to undergo hearing screening, and out of the 14 subjects only 3 had normal hearing, 3 had mild to moderate sensorineural hearing loss, 4 had moderate mixed hearing loss and the remaining 4 had severe to profound hearing loss. Patients with normal hearing showed a normal VEMP finding except for 1 subject who was diagnosed with Meniere's disease (Fig. 3). This can be attributed with the fact that Meniere's disease has a characteristic fluctuating hearing loss in the early stage of the condition. In patients who have sensorineural hearing loss, there appears to be no correlation between the degree of hearing loss and the VEMP, suggesting that the response is not mediated by cochlear afferents. Conductive hearing loss on the other hand, leads to poor movement of the stapes in the oval window, thereby reducing the intensity of the saccule stimulation.

B. Electronystagmography and VEMP findings

Thirteen out of the 14 subjects underwent electronystagmography (ENG) examination. From this 13, three had a normal ENG reading. These patients who have normal ENG findings have a likewise normal VEMP results except for 1 subject who manifested with amplitude asymmetry. Two out of 12 subjects had cervicogenic with paroxysmal and positional nystagmus on ENG but had a normal VEMP result. The remaining 8 subjects had canal paresis or caloric weakness on their affected ear and all of them were compatible with an ipsilateral delay in VEMP threshold.

C. Auditory Brain Evoked Response versus VEMP findings

Only 7 of the 14 subjects underwent auditory brain evoked response (ABR) testing. Five of them had normal ABR results, which were

Table 1. Summary of the 14 patients complaining of vertigo and the results of neuro-otological tests.

Subject No.	Name	Age Sex	Diagnosis	Symptoms	Audiogram	ENG	VEMP	ECoG	ABR	Radiographic studies	Management
1	A.D.	55 / F	BPPV, bilateral	vertigo	Normal	Cervicogenic nystagmus	Normal	-	-	Degenerative OA C4-C5 narrowing	Nimesulide, Myonal
2	A.L.	55 / F	Cervicogenic vertigo	tinnitus dizziness hearing loss	Bilateral Severe – profound mixed HL	Normal	Normal	-	Normal	Degenerative OA Age related cerebro-cerebellar atrophy	Vestibular exercise
3	F.A.	52 / F	Labyrinthitis R r/o Hydrops 2° infxn	vertigo hearing loss	L- mild-mod CHL R-Severe-profound mixed HL	Abnormal saccade/pursuit R canal paresis	Amplitude asymmetry R IVN invol	-	Normal	Normal CT temporal bone MRI - no evidence of acoustic neuroma	Almitrine-Raubasine Betahistine EMES Vestibular exer
4	M.P. *	46 / M	Meniere's disease, right	tinnitus slight imbalance	Normal tympa Normal PTA	Abnormal saccade/pursuit R canal paresis	Amplitude asymmetry R IVN invol	Abnormal right SP/AP Ratio	Normal	-	Tebokan Mecobalamin
5	T.U.	42 / M	Meniere's disease, right	vertigo	Severe-profound mixed HL Right Type A tympanogram bilateral	Normal	Normal	Abnormal right SP/AP ratio	-	Normal MRI	Meclizine, Duxaril Ranitidine, Tebokam Cinnarizine
6	R.S.	35 / F	Meniere's disease, left	tinnitus Left vertigo	Moderate Mixed HL left ear	Abnormal saccade/pursuit L canal paresis	Amplitude asymmetry weak response L	Abnormal Left SP/AP ratio	-	Normal MRI	Mecobalamin, Diazide, Cinnarizine, Betahistine
7	G.L.	55 / F	Meniere's disease, left	dizziness	Moderate mixed HL Left Normal Right	L canal paresis	Amplitude asymmetry L IVN invol	Abnormal left SP/AP ratio	Normal	-	Betahistine EMES
8	I.M.	62 / F	Cervicogenic vertigo	dizziness	Bilateral mild SNHL Type A – bilat. Tympanogram	Normal	Amplitude asymmetry R IVN invol	–	Normal	-	Dormicum, Betahistine Vitamin E
9	R.V.	39 / F	BPPV Cervicogenic vertigo	dizziness headache	Normal Hearing bilateral Tympa L – Type A Tympa R – Type As	Cervicogenic and paroxysmal positional Nystagmus	Normal	-	-	Cervical spondylosis / lordosis Normal MRI	Betahistine, Flunarizine, Tramadol
10	F.M.	22 / F	Bilateral Acoustic Schwannoma (Left>Right)	hearing loss Slight dizziness	R – mild-mod SNHL L-moderately severe SNHL	L canal paresis (pre-operative)	R – Normal asymmetry Left IVN involvement (post-op)	-	Suggestive R retrocochlear pathology Bilateral HL	Bilateral (L>R) vestibulocochlear schwannomas on MRI	s/p L suboccipital craniectomy
11	M.F.	27 / M	BPPV Left Cervicogen ic vertigo	dizziness hearing loss R	Bilateral mild CHL	Left canal paresis	Left ear slightly weak response	Abnormal bilateral	-	Cervical spondylosis with mild neural foraminal intrusion at C3-C4 on left	Betahistine, Nimesulide Diazide, Orphenadine
12	M.L.	30 / F	SSCD Left	dizziness hearing loss	Moderate mixed hearing loss L Normal audiogram Right	Torsional horizontal beating nystagmus R	Weak response on right	-	-	-	Betahistine EMES
13	L.C.	36 / F	Acoustic Schwannoma Right	hearing loss tinnitus COM, AD dizziness	Right - Severe-profound mixed Left – mild CHL	-	Amplitude asymmetry R IVN invol	-	L- Normal ABR Right – suggestive of retrocochlear pathology	Normal Cervical APO Vestibular Schwannoma right on MRI / CT scan - Cholesteatoma Right dehiscent jugular bulb R	s/p subtotal petrosectomy with resection of R Acoustic Schwannoma Ciprofloxacin
14	E.C. **	79 / M	SSCD right	dizziness hearing loss	Moderate to severe mixed hearing loss	Torsional horizontal beating nystagmus L	Reduced response on the left	-	-	s/p mastoidectomy changes right SDCD right	Flunarizine Betahistine

ENG – Electronystagmography **VEMP** – Vestibular Evoked Myogenic Potential **ECoG** – Electrocochleography **ABR** – Auditory Brain Evoked Response **SSCD** – Superior semicircular canal dehiscence syndrome
CHL - Conductive hearing loss **SNHL** – Sensorineural hearing loss
* - normal computerized dynamic posturography ** - abnormal computerized dynamic posturography (Moderate visual / marked vestibular dysfunction)

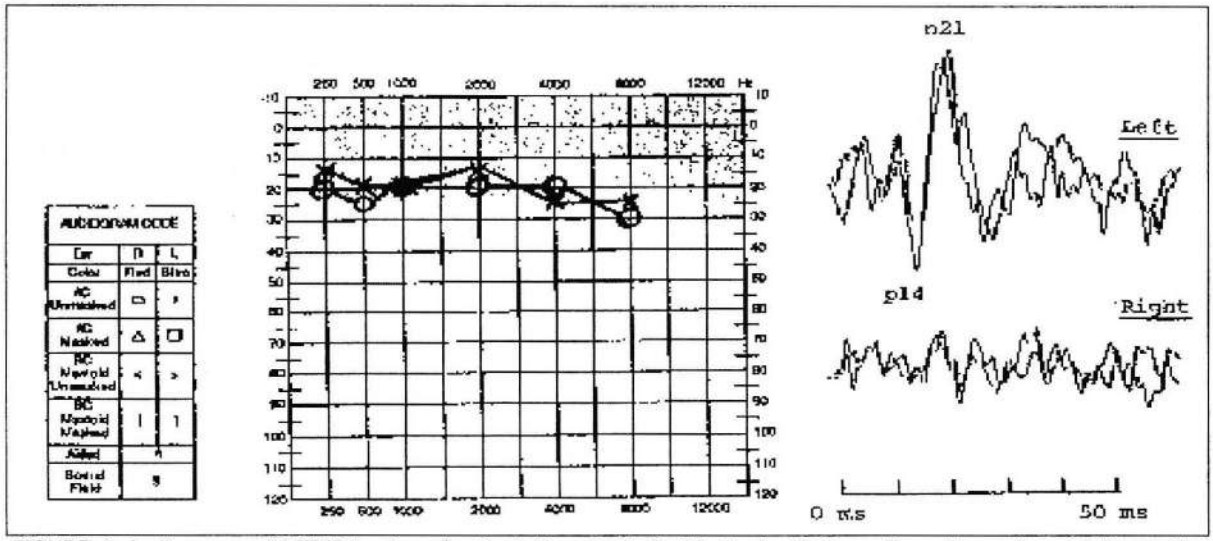

FIGURE 3. Audiogram and VEMP tracing of patient diagnosed with Meniere's disease. From the audiogram, the auditory thresholds are within normal limits. Note the presence of the potential on left and its absence on the right

not compatible with the VEMP findings. This is because ABR evaluates mainly the cochlear pathway while the VEMP evaluates the inferior vestibular nerve. ABR and VEMP findings were helpful in screening patients suspected with acoustic neuroma. One subject was diagnosed with bilateral acoustic neuroma; the ABR result was suggestive of right retrocochlear pathology while the VEMP result showed left inferior vestibular nerve involvement. In a study made by Murofushi et al [2], they assumed that the VEMP is more sensitive than other physiologic examinations for early acoustic neuromas selectively affecting only the inferior vestibular nerve given the fact that ENG caloric investigates horizontal canal function from the superior vestibular nerve. The absence of an effective parameter such as interpeak latency for wave I-V in ABR might be one of the reasons for this lower rate of detecting minute acoustic neuroma with normal caloric function on ENG testing.

D. Electrocochleography versus VEMP findings

Electrocochleography (ECoG) was only performed in patients diagnosed with Meniere's disease and all of them revealed an abnormal SP/AP ratio as well as abnormal VEMP findings. Only 1 patient showed an abnormal ECoG but with a normal VEMP threshold implying cochlear hydrops without saccular dilatation.

VEMP findings in the differential diagnosis of Vertigo

VEMP was requested in all of our patients, only 2 had normal result. There were five patients diagnosed with Meniere's disease and VEMP findings were normal in 2, while the remaining 3 showed marked asymmetric response on the affected ear. One patient diagnosed solely with cervicogenic vertigo showed normal VEMP. The 2 patients diagnosed with BPPV elicited a contrasting response in relation to the VEMP findings, only 1 showed slightly weak response on the affected ear. Patients with acoustic neuroma and superior semicircular canal dehiscence consistently elicited amplitude asymmetry on the diseased ear.

Ratio of Amplitude on both Ears

The peaks of the wave measured were labelled p1 for the first positive deflection and n2 for the first negative deflection. The averages of these amplitudes used were measured after repeated examination (Fig. 4). The ratio of these amplitudes were compared to the contralateral side using the formula R= L / R and L= R / L. After which, these values were compared and any values more than 1.5 is considered significant. There are some patients who did not have any identifiable peaks on their wave pattern as seen on table 2.

FIGURE 4. Vestibular evoked myogenic potential wave pattern. Superimposed traces show the result of two trials. Amplitude is measured from the peak of p1 to the peak of n2

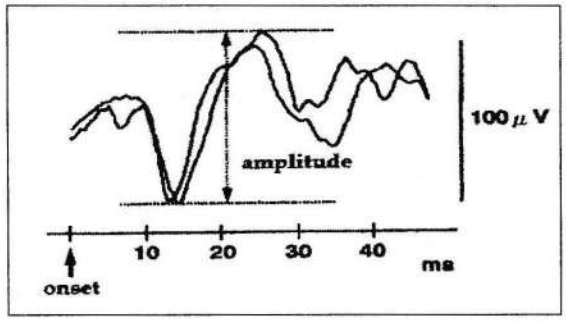

Table 2. Ratio of VEMP amplitudes on both ears

Subject number	Patient	Impression	Left threshold	Right threshold	Left ratio	Right ratio
1	A.D.	BPPV, bilateral	140.78	59.89	0.43	2.35
2	A.L.	Cervicogenic Vertigo	83.97	54.37	0.65	1.54
3	F.A.	Labyrinthitis right	21.195	no wave	21.95	no wave
4	M.P.	Meniere's Disease, right	24.91	5.68	0.23	4.39
5	T.U.	Meniere's Disease, right	19.9	17.42	0.88	1.14
6	R.S.	Meniere's Disease, left	48.98	85.35	1.74	0.57
7	G.L.	Meniere's Disease, left	no wave	20.86	no wave	20.86
8	I.M.	Cervicogenic Vertigo	1.83	13.67	7.47	0.13
9	R.V.	BPPV Cervicogenic Vertigo	14.42	17.86	1.24	0.81
10	F.M.	Bilateral Acoustic Neuroma (L>R)	no wave	17.22	no wave	17.22
11	M.F.	BPPV, left Cervicogenic Vertigo	10.03	17.6	1.75	0.57
12	M.K.L.	SSCD left	25.44	6.25	0.25	4.07
13	L.C.	Acoustic Neuroma, right	38.52	no wave	38.52	no wave
14	E.C.	SSCD right	no wave	56.5	no wave	56.5

DISCUSSION

History and physical examination of the dizzy patients are very important as well as to differentiate vertigo from non-vertigo symptoms. Vertigo is the sensation of rotation either complete or partial while non-vertigo symptoms include light-headedness, imbalance, tilt, motion intolerance and tendency to fall. As a rule, vertigo is due to peripheral vestibular diseases while nonvertigo symptoms are due to nonvestibular causes[8]. Patients presenting with dizziness are often misdiagnosed because of the multitude of differentials a clinician has to consider. Often times these patients need to undergo a battery of vestibular examinations and trials of different medications to experience relief of their symptoms.

An organized neurotologic evaluation encompasses the ear, eye movement, vestibular system, and the central nervous system. Clinical vestibulospinal reflex is best evaluated by checking the neck range of motion and flexibility and strength of the main muscle groups and by observing the patient's postural stability during Romberg, gait, and stepping test. In addition, clinically useful vestibular tests include valsalva, pressure, sound, and hyperventilation induced symptoms and nystagmus[8]. These tests are indicated if the history is suggestive of perilymph fistula, dehiscence of the superior semicircular canal, or posterior fossa lesions.

Studies made by Bickford et al [9] on the myogenic potentials in human neck muscles after loud click stimuli were proven to be of saccular origin. This was likewise confirmed by Robertson and Ireland [10], who proposed the pathway of these sound evoked myogenic potentials. They claimed that it came from the vestibular saccule to the inferior vestibular nerve, vestibular nucleus, lateral nucleus, and lateral vestibulospinal tract finally reaching the sternocleidomastoid muscle. Colebatch et al [11] provided an evidence for an otolithic component of an acoustically evoked, myogenic response by measuring the EMG responses of the sternocleidomastoid muscle evoked by loud sound.

Ochi et al[12] suggested that the vibration of the footplate results in the stimulation of the sacculus, which results in a nerve impulse that is conducted to the SCM through the inferior vestibule-spinal neural projection. Because the VEMP is induced by the inhibitory impulse for SCM tension, the amplitude might be more or less dependent on the tension of the SCM during the examination. While doing this study, modifications were made in putting tension over the SCM in an effort to produce better amplitudes. Initially, the subjects were asked to face the contralateral side but it did not elicit a good wave pattern. Thus the modification proposed by Colebatch[11] was adapted which is head elevation of 45° while laying supine since muscle tonus is required for the generation of the VEMP.

In 14 patients with vertigo, 12 were presumed to have a vestibular origin. Almost all of these patients exhibited an amplitude asymmetry on the affected ear. The VEMP tracing on these patients when compared with the various studies done by numerous authors for the differential diagnosis of vertigo were almost the same. Listed below are the list of differential diagnosis for vertigo and their characteristic VEMP findings.

A. Labyrinthitis

Normally the superior vestibular nerve innervates the semicircular canals, the anterior SCC and the utricle, while the inferior vestibular nerve innervates the posterior SCC and the saccule. In a study made by Murofushi [13], he claimed that in patients with acute

neurolabyrinthitis, the absence or presence of p13-n23 was independent of the results of caloric tests, pure tone audiometry, and auditory brain evoked responses. One of our patients who complained of an acute attack of dizziness with a profound hearing loss and an abnormal saccade and pursuit with right canal paresis on ENG showed an amplitude asymmetry with lower amplitude on the affected ear. This finding clearly demonstrates the possible involvement of the inferior vestibular nerve. The symptoms that this patient has experienced may then be attributed not only to the superior vestibular involvement as documented by ENG but also the inferior vestibular pathology as demonstrated on VEMP findings.

B. Benign paroxysmal positioning vertigo (BPPV)

Benign paroxysmal positioning vertigo (BPPV) is generally thought to be caused by culpolithiasis or canalolithiasis in the posterior semicircular canal, an organ that is innervated by the inferior vestibular nerve. In the study made by Heide et al [1], they found out that patients diagnosed with BPPV had a normal caloric examination and VEMP finding. However, in this study we noted that 1 out of the 3 subjects with BPPV had abnormal VEMP finding. This can be partly attributed to the mild conductive hearing loss, which was evident in the audiogram of the patient. Welgampola et al [14] proved that bone conducted sound would elicit a VEMP; however in patients confounded with conductive hearing loss, it will not be evident. This is because the difference between hearing thresholds and VEMP thresholds is much larger for air-conducted sound than for bone vibration. Bone vibration at a given perceptual intensity proves to be a more effective vestibular stimulus than air conducted sound, implying a relatively greater sensitivity of the vestibular apparatus to bone conducted sound.

C. Meniere's disease

Meniere's disease is characterized by fluctuating hearing loss, tinnitus, aural fullness, and episodic rotatory vertigo. Clinically, increased summating potential/action potential (SP/AP) amplitude ratio has been shown to be the most effective electrocochleographic measure to identify cochlear hydrops which is considered the cause of fluctuating hearing loss. VEMP has been studied extensively in patients with Meniere's disease in an effort to shed light to the possibility of saccular hydrops [15]. Absence of VEMP or decreased peak-to-peak amplitude indicates that lesion may affect the pathway [11]. In our study, 3 out of 4 patients diagnosed with Meniere's disease had a compatible asymmetry in the VEMP amplitude of the affected ear. The other subject showed a normal VEMP finding. The presence of a normal VEMP implies that the sacculocollic reflex has retained normal velocity conduction; thus a normal saccule with intact saccular macula accounts for a normal VEMP [16]. Presumably, hydropic conditions involving the saccule may be responsible for VEMP findings in patients with Meniere's disease while hydrops confined to the cochlea alone will present with normal VEMP but abnormal ECoG.

D. Superior Semicircular Canal Dehiscence

Patients with superior semicircular canal dehiscence (SSCD) experience vertigo and oscillopsia in response to loud sounds (Tullio's phenomenon) and to stimuli that result in changes in middle ear or intracranial pressure. They may also experience hyperacusis to bone conducted sounds. The evoked eye movement in this syndrome align with the plane of the dehiscent superior canal. The signs and symptoms can be understood in terms of the effect of the dehiscence in creation of a third mobile window into the inner ear. Although SSCD can be inferred by history and physical findings, radiographic imaging has been used to confirm the diagnosis. Brantberg et al [19] made a study on the VEMP findings of SSCD and reported an abnormally large VEMP in response to sound stimuli in the frequency range of 0.5 – 1 kHz. The VEMP in both of our subjects were also noted to be abnormally higher compared to the contralateral ear.

E. Acoustic Neuroma

Acoustic neuroma in patients normally present with cochlear symptoms such as tinnitus or hearing loss. Vertigo may also be present in the initial stage of tumor growth in the vestibular nerve as described by Jackler. Its diagnosis on the loose basis of results of hearing test is not feasible, and MRI is always deemed necessary for its definitive diagnosis. As a standard for screening, ABR is usually employed to check only for the involvement of the cochlear nerve. With the advent of VEMP, earlier diagnosis is possible in inferior vestibular nerve involvement and better localization can be done to determine the extent of the lesion. Considering that VEMP reflex is a response through the inferior vestibular nerve, VEMP response proves to be highly useful for the diagnosis of acoustic neuromas, which are thought to develop mostly in the inferior vestibular nerve. Studies by Murofushi et al [2] reported an abnormal VEMP in 17 (80%) out of the 21 patients diagnosed with acoustic neuromas. VEMP could be useful for its diagnosis, especially for classifying acoustic neuroma according to the

nerves involved. In the study of Takeichi [17], wherein he compared the tumor size with ENG and VEMP, the larger size tumor over 14.1 mm showed abnormalities in the ENG while tumor size was not particularly related with abnormalities in the VEMP.

As seen in 1 of our patients, the MRI showed bilateral acoustic neuroma with the left mass noted to be greater than the right; however the ABR only showed findings suggestive of a right retrocochlear lesion. Studies have shown that ABR findings are attributed to cochlear nerve compression by the tumor growing from the vestibular nerve and it could be normal despite a large size when medially located. Thus electronystagmography was requested pre-operatively to determine the involved segment and was noted to be compatible with a left canal paresis. This patient underwent excision on the left side. In this particular patient, ABR and VEMP complemented each other in localizing a more extensive lesion on the left side, with the MRI documenting a large tumor side on this side.

F. Cervicogenic Vertigo

Decreased perfusion in the neck coming from the vertebrobasilar artery may provoke ischemic change in the cerebellum, brainstem, or inner ear leading to a vertiginous attack.

Diagnosis can be made by the history, physical examination findings and radiographic studies. In patients with cervical osteoarthritis and spondylosis like in 4 of our subjects, a mere hyperextension and rotation may aggravate the spurs compressing the vertebral artery, leading to reduction in vertebral artery circulation. A study made by Young et al[16] claimed that most ears displayed normal VEMP findings (83%) after cervical manipulation. Two of our patients elicited the same result; however the other 2 had a weak response with VEMP. Both of these VEMP findings may be attributed to the concomitant peripheral problem, which is BPPV.

CONCLUSION

In this study, we noted that generation of VEMP recording is simple, inexpensive, rapid, and was well tolerated by patients. We found a good correlation, albeit not statistically, of VEMP and the other vestibular test employed to diagnose patients with vertigo. One may judiciously choose which test to request only after a complete history and neurotologic examination are done. Oftentimes, VEMP may complement tests like ABR to localize involvement of the inferior vestibular nerve for acoustic neuroma, electrocochleography for Meniere's disease and electronystagmography for BPPV and acoustic neuroma. In some cases, VEMP may be the only pathologic result that may warrant further investigations such as in SSCD for example.

In general, VEMP can be used as a screening examination for patients complaining primarily with vertigo of peripheral origin and sudden hearing loss. VEMP may not be requested for those patients with a definite cervical cause of dizziness except if they have multifactorial cause and cannot rule out the possibility of vestibular involvement.

Based on our preliminary experience, VEMP is an added armamentarium for clinicians to further help in the diagnosis of patients debilitated by vertigo and provides early appropriate treatment. Clinical usefulness of this potential is its ability to identify right and left vestibular end-organ response asymmetry, particularly those end organs supplied by the inferior vestibular nerve specifically the saccule and the posterior semicircular canals.

Certain limitations were observed during the examination. VEMP is not possible in unconscious or uncooperative patients because one has to maintain head elevation for a period of time. Patients with neck pathologies might also contraindicate the test.

VEMP can be used as a means of monitoring the progression of a disease like acoustic neuroma and Meniere's disease by doing a serial VEMP examination. Normalization of VEMP waves may likewise indicate resolution of active disease processes such as Meniere's Disease. Further studies needs to be done to prove its effectiveness in monitoring the disease. Additional study is suggested to establish the threshold of VEMP for Filipino patients and to determine the optimal stimulus to evoke the response in our local setting.

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APPROACH TO TINNITUS PATIENTS: APROPOS OF FIFTY-THREE PATIENTS*

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ABSTRACT

OBJECTIVES: 1. To describe the demographic profile of fifty-three (53) patients with subjective tinnitus; 2. To describe the audiologic measurements done on these patients; 3. To present the most common etiologies found in these patients; 4. To present the tinnitus handicap inventory profile of some of these patients; 5. To present an algorithm for the approach to patients with tinnitus.
STUDY DESIGN: Restrospective chart review
SETTING: Tertiary referral center
PATIENTS: Fifty-three patients who sought consultation for tinnitus from 1998 to 2000.
INTERVENTIONS: All patients were asked to fill up a tinnitus questionnaire based from NODAR tinnitus classification system and a tinnitus handicap questionnaire prior to treatment with medications including methylcobalamin, gingko biloba, almitrine raubasine or betahistine hydrochloride. Audiometric measurements in all patients included pure tone audiometry, tinnitus loudness and pitch matching, minimal masking level and residual inhibition test.
RESULTS: The majority of patients (70%) belonged to the 30-59 age group. There was a male-female predominance of 1:5:1. In terms of occupation, rank and file employees (23%), businessmen (19%) and lawyers (15%) had the most prevalence. Despite an extensive work-up, no demonstrable cause was noted in 30% of subjects while noise induced hearing loss (11%), presbycusis (11%), and ischemia (11%) comprised the most common etiologies. Most patients described the tinnitus as ringing (60%), as hissing (26%) and cricket-like (21%); the rest comprising 4%. The tinnitus was more continuous (55%) than intermittent (45%); and more constant (66%) than fluctuating (34%). The left ear was more commonly involved whether alone or when binaural and unequal, it predominated. The presence of a sensorineural hearing loss was the most common abnormal finding on pure tone audiometry but around 24% had normal hearing. There were 39 patients in whom tinnitus could be matched and in 25 patients tinnitus could be matched only in one ear. Eleven of 14 patients in whom tinnitus could be matched on both sides were noted. The majority had a tinnitus matched at the high frequencies (3000-8000Hz) with an intensity ranging at 30-80db. Finally of 21 of these patients who answered a tinnitus handicap inventory questionnaire, 14 had a score <50, 6 scored 51-75 while only 1 had a score of 76-100, signifying that majority had no or only a mild handicap from the tinnitus.
CONCLUSION: A systematic approach to patients with tinnitus is recommended. In our experience, a diagnostic algorithm which incorporates the basic history and physical examination with audiometric measurements can yield a diagnosis in about 70% of patients. This diagnostic approach helped guide treatment using a variety of pharmacologic agents with an overall efficacy rate of 88%(31/35).

INTRODUCTION

Tinnitus is described as the sensation of any sound perceived without any evident external stimulus[1]. Patients complaining of tinnitus are not rarely encountered in an otorhinolaryngologist's clinic. Some studies reported that around 17% of the general population may be affected[2,3] with frequency increasing to 33% in the elderly[4,5]. In the United States, it is estimated that about 36 million people are experiencing tinnitus and about 30% severe enough to actively seek help[6]. In the Philippines, there has been no systematic data published on tinnitus although a local study regarding the efficacy of methycobalamin on tinnitus has been previously reported[7].

First, this descriptive study aims to

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describe the demographic profile and audiometric findings on a consecutive series of 53 patients seen in a local tertiary medical center from 1998 to 2000. Based on a review of the tinnitus questionnaire and tinnitus handicap inventory scores, more relevant information are gathered to provide useful parameters that may form the basis by which further work-up are requested and treatment formulated. These include the tinnitus as to its character, localization, its association with hearing loss, and the level of psychological distraught tinnitus is to the patients.

The audiometric measurements in a majority of the patients will also be described. Then, the most common etiologic diagnosis will be presented. Lastly, an algorithm for the evaluation of patients with tinnitus is outlined. It is hoped that a heightened awareness among otorhinolaryngologists regarding the need to have a more discerning and systematic approach to these patients will be achieved.

METHODS

Subjects are 53 patients who sought consult for tinnitus from 1998-2000 in a tertiary hospital setting in Manila, Philippines whose data were reviewed. A complete history was taken and physical examination was done in all cases prior to treatment. Pretreatment, the patients were asked to fill-up a tinnitus questionnaire and a tinnitus handicap inventory. Thereafter, baseline audiometric evaluation which included pure tone audiometry, tinnitus matching level, minimal masking level and residual inhibition testing were performed.

TABLE 1. NODAR tinnitus classification system. Tinnitus reclassified: New oil in an old lamp. Otolaryngology Head and Neck Surgery 1996. Vol 112:582-585.

A	Aurium (Unilateral)
B	Binaural (Bilateral)
C	Cerebri (Centered in the head)
C	Cause (ie. Noise, presbycusis, acoustic neuroma,idiopathic)
C	Composition (ring, buzz, hiss, roar, crickets, multiple sounds)
L	Loudness (1 to 10; 10 being very loud)
A	Annoyance (1 to 10; 10 being very annoying)
P	Pitch (high or low)

Diagnostic modalities

a. Pure tone audiometry
   In a sound proof booth where the examination was conducted by an audiology technician, the patient was subjected to determine air and bone conduction hearing threshold to pure tones and using the appropriate masking techniques, when necessary. Hearing levels were determined at eight frequencies (250Hz, 500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz, 6000Hz and 8000Hz).

b. Tinnitus matching and residual inhibition test The following procedures in tinnitus matching and residual inhibition test were done in the center and is based from J. Vernon (1990):

   i. Pitch matching
   This can be achieved in the majority of patients by using pure tones for tonal tinnitus or white, narrow band, or speech noise for complex tinnitus[8,9].

   ii. Loudness matching
   Tinnitus was matched first by pitch and then by increasing the intensity level from threshold to a level that was equal to the intensity of the tinnitus. When a repeated loudness matching test revealed result within 2 to 3 dB SL, it can be used as an objective test for the presence of tinnitus[8,9].

   iii. Minimum masking level (MML)
   This test was recorded in dB SL and the difference between the threshold intensity of the masking sound and the lowest intensity at which the masking occurred was determined[8,9].

   iv. Residual inhibition test (RIT)
   According to Vernon, this phenomenon is characterized by decreased or absent tinnitus following exposure to MML plus 10dB for 1 minute[8,9]. When there was a change of the tinnitus intensity or a disappearance of the tinnitus, this was considered a positive RIT. When there was no change, this was considered a negative RIT.

D. *Treatment*
   During treatment, patients were prescribed with the following medications (alone or in combinations): Almitrine+Raubasine, Betahistine Dihydrochloride, Methylcobalamine, and Gingko Biloba from 1 month to 6 months duration. Patients were asked to follow-up and a re-evaluation done after treatment.

RESULTS

Approximately 37 of the 53 patients (70%) belonged to the 30-59 age group with a 1:5:1 male to female predominance as shown in Figure 1.

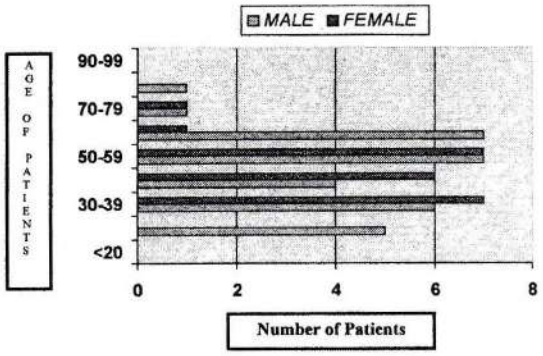


FIGURE 1. Frequency distribution of tinnitus patients in terms of gender and age.

While most patients were rank and file employees of companies (23%), businessmen and lawyers comprised 19% and 15% respectively as shown in Figure 2.

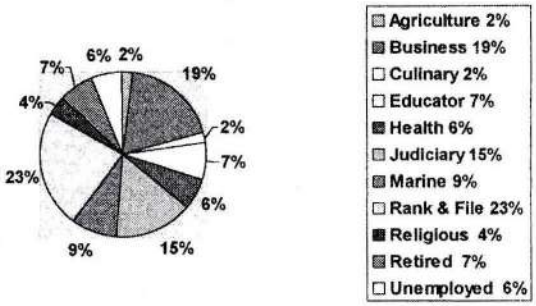


FIGURE 2. Distribution of the different occupations of tinnitus patients

Tinnitus was commonly described as ringing in 60% of patients, followed by hissing (26%) and cricket like (21%) in character; other descriptions comprised of the remaining 3%. The symptom was continuous in 55% and intermittent in 45%. The loudness was constant in 35 (66%) and fluctuating in 18 (34%). Tinnitus localization is summarized in Table II. As to laterality, most patients (40%) localized it to the left ear. In cases where tinnitus was binaural and unequal, the left ear predominated. A few others (26%) localized it to the right, binaural in 21% and only 2% as diffused and coming from within the head.

TABLE 2. Localization of tinnitus (1998-2000)

Tinnitus heard	No. of patients	Percentage
Aurium (right)	14	26%
Aurium (left)	22	42%
Binaural (R>L)	1	2%
Binaural (R<L)	4	7%
Binaural (R=L)	11	21%
Head	1	2%
TOTAL	53	100%

Pure tone audiometry showed the predominance of sensorineural hearing loss most commonly on the left ear. A small percentage of patients however had normal audiometric findings(Table II).

Table 4 shows the results of tinnitus matching in 39 patients in whom this was possible. It is notable that 11 out of 14 patients with binaural tinnitus matching had equal frequency matches in both ears and the loudness matched from 30-80dB. It was possible to match the tinnitus on the left on 30 out of 39 patients, while this was feasible in 23 patients on the right. In those were matching can only be done on one side, the left was more commonly matched at a ratio of 1:8:1.

The subjective pitch and loudness scores in 21 patients are summarized in Figure 3.

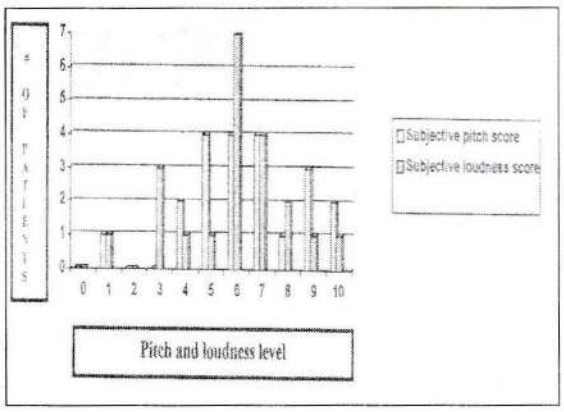


FIGURE 3. Subjective pitch and loudness score
***33 out of 53 patients were unable to answer the tinnitus questionnaire**

TABLE 3. Hearing loss based on pure tone audiometry from tinnitus patients

Hearing Loss	# pxs	Hearing Loss	# px	Hearing Loss	#pxs
Sensorineural (AD)		Conductive (AD)		Mixed (AD)	
Mild	12	Mild	6	Mild	2
Moderate	5	Moderate	3	Moderate	4
Severe	6	Severe	1	Severe	0
Profound	3	Profound	0	Profound	0
Sensorineural (AS)		Conductive (AS)		Mixed (AS)	
Mild	13	Mild	7	Mild	0
Moderate	8	Moderate	3	Moderate	1
Severe	2	Severe	0	Severe	1
Profound	1	Profound	0	Profound	2
Normal (AD)	13				
Normal (AS)	14				

TABLE 4. Tinnitus matching done on 39 out of 53 patients

pretreatment	Tinnitus Match AD	Tinnitus match AS pretreatment		Tinnitus match AD pretreatment	Tinnitus match AS pretreatment
1	1000Hz at 60dB	1000Hz at 60dB	21	8000Hz at 30dB	None
2	None	6000Hz at 80dB	22*	500Hz at 40dB	None
3	6000Hz at 80dB	None	23*	8000Hz at 45dB	8000Hz at 50dB
4	None	8000Hz at 50dB	24	None	2000Hz at 40dB
5*	4000Hz at 30dB	6000Hz at 45dB	25	1000Hz at 30dB	1500Hz at 35dB
6*	8000Hz at 65dB	None	26	None	1500Hz at 60dB
7*	6000Hz at 30dB	6000Hz at 30dB	27	None	6000Hz at 55dB
8	CNT	8000Hz at 50dB	28*	750Hz at 35dB	1000Hz at 60dB
9*	None	750Hz at 25dB	29*	2000Hz at 30dB	4000Hz at 40dB
10*	750Hz at 80dB	750Hz at 60dB	30	3000Hz at 50dB	3000Hz at 35dB
11*	8000Hz at 60dB	8000Hz at 60dB	31	8000Hz at 40dB	8000Hz at 30dB
12	None	1000Hz at 40dB	32	None	8000Hz at 45dB
13	None	4000Hz at 40dB	33*	None	2000Hz at 60dB
14	3000Hz at 45dB	3000Hz at 35dB	34	None	500Hz at 70dB
15*	None	4000Hz at 45dB	35	None	2000Hz at 40dB
16*	4000Hz at 45dB	4000Hz at 40dB	36	None	8000Hz at 40dB
17	500Hz at 50dB	500Hz at 55dB	37	2000Hz at 30dB	None
18	6000Hz at 55dB	None	38	3000Hz at 70dB	None
19	None	1000Hz at 30dB	39	6000Hz at 70dB	None
20	8000Hz at 55dB	None			

TABLE 5 (a-d). Hearing levels in relation with residual inhibition levels

I.a. Right ear with normal Hearing

	With improvement	Without improvement
(+) RIT	2	1
(-) RIT	6	0

I.b. Right ear with Hearing loss

	With improvement	Without improvement
(+) RIT	5	0
(-) RIT	13	2

II.a. Left ear with normal Hearing

	With improvement	Without improvement
(+) RIT	2	1
(-) RIT	5	0

II.b. Left ear with normal Hearing

	With improvement	Without improvement
(+) RIT	4	0
(-) RIT	17	3

In 21 patients who submitted a tinnitus handicap questionnaire, the majority had scores below 50 as shown on Table 6.

TABLE 6. Tinnitus Handicap Score

Tinnitus Handicap Score	Degree of Severity	Number of Patients
0-25	No handicap	5
26-50	Mild	9
51-75	Moderate	6
76-100	Severe	1
TOTAL		21

Based on the history, physical examination, audiologic and a variety of other tests including ABR, CT or MRI scans, cervical x-rays and Doppler studies were requested when warranted. It was possible to arrive at a specific etiologic diagnosis in approximately 70% of patients as shown in Table 7.

TABLE 7. Common etiologic agents of tinnitus in Filipino patients

Diagnosis of pxs with tinnitus	#px	%
Idiopathic	16	30%
Noise induced hearing loss	6	11%
Presbycusis	6	11%
CNS ischemia	5	9%
Eustachian Tube Dysfunction	4	7%
Meniere's Disease	4	7%
Atypical Meniere's Disease	3	6%
Sensorineural hearing loss	2	4%
Autoimmune Disease	1	2%
BPPV	1	2%
Cervicogenic vertigo	1	2%
Bell's Palsy	1	2%
CVS ischemia	1	2%
TOTAL	53	100%

TABLE 8a&b. The different medications prescribed to tinnitus patients

(a)

MEDICATIONS	
Almitrine-Raubasine	14
Betahistine HCl	12
Gingko Biloba	25
Methylcobalamin	33

(b)

Medications Taken	#of patients
Almitrine-Raubasine alone	2
Betahistine dihydrochloride alone	2
Gingko Biloba alone	5
Methylcobalamin	10
Methylcobalamin+Gingko Biloba	16
Methylcobalamin+Almitrine-Raubasine	3
Methylcobalamin+Betahistine dihydrochloride	1
Almitrine-Raubasine+Betahistine dihydrochloride	2
Almitrine-Raubasine+Betahistine dihydrochloride +Gingko Biloba	4
Almitrine-Raubasine + Betahistine dihydrochloride + Methylcobalamin	3

A variety of pharmacological agenda used roughly or in combinations included the following Methylcobalamin, gingko biloba, almitrine-raubasine and betahistine hydrochloride (Table 8). At the time of review the majority of patients have taken these medications for at least one month as shown in Table 9.

TABLE 9. The number of patients who underwent medical treatment of different duration

DURATION OF THERAPY	NO. OF PX
≤ one month	19
1 to 2 months	13
2 to 3 months	9
3 to 4 months	5
≥ 4 months	7

Of the 35 patients with follow-up visits recorded, there was note of symptomatic improvement in 31 patients, same in 2, and worse in another 2. While some of those who did not follow-up probably lived geographically far from the hospital, others were actually referred back to their primary physicians.

DISCUSSION

Making sense of a subjective like tinnitus need not be fraught with negative feelings on the part of physician. While much has been said of the fact that no definite cure for tinnitus has been found, the patient need not be told to "live with it" without a systematic method of understanding the character of the patient's tinnitus, its association with hearing loss, other medical problems, and even its impact on the patients in terms of handicap. Not much can be said of treatment outcomes without a methodological means of objectifying quite a subjective symptom as tinnitus. Northwithstanding, this study provides a demographic and audiologic profile of patients with tinnitus where tinnitus questionnaire and audiometric measurements were systematically applied.

In a study made by Shiraski and Eura (1999), they reported that most tinnitus patients are within the ages 30 to 49 years.[10] Axelsson and Rangdahl also reported that tinnitus in Sweden is often found in males and are with those with subjective hearing loss.[11] This local report revealed that most tinnitus patients were within the ages of 30 to 49 years and of male preponderance. In terms of age and sex, there was similarity of local and foreign data.

According to Tzaneva, et.al., they concluded that people who were frequently exposed to noise, dust, toxic substance, and vibrations predominantly complained of tinnitus.[12] Their subjects were 67 miners with a mean age of 44.5 years of which 43% complained of tinnitus. In our study, the majority of people who complained of tinnitus were from the rank and file, businessmen, and lawyers. Their probable exposure to machineries, chemicals in the workplace, and perhaps the presence of constant noise such as those in court hearings and conferences may contribute to this predicament.

Similar to our local review of tinnitus patients, Schonweiler reported that most of his 79 patients reported that tinnitus was frequently described as ringing and hissing.[13] A review of Reiss and Reiss (2001) on several tinnitus studies revealed that it more often occurs bilaterally (48%), than on the left (28%) or the right (23%). Thus, it was concluded that there is no general predominance of the left ear. However, results revealed that 60% of 58 tinnitus patients in their own study showed predominance to the left ear. They also noted that preference the left ear than

to the right may deduce the possibility of a link between affectation of tinnitus and hemispheric dominance.[14] Axelsson, et. al. (1989) also reported in their study that tinnitus has been frequently found more on the left ear.[15] In our study, patients normally describe their tinnitus to be ringing and hissing in character. A number of patients complained as well of tinnitus from the left ear similar to other studies. This may indicate a possible link of hemispheric dominance. However, the study was unable to elicit the handedness of the patient for correlation.

A six months study of 500 subjects made on tinnitus at the Brasilia University Medical School by Oliveira, et. al. showed that 81% rated their tinnitus as mild; 18% as moderate, and only 1% to be severely disabling. Furthermore, they consummated that mild and moderate degree of tinnitus might isolate a particular etiology as none to those in severe conditions.[16] Similarly in this study, most patients reported that their tinnitus are mild to moderately disabling.

Our study revealed that there is improvement in tinnitus after treatment even if there was a negative outcome in the residual inhibition test. The minimal masking level (MML) may provide some information regarding the use of a tinnitus wearable masker. If the MML is lower or equal to the loudness matching, then it is likely that maskers will be effective.[1,6]

Although residual inhibition cannot be used as a predictor of successful masking, nevertheless it is an important demonstration to tinnitus patients because it indicates that their tinnitus is amenable to change.[8,9]

The loudness of tinnitus reported by Hulshof in 1986 showed that although tinnitus was a usual complaint, its loudness is comparably small in most cases.[17] However for patients with severe degree of tinnitus, there was a positive correlation of hyperacusis and discomfort level according to the preliminary report by Goldstein and Shulman.[18] Most of our patients complained of moderate level of pitch and loudness of tinnitus.

Numerous foreign studies on the pathophysiology of tinnitus have been proposed but never established. Tinnitus is described as the sensation of any sound perceived without any evident external stimulus.[19] Vesterager (1997) reported that tinnitus may be secondary to inner ear pathology associated with hearing loss, drug ingestion, cardiovascular, neurologic, and psychiatric disorders.[20] In a study by Lockwood, et. al. (1998) they revealed that damage of microscopic nerve endings of the inner ear results to tinnitus.[21] Listed below are some of the common etiologies of tinnitus according to the American Academy of Otolaryngology (1999):

TABLE 10. Common etiologies of tinnitus. Tinnitus: Advances in Diagnosis and Management. American Academy of Otolaryngology-Head and Neck Surgery Foundation, Inc. 1999.

OTOLOGIC	*CENTRAL NERVOUS SYSTEM*
Noise induced hearing loss	Closed head injury
Presbycusis	Temporal bone fracture
Meniere's Disease	Multiple sclerosis
Labyrinthitis	Post-meningitis
Chronic Otitis Media	Vascular loop compression
Otosclerosis	
Acoustic Neuroma	*METABOLIC*
Cerumen Impaction	Hyperlipidemia
	Diabetes mellitus
TRAUMA	
Neck injury/whiplash	*Temporomandibular joint disorders*
Explosion injury	*Depression/anxiety*

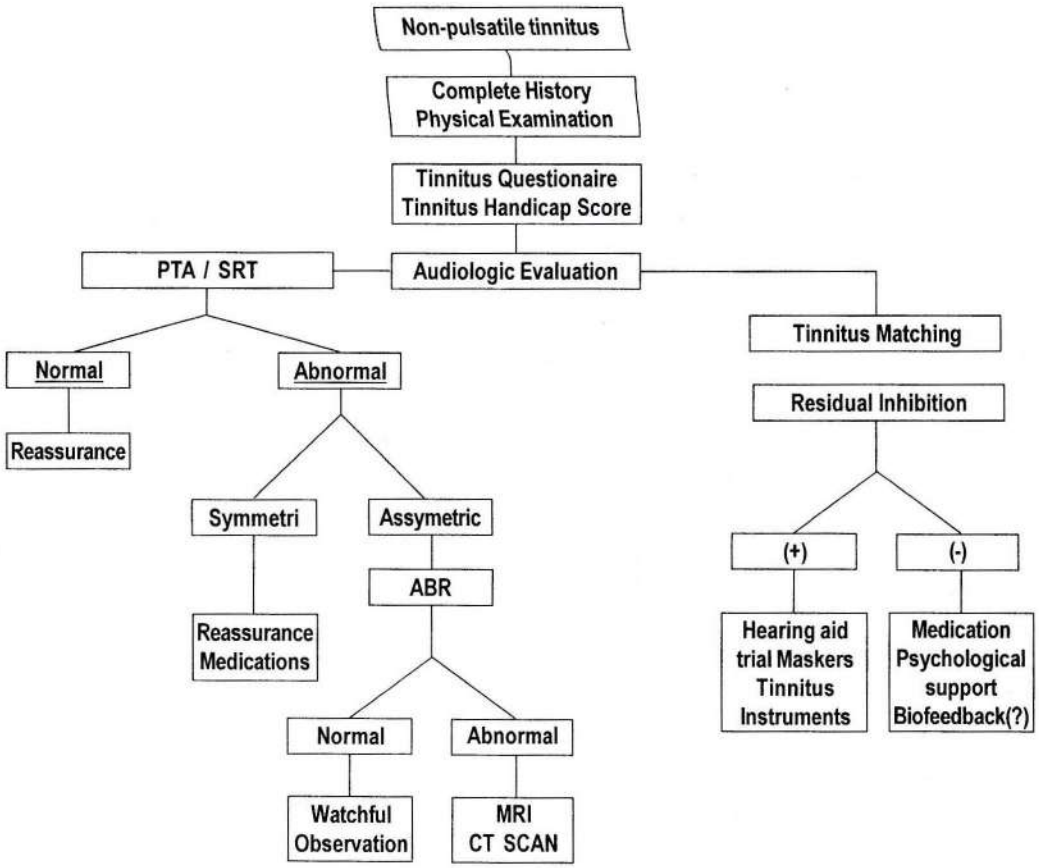
TABLE 11. Medications associated with tinnitus. Tinnitus: Advances in Diagnosis and Management. American Academy of Otolaryngology-Head and Neck Surgery Foundation, Inc. 1999.

Salicylates (aspirin)	*Aspirin-containing compounds*	*NSAIDS*
Quinin	Alka-Seltzer	Fenoprofen
Quinidine	Aspergum	Ibuprofen
Aminoglycoside antibiotics	Buffenn	Indomethacin
Streptomycin	Concidin	Ketoprofen
Neomycin	Darvon compound	Meclofenamate
Gentamycin	Dristan	Naproxen
Tobramycin	Ecotrin	Phenylbutazone
Amikacin	Empirin compound	Piroxicam
Other antibiotics	Exedrin	Sulindac
Vancomycin	Fiorinal	Tolmetin
Polymyxins	Midol	
Erythromycin (IV)	Pepto-Bismol	
Cisplatin	Percodan	
Furosemide	Theracin	
Heavy metals	Trigesic	
Mercury		
Arsenic		
Lead		

Most of our tinnitus subjects were diagnosed with noise induced hearing loss, presbycusis, and Meniere's disease. However, inspite of an extensive diagnostic evaluation, there were a number of subjects whose cause of tinnitus were idiopathic (30%).

This study presents the results of a diagnostic protocol applied to a consecutive series of patients in a tertiary care center. The primary aim of the diagnostic protocol was to rule out the presence of a retrocochlear pathology in all cases of unilateral tinnitus. It is notable that despite a careful history and physical examination, detailed audiologic evaluation and radiographic studies in some, there was still 30% of the subjects where no diagnosis could be made. Notable in such patients, the presence of a retrocochlear problem would have been accomplished using the algorithm presented in this paper (Figure 8).

FIGURE 8. Algorithm in the treatment of non-pulsatile tinnitus



While treatment results in this study are reported to be promising with an overall efficacy rate of 88%, the need for randomized placebo controlled trials cannot be overemphasized. The authors will use this study as a groundwork for the initiation of such controlled trials to look at the various effects of pharmacological agents and the predictive factors for success of treatment.

A previous local study using methylcobalamin has reported that the duration of tinnitus is important such that patients treated earlier in the course of their symptoms would most likely respond best.[7] Another study on microvascular loop decompression as reported by Moller et. al. has shown that this procedure resulted in a cure in patients with less duration of severe tinnitus.[22] An additional important consideration reported therein was the duration of treatment such that at least a month of treatment would be needed before results of efficacy can be ascertained.[7]

CONCLUSION

The data provided in this study gives a detailed and comprehensive data base regarding a consecutive series of 53 patients seen in a tertiary medical center. The use of tinnitus questionnaires and handicap inventory yields useful information regarding the character, location, frequency, and intensity of the tinnitus in addition to other medical information. Audiometric measurements of pure tone thresholds, tinnitus loudness and pitch matching as residual inhibition tests provide useful objective measures in these patients that may be correlated with treatment results. In our view, a careful history and these objective approaches yield a diagnostic etiology in about 70% of patients. With this in mind, an emphatic message is that the otorhinolaryngologist is doing his best to positively address the problem of tinnitus.

RECOMMENDATION

It is our recommendation that tinnitus questionnaire and handicap inventory as well as audiologic measurements may be helpful in analyzing treatment outcomes from randomized controlled trials of different pharmacological agents.

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