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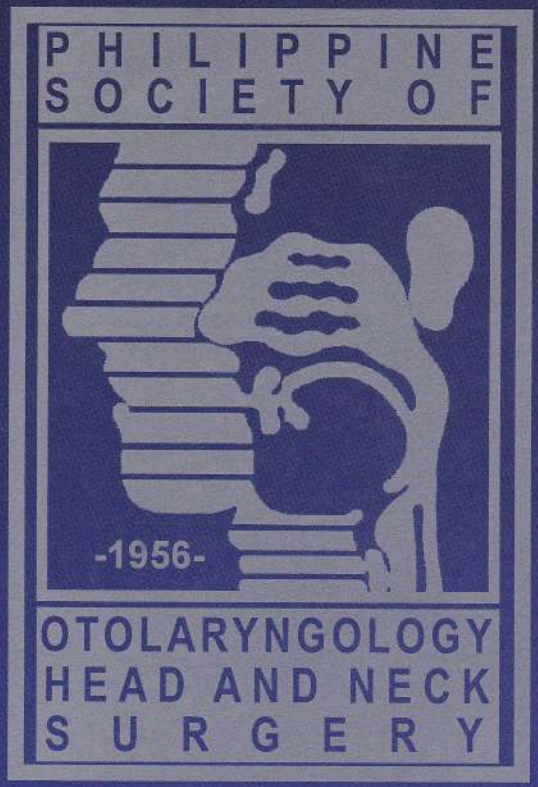

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Guidelines for Authors

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Unit 2512, 25th Floor, Medical Plaza Ortigas Condo
San Miguel Avenue, Ortigas Center
Ortigas, Pasig City
TeleFax: 633-2783, Telephone: 633-8344

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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.

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HEARING ASSESSMENT TEST IN VISAYA FOR PRIMARY EAR CARE*

MERVIN LOUIS C. VARONA, MD**
VICTOR JOHN C. LAGMAN, MD, FPSO-HNS***

ABSTRACT

OBJECTIVES: The study aims to construct and validate the reliability of the Visayan version of Hearing Assessment Test (HAT) by correlating the results to pure tone audiometry results obtained in the same patients.

METHODOLOGY: The research used the causal-comparative study method. Included in the study were sample-respondents coming from the seven strategic locations, namely Argao, Cebu; Cebu City; Danao City, Cebu; Ormoc City, Leyte; Baybay, Leyte; Dumaguete City, Negros Oriental; and Cagayan de Oro City. The said population comprised of both sexes from age 15 to 90. The population was treated through stratified-cluster sampling approach. The sample-respondents included were those able to read and understand Visaya and were within the age limit set in this study. The sample-respondents were made to answer the HAT questionnaire and after which history, otoscopic examination and pure tone audiometry were done.

RESULTS: Included in the study was a total of 293 sample-respondent, of whom 45% were males and 55% females. Ages ranged from 15 to 90 years, with mean age at 36 years old. Almost 3/4 (72% had normal audiometric results. Of the total population, 39% had abnormal otoscopic exam as well as audiometric exam. Spearman's Rho value of 0.748 indicated a high correlation between the mean audiometric results and that of the Visayan version of HAT. With a 73.04% sensitivity, 72.33% specificity and an accuracy of 72.92% the cut-off score of the Visayan version of HAT was set at 15.

CONCLUSION: The Visayan version of HAT was found to be significant as a screening tool in determining hearing impairment among the Visaysan speaking population.

INTRODUCTION

Hearing loss is an extremely common disorder and in fact a problem of immense international proportions affecting millions worldwide.[1] It has a prevalence of 8.6% in all ages. But most commonly it would involve older adults affecting one in every four people over the age of 65 years old.[8]

This disorder has a wide spectrum of presentation ranging from an almost undetectable degree of disability to a profound alteration in the ability to function in society. Many people, both children and adults suffer from this disorder, and the handicaps that may arise from this are economical, educational and above all, social. These persons need help, both medical and educational.[4]

In the Philippines, wherein health comes only as a lesser priority in programs of the government, a well-defined program for the identification and treatment of people afflicted with hearing loss is lacking. This, coupled with the reluctance of most people to seek early help because of ignorance and poverty, the magnitude of hearing loss in our country is difficult to assess.

Over the past years, there was already an increasing concern worldwide over the growing population afflicted with this problem. Civic organizations whose main focus was on hearing loss and deafness were established in the United States and Europe for the purpose of helping hearing impaired populace. Screening programs were developed to identify those with hearing impairment. An example of this was the mobile audiologic units, which included portable pure tone audiometry equipment, being provided by the League for the Hard of Hearing in the United States. These units were stationed in public places and the test were done for free.[7] However, a reliable diagnostic modality to be used as a screening tool tends to be expensive. This kind

*First Place, PSO-HNS Analytical Research Contest, December 02, 2002, Westin Philippine Plaza Hotel, Manila
**Resident, Department of Otolaryngology-Head and Neck Surgery, Vicente Sotto Memorial Medical Center
***Consultant, Department of Otolaryngology-Head and Neck Surgery, Vicente Sotto Memorial Medical Center

of screening tool would be difficult to realize especially in our country wherein financial funding would be difficult to find. And provision of such a tool to each and every island group that comprises our country would be impractical.

In 1992, the American Academy of Otolaryngology/Head & Neck Surgery (AAO-HNS) developed a quick paper and pencil questionnaire called the Five-Minute Hearing Test (FMHT). This tool was validated and found to be significantly correlated to standard audiologic examinations like the Pure Tone Audiometry (PTA) and speech test. In 1994, the FMHT was translated in Filipino (Tagalog) which was called the Hearing Assessment Test (HAT) and showed a consistently high correlation with pure tone audiometry. This proved that a cost-effective and socio-culturally acceptable hearing screening tool could be developed.[6]

In the Philippines, there is an estimated 100 dialects being spoken. Nearly ¼ of the total population according to the National Statistics Office speaks Visaya. In the Visayas and Mindanao areas where Visaya is predominantly spoken, many people especially those in the rural areas may not be able to accurately answer the Tagalog version questionnaire. This may affect the validity of such tool in relation to its results compared to a standard audiologic examination like PTA.

It was in the light of this concept that this study was made.

Significance of the Study

The main purpose of the study was to develop a meaningful and applicable Visayan version of the Hearing Assessment Test and to validate the reliability of the test as compared to pure tone audiometry.

This test may provide us with a cost-effective and socio-culturally acceptable tool that maybe used by primary health care physicians in screening for hearing loss afflicted Visaya speaking populace.

Research Problem

The study sought to answer the question "does the Visayan version of the Hearing Assessment Test correlate to pure tone audiometry conducted in seven strategic locations in four provinces which are predominantly Visaya speaking?"

HYPOTHESIS

The hypothesis presented is non-directional and proved using α level of significance of 0.05.

H_o: The Visayan version of Hearing Assessment Test does not have any significant correlation to pure tone audiometry.

OBJECTIVES OF THE STUDY

General Objective:

The study aims to construct and validate the reliability of the Visayan version of Hearing Assessment Test by correlating the results to pure tone audiometry results obtained in the same patients.

Specific Objectives:

1. To construct a Visayan version of the Hearing Assessment Test.
2. To determine if there is correlation between the Visayan version of Hearing Assessment Test scores, PTA, otoscopic findings and otologic history.
3. To determine the sensitivity, specificity, positive and negative productive values and accuracy of the Visayan version of HAT.
4. To determine a Visayan version of HAT cut-off score among Visaya speaking Filipino that will correctly segregate patients to be referred to an Otolaryngologist.

Theoretical Background

Hearing loss is one of the most common sensory disorders in humans. For some this impairment presents early in life. However, hearing loss can present in any age (Paparella, et.al.).

Hearing loss results from disorders affecting the auricle, external auditory canal and middle ear and this is called conductive type of hearing loss. Those disorders affecting the inner ear, the cochlea and VIII nerve as sensorineural type of hearing loss. Disorders affecting the auditory system in the brainstem and cortex are called central type of hearing loss (Cummings, et.al.).

A conductive type of hearing loss may result from obstruction of the external auditory canal by cerumen, debris and foreign bodies. Likewise, swelling of the lining of the canal, perforation of the tympanic membrane and disruption of the ossicular chain that may occur in infections and trauma, can lead to conductive type of hearing loss (Lee, K).

Sensorineural hearing loss may result from any infection, trauma, degenerative disease,

vascular and or neoplasm affecting the cochlea and VII nerve. A mixed type hearing loss is a combination of conductive and sensorineural hearing loss (Lee, K.).

Detection of any signs of hearing loss, a complete otologic history and examinations are needed. Likewise, pure tone audiometry, which is the gold standard diagnostic modality for hearing screening, is done. Afterwhich, a treatment modality for the specific type of hearing impairment can now be instituted.

Provision of a diagnostic modality such as a pure tone audiometry tends to be expensive. In fact, in the Philippines this is a scarce resource. Most of this PTA's are situated in highly urbanized areas thereby depriving those in the provinces easy access and early detection of any type of hearing impairment.

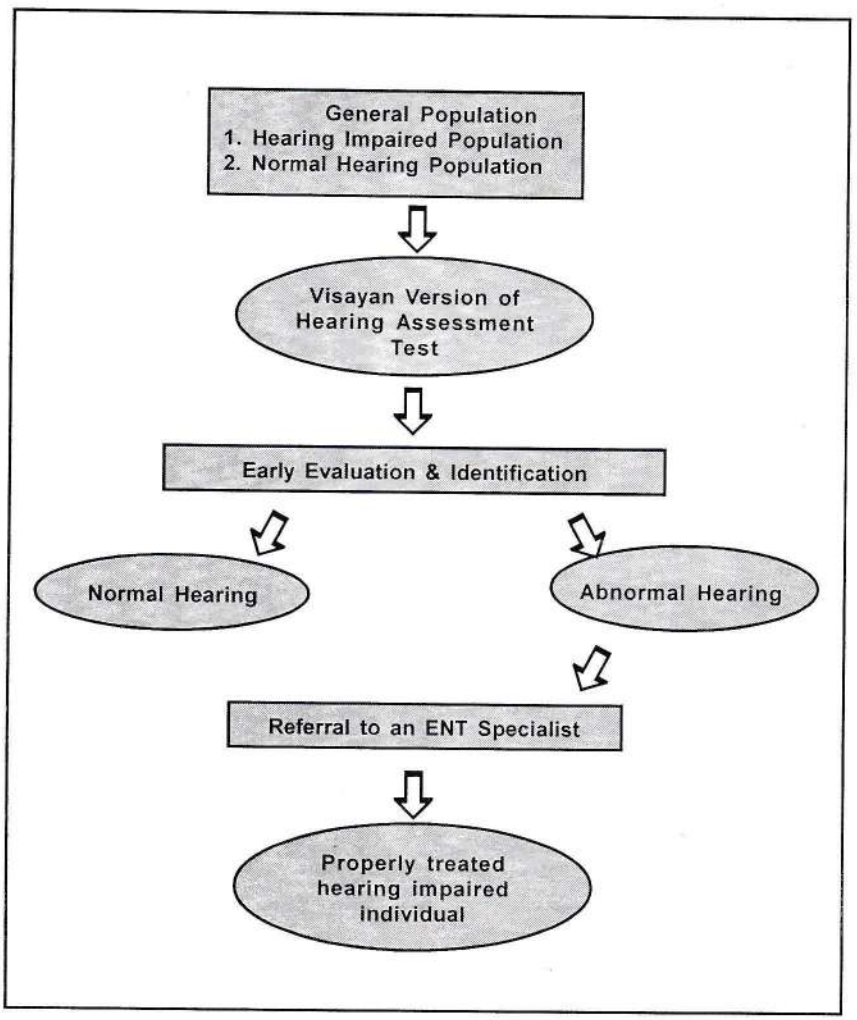
This problem is aggravated by the fact that poverty affects more than half of the total population in the Philippines. These, together with ignorance of the people and the inadequate programs of the government makes early detection and treatment of any hearing impairment difficult.

The development of Hearing Assessment Test which is a questionnaire approximating the hearing status of an individual, provided us with an inexpensive screening tool for the hearing impaired populace.

HAT however is written in Tagalog. This poses a possible language barrier and thus may affect the reliability of this test. In the Philippines, nearly ¼ of the total populace are Visaya speaking. Because of this, the authors came across with the idea of developing a Visaya version of HAT to cater to the Visaya hearing impaired populace. This likewise would fasten primary health physicians to identify and refer this hearing impaired populace to an ENT specialist for early treatment.

This idea is elaborated through the schematic presentation below.

FIGURE 1
THEORETICAL FRAMEWORK



Conceptual Background

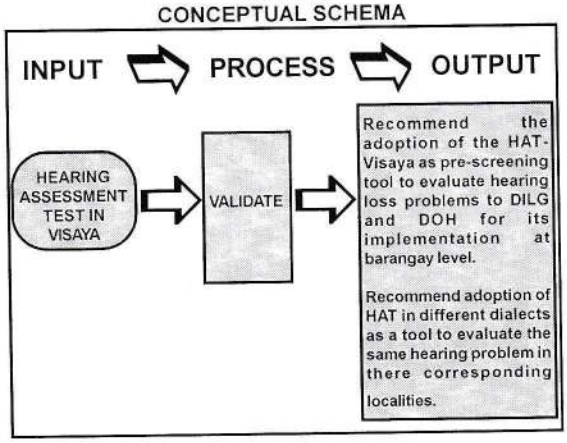
The starting premise of this analysis is that patient with hearing loss problem either from what age bracket they belong needs pre-screening test so primary physicians can refer them to ENT specialist without any prejudice encountered. Central to this concern is the role of a questionnaire made in accordance to its dialect or vernacular (Visaya) and to what extent it can help the attending physician and ENT specialist in treating the hearing loss patient. In this concept, those who are included in the study are the subjects.

The assumption in this analysis is that sample-respondents coming from seven strategic localities from four provinces namely: Argao, Cebu; Cebu City; Danao City (Cebu), Ormoc City (Leyte); Baybay, Leyte; Dumaguete City (Negros Oriental); and Cagayan de Oro City undergo the test (written and pure tone audiometry), the written test has influence in the proper treatment of patient. The subject of this analysis is the sample-respondents aging 15 to 90 and who are able to read and understand Visaya.

With this flow information imparted by the corresponding respondent is evaluated. The result of the evaluation can help the diagnosing ENT specialist do or perform efficiently the treatment of problem experienced by the individual patient.

To elaborate the conceptual background, a schema is presented to give the reader a full picture of the activities. The schema is presented below:

FIGURE 2
CONCEPTUAL SCHEMA



REVIEW OF RELATED LITERATURE

Hearing loss is one of the most common disorders that an otolaryngologist encounters. It is a disorder which usually develops gradually but when it does, it can be devastating and cause communication difficulties. This can be difficulty in hearing whispered voices, understanding female or soft voices, hearing a person speaking faraway and communicating in a crowd or in a noisy environment.[4] These communication problems may cause embarrassment and frustrations on oneself, among family members and close friends. This can eventually lead to social isolation of these individuals making them less productive.

This impairment continues to be a major global problem-affecting people in different countries. Epidemiologic data suggest that more than 120 million people worldwide have a hearing loss of at least 40 decibels in the better hearing ear. This level is sufficient to interfere markedly with communication.[7]

Statistics in the United States reveals that 15 of every 1000 person under age 18 have some type of hearing impairment and 1 of every 4 people over the age 65 has a hearing disorder. A comparison of hearing loss incidence in rural and urban areas reveals a 7.9% for the former and 11.1% for the latter. On etiology 33.7% were noise induced. 28% age-related, 17.1% infection and 4.4% congenital.[7]

In the early 90's, there was an increasing concern over the growing population afflicted with hearing loss. Hearing loss or deafness civic organization was established in the US and Europe for the purpose of helping people afflicted with this problem. Screening programs were developed for the purpose of early identifying the involved population. An example of this was the mobile audiologic units, which included a pure tone audiometry, being provided by the League for the Hard of Hearing in the US.[7]

In the 1992, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) developed a cost-effective screening tool via a quick paper and pencil questionnaire called the Five-Minute Hearing Test (FMHT).[6]This FMHT is a screening tool dealing with daily activities which requires hearing and used in the early identification of hearing impaired individual. Subsequently, early referral of these patients to an ear specialist with further audiological study and treatment. This tool was field tested on 71 individuals by the AAO-HNS. This was further field tested by Kioke et. al..They found this tool to be valid but made some modifications on the questionnaire content to make it more reliable. The AAO-HNS and hearing loss and deafness civic organizations are currently using this same FMHT as a screening tool. This same tool is even presented in the different websites of this organization.

In the Philippines, Pio et al developed a similar screening tool called Hearing Assessment Test. This tool was formulated in

Tagalog. It was field tested and found to have good correlation to PTA with cut-off score for referral at 20.[5]

DEFINITION OF TERMS

For the purpose of this study, the following terms are operationally defined:

Five-Minute Hearing Test is quick-paper and pencil questionnaire which deals with daily activities involving hearing which approximates the hearing ability of an individual thru scoring.

Hearing Assessment Test is a hearing screening tool developed as an adaptation of the FMHT and formulated in Tagalog.

Hearing Assessment Test in Visaya is an adaptation of HAT formulated in the Visayan dialect made to cater the Visaya speaking hearing impaired populace.

Pure Tone Audiometry refers to the gold standard hearing test which is used as basis to correlate with the HAT scores.

Primary Ear Care refers to the health care with regards to the normal condition of the ear with the prevention of ear disease and hearing loss.

Profile is the relevant information of a client gathered through otologic history and otoscopic findings.

Sensitivity is the capacity of a test to pick up or label positive those who have a certain disease/ condition.

Specificity is the capacity of a test to exclude or label negative those who do not have a certain disease/condition.

Positive Predictive Value is the chance that a positive result is truly indicative of the presence of the disease/condition

Negative Predictive Value is the chance that a negative result is truly indicative of the absence of the disease/condition.

METHODOLOGY

The research conducted used the causal-comparative study approach. In the conduct of the research, the following areas were looked into, such as the research population and its size (inclusion and exclusion), research environment, research data gathering and the research data analysis.

The Population and its Sample Size

The research population included 293 sample-respondents coming from the seven strategic location namely; Argao, Cebu; Cebu City; Danao City, Cebu; Ormoc City, Leyte; Baybay, Leyte; Dumaguete City, Negros Oriental; and Cagayan de Oro City. The first three areas were those located in the province of Cebu. Cebu City being representing the central area and Argao, Cebu and Danao City being in the south and north respectively. The other four areas where located in provinces surrounding Cebu and were predominantly Visaya speaking.

The sample-respondents included in the study were both male or female aging between 15 to 90 and were able to read and understand Visaya. Such population was treated as stratified-cluster sampling approach.

The research population size was drawn using the scientific sampling size determination formula. Such procedure in determining the sample size was made to make sure that the test was valid and significant.

Research Environment

Of the seven locations there were six study locations conducted in untreated rooms. Only one location used the PTA laboratory.

The testing center of the six localities were places free from loud noises. A sound level meter (Radioshock Model 100A) was used to ensure that the ambient noise was within the maximum allowable limit as proposed by the American Speech and Hearing Association (ASHA) which was set at 50 dB.

Research Data Gathering

Data gathered included the patient's profile, otologic history and otoscopic findings, HAT results and the results of the PTA.

The patient profile data sheet consisted of age, sex, address and occupation. This data sheet included a checklist of otologic history and symptoms as well as a checklist of the otoscopic findings present in the patient. Otoscopy was done by the author using a Welch Allyn otoscope.

After the above activities had been done, the sample-respondents were made to answer the HAT questionnaire. This questionnaire was a set of 15 questions written in Visayan dialect. The questions contained were related to common daily activities of an individual. This had been patterned after the American Academy of Otolaryngology-Head & Neck Surgery: The Five Minute Hearing Test (Appendix E) and the Hearing Assessment Test in Filipino (Tagalog) by Pio, et. al.(Appendix D).

There were four possible answers with corresponding scores: "pirmi" (always) = 3 points, "halos pirmi" (half the time) = 2 points, "usahay" (occasionally) = 1 point, and "wala gyud" (never) = zero. The highest obtainable score was 45 and the lowest was zero.

Pure Tone Audiometry, considered to be the gold standard, was done after the volunteers had answered the HAT in Visaya questionnaire. The audiometric study was done by the author without the knowledge of the HAT results. Air conduction audiometry with pure tone threshold at 0.5, 1, 2 and 4 Khz was taken on both ears using the Interacoustic Diagnostic Audiometer AD17. The audiometer was calibrated by a qualified electronics technician at the Manila Hearing Center along Quezon Blvd., Quezon City.

During the conduction of audiometric exam, the respondents were instructed to raise the hand on the side of the ear tested and to continue to respond as long as he/she detects the test signal. The pure tone audiometry results were plotted on the audiogram based on the hearing threshold level.

The responses of the volunteer-patient gathered were kept confidential as to protect the respondent individual's physical condition.

Research Data Analysis Tools

The data gathered through the written test, that of the HAT-Visaya version was tested for correlation with that of the PTA. After its correlational test, it was further tested for its significance using the Friedman test of significance. Aside from this, the other statistical tools used were the Kendall test of Concordance and the Spearman test of Rank Correlation.

Friedman test of Significance. This statistical tool test the significance using variance. This is represented by its formula:

$$\chi_r^2 = \frac{12}{Nk(k+1)}\sum\left(R_j\right)^2 - 3k(n+1)$$

where χ_r^2 = the Friedman test
N = the number of columns
k = number of rows
R_j = sum of columns

Kendall test of Concordance. This test the concordance of ranks or assigned to each sample. At the same time this test also test the correlation between the two samples. The formula is

$$W = \frac{12\sum D^2}{n\left(n^2+1\right)}$$

where W = Kendall test of Concordance
D^2 = square difference of ranks
n = number of samples

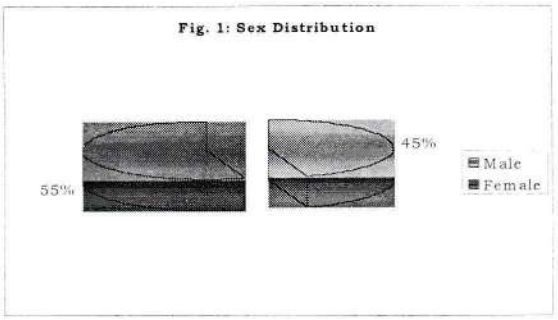
Spearman test of Rank Correlation. This statistical tool test the ranks assigned to each sample with less than 30 samples being tested for correlation. The formula is

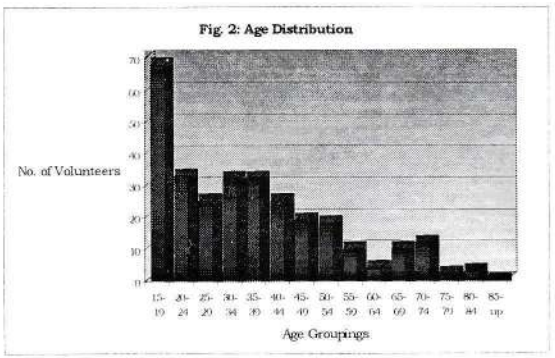
$$\rho_s = 1 - \frac{6\sum D^2}{n\left(n^2-1\right)}$$

where ρ_s = the Spearman test of rank correlation
D^2 = squared difference of ranks
n = number of samples being tested

RESULTS

Included in the study was a total of 293 volunteers coming from seven areas in four provinces which were predominantly Visaya speaking, 132 (45%) of whom were males and 161 (55%) were females (Fig. 1). Their ages ranged from 15 to 90 with the youngest at 15 and oldest at 84 years of age. The mean age was at 36 years old (Fig. 2).



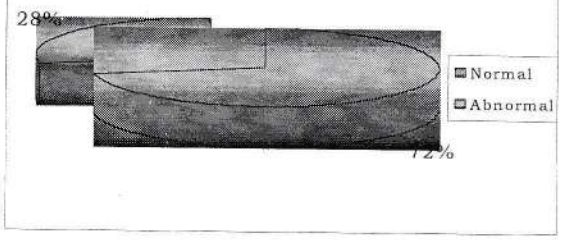


The questionnaire which was constructed in Visaya was understood and answered easily by the respondents which took them approximately 4 to 5 minutes to be done. This applicability and effectivity of the questionnaire as a screening tool was confirmed thru the Kendall Concordance Test with result at W = 0.86.

Of the total number of volunteers, there were 211 (72%) who had normal audiometric results while the remaining 82 (28%) had

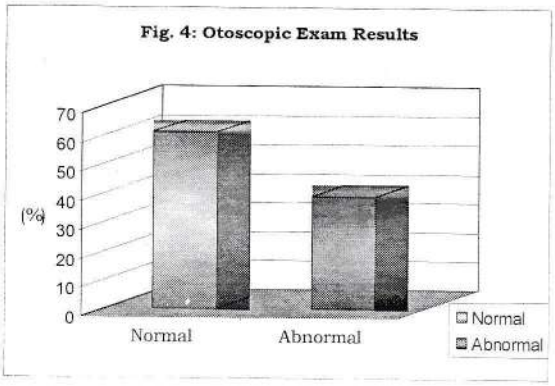
abnormal results which were commonly noted at the middle to elderly age group (Fig. 3). Among the volunteers with abnormal audiometric results, 50 (61%), 18(22%), 9 (11%) and 5 (6%) had mild, moderate, severe and profound hearing impairment respectively.

Fig. 3: Audiometric Results



Otoscopic examinations were than on all of these volunteers. Of the total population there were 115 (39%) had abnormal findings consisting of impacted cerumen, tympanic membrane perforation and otorrhea. There were only 46(16%) who had both abnormal results in otoscopic exam as well as audiometric exam. All of these patients were managed medically and or referred to an ear specialist in their locality (Fig. 4).

Fig. 4: Otoscopic Exam Results



Spearman's Rho results showed that there was a high correlation between the mean audiometric results as against the HAT scores at a value of 0.748. Between the sex and the HAT scores, there was a high correlation. However, between the age, otoscopic findings and HAT, there was low correlation found. Of the different cut-off scores: 5, 10, 15, 20 and 25 points, the recommended score in this study was 15. This cut-off score has a 73.04% sensitivity, 72.33% specificity and an accuracy of 72.92% (Table VII). This shows that the probability of HAT to correctly identify those with hearing impairment was high thereby lowering the probability of having a false positive result.

HAT is significant as a screening tool in determining those patients with hearing impairment as evaluated through Friedman Test of significance with computed value greater than the tabled value at = 0.05 with degree of freedom 1. Furthermore, as based on the positive predictive value at a cut-off score of 15, a patient is labeled of having hearing impairment 81.42% of the time. This shows that the probability that a person with HAT score of 15 and below be labeled as having a hearing impairment is high.

DISCUSSION

The main purpose was to develop a meaningful and applicable Visayan version of the Hearing Assessment Test and to validate the reliability of this test as compared to pure tone audiometry. This test aims to provide us with a cost-effective and socio-culturally acceptable tool that may help primary health care physicians identify the hearing impaired populace and know when to refer this patients to ear specialists.

As many as a little over a quarter (28%) of the 293 sample-respondents were found to have varying degrees of hearing loss. Most of these people where not aware of their condition or did nothing about it. Perhaps ignorance and inaccesible medical care units may be contributory factors.

The mean age of volunteers however was 36 years old and most of the causes of the hearing impairment may not be that of the sensorineural type. Sixteen percent of those found to have varying degrees of hearing impairment was also found to have problems affecting the external and middle ear. Most of this sample-respondents had impacted cerumen and some had either acute or chronic otitis media or acute or chronic otitis externa. This hearing loss is of conductive type which would either mean that the cause of the hearing loss may be temporary, depending on the degree of the disease and depending on the treatment which could either be medical or surgical.

Conductive type of hearing loss is preventable and at times curable and almost always treatable. It is rather frustrating for a clinician to be confronted with these data where one is capable of improving the health status of the people but is unable to so so simply because of ignorance or inaccesibility of data.

Parallel to the aims of primary health care of being able to prevent and or detect early disease processes, the success of primary ear and hearing care depends on the availability of facilities and manpower that would cater to these kind of problems. Sad to say, in the Philippine setting, these facilities which would include a pure tone audiometry is a scarce resource. Most of these facilities are concentrated in major urban areas thus causing hindrance for those living in

the provinces easy and early evaluation of any ear or hearing problems.

With the development of the Hearing Assessment Test in Tagalog by Pio., et. al., provided a valuable tool in making early detection and prompt rehabilitation of impaired hearing in the Philippines, possible and accessible to all. However, because of the variations in regional dialects among Filipinos, this is inapplicable to non-Tagalogs.

In this study, it aimed at providing a HAT questionnaire that would cater to the Visaya speaking populace. Through the various statistical treatment used in this study, it is now known that this tool is an effective screening tool for the Visayans and that this correlates well with audiometric results. The calculated sensitivity and specificity values showed its reliability. *However, it should be stressed that this tool does not aim to be a replacement of the standard pure tone audiometry but instead serves as an adjunct in the early detection of hearing impairment which may be used by primary health care physicians.*

Conclusion

Hearing Assessment Test in Visaya correlated well with audiometric results having a high correlation coefficient of 0.748. Correlation however, to age, sex and otoscopic examinations was poor. The sensitivity, specificity and accuracy rate was found to be acceptable at HAT cut-off score of 15 which had 73.04% sensitivity, 72.33% specificity and an accuracy of 72.92%. At this score, this will correctly segregate patients with hearing loss and be referred promptly to an ear specialist.

HAT in Visaya is a good screening tool in identifying hearing impaired populace. This was proven through the statistical finding of a computed value greater than the tabled value at = 0.05 with degree of freedom 1. Thereby, rejecting the null hypothesis of Visayan version of HAT having no significant correlation to pure tone audiometry.

Recommendations

To test for reliability and validity of the Hearing Assessment Test in Visaya should be conducted in a much larger population that would represent every island group in the Visayas and Mindanao regions which are predominantly Visaya speaking.

Also suggested is to construct a HAT questionnaire in the different dialects and test its reliability and validity. With this, it will truly provide an easy, inexpensive and socio-culturally acceptable screening tool that maybe used by not only the primary health physicians but also other primary health care providers.

To make a study that will determine the applicability and acceptability of all future HAT in the different dialects by the end users who are the primary health physicians, nurses, midwives and barangay health workers.

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APPENDICES

Appendix A: Letters to Head of Offices (Municipalities, Barangays).

VICENTE SOTTO MEMORIAL MEDICAL CENTER
Department of Otolaryngology-Head & Neck Surgery
Cebu City

Eduardo R. ArcenasM.D.
Chairman

Gina M. Seredrica M.D.
Training Officer

Consultant Staff:
Arthur Y. Dy M.D.
Felicidad C. Felicilda M.D.
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Marlon T. Oclarence M.D.
Roman M. Cruz M.D.
Victor John C.LagmanM.D.

Resident Staff:
Nilson L. Gelbolingo M.D.
Chief resident

MervinLouisC.VaronaM.D.
Third year

Edgar C. Llamar M.D.
Second year

Simon John Eric T. Flores M.D.
Second year

Cris Bernard Abrea, M.D
First year

September__, 2002

Sir, Greetings!

The Department of Otolaryngology-Head & Neck Surgery of the Vicente Sotto Memorial Medical Center (VSMMC) together with a group of first year medical students of Cebu Doctor's College of Medicine has embarked on a study that will greatly aid in the early detection of hearing loss among the Visayan speaking population. The study, "A Hearing Assessment Test (HAT) in Visaya for Primary Ear Care", is a concise and rapid paper-and-pencil test in the Visayan dialect that will screen the hearing level of patients. To be able to determine the reliability and validity of this screening tool, this has to be field tested. The volunteers will be made to answer the questionnaire and ear examinations including hearing test will be done. It is for this reason that we wish to seek permission from your office to conduct this study.

Your support will then be indispensable in screening the hearing impaired Visayan population, for which your constituents are a part of. Also, this will give opportunity for your constituents to have ear examinations and hearing test for free . Rest assured that all examinations that will be done on the volunteers will be non-invasive and that we will accord the necessary acknowledgement of your institution in the scientific paper.

We are hoping and praying for your kind consideration on this request. Thank you, and we look forward to your favorable response.

Respectfully yours,

MERVIN LOUISC.VARONA, M.D.
Resident
Dept. of Otolaryngology-HNS
VSMMC

Noted by:

Eduardo R. Arcenas, M.D., FPSO-HNS
Chairman, Dept. of Otolaryngology-Head & Neck Surgery
VSMMC

Appendix B: Results in Tables

Table I
Age Distribution

Age Groups (Years)	n	(%)
15-19	68	23
20-24	33	11
25-29	25	8.5
30-34	32	10.9
35-39	32	10.9
40-44	25	8.5
45-49	19	6.5
50-54	18	6.1
55-59	10	3.4
60-64	4	1.4
65-69	10	3.4
70-74	12	4.1
75-79	2	1.0
80-84	3	1.02
85-up	0	0
Total	293	

Table II: Sex Distribution

Sex	n	(%)
Male	132	45.05
Female	161	54.95

Table III: Audiometric Test Results

	AD	AS	x
Normal	196	218	211
Abnormal	97	75	82
Total		293	293

Table IV: Otoscopic Examination

	n	%
Normal	178	61
Abnormal	115	39
Total	293	

Table V: Otoscopy VS Audio Otoscopy

Audio	Normal	Abnormal	Total
Normal	147	64	211
Abnormal	36	46	82
Total	183	110	293

Table VI: Audio VS HAT

HAT Score	Audio		
	Normal	Abnormal	Total
0-5	62	5	62
6-10	65	12	77
11-15	57	13	70
16-20	22	17	38
21-25	3	12	15
26-30	0	11	11
31-35	0	4	4
36-40	0	5	5
42-45	0	5	5
Total	209	84	287

TABLE VII
COMPARISON OF TEST OF VALIDITY
BETWEEN DIFFERENT CUT OFF SCORES

HAT SCORE	SENSI-TIVITY	SPECI-FICITY	PPV	NPV	ACCU RACY
5	22.87	90.76	92.54	7.46	46.53
10	49.15	80.66	84.42	15.58	52.38
15	73.04	72.33	81.42	18.57	72.92
20	86.35	57.42	56.41	43.59	72.22
25	91.47	28.86	20.00	80.00	80.02

Appendix C - 1
Sample questionnaire of HAT in Visaya

Hearing Assessment Test (Visaya version)

Name: _____

Sitwasyon **Palihug marka-hi ang gigahin sa unahan alang sa imong tubag.**	Pirmi	Halos pirmi	Usahay	Wala gyud
1. Maglisud ko ug dungog sa telepono o radyo.				
2. Maglisud ko ug sabot kung dunay duha o daghan ngatawo nga magdungan ug istorya.				
3. Mureklamo ang mga tawo kung akong pakusgan ang tingog sa radyo o telebisyon.				
4. Kinahanglan gyud nga maminao usa ko ug maayo aron makasabot ko sa gi istoryahan.				
5. Dili nako mabantayan ang pag tingog sa telepono, "door bell" o pagtok-tok sa purtahan.				
6. Maglisud ko ug dungog sa istorya kung adunay banha sa akong palibot.				
7. Maglibog ko kung asa gikan ang tingog.				
8. Dili nako masabtan ang uban nga pulong mao nga ipausab gyud nako nila ang ilang gi-sulti.				
9. Labing lisod kanako ang pagsabot sa mga babaye ug mga bata nga ako ikahinabi.				
10. Banha kaayo ang akong gitrabaho-an				
11. Kadaghanan sa mga tawo nga akong ika-hinabi, murag walay klaro musulti.				
12. Ang mga tawo nga akong kahinabi maglagot kung dili nako mahisabtan ang ilang gisulti kanako.				
13. Dili nako mahisabtan ang uban nilang gisulti mao nga lain ang akong maitubag.				
14. Ginalikayan ko ang mga kalihukan kay dili mayo ang akong pangdungog, ug mahadlok ko nga masayop ang akong mga tubag.				
15. Niingon ang akong mga paryente ug mga kauban sa balay nga aduna akoy deperensya sa pangdungog.				

Appendix C – 2
Sample Checklist used to determine History, Otoscopic findings & Audiometry

Hearing Assessment Test (Visaya Version)

*Patient No.:*_____
*Date:*_____
*Name:*_____
*Adress:*_____
*Age:*_____ *Sex:* ( ) Male ( ) Female
*Occupation:*_____

I. History:

	AD YES	NO	AS YES	NO
Otalgia	( )	( )	( )	( )
Otorrhea	( )	( )	( )	( )
Hearing Loss	( )	( )	( )	( )
Tinnitus	( )	( )	( )	( )
Vertigo	( )	( )	( )	( )

Past Medical/Surgical History: ( ) None ( ) Yes, Specify:_____

II. P.E.

A. Pinna ( ) Normal ( ) Abnormal
External Auditory Canal ( ) Normal ( ) Abnormal
B. Otoscopy

	AD		AS	
Otorrhea	( ) Present	( ) Absent	( ) Present	( ) Absent
Tympanic Membrane	( ) Intact	( ) Perforated	( ) Intact	( ) Perforated
Foreign bodies	( ) Present	( ) Absent	( ) Present	( ) Absent
Impacted cerumen	( ) Present	( ) Absent	( ) Present	( ) Absent

III. *Pure Tone Audiometry*

	AD (use o)	AS (use x)
(KHz)	.5 ___ 1 ___ 2 ___4	.5 ___ 1 ___ 2 ___4
0	|_____|____|____|	|____|____|____|
10	|_____|____|____|	|____|____|____|
20	|_____|____|____|	|____|____|____|
30	|_____|____|____|	|____|____|____|
40	|_____|____|____|	|____|____|____|
50	|_____|____|____|	|____|____|____|
60	|_____|____|____|	|____|____|____|
70	|_____|____|____|	|____|____|____|
80	|_____|____|____|	|____|____|____|
90	|_____|____|____|	|____|____|____|
(dB) 100	|_____|____|____|	|____|____|____|

Appendix D
Sample of HAT (in Filipino)

HEARING ASSESSMENT TEST QUESTIONAIRE:

	PALAGI	MADALAS	MINSAN	HINDI
1. Mayroon akong suliranin sa pakikinig sa telepono/radyo.				
2. Nagkakaroon ako ng problema sa pakikinig kung dalawa o higit pa sa dalawa ka tao ang nag-uusap ng sabay.				
3. Nagrereklamo ang mga tao dahil ang TV ay nilalakasan ko ng todo.				
4. Kailangan kong pakinggang mabuti ang usapan upang aking maunawaan.				
5. Nakakaligtaan ko ring pakinggan kung minsan ang karaniwang tunog gaya ng telepono, katok sa pinto o doorbell.				
6. Nagiging suliranin ko rin ang pakikinig sa mga usapan kung ang kapaligiran ay maingay lalo na sa mga pagtitipon.				
7. Nalilito ako kung saan nanggaling ang tunog.				
8. Hindi ko naiintindihan ang ilang mga salita sa pangungusap kaya't kinakailangan ko itong ipaulit.				
9. Lalong suliranin kong unawain ang mga salita ng mga kababihan at bata.				
10. Nagtratrabaho ako sa isang maingay na kapaligiran (asamblea o samahan, mga pukpukan , ingay ng makina at iba pa.				
11. Karamihan sa mga taong aking nakausap ay parang nauutal o kaya'y hindi nag sasalita ng maliwanag.				
12. Naiinis ang mga tao dahil ko maintidihan ang kanilang sinasabi.				
13. Hindi ko maunawan ang sinasabi ng iba kaya't hindi akma ang aking mga katugunan.				
14. Iniiwasan ko ang mga pagtitipon o pulong-pulong dahil hindi ako lubusang makarinig at natakot akong masagot ng di tama.				
15. (Dapat ay sagutin ng isang kasambahay o kaibigan.) Naniniwala ka ba na ang taong ito ay nawawalan ng pandinig?				
Kabuuang Puntos:				

Appendix E
Sample of AAO-HNS Five-Minute Hearing Test

SituationPlease mark the column that best describes the Frequency with which you experience eachsituation or feeling listed below.	Almost Always	Half the time	Occasionally	Never
1. I have a problem hearing over the telephone.				
2. I have trouble following the conversation when two or more people are talking at the same time.				
3. I have trouble understanding things on TV.				
4. I have to strain to understand conversations.				
5. I have to worry about missing a telephone ring or doorbell.				
6. I have trouble hearing conversation in a noisy background such as crowded room or restaurant.				
7. I get confused about where sounds come from.				
8. I misunderstood some words in a sentence and need to ask people to repeat themselves.				
9. I especially have trouble understanding the speech of women and children.				
10. I have trouble understanding the speaker in a large room such as a meeting or church.				
11. Many people I talk to seem to mumble.				
12. People get annoyed because I misunderstood what to say.				
13. I misunderstand what others are saying and make inappropriate responses.				
14. I avoid social activities because I cannot hear well and fear I will reply improperly.				
15. Family members and friends have told me they think I may have a hearing loss.				
TOTAL SCORE:				

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CARRAGEENAN HYDROGEL DERIVED FROM EUCHEUMA VARIETY SEAWEED AS A TOPICAL HEMOSTATIC AGENT*

DENNIS CRISTOBAL S. MANGOBA, MD**
SAMANTHA SORIANO-CASTAÑEDA, MD**
NATHANIEL W. YANG, MD***

ABSTRACT

Carrageenan hydrogel was tested for hemostatic effectiveness and biodegradability and tissue reactivity in surgically created muscular flaps in the thigh muscles of New Zealand rabbits (Orytolagus cuniculus). This was compared to negative controls and to commercially available Gelfoam™ Eighteen out of 40 rabbits successfully underwent testing. Hemostasis was achieved by application of one of the topical agents plus moderate digital presure. The time necessary for complete hemostasis was recorded for each site. The mean Bleeding time was significantly lower in the Carrageenan hydrogel group (16.9±6.9 seconds) compared to 38.0±27.6 seconds fo the Control group but was not significantly different from the Gelfoam™ group (26.0± 24.6 seconds) at p=.05. Microscopic studies showed comparable healing and biodegradability with varying degrees of residual material and inflammation. Carrageenan hydrogel was found to be effective as a topical hemostatic agent comparable, if not superior to the more expensive, commercially available agents. Likewise, its biodegradability and tissue reactivity are similar to the presently available and approved hemostatic agents.

Keywords: Carrageenan hydrogel, hemostatis, bleeding time

INTRODUCTION

Surgical situations may arise wherein bleeding ocurs over an area where there is no identifiable blood vessel amenable to the clamp and tie method, the electrocautery method, or attempting to do so would do more harm. In such cases, the use of hemostatic materials may be indicated. In a study by Chvapil et al (1983), it was proposed that the ideal hemostatic agent should have ample hemostatic action and minimal tissue reactivity. It should be low cost, *biodegradable in vivo and non-antigenic. it should* be easy to sterilize and easy to apply over the bleeding area(1).

Various materials have been investigated for use as a hemostatic agent like microcrystalline collagen hemostat, oxidized cellulose (Surgicel™) and Gelfoam™ and have been marketed as such. Microcrystalline collagen hemostat is prepared from edible bovine corium and is in a fibrous form, which adheres easily, to wet, bleeding surfaces(2). The hemostatic effect of cellulosic acid is based on its physical matrix, which collects blood into its interstices, entrapping and concentrating the coagulation factors(3). Gelfoam™ consists of an insoluble, organic polymer derived from formalin-tanned gelatin and which effects coagulation by physically absorbing blood into its interstices(4). While the effectivess of each in promoting hemostasis has been adequately demonstrated, the cost of these commercial hemostatic agents is quite prohibitive and all have to be imported from foreign sources. Is there an alternative, locally produced, inexpensive hemostatic agent comparable to these commercial agents?

The Philippines as an archipelago of 7,100 islands has one of the richest and most biodiverse marine resources in the world. An important industry is based on a relatively abundant seaweed belonging to the variety Eucheuma(5). Carrageenan is the world's most widely used seaweed product and is extracted from the

*Second Place, PSO-HNS Analytical Research Contest, December 2002, Westin Philppine Plaza Hotel, Manila, Philippines
**Resident, Department of Otorhinolaryngology, College of Medicine-University of the Philippines-Philippine General Hospital
**Consultant, Department of Otorhinolaryngology, College of Medicine-University of the Philippines-Philippine General Hospital

seaweed by alkali treatment at high temperature. It is then purified and converted into powder(6). Both Philippine Natural Grade (PNG) carrageenan and refined versions have been found in studies to possessno direct DNA damaging potential, no mutagenic activity before and after metabolic activation and even inhibits the genotoxicity of three common carcinogens: dimethylhyxdrazine, dimethylnitrosamine and benzo(a)pyrene(7). Carrageenan is used in a wide variety of purposes as gelling agent, stabilizer, thickener and binder in the food and pharmaceutical industries(5).

The Philippine Nuclear Institute (PNRI) has been conducting studies to explore the potential of carrageenan for non-food applications. Using radiation cross-linking technology, researchers have successfully developed PVP-Carrageenan hydrogel from carrageenanand polyvinyl pyrrolidone (PVP)(6). Hydrogels or water-containing gels are polymers characterized by hydrophilicity and insolubility in water. In water they swell to an equilibrium volume but preserve their shape. PVP and Carrageenan are treated with 25 kilograys of ionizing radiation. This dose is sufficient for sterilizing the material and to provide for the formation of a 3-dimentional network that allows water to penetrate into the structure to a certain volume without destroying its shape, thus the term-radiation cross-linking(6). Carrageenan contributes to the increased swelling capacity, increased gel strength and response to environmental stimuli (e.g. temperature, ph, ionic strength) than commercial hydrogels. In clinical trials at the Philippine General Hospital Burn Unit and at the East Avenue Medical Center, PVP-Carrageenan hydrogels have been effectively and safely used as dressing for burns and wounds(6).

It was noted that in its hydrogel form, carrageenan mimics or comes close to the definition of an ideal hemostatic agent. Experimenting with carrageenan, researchers at the PNRI, working together with the investigators have come up with a carrageenan hydrogel that is low cost, easy to produce, easy to apply, easy to sterilize and is of uniform thickness. Its water absorption capabilities and biodegradability in vitro has been well studied(8). Thus, if a likewise effectiveness as a topical hemostatic agent can be demonstrated for the carrageenan hydrogel then a locally manufactured replacement can be made available at a fraction of the cost of commercial hemostatic agents. This would help in bringing down expenses at the operating theatre. This can be used in several clinical applications such as in thyroid and mastoid surgeries as well as replacements for the currently available Merocel™ sinus sponges used in sinus surgeries.

This study aims to compare carrageenan hydrogel as a topical hemostatic agent with Gelfoam™
and direct pressure using gauze alone and determine the biodegradability and tissue reactivity grossly and histopathologically when left implanted in viable tissue after a period of time.

MATERIALS AND METHODS

Subjects

40 New Zealand rabbits (Orytolagus cuniculus) weighing around 450-1000g were used. The rabbits were acclimatized for 1 week, given commercial rabbit pellets and water ad libitum.

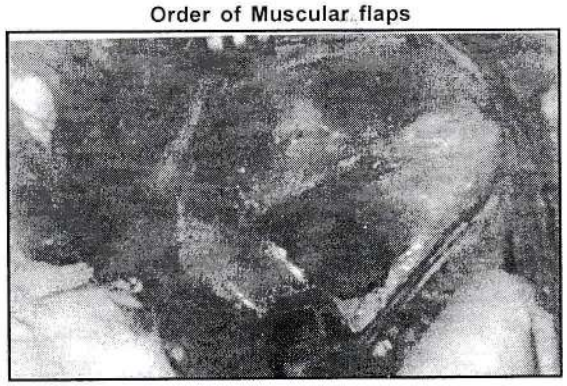
Materials

The carrageenan hydrogel was developed by the PNRI using radiation-linked technology using carrageenan alone. Gelfoam™ manufactured by Johnson and Johnson was obtained from a local pharmacy.

METHODOLOGY

The rabbits were each weighed prior to the proceure. The rabbits were then anesthetizedwith an intramuscular injection of 1mg/kg body weight of Ketamine HCl on the right thigh. The lateral side of the rabbit's left thigh was shaved. Under aseptic conditions, a horizontal incision parallel to the femoral bone was created on the left side. Skin flaps were developed and the quadriceps muscle exposed. Using a previously created sterile template, three 1x1 cm inferiorly based flaps 4mm deep 1 cm apart were created in the left quadriceps muscle of each rabbit. Incisions were made across the grain of the muscle thus inducing reproducible bleeding. The muscular flaps were created invariably in order from right to left to inferior as shown in picture below. (Figure1)

FIGURE 1
Order of Muscular flaps



The investigator who created the muscle flaps was blinded as to which treatment is to be tested. The rabbits were randomly assigned to 6 groups given different position combinations of topical applications of carrageenan hydrogel, or a positive control of Gelfoam™ or a negative control using direct pressure using gauze alone as shown in the table below.

	TREATMENT ORDER (From right to left to inferior)		
1	Hydrogel (H)	Gelfoam (G)	Control (C)
2	H	C	G
3	G	C	H
4	G	H	C
5	C	H	G
6	H	G	H

Bleeding time, or the amount of time it takes for the bleeding to stop was then measured for each area. Immediately after the creation of the flap, the bleeding muscular surface was blotted with sterilesurgical gauze prior to the application of the test material. Measurement of the bleeding site with the test material whether carrageenan hydrogel or Gelfoam™ (positive control) or none (negative control), moderate digital pressure was alternately applied using sterile surgical gauze for 5 seconds then observed for 5 seconds until bleeding ceased for at least 5 seconds. Observed cessation of bleeding by two investigators concurring of at least 5 seconds was taken as hemostasis and marked the end of timing. A precision Swiss chronograph was used in all trials.

Both the carrageenan hydrogel and Gelfoam™ control were left implanted in the wound and the incision closed. The flaps were not sutured close to prevent the possibility of tissue reaction from the suture.

After 10 days, the rabbits were again anesthetized using the same method and opened up along the same incision site. The flaps were observed grossly and findings noted. The three muscular flaps were then harvested by the investigators with a `0.5cm margin of normal tissue included. The specimens taken were fixed in formalin. These were then sent for slide processing and histophathological examination at the Department of Pathology for determination of biodegradability and tissue reactivity. Biodegardability and acute tissue inflammation was noted to be either present (+) or absent (-) in the specimen by one pathologist.

Data Analysis

Results in the different treatments were compared and statistical analysis done using the analysis of variance (ANOVA) repeated measures design using Statistical Program for the Social Sciences Version 10 (SPSS ver 10).

RESULTS

Of the 40 New Zealand rabbits procured, 22 died during the acclimatization period. Eighteen rabbits successfully underwent testing. Hemostasis was achieved in all the subjects who were tested. Mean weight of the rabbits was 645.59 grams.

Mean bleeding time for the carrageenan hydogel was found to be 16.9+/-6.9 seconds, for the Gelfoam™ group was found to be 26.0+/-24.6 seconds and for the control group 38.0+/-27.6 seconds.

TABLE 1

	Mean Bleeding Time	STd Deviation	N
Gelfoam™	26	24.6	18
Carrageenan	16.9	6.9	18
Control	38	27.6	18

Mean Bleeding Time of Rabbits (N=18)

Using a one-way repeated measures analysis of variance (ANOVA), there is a least one statistically different bleeding time in one of the treatment groups. (Table 2)

TABLE 2
Repeated Measures ANOVA of Bleeding Time of Rabbits

Source	Sum of Squares	df	Mean Square	F	Sig
Bleeding Time	4036.1	2	2018.1	4.7	0.016*
Error	14561.2	34	428.3		
Total					

*Significant at p=0.05

Multiple comparisons test using the Bonferroni method showed that rabbits applied with the carrageenan hydrogel have a statistically significant difference in bleeding time when compared to the control. The bleeding time using the carrageenan hydrogel however, is not significant when compared to the Gelfoam™.(Table 3)

TABLE 3
Multiple Comparison Test (Bonferroni) of Bleeding Time of Rabbits

Treatment	Mean	95% Confidence Interval for Difference		P
Pair	Difference	Upper Bound	Lower Bound	
Gelfoam™ vs. Control	12	9.14	-33.14	0.45
Gelfoam™ vs. Hydrogel	9.11	24.18	-5.96	0.38
Hydrogel vs. Control	21.11	39.34	2.88	0.021*

*The mean difference is significant at the .05 level

Ten (10) days after the initial study, the animals were again anesthetized and opened up. Out of the 18 rabbits initially tested, only 11 survived after 10 days. There were no hematomas or evidence of uncontrolled bleeding in all surviving animals. There were some post-operative adhesions noted localized to the site of the hemostatic agents and even the negative control site. The muscular flaps were then harvested and sent for histopathologic examination. Grossly, it was noted that there was little to no retention of the Carrageenan hydrogel and the Gelfoam. In some cases, there was little difference in the findings between the negative control group and that of the carrageenan hydrogel treatment group in terms of evidence of acute inflammation.

Microscopically, there were more traces of retained fragments of the Gelfoam™ (6 out of the 11 slides) as compared to the carrageenan hydrogel (5 out of the 11 slides) but this is not statistically significant. Evidence of inflammation was seen in 8 out of 11 slides in the hydrogel specimens as compared to 5 out of the 11 Gelfoam™ slides. This difference however, is also not statistically significant. (Table 4 & 5, Appendix for the pictures of the histopathologic slides)

TABLE 4
Distribution of Presence of Residual Material after 10 days

Treatment	Inflammation			
	+	%	–	%
Hydrogel	8	72.7	3	27.3
Gelfoam™	5	45.5	6	54.5
Control	2	18.1	9	81.9

(not significant at P=.05)

TABLE 5
Distribution of Presence of Inflammation after 10 days

Treatment	Residual			
	+	%	–	%
Hydrogel	5	45.5	6	54.5
Gelfoam™	6	54.5	5	45.5
Control	0	0	11	100

(not significant at P=.05)

DISCUSSION

The hemostatic capability of Gelfoam™ and oxidized cellulose has been well documented. However, the cost remains prohibitive especially when taken in the light of rising health care costs.

In this study, the mean bleeding time of the carrageenan hydrogel was noted to be even less than of the Gelfoam™. This suggests hemostatic action comparable with existing agents. However, as previously noted, this difference is not statistically significant. a possible reason for this is that, in a study by dela Rosa et al, the carrageenan hydrogel was noted to have increased swelling capacity thus, it could have probably absorbed the blood faster than the Gelfoam™.(8) It was found to be significantly different statistically, in comparison to the negative control. This thus theorizes a good hemostatic action. It was also seen that the mean bleeding time of Gelfoam™ was not statistically different from the negative control. Significant differences may be observed if the sample size is enlarged.

Residual material was noted both for the carrageenan hydrogel and the Gelfoam™ The specimens were harvested after 10 days in the post-operative period so a longer time might be needed for these hemostatic agents to be absorbed. Inflammation, characterized as the presence of imflammatory cells was also noted for both groups. This is expected with the introduction of foreign bodies into viable tissue. This inflammatory reaction would probably resolve after approximately 2 weeks or longer.(10)

It was noted that carrageenan hydrogel is remarkably easy to apply,cut, tailor or fold over the bleeding area. It adheres to the bleeding site fast by quick absorption of blood with fast coagulation at the interface. This approaches the definition of an ideal hemostatic agent as set down by Chvapil et al in their study.(1) It is also easy to sterilize using ionizing radiation and storage requirements are limited to keeping it at room temperature and below.(6)

A major assumption from the beginning was that all the test subjects were free from any congenital or acquired bleeding disorders. Chvapil and his co-investigators evaluated various animal models in testing hemostatic effectiveness. They made the conclusion that it is clear that any bleeding site can be used to evaluate the effectiveness of a hemostatic agent. The problem arises in the reproducibility (variability) and the severity of the bleeding of the method, which may be a very selective factor in the control of bleeding by only a few highly effective hemostatic materials.(1) The area used to test for the bleeding

time was chosen due to its accessibility and to diffuse moderate bleeding with no identifiable blood vessel. The depth of muscular flaps varied to some extent and is one of the limitations of the study. Attempts to cancel out this factor were done by blinding the surgeon as to the material to be tested when the flap was being developed. Bleeding time is currently the only clinically available comprehensive test to explore primary hemostasis.(9) To cancel out the bias in measuring the bleeding time, two investigators measured the bleeding time.

CONCLUSION

In summary, Carrageenan hydrogel has demonstrated its effectiveness as a topical hemostatic agent comparable, if not superior to the more expensive, commercially available agents. Likewise, its biodegradability and tissue reactivity are similar to the presently available and approved hemostatic agents.

RECOMMENDATIONS

The potential aplications for this material are tremendous. It is the recommendation and the intention of the authors to do follow-up studies including further clinical trials in different models to explore these possibilities. A Carrageenan-based polyvinyl pyrrolidone (PVP) hydrogel developed by the Philippine Nuclear Research Institute is now being used as an occlusive dressing for burn patients. The carrageenan hydrogel, available at a fraction of the present price of commercially available hemostatic agents, would help in bringing down expenses at the operating theater. This can be used in several clinical applications such as in thyroid and mastoid surgeries as well as replacements for the currently available Gelfoam™ and Merocel™ sinus pack sponges used in sinus surgeries.

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APPENDIX

HISTOPATHOLOGICAL SLIDES

FIGURE 1
Photomicrograph shows inflammatory infiltrates adjacent to the residual basophilic material (carrageenan hydrogel) (H & E, x 40)

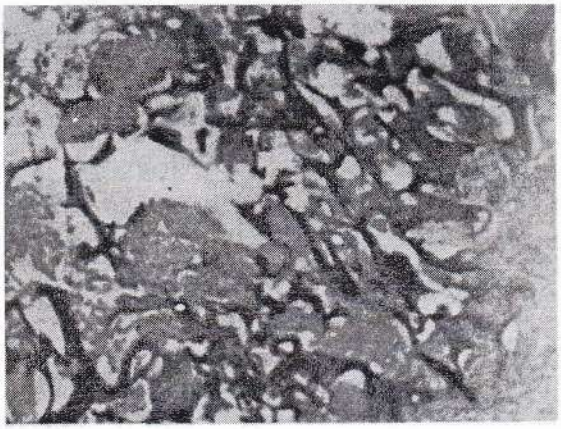


FIGURE 2
Photomicrogrph shows inflammatory infiltrates with a rim of viable tissue (in the carrageenan hydrogel specimens) (H & E, x 40)

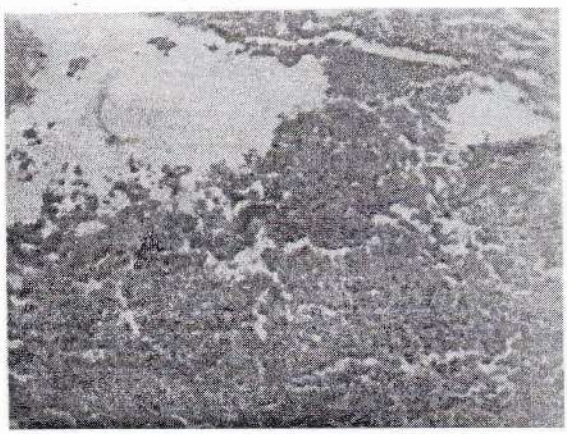
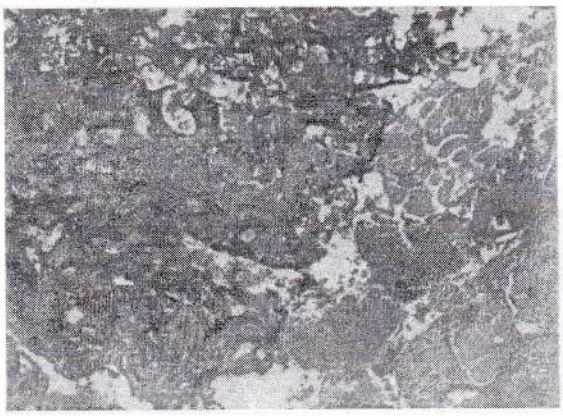


FIGURE 3
Photomicrograph shows residual material (Gelfoam^{TM}) stained deeply basophilic within muscle fibers (H & E, x 400)



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COMPARISON OF FINE NEEDLE ASPIRATION WITH PERCUTANEOUS ETHANOL INJECTION VERSUS FINE NEEDLE ASPIRATION ALONE IN THE TREATMENT OF SOLITARY THYROID CYST*

EDGARDO S. ABELARDO, MD**
NATIVIDAD A. ALMAZAN-AGUILAR, MD, FPSO-HNS ***
MICHELANGELO L. SABAS, MD****
MA. TERESA P. QUE, MD*****
STEPHANIE JENNIFER H. PE, MD******

ABSTRACT

OBJECTIVES: To compare the effectiveness and safety of fine needle aspiration (FNA) with percutaneous ethanol injection (PEI) versus fine needle aspiration alone as an adjunctive therapy in the treatment of solitary thyroid cyst.
DESIGN: Single-blinded randomized controlled trial.
Setting: The study was conducted between April 1, 2000 and September 30, 2001 at the Out-Patient Department (ENT-HNS Clinic and Endocrine Clinic) in a tertiary government hospital.
SUBJECTS: Twenty-seven biochemically euthyroid patients with uninodular goiter which was cystic in ultrasound and benign by fine needle aspiration biopsy (FNAB). All subjects gave informed consent.
METHODS: The patients were randomized into two treatment groups: Group 1 – fine needle aspiration with percutaneous ethanol injection and Group 2 – fine needle aspiration alone. Resolution and recurrence were determined 6 months after the intervention by palpation and by doing repeat ultrasound. Drug side effects were noted after a week, then monthly thereafter, for 6 months.
RESULTS: Of the 13 patients randomly assigned to Group 1 (FNA with PEI), 5 had complete resolution, 4 had clinical resolution, 1 had partial recurrence, and 3 had complete recurrence. Of the 14 patients in Group 2 (FNA alone) , 3 had complete resolution, 8 had partial recurrence, and 3 had complete recurrence. There was a significant difference in the resolution rate between the Group 1 (69.2%) and Group 2 (21.4%), $p<0.05$. The corresponding recurrence rates were 30.8% for Group 1 and 78.6% for Group 2, $p<0.05$. Among the side effects, burning sensation lasting for 10-15 minutes was seen in 30.8% of patients assigned to Group 1 and none among those with Group 2, $p<0.05$.
CONCLUSION: Fine needle aspiration with percutaneous ethanol injection using 70% ethanol solution is more effective than fine needle aspiration alone in the treatment of benign, solitary thyroid cysts. It is a safe procedure associated with mild and transient burning sensation during ethanol injection.

INTRODUCTION

Anywhere from 15 to 25% of all thyroid nodules are cystic. These cysts represent degenerated benign colloid nodules in 80 to 95%. The incidence of malignancy varies from 5 to 20% with an average of less than 10% in most series. Fine needle aspiration (FNA) or surgery have been used to treat these lesions. Aspiration usually causes a decrease in size of the cystic nodules but fewer than 20% are cured. In majority of cases, thyroid cysts recur after aspiration[1].

Recently, percutaneous ethanol injection (PEI) has been proposed as an adjunctive therapy for the management of thyroid cysts because of the sclerosing properties of ethanol. The mechanism of action appears to be related to a direct coagulative necrosis and local partial or

*Third Place, PSO-HNS Analytical Research Contest, December 02, 2002, Westin Philippine Plaza Hotel, Manila
**Resident, Department of Otolaryngology-Head and Neck Surgery, East Avenue Medical Center
***Consultant, Department of Otolaryngology-Head and Neck Surgery, East Avenue Medical Center
****Resident, Department of Internal Medicine, East Avenue Medical Center
*****Consultant, Department of Endocrinology, East Avenue Medical Center
******Resident, Department of Radiology, East Avenue Medical Center

complete thrombosis[2,3]. Several studies have noted significant nodule volume reduction and decreased recurrence rate of thyroid cysts with PEI after percutaneous aspiration[4,5,6,7]. Cummings cited sonographically-guided percutaneous injection of ethanol is useful in management of hot nodules[8]. Even the patient's signs and symptoms subside and hormone levels return to normal in most cases. Furthermore, a randomized study done by Verde et al in 1994 comparing nodule volume reduction between FNA and FNA with PEI showed significantly higher nodule volume reduction with the latter[6]. Review of current literature reveals a paucity of controlled trials to establish the effectivity of this treatment modality.

At present times when surgeons are more cautious in their management due to the threats of malpractice suits, this alternative approach is desirable especially to patients who are poor candidates for surgery or those who refuse standard treatment.

GENERAL OBJECTIVE

To compare the effectiveness and safety of FNA with PEI and FNA alone in the management of solitary thyroid cyst.

SPECIFIC OBJECTIVES

•To compare the frequency of resolution of thyroid cyst after FNA with PEI and FNA alone.

• To compare the frequency of recurrence of thyroid cyst after FNA with PEI and FNA alone.

•To compare the occurrence of side effects after FNA with PEI and FNA alone.

Definition of Terms

Complete Resolution – disappearance of cyst clinically and by ultrasound

Clinical Resolution – clinical disappearance of cyst and decrease in cyst size by 70% by ultrasound

Complete Recurrence – no decrease in cyst size on ultrasound at 6 months after the intervention

Partial Recurrence – decrease in cyst size on ultrasound but remaining cyst is significantly visible and palpable at 6 months after intervention

Percent Decrease (by ultrasound) – $\frac{\text{initial volume} - \text{final volume}}{\text{initial volume}} \times 100$

MATERIALS AND METHODS

This prospective single-blind randomized study was conducted by authors from three different specialties — otorhinolaryngology-head and neck surgery, internal medicine, and radiology. This was done between April 1, 2000 and September 30, 2001 at the ENT Clinic and Endocrine Clinic, Out-Patient Department, of a tertiary government hospital.

Inclusion criteria were as follows:

1. adult patient
2. biochemically euthyroid (normal FT4 and TSH)
3. solitary thyroid nodule on ultrasound
4. histologically benign mass on fine needle aspiration biopsy

Exclusion criteria were as follows:

1. pregnant patients
2. known allergy to alcohol
3. multiple thyroid cysts on palpation and on ultrasound
4. on anti-thyroid medications at the time of study

All subjects gave informed consent. Subjects were randomly assigned using a computer-generated random number table into two groups: Group I to undergo FNA with PEI and Group 2 to undergo FNA alone. Initial volume of the cyst on ultrasound were noted among those enrolled to the study.

The procedure was done with the patient lying supine, the neck slightly hyperextended. Cleansing with 70% ethanol was done on the injection site prior to needle aspiration, using 10 or 20 ml plastic syringe with gauge 21, 1-inch needle. After aspiration of the thyroid cyst, the needle was kept in place and the aspirate was replaced with 70% ethanol solution injected intracystically as a single bolus in Group 1 patients. The amount of ethanol administered is equal to the amount of aspirate removed from the cyst. In Group 2 patients, only aspiration was done and no solution was instilled. The puncture site was covered with sterile gauze after the procedure. To avoid interpersonal bias, only one operator, the ENT-HNS resident-author, did the procedure to all the subjects.

Follow-up was routinely done after a week, then monthly thereafter for 6 months to note for drug side effects. To avoid interpersonal bias, only one evaluator, the internal medicine resident-author, conducted the follow-up. The evaluator did not know who received the percutaneous ethanol injection.

Six months after the intervention, the subjects were evaluated clinically for resolution or recurrence of thyroid cyst. Repeat ultrasound of the neck were done on all patients. To avoid interpersonal bias, only one sonographer, the radiology resident-author, did the reading of the ultrasound. The latter compared the reading from

the initial reading which was done prior to intervention. The sonographer, likewise, did not know who received the interventional drug.

Statistical Analysis

All categorical variables were analyzed by chi-square tests. Comparison of continuous variables was done using student's t-test.

Data were evaluated with 'intention to treat' analysis.

RESULTS

The study population consisted of 27 patients, 22 females and 5 males, with a median age of 42 years. (see Table 1)

Of the 27 patients, 13 were assigned to undergo FNA with PEI (Group 1) and 14 were assigned to undergo FNA alone (Group 2). There were 3 patients who dropped out of study due to lost to follow-up: 2 from Group 1 and 1 from Group 2. (see Figure 1)

In Group 1, 9 (69.2%) patients had complete or clinical resolution while 4 (30.7%) had recurrence of the thyroid cyst. (see Table 2) In Group 2, three patients (21.4%) had complete resolution while 11 patients (78.6%) had recurrence of the thyroid cyst. (see Table 3)

The difference between the resolution rate of Group 1 (69.2%) and Group 2 (21.4%) was significant, $p<0.05$. Furthermore, the difference between the recurrence rate of Group 1 (30.8%) and Group 2 (78.6%) was significant, $p<0.05$.

In Group 1, the side effects were mild and transient, mainly local discomfort described as burning sensation on introduction of ethanol, noted on 4 patients. In one patient, a 'drunken-feeling' was reported immediately after PEI which lasted for 30 minutes. The percentage of patients who complained of pain on the injection site was not significantly different when compared to FNA without PEI. No other adverse reactions were observed. (see Table 4)

Distribution of the studied population according to the intervention performed in the treatment of thyroid cyst and the outcome of the study are summarized in Figure 1.

DISCUSSION

This study shows that nodule volume reduction and recurrence were significant in patients treated by PEI after FNA than in those who underwent FNA alone. This is similar to the findings previously reported by Verde et al[6].

The results are primarily attributed to the sclerosing properties of ethanol which have been recognized for many years and have offered interventional possibilities in the management of various lesions. PEI-induced thyroid damage is characterized by coagulative necrosis and hemorrhagic infarction due to vascular thrombosis that is well defined from the surrounding thyroid parenchyma[3].

The procedure was very well tolerated, with only mild, transient local discomfort, described as mild burning sensation lasting for 10-15 minutes upon injection of ethanol noted in one-third of patients who underwent FNA with PEI. The other mild adverse effects noted like pain on injection and 'drunken-feeling' were not significantly different when compared with FNA alone. No neck hematoma, infection, dysphonia nor allergic reactions to alcohol were noted in this study.

Many of the patients recruited to the study are those who had visible neck mass yet could not be granted cardio-pulmonary clearance due to other co-existing medical problems. A few simply refused surgery as management for their thyroid pathology for various personal reasons. This alternative approach is desirable especially to patients who are poor candidates for surgery or those who refuse standard treatment.

CONCLUSION

Percutaneous ethanol injection after fine needle aspiration is a more effective treatment in terms of volume reduction and recurrence for benign, solitary thyroid cyst when compared to fine needle aspiration alone. It is a safe procedure associated with mild and transient burning sensation during ethanol injection.

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TABLE 1
Demographic Data and Characteristics of Cyst

	Group 1 (FNA with PEI)	Group 2 (FNA alone)	p value
No. of subjects	13	14	
Age Range	20-62 yrs old	25-64 yrs old	p>0.05
Mean	42.25 yrs old	41.20 yrs old	
Sex Male	2	3	p>0.05
Female	11	11	
Volume Range	3.6-16.8 ml	2.8-18.0 ml	p>0.05
Mean	8.7 ml	8.0 ml	

TABLE 2
Treatment Outcome: Resolution Rate

	Group 1 (FNA with PEI)	Group 2 (FNA alone)	p value
No. of subjects	13	14	
Resolution Rate	9(69.2%)	3(21.4%)	p<0.05
Complete	5(38.5%)	3(21.4%)	
Clinical	4(30.7%)	0	
Mean Decrease in Size	82%		

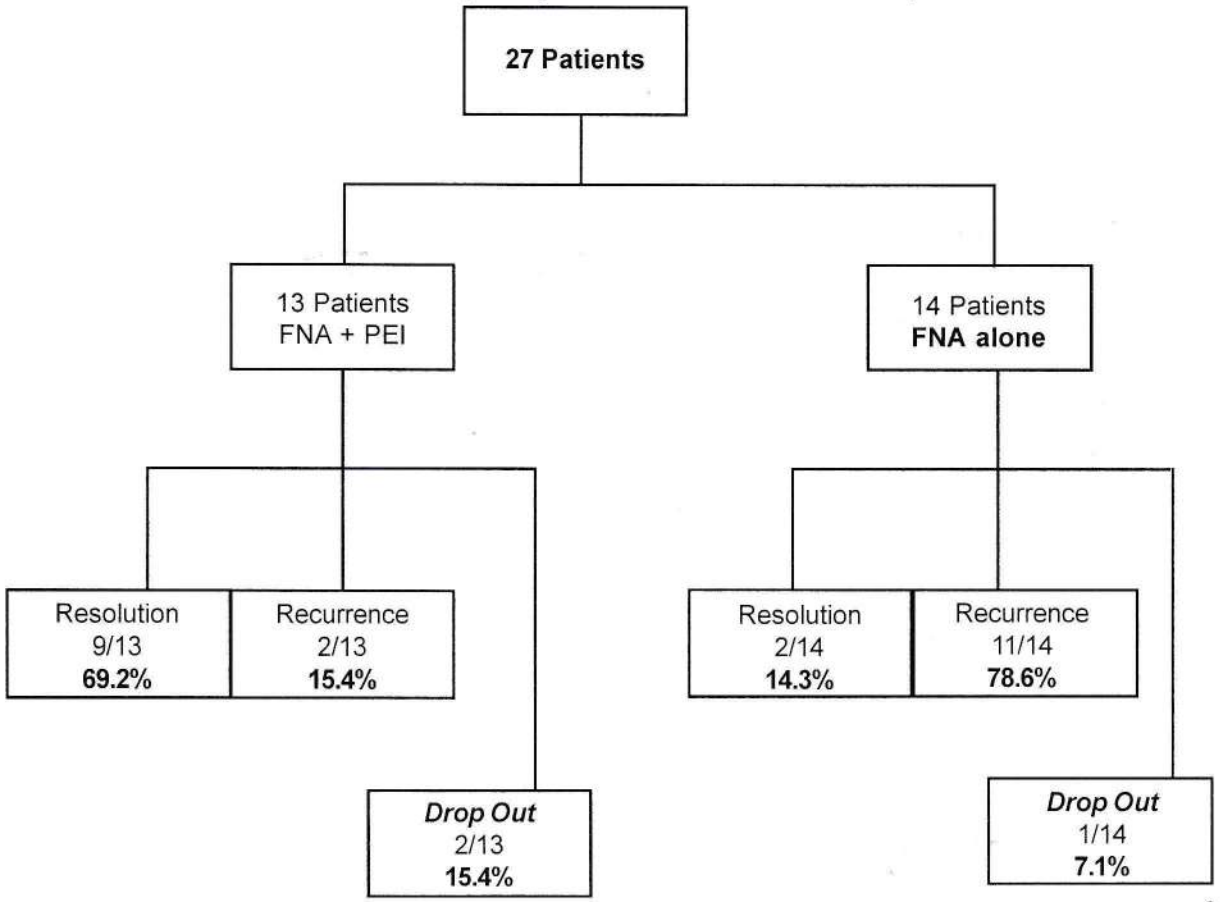
TABLE 3
Treatment Outcome: Recurrence Rate

	Group 1 (FNA with PEI)	Group 2 (FNA alone)	p value
No. of subjects	13	14	
Recurrence Rate	4(30.8%)	11(78.6%)	p<0.05
Complete	3(23.1%)	3(21.4%)	
Partial	1(7.7%)	8(57.1%)	
Mean Decrease in Size	20%	42%	

TABLE 4
Treatment Side Effects

	Group 1 (FNA with PEI)	Group 2 (FNA alone)	p value
No. of subjects	13	14	
1. Pain on injection site	6(46.2%)	7(50.0%)	p>0.05
2. Burning sensation	4(30.8%)	0	p<0.05
3. Drunken feeling	1(7.7%)	0	p>0.05

FIGURE 1
Distribution of the studied population according to the intervention performed in the treatment of thyroid cyst and the outcome of the study



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THE PREVALENCE OF LARYNGOPHARYNGEAL REFLUX AMONG HOARSE PATIENTS AT THE VOICE LABORATORY OF A TERTIARY HOSPITAL*

PRINCESS DL. CARLOS, MD**
PATRICK HENRY S. ENRIQUEZ, MD***
MA. CLARISSA S. FORTUNA, MD, FPSO-HNS***
FILIPINA ENCARNACION T. CEVALLOS, MD***

ABSTRACT

Laryngopharyngeal Reflux (LPR) is an emerging health issue, it is estimated to be the primary cause or a significant etiologic co-factor in 25% to 50% of laryngeal and voice disorders. Dysphonia (Hoarseness) is the most common symptom of patients with reflux laryngitis. The current gold standard for diagnosis of LPR is the ambulatory 24-hour double –probe pH monitoring. Unfortunately, this is not yet available in our setting. The Voice Laboratory of this teriary hospital has diagnosed LPR since 1997 using clinical history and laryngeal videoendo-stroboscopy.

Objectives:

1. To measure the prevalence of LPR among hoarse patients in The Voice Laboratory.
2. To describe the patients with LPR as to age, sex, occupation, voice use, smoking and alcohol history, and vocal hygiene.
3. To grade the videolaryngoscopic findings according to the Reflux Finding Score (RFS) for LPR by James Koufman, MD of the Center for Voice Disorders of the Wake Forest University

Study Design: Retrospective Descriptive Study
Setting: Voice Laboratory of a Tertiary Hospital
Methodology: Review of charts and video recordings of Voice Laboratory patients from August 1997 to January 2001 was undertaken. Only patients presenting with hoarseness were included in the study. Patients diagnosed with LPR were subjected to the Reflux Finding Score (RFS) grading system.
Results: 871 out of 1,089 (80%) Voice Laboratory patients presented with hoarseness. *148 (17%) were diagnosed with LPR.* Profile of LPR patients: 59 males (40%) and 89 females (60%); 6 to 89 years old (average = 44). 28 (19%) were voice professionals; voice abuse history was positive in 132 (89%) with fair vocal hygiene. The Reflux finding score (RFS) was greater than 7 in all the patients diagnosed with LPR.
Conclusion: LPR is a disease entity that is not easily diagnosed. Left untreated, LPR can lead to serious complications like laryngeal stenosis or even malignant degeneration. This paper shows that about 2 in every 10 hoarse patients will have signs of LPR detectable by laryngeal videoendoscopy. In the absence of the gold standard for LPR diagnosis, a thorough history for LPR symptoms and a standardized laryngeal videoendoscopy may be a useful alternative.

INTRODUCTION

Gastroesophageal reflux disease (GERD) was originally identified in 1968 by Cherry and Margulies as an etiologic factor in laryngeal disease.[1] But it was Virchow who, as early as 1880, coined the term *pachydermia verrucosa laryngis* to describe the annular epithelial overgrowth centered on the posterior glottis. And although Virchow believed it to be related to gross vocal abuse, it would be later recognized as pathognomonic for laryngopharyngeal reflux.

The term, Laryngopharyngeal Reflux (LPR), was first coined by James A. Koufman, M.D., for the constellation of extraesophageal or otolaryngologic symptoms and clinical manifestations secondary to retrograde gastric acid flow to the pharynx and larynx. On

*First Place, PSO-HNS Descriptive Research Contest, December 02, 2002, Westin Philippine Plaza Hotel, Manila
**Resident, Department of Otolaryngology-Head and Neck Surgery, The Medical City Hospital
***Consultant, Department of Otolaryngology-Head and Neck Surgery, The Medical City Hospital

September 16, 1995 a Consensus Conference was convened in New Orleans, Louisiana designating LPR as the appropriate and official label for the clinical entity. [2]

LPR patients infrequently have the classic symptoms of GERD such as, heartburn and/or regurgitation, making diagnosis easily missed. Chronic, intermittent hoarseness is the most common head and neck symptom of LPR.[3, 4, 5, 6, 7, 8, 9] Other clinical symptoms include: globus, throat pain, frequent throat clearing, excessive throat mucus, halitosis, and for singers the inability to reach high notes.

The optimal diagnostic test battery for patients with LPR include:

- comprehensive history
- complete head and neck examination
- videolaryngoscopy
- 24-hour double probe pH monitoring
- Barium swallow/ esophagogram
- Therapeutic trial with proton pump inhibitors

Presently, the gold standard or the definitive diagnostic test for LPR is the 24-hour double probe pH monitoring (pH-metry), wherein 2 small flexible catheters are passed through the nose into the esophagus and another at the laryngeal inlet to monitor the amount and type of reflux during a typical day.[3] The amount of acid recorded by the probe indicates the amount of reflux present. Studies show that about 70% of patients with signs and symptoms of LPR undergoing pH studies will give abnormal results.[3, 4] Unfortunately, this technology or diagnostic modality is not yet available in our country. There are some authors who believe that a therapeutic trial with a proton pump inhibitor is the "ultimate" diagnostic/therapeutic test. However, others contend that subjecting patients to expensive and unconventional therapy without objective documentation of the disease is unjustified.

The Otolaryngologic community is gaining increasing awareness of the epidemiologic significance of LPR. In two separate studies, Koufman et al of the Center for Voice Disorders at Wake Forest and Stasnes of the Texas Voice Center reported the prevalence of LPR to be 25% to 50% in patients with laryngeal and voice disorders.[5, 6]

Here in the Philippines, the diagnosis of LPR is based primarily on clinical symptoms. The Voice Laboratory of this Tertiary Hospital has recognized this emerging health issue since 1997. And it has been helping both the patients with chronic laryngitis and the otolaryngologist in arriving at the correct diagnosis and recommending the proper management for LPR.

STUDY DESIGN

Retrospective Descriptive Study

METHODOLOGY

The Voice Laboratory charts and laryngeal videostroboscopic recordings of 1,089 hoarse patients seen from August 1997 to January 2001 were reviewed. The history was reviewed with particular attention on: age, sex, occupation, voice use history, smoking and alcohol history and vocal hygiene. All laryngeal videostroboscopic recordings were performed using a 70° Laryngo-scope with a halogen and a strobe light source (Kay Instrument Model 1905, Kay Instruments, Lincoln Park, NJ). The Reflux Finding Score (RFS) is an 8-item clinical severity scale based on findings during fiberoptic laryngoscopy.[10] (Table 1) A Reflux Finding Score greater than 7 will be considered as LPR. The RFS rating was performed, by the author, on the recordings in halogen light from images captured using a CCD camera coupled to a super VHS recorder (Mitsubishi model BV-1000, Mitsubishi Electric Inc, Cypress, Ca) and viewed on a 13-inch high definition Viewsonic computer monitor and a Sony trinitron 13-inch TV monitor. The prevalence was computed using the formula:

Formula:

$$\text{Prevalence of LPR} = \frac{\text{\# of patients diagnosed with LPR}}{\text{\# of hoarse patients who underwent LVES}} \times 100$$

RESULTS

The charts and video recordings of 1,089 patients seen at The Voice Laboratory from August 1997 to January 2001 were reviewed. 871 patients presented with hoarseness. 148 patients (17%) were clinically diagnosed as Laryngopharyngeal reflux disease. There were 59 males (40%) and 89 females (60%). Age ranged from 6 years old to 89 years old with an average of 44 years. 28 (19%) are voice professionals. 132 (89%) have a positive voice abuse history. 40 (27%) have a positive history of smoking and alcohol ingestion. Vocal hygiene was fair in 64 subjects (44%), poor in 48 (32%) and good in 36 (24%). Table 2

Using the reflux findings score (RFS), all of the patients diagnosed with LPR (100%) scored greater than 7. The lowest score was 8 and the highest score was 19. The most consistent findings were: moderate posterior commissure hypertrophy (2), arytenoids erythema/hyperemia

(2), moderate to severe vocal fold edema (2-3), partial ventricular obliteration (2), mild to moderate diffuse laryngeal edema (1-2).

DISCUSSION

The reflux finding score (RFS) was developed by Belafsky, Postma and Koufman from The Center for Voice Disorders of Wake Forest University in North Carolina. It is an 8-item clinical severity scale based on findings during fiberoptic laryngoscopy. The scale ranges from 0 (no abnormal findings) to a maximum of 26 (worst score possible). The 8 items were derived from a pool of the most common laryngeal findings of patients with LPR. [10] (Table 1) The scale was developed to standardize the laryngeal findings of LPR so that clinicians may better diagnose, evaluate clinical improvement and assess therapeutic efficacy of patients with LPR. In their study, they compared a cohort of 40 pH-documented LPR subjects against 40 age-matched control subjects with no symptoms of LPR. From this data, they were able to derive normative values and establish that RFS > 7 indicates the presence of LPR.

Subglottic edema also called pseudosulcus vocalis refers to the subglottic swelling that extends from the anterior commissure to the posterior larynx. (Figure 1)

Ventricular Obliteration results from edema of the true and false vocal folds when viewed superiorly. (Figure 2)

Laryngeal erythema/hyperemia is a non-specific finding and significantly dependent on the videoendoscopic equipment.

Diffuse laryngeal edema *judged by the size of the airway relative to the size of the larynx.*

Posterior commissure hypertrophy:

Mild = minimal changes ("opalescent mucosa") concave configuration is preserved

Moderate = appears as a straight line across the posterior commissure

Severe = edema that encroaches into the endolaryngeal lumen

Obstructing = a mass-like configuration of the posterior commissure

Laryngopharyngeal reflux disease is fairly common, but its diagnosis is often missed for two main reasons. First, patients do not experience symptoms of heartburn or regurgitation, thus the likelihood of gastric acid backflow as a primary etiology is disregarded. Second, the findings of LPR vary considerably. Traditional diagnostic tests like: Barium esophagography, Radionuclide scanning, or even double probe pH-metry are subject to false negative results, since LPR is frequently intermittent.

The larynx is very susceptible to injury from acid reflux. Its mucosa is thin and not well-adapted to peptic injury, it also lacks the mechanism for acid clearance. Thus in the presence of LPR, videolaryngoscopy to document early mucosal changes is critical. It is now accepted that laryngeal edema and NOT posterior laryngitis is the principal finding in LPR. Ventricular obliteration and "pseudosulcus vocalis" are the most common reflux-associated findings.

Our study revealed a prevalence rate of 17%, that means about 2 in every 10 patients complaining with hoarseness will already have signs of LPR detectable by laryngeal videoendoscopy. The symptom of hoarseness or dysphonia was chosen because it was the most common reason for referral (80%) to The Voice Laboratory. However, patients with LPR may manifest with other symptoms like globus, excessive throat mucus, sorethroat, chronic cough, etc. and this partly explains why our figures are much lower than those published internationally (25%-50%).

Left untreated, LPR is considered to be a critical co-factor in virtually all laryngeal and respiratory diseases. And although still unproven, a strong relationship exists between LPR and malignant degeneration (Laryngeal Carcinoma).

The treatment of LPR is simple and well-documented. There are three levels of antireflux therapy: Level I – dietary and lifestyle modification plus antacids, Level II – level I plus use of an H2 blocker, Level III – antireflux surgery (fundoplication) or omeprazole therapy. The "endpoint" of treatment is the cessation of symptoms although some recommend a decrease in the Reflux Finding Score. Patients are then weaned off of the medication and good lifestyle habits are encouraged.

CONCLUSION

Laryngopharyngeal Reflux (LPR) is an important consideration for patients presenting with chronic hoarseness. It is present in two of every 10 patients presenting with dysphonia or hoarseness. In the absence of a gold standard (24-hour, double-probe, ambulatory pH-metry) for the diagnosis of LPR, laryngeal videoendoscopy to document the injurious effects of gastric acid backflow to the unprotected laryngeal lining,

standardized by the reflux finding score (RFS) and a thorough clinical history to extract LPR symptoms may serve as a useful alternative.

LIMITATIONS

Lack of a gold standard diagnostic test RFS is subject to observer bias or quality of video equipment

RECOMMENDATIONS

- Include a Clinical LPR Symptom questionnaire form and a reflux finding score sheet to the basic Voice Laboratory analysis report.
- Include a Body mass index determination
- Do a Prospective study using more than one laryngologist to evaluate interobserver variability.
- Use of acoustic analysis or Flexible endoscopic examination of swallowing (FEES) to further document laryngeal pathology or monitor therapeutic response.

TABLE I

REFLUX FINDING SCORE

Subglottic EdemaVentricular Obliteration	0 = absent 2 = partial	2= present 4 = complete		
Erythema/ Hyperemia	2 = arytenoids only	4 = diffuse		
Vocal Fold Edema	1 = mild	2 = moderate	3 = severe	4 = polypoid
Diffuse Laryngeal Edema	1 = mild	2 = moderate	3 = severe	4 = obstructing
Posterior Commissure Hypertrophy	1 = mild	2 = moderate	3 = severe	4 = obstructing
Granuloma/ Granulation Tissue	0 = absent	2= present		
Thick Endolaryngeal Mucus	0 = absent	2= present		
TOTAL SCORE >7 = LPR				

Table 2 Profile of LPR Subjects with RFS

Patient	Age	Sex	Occupation	Voice Abuse	Smoking\Alcohol	Vocal Hygiene	Diagnosis	RFS
GA	43	M	businessman	(-)	1 pack,3 btls/day	fair	TVC polyp, L; Hyperfunctional Dysphonia; LPR	10
AA	23	M	businessman	(+)	occ. ETOH	good	Acute Laryngitis(resolving); LPR	9
AA	43	F	Housewife	(+)	N/a	fair	Intracordal cyst, R; LPR	9
CA	77	F	opera singer	(+)	fair	LPR	(mild polypoid corditis); Vallecular cyst R	16
ZB	56	F	sales agent	(+)	N/a	good	LPR	12
BR	41	F	Teacher	(+)	N/a	poor	LPR	12
MB	35	F	businesswoman	(+)	N/a	poor	LPR, sulcus vegeture	9
JB	35	F	govt. employee	(+)	14 pack yrs.	poor	LPR, Spasmodic dysphonia	11
RB	63	M	Priest	(+)	N/a	fair	Presbylaryngis, LPR	10
HB	26	M	computer engr.	(+)	N/a	fair	LPR	19
J B	25	F	telecommunicator	(+)	N/a	good	Mild diffuse corditis, LPR	14
RB	41	F	canteen operator	(+)	N/a	good	Granuloma, Ant commissure; LPR	14
JB	30	M	Singer	(+)	N/a	good	Chronic Laryngitis, LPR	13
LB	29	F	Optometrist	(+)	N/a	fair	LPR	12
JB	74	M	Lawyer	(+)	occ. cig.	poor	Vocal cord atrophy, R; Fungal laryngitis, LPR	9
JB	25	F	church intern	(+)	N/a	fair	PNS, LPR	10
RB	50	F	Housewife	(+)	N/a	fair	Hgic Polyp,L; Reinke's R; LPR	12
NB	48	F	Brgy. Kagawad	(+)	N/a	fai	rChronic Laryngitis, LPR	11
YB	34	F	businesswoman	(+)	N/a	good	Mild corditis, LPR	9
PB	40	M	Lawyer	(+)	seldomETOH	fair	Intracordal cyst, L; LPR	13
SC	48	M	businessman	(+)	wine 1x/wk	fair	Chronic Laryngitis, LPR	15
PC	72	F	Housewife	(-)	N/a	fair	LPR	14
JC	40	F	businesswoman	(+)	N/a	fair	LPR	11
PC	69	M	Teacher	(+)	N/a	poor	Chronic Laryngitis, LPR	12
HC	44	M	chief sec.officer	(+)	10 sticks/d x 10 yrs.	poor	Vocal cord nodule, LPR	10
AC	42	M	Employee	(+)	N/a	fair	LPR	8
AC	37	F	Secretary	(+)	N/a	fair	PNS, LPR	12
RC	47	M	businessman	(+)	N/a	fair	Glottic Ca, RTVF; Reinke's edema, LTVF; LPR	14
LC	27	F	sales agent	(+)	6 btls,1/2 p/d x11yrs	poor	PNS, LPR	11
AC	48	M	businessman	(+)	n/a	fair	Granuloma R FVF; LPR	12
MC	78	M	retired electrician	(+)	N/a	fair	Cyst, RTVF; LPR	10

Patient	Age	Sex	Occupation	Voice Abuse	Smoking\Alcohol	Vocal Hygiene	Diagnosis	RFS
CC	37	F	Employee	(+)	N/a	fair	Vocal cord nodule, LPR	11
AC	46	F	Vendor	(+)	N/a	good	Vocal cord nodule, LPR	10
ED	58	M	bank employee	(-)	N/a	good	LPR	14
LDJ	54	F	businesswoman	(+)	N/a	fair	Reinke's Edema, LPR	12
LD	40	F	Housewife	(-)	N/a	Fair	LPR	9
JD	29	F	sales agent	(+)	N/a	Fair	Hyperfunctional Dysphonia, LPR	10
JD	38	M	Employee	(+)	2 btls/wk	Fair	Reinke's Edema, LPR	12
MD	25	F	Meatshop owner	(+)	N/a	Fair	Laryngeal Varices LPR	15
TE	39	F	Employee	(+)	N/a	Fair	Hyperfunctional Dysphonia, LPR	12
ME	51	F	teacher/singer	(+)	N/a	Fair	Mild Polypoid corditis; LPR	17
VE	58	M	fish trader	(+)	N/a	good	LPR, Beg. Contact granuloma, L	18
JF	27	F	bank employee	(+)	N/a	Fair	LPR, Granuloma Lvocal process;RLNP	13
RF	30	M	Performer	(+)	N/a	good	LPR	11
FF	34	F	Teacher	(+)	N/a	Fair	Reinke's Edema, LPR	16
SF	39	F	Employee	(+)	15 sticks/day	Poor	Mild diffuse corditis, LPR	12
RF	64	M	Retired	(-)	1/2 gin/wk,1-2 p/d	Poor	Glottic Ca, LPR	9
AF	37	F	Housewife	(+)	N/a	FairL	PR	11
SF	63	M	Engineer	(-)occ roh; (-)	smoking	Fair	LPR	14
EF	61	M	Employee	(-)	N/a	Poor	LPR, Contact granuloma, L	14
RF	53	F	Teacher	(+)	n/a	Fair	LPR	11
EF	59	M	retired lineman	(+)	10 btls/d, 45pack yrs.	Poor	VC paralysis, L; LPR	13
EF	55	F	Teacher	(+)	N/a	good	Vocal cord cyst, L; LPR	12
GG	28	M	Singer	(+)	N/a	Fair	Polypoid corditis, PNS; LPR	16
TG	45	M	Computer engr.	(+)	10py; 10 bot/wk	Poor	Diffuse Corditis; LPR	16
SG	34	F	Accountant	(+)	N/a	Poor	Mild diffuse corditis, LPR	12
EG	29	F	Teacher	(+)	N/a	Fair	Polypoid corditis, RTVF; LPR	18
VG	74	M	Professor	(+)	N/a	Fair	Hyperfunctional Dysphonia,Vocal cord atrophy,LPR	10
WG		M	pest controller	(+)	7-8 sticks	Poor	Glottic ca, LPR	12
LG	62	M	businessman	(+)	20 pack yrs	Poor	Contact Granuloma, L; LPR	10
EG	37	F	Professor	(+)	N/a	Poor	LPR	11

Patient	Age	Sex	Occupation	Voice Abuse	Smoking\Alcohol	Vocal Hygiene	Diagnosis	RFS
TG	58	M	priest/school director	(+)	occ smoking	Fair	Vocal Cord atrophy, bil; LPR	9
LG	84	F	retired	(+)	N/a	Fair	Mild Polypoid corditis; LPR	12
MG	60	F	Nun	(+)	N/a	Poor	Spasmodic dysphonia; LPR	11
GK	35	F	Housewife	(+)	N/a	Poor	Vocal cord polyp, L w/ contact swelling, R; LPR	14
JL	28	F	store manager	(+)	N/a	Fair	LPR	13
BL	46	F	office work-trucking	(+)	N/a	Fair	Mild diffuse corditis, LPR	14
JL	46	M	businessman	(+)	N/a	Fair	Chronic Laryngitis, LPR1	1
YL	38	F	Housewife	(+)	N/a	good	LPR	9
SL	56	M		(-)	N/a	good	LPR	10
EL	47	F	houswife	(+)	N/a	Fair	Hyperfunctional dysphonia; LPR	11
RL	40	F	businesswoman	(+)	N/a	poor	LPR	9S
L	10	F	student	(+)	N/a	Fair	PNS, LPR	12
JL	36	F	marketing executive	(+)	2 btls/d,10 sticks/d	poor	LPR, reinke's edema	16
LL	42	F	researcher	(+)	N/a	good	Polypoid corditis;LPR	14
ML	25	F	process trainor	(+)	N/a	good	PNS, LPR	11
RL	36	M	salesman	(+)	4 btls/d,5 sticks/d	poor	Chronic Laryngitis, LPR	10
CL	36	F	teacher	(+)	N/a	good	Vocal cord cyst, R; LPR	12
LM	42	M		(+)	N/a	good	LPR	10
JM	32	F	professional singer	(-)	N/a	Fair	LPR	9
DM	35	F	singer	(+)	1 pack/day	FairL	PR	11
MM	34	F	teller	(+)	4 sticks/day	poor	LPR	11
DM	36	F	housewife	(+)	5pack yrs., 2x/wk	poor	LPR	10
MM	22	F	singer	(+)	2-3sticks/day	Fair	Polypoid corditis;LPR	18
EM	39	F	employee	(+)	N/a	Fair	Vocal cord polyp, R ; LPR	10
RM	51	M	retiree	(+)	60 pack yrs.	Fair	Glottic ca; s/p RT, LPR	10
JM	28	F	kitchen crew	(-)	N/a	good	Polypoid corditis;LPR	14
PM	43	F	Catechist	(-)	N/a	good	PNS, LPR	11
HN	29	F	Consultant	(+	)N/a	Fair	Hypokinetic Dysphonia; t/c laryngeal myasthenia; LPR	10
MN	61	M	supervising parole	(+)	N/a	poor	LPR	12

NAME	AGE	SEX	JOB	VOICE ABUSE	smoking/roh	VOCAL HYGIENE	DIAGNOSIS	RFS
RN	23	F	Singer	(+)	occ. ETOH	good	Polypoid corditis;LPR	13
EO	38	F	businesswoman	(+)	N/a	poor	Diffuse Corditis; LPR	12
JO	53	M	Employee	(-)	N/a	good	Vocal cord polyp, L;LPR	11
EP	42	F	restaurant owner	(+)	N/a	Fair	Diffuse Corditis; LPR	14
AP	28	F	staff nurse	(+)	N/a	Fair	LPR	11
RP	50	M	driver	(+)	30 pack yrs.	poor	Intracordal cyst, L; LPR	12
MP	49	M	driver/operator	(+)	N/a	Fair	LPR	9
RP	29	F	businesswoman	(+)	N/a	good	LPR; Reinke's Edema	14
EP	41	F	businesswoman	(+)	N/a	good	LPR	11
CP	52	F	Nun	(+)	N/a	good	PNS, LPR	15
JP	45	M	congressman	(+)	N/a	good	LPR	9
PP	53	M	Veterinarian	(+)	40pack yrs.,1btl/wk	poor	Chronic Laryngitis, LPR	13
UP	49	F	Teacher	(+)	N/a	good	Vocal cord nodule, LPR	12
IP	37	M	electronic operator	(+)	N/a	poor	LPR; Reinke's Edema	16
JQ	29	F	service associate	(+)	N/a	Fair	Chronic Laryngitis, LPR	12
SR	64	M	retired airline pilot		1 pack/d,stopped 5yrs		FairChronic Laryngitis, LPR	11
AR	45	M	Contractor	(+)	N/a	poor	Chronic Laryngitis, LPR	14
NR	53	F	sch.principal	(+)	N/a	good	LPR	8
PR	57	M	employee	(+)	15 pack yrs.poor	Mild	Polypoid corditis; LPR	13
JR	35	M	acct. specialist	(+)	10pack yrs./1 btl/wk	poor	Chronic Laryngitis, LPR	9
RR	28	F	med. Representative				Sulcus vergeture, LPR	14
AR	44	M	engineer	(+)	occ. ETOH	good	Chronic Laryngitis, LPR	11
JS	17	F	student	(+)	N/a	Fair	Hyperfunctional dysphonia t/c LPR	13
ES	54	F	accountant	(+)	4 sticks/day	Fair	Left vocal cord paresis, LPR	9
MS	49	F	housewife	(+)	N/a	good	Chronic Laryngitis, LPR	13
ES	49	F	employee	(+)	31 pack yrs.	poor	Corditis, LPR	10
DS	73	M	farmer/gardener		40 pack yrs.	Fair	Submucosal Hemorrhage t/c laryngeal TB, LPR	11
GS	37	M	employee	(+)	10pack yrs,1 btl/day	poor	Hyperkeratosis, LPR	12
ES	45	F	store owner	(+)	N/a	Fair	Pre-nodular swelling, LPR	11

NAME	AGE	SEX	JOB	VOICE ABUSE	smoking/roh	VOCAL HYGIENE	DIAGNOSIS	RFS
TS	34	M	police	(-)	3 btls/day	poor	Contact Granuloma, L; LPR	12
ES	47	F	factory worker	(+)	N/a	Fair	Pre-nodular swelling, LPR	11
AS	34	F	businesswoman	(+)	N/a	poor	Chronic Laryngitis, LPR	10
ES	28	M	supervisor	(+)	N/a	poor	LPR	11
CS	32	F	PR/MKTG mngr	(+)	occ. ETOH	poor	t/c vocal cord cyst L, LPR	12
LS	51	F	housewife	(-)	N/a	Fair	Vocal Cord cyst L, LPR	9
FT	57	F	teacher	(+)	N/a	Fair	Acute Laryngitis(resolving); LPR	9
ST	6	M	student	(+)	N/a	poor	Diffuse Corditis; LPR	11
RT	48	F	businesswoman	(+)	N/a	Fair	Vocal cord nodule, LPR	12
ET	54	F	reflexologist	(+)	N/a	good	Reinke's Edema, LPR	15
DT	11	M	student	(+)	N/a	good	Vocal cord nodule, LPR	11
CU	40	M	businessman	(+)	1 btl/day	poor	Chronic Laryngitis, LPR	12
MU	36	F	businesswoman	(+)	N/a	poor	LPR	12
SU	72	F	housewife	(+)	N/a	poor	Reinke's Edema, LPR	13
CV	33	F	Housewife	(+)	N/a	poor	LPR	16
SV	40	M	Auditor	(+)	N/a	good	t/c Tuberculous Laryngitis, LPR	9
RV	45	F	Housewife	(+)	N/a	poor	PNS, LPR	9
EV	44	M	businessman	(-)	> 1 pack/day	Fair	Chronic Laryngitis, LPR	9
AV	37	M	INC minister	(+)	N/a	good	Chronic Laryngitis, LPR	10
CV	29	F	bank employee	(+)	N/a	good	LPR	12
CV	49	M	woodcrafting	(+)	15-20sticks/day	poor	Reinke's Edema, LPR	16
TV	30	F	Cashier	(+)	N/a	Fair	Reinke's Edema, LPR	12
SV	41	M	Employee	(+)	N/a	poor	Vocal cord nodule, LPR	11
EV	46	F	Employee	(+)	N/a	good	Mild Polypoid corditis; LPR	15
LV	47	F	system analyst	(+)	N/a	good	Mild Polypoid corditis; LPR	11
TY	37	F	Minister	(+)	N/a	Fair	Reflux Laryngitis	12
IY	44	M	businessman	(+)	N/a	Fair	Mild diffuse corditis, LPR	14
TOTAL:148								

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ACCEPTABILITY OF THE PHILIPPINE SOCIETY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY (PSO-HNS) CLINICAL PRACTICE GUIDELINE FOR SINUSITIS AMONG EAR, NOSE AND THROAT SPECIALISTS*

MARY JANE S. MALLILLIN, MD**
FLORDELINA E. PIO, MD, FPSO-HNS***

INTRODUCTION

Sinusitis is one of the most common conditions seen in an out-patient clinic. The U.S. National Ambulatory Medical Care Survey (NAMCS) identified it as a leading health-care problem in the U.S. with a prevalence of 14% in adults and 5-13% in children.[1] Because many individuals with symptoms related to sinus disease do not seek medical attention the actual number of affected individuals may be much higher. Those who seek treatment spend an estimated 16 million office visits per year and more than $2 billion is spent annually for over-the counter medications for sinusitis. According to the survey, sinusitis is the fifth most common diagnosis for which an antibiotic is prescribed. Sinusitis accounted for 7% to 12% of all antibiotic prescriptions written from 1985- 1992.[1]

Improvements in the diagnostic and therapeutic options for sinusitis subsequently improved the management of these conditions and yet, considerable variations still exist. Prescribing practices of physician alone may contribute significantly to these variations. A study by Werning revealed that physician specialty is associated with differences in the evaluation and management of acute bacterial Rhinosinusitis.[2] It showed that otolaryngologists use more health care resources to diagnose and treat sinusitis than primary care physicians, despite an absence of evidence that such tests and treatments lead to a better outcome. It illustrates a lack of consensus within the medical community regarding the diagnosis and treatment of community-acquired acute sinusitis suggesting that widely accepted evidence-based practice guideline needs to be developed.

Clinical practice guidelines are currently a popular method for standardizing the healthcare process[3]. They have been defined as "systematically developed statements to assist practitioner decisions about appropriate health care for specific clinical circumstances[4]. They are used to assist physicians in clinical decision making (e.g. clinical algorithms); to evaluate physician practices (e.g. utilization review); and to set limit to physician choices (e.g. reimbursement). The PSO-HNS recognized these needs and subsequently developed a local CPG for the most common ear, nose and throat morbidities, namely: otitis media, rhinitis, sinusitis and tonsillitis.

Evidence-based clinical practice guideline for sinusitis not only serves as a guide in the diagnosis and management of the condition, but also provides an analytical framework for its evaluation and treatment[5]. Despite the availability of the guideline since 1996, no evaluation has been made regarding its impact on the clinical practice of the target population. Hence, the authors came up with the following objectives:

General Objective

To determine the impact of Philippine Society of Otolaryngology-Head and Neck Surgery (PSO-HNS) Clinical Practice Guidelines (CPG) for Sinusitis to the clinical practice of Otolaryngologists-Head and Neck Surgery (ENT-HNS) consultants and residents.

*Second Place, PSO-HNS Descriptive Research Contest, December 02, 2002, Westin Philippine Plaza Hotel, Manila
**Resident, Department of Otolaryngology-Head and Neck Surgery, FEU-NRMF Medical Center
***Consultant, Department of Otolaryngology-Head and Neck Surgery, FEU-NRMF Medical Center

Specific Objectives

1. To determine the acceptability of the PSO-HNS Clinical Practice Guidelines for Sinusitis ENT-HNS Consultants and Residents using a survey questionnaire.
2. To determine the acceptability of the specific recommendation on the diagnosis and management of Sinusitis to the ENT-HNS consultants and residents.

METHODOLOGY

A. Study Design

A descriptive study design using a cross-sectional survey was utilized.

B. Study Sites

PSO-HNS Midyear Convention in Subic Bay, Zambales and other institutions in Metro Manila namely: UP-PGH; Manila Doctors Hospital; Veterans Memorial Medical Center; Manila Central University; Quirino Memorial Medical Center; and Armed Forces of the Philippines Medical Center.

C. Subject Selection Criteria:

The sample population consisted of ENT-HNS consultants and residents and EENT specialists. The selection of sample population was done using sampling by convenience. Sample size was determined based on the standard methodology computation:

Of items x 3 = # of respondents
24 x 3 = 72
Response rate: 62/ 72 (89%)

D. Instrument:

The questionnaire (see Appendix no. 1 page 17) was based on the recommendations of the Clinical Practice Guidelines. The following issues were addressed:

A. Awareness of the existence of any clinical practice guidelines in the treatment of sinusitis
B. Awareness of the existence of the PSO-HNS' Clinical Practice Guideline in the treatment of sinusitis
C. Agreement with the PSO-HNS' Clinical Practice Guidelines on the definition of:
    a. Acute Sinusitis
    b. Chronic Sinusitis
D. Agreement with the diagnosis and treatment of acute and chronic sinusitis
E. Acceptability of the PSO-HNS Clinical Practice Guidelines on the treatment of sinusitis
F. Compliance with clinical practice guidelines
G. Need for the revision of clinical practice guidelines
H. Dissemination of the guideline to others

The initial questionnaire had 3 parts:

A. Cover letter
B. Sociodemographic data about the respondent
C. Main questionnaire containing the 24 items

The questionnaire was critique for its validity by the consultants of a tertiary hospital in Metro Manila. This was rephrased until better-stated questions were developed. A 5-pt Likert scale was devised appropriate for each question on the issues involved.

E. Data Collection and Analysis

The survey was conducted among those who attended the PSO-HNS Midyear Convention in April 19-21, 2002. A second survey was done from April to July 2002 for those who have not responded and the forms were sent to the different institutions mentioned above. Data encoding was done using Epi Info 6 and subsequently, frequency tables were generated and data was summarized into percentages.

DEFINITION OF TERMS

ENT Specialists- include Otolaryngology consultants and residents and Eye, Ear, Nose and Throat Specialists

Acute Sinusitis – episode of sinonasal infection usually lasting form more than seven days characterized by purulent nasal discharge with no significant residual damage

Chronic Sinusitis – a persistent sinus disease usually lasting for more than three months with or without medical treatment characterized by purulent nasal discharge with significant residual damage

RESULTS:

A total of 64 respondents completed and returned the questionnaire. Majority of the consultants and residents came from government teaching hospitals as seen in table 1. Twenty-eight percent of the consultants came from the National Capital Region (NCR), 9% came from Luzon and 2% each form Visayas and Mindanao. Forty-seven percent of the residents came from the NCR, 5% came from Luzon, 2% from Visayas and 5% from Mindanao.

TABLE 1
Characteristics of Respondents

CHARACTERISTICS	CONSULTANTS	RESIDENTS	OTHERS	TOTAL
Institution:				
1. Government Teaching	16 U (25%) . U25 (39%)		-	41 (64%)
2. Government Non-teaching	-	2 (3%)	1 (2%)	3 (5%)
3. Private Teaching	7 (11%)	8 (12%)	-	15 (23%)
4. Private Non-teaching	4 (6%)	1 (2%)	-	5 (8%)
TOTAL	27 (42%)	36 (56%)	1 (2%)	64 (100%)
Place of Practice:				
1. National Capital Region	18 (28%)	30 (47%)	-	48 (75%)
2. Luzon	6 (9%)	3 (5%)	-	9 (14%)
3. Visayas	1 (2%)	1 (2%)	-	2 (4%)
4. Mindanao	1 (2%)	3 (5%)	1(2%)	5 (8%)
TOTAL	**26 (41%)**	**37 (58%)**	**1 (2%)**	**64 (100%)**

Awareness of the existence on any clinical practice guidelines on the treatment of sinusitis is shown in Table 2. Sixty-two respondents were aware that there is an existing guideline in the treatment of sinusitis (96%). Two respondents, 1 EENT and 1 resident (4%) were not aware of any clinical practice guideline in the treatment of sinusitis.

TABLE 2
Awareness of Existence of any Clinical Practice Guidelines in the Treatment of Sinusitis Of Different Physician Category

CATEGORY	AWARE	NOT AWARE	TOTAL
	N (%)	N (%)	N (%)
Fellow	17 (27%)	-	17 (27%)
Diplomate	8 (12%)	-	8 (12%)
Resident	35 (54%)	1 (2%)	36 (56%)
Non-fellow	2 (3%)	-	2 (3%)
EENT	-	1 (2%)	1 (2%)
TOTAL	62 (96%)	2 (4%)	64 (100%)

The frequency distribution of those who are aware that there is a PSO-HNS Clinical Practice Guidelines in the Treatment of Sinusitis is shown in Table 3. A total of 61 respondents (98%) were aware that there is an existing PSO-HNS CPG while 1 resident (2%) is not aware that there is a PSO-HNS Guideline.

TABLE 3
Awareness of Existence of PSO-HNS' Clinical Practice Guidelines In the Treatment of Sinusitis

CATEGORY	AWARE N (%)	NOT AWARE N (%)	TOTAL N (%)
Fellow	17 (27%)	-	17 (27%)
Diplomate	8 (13%)	-	8 (13%)
Resident	34 (55%)	1 (2%)	35 (57%)
Non-fellow	2 (3%)	-	2 (3%)
EENT	-	-	-
TOTAL	61 (98%)	1 (2%)	62 (100%)

Majority of the consultants and residents (98%) agree on the definition of Acute Sinusitis. Only 1 resident disagree with the definition of Acute Sinusitis. Three Consultants (5%) and 4 residents (7%) disagree with the definition of Chronic Sinusitis. The rest of the respondents (88%) agree with the definition of chronic Sinusitis.

TABLE 4
Agreement with PSO-HNS Clinical Practice Guidelines in the Definition of Sinusitis

DEFINITION OF SINUSITIS	STRONGLY AGREE N (%)		AGREE N (%)		UNSURE N (%)		DISAGREE N (%)		STRONGLY DISAGREE N(%)		TOTAL N (%)
	Cons	Res	Cons	Res	Cons	Res	Cons	Res	Cons	Res	
ACUTE SINUSUTIS	13 (21%)	7 (11%)	12 (19%	26 (42%)	2 (3%)	1 (2%)	-	-	-	1 (2%)	62 (100%)
CHRONIC SINUSITIS	9 (14%)	7 (11%)	15 (24%)	23 (37%)	1 (2%)	-	3 (5%)	3 (5%)	-	1 (2%)	62 (100%)

According to the respondents, the most common signs and symptoms of patients with Acute Sinusitis include: purulent nasal discharge, purulent post-nasal discharge, nasal obstruction, periorbital pain, facial pain, anosmia or decreased sense of smell as seen on Table 4. Other less common signs and symptoms include tooth pain, cough, sore throat and earache.

TABLE 5
Signs and Symptoms of Patients with Acute Sinusitis

SIGNS AND SYMPTOMS	CONSULTANTS	RESIDENTS	TOTAL N (%)
Purulent Nasal Discharge	26 (42%)	33 (53%)	59 (95%)
Purulent Post-nasal Discharge	21 (34%)	30 (48%)	51 (82%)
Cough	12 (19%)	15 (24%)	27 (43%)
Periorbital Pain	22 (35%)	23 (37%)	45 (72%)
Headache	24 (39%)	31 (50%)	55 (89%)
Facial Pain	22 (35%)	23 (37%)	45 (72%)
Tooth pain	10 (16%)	19 (30%)	29 (46%)
Earache	6 (10%)	12 (19%)	18 (29%)
Sore throat	8 (13%)	17 (27%)	25 (40%)
Nasal Obstruction	25 (40%)	30 (48%)	55 (88%)
Anosmia or Decreased Sense of Smell	14 (22%)	24 (39%)	38 (61%)

Twenty-six consultants (42%) and 33 residents (52%) agree that anterior and posterior rhinoscopic findings of purulent nasal discharge suggest Acute Sinusitis. Twenty-three consultants (38%) and 26 residents (29%) believe that X-ray is not recommended for Acute Sinusitis. Twenty-four consultants (38%) and 29 residents (47%) agree that CT Scan is not recommended to diagnose Acute Sinusitis (see Table 6).

TABLE 6
Diagnosis of Acute Sinusitis

DIAGNOSTIC	STRONGLY AGREE N (%)		AGREE N (%)		UNSURE N (%)		DISAGREE N (%)		STRONGLY DISAGREE N(%)		TOTAL N (%)
	Cons	Res	Cons	Res	Cons	Res	Cons	Res	Cons	Res	
ANT/ POST. RHINOSCOPY	10 (16%)	6 (9%)	16 (26%)	27 (43%)	1 (2%)	1 (2%)	-	-	-	1 (2%)	62 (100%)
X-RAY	7 (12%)	6 (9%)	16 (26%)	23 (38%)	-	2 (3%)	4 (6%)	4 (6%)	-	-	62 (100%)
CT SCAN	9 (14%)	10 (16%)	15 (24%)	19 (31%)	1 (2%)	3 (5%)	2 (3%)	3 (2%)	-	-	62 (100%)

Sixteen consultants (26%) and 27 residents (44%) agree that Amoxicillin is the first drug of choice on the treatment of Acute Sinusitis. Augmented penicillin and the cephalosporins ranked 2nd and 3rd respectively (see Table 7).

TABLE 7
Definitive Treatment for Acute Sinusitis

MEDICATIONS	CONSULTANTS	RESIDENTS	TOTAL
	N (%)	N (%)	N (%)
AMOXICILLIN	16 (26%)	27 (44%)	43 (70%)
AUGMENTED PENICILLIN	9 (14%)	10 (16%)	19 (30%)
1st GEN CEPHALOSPHORIN	6 (10%)	9 (14%)	15 (24%)
2nd GEN CEPHALOSPHORIN	6 (10%)	9 (14%)	15 (24%)
SULFONAMIDES	3 (5%)	4 (6%)	7 (11%)
OTHERS	-	-	-

Twenty-six consultants (41%) and 29 residents (47%) agree on the addition of topical decongestants on patients with severe nasal obstruction. Twelve percent of the respondents were unsure or disagree on the use of topical decongestants. Forty-two percent of the respondents agree on the use of mucoevacuants, saline and steam inhalation. Twenty-five consultants (39%) and 32 residents (53%) agree that topical steroids and antihistamine can be given to patients with allergic background (see Table 8).

TABLE 8
Supportive Treatment of Acute Sinusitis

SUPPORTIVE TREATMENT	STRONGLY AGREE N (%)		AGREE N (%)		UNSURE N (%)		DISAGREE N (%)		STRONGLY DISAGREE N(%)		TOTAL N (%)
	Cons	Res	Cons	Res	Cons	Res	Cons	Res	Cons	Res	
TOPICAL DECONGESTANT	6 (9%)	5 (8%)	20 (32%)	24 (39%)	-	3 (5%)	1 (2%)	2 (3%)	-	1 (2%)	62 (100%)
MUCOEVACUANTS SALINE & STEAM	7 (11%)	11 (18%)	19 (31%)	21 (33%)	1 (2%)	2	-	-	-	1 (2%)	62 (100%)
TOPICAL STERIODS & ANTIHISTAMINE	6 (9%)	11 (18%)	19 (30%)	21 (34%)	1 (2%)	2 (3%)	1 (2%)			1 (2%)	62 (100%)

Twenty-three consultants (37%) and 31 residents (49%) agree that the presence of nasal polyps is frequently associated with chronic sinusitis. Nineteen consultants (30%) and 31 residents (49%) agree that the routine use of Sinus x-rays is recommended for chronic sinusitis. Twenty-six consultants (41%) and 33 residents (58%) agree that CT scan is recommended for patients with chronic sinusitis in whom medical therapy fails.

TABLE 9
Diagnosis of Chronic Sinusitis

BASIS OF DIAGNOSIS	STRONGLY AGREE N (%)		AGREE N (%)		UNSURE N (%)		DISAGREE N (%)		STRONGLY DISAGREE N(%)		TOTAL N (%)
	Cons	Res	Cons	Res	Cons	Res	Cons	Res	Cons	Res	
PRESSENCE OF POLYPS	7 (11%)	3 (4%)	16 (26%)	28 (45%)	1 (2%)	1 (2%)	3 (5%)	2 (3%)	-	1 (2%)	62 (100%)
SINUS X-RAY	7 (11%)	10 (16%)	12 (19%)	21 (34%)	3 (5%)	1 (2%)	5 (8%)	2 (3%)	-	1 (2%)	62 (100%)
CT SCAN	11	12 (17%)	15 (19%)	21 (24%)		1 (2%)	1 (2%)			1 (2%)	- 62 (100%)

Most of the consultants (35%) and residents (49%) agree with the PSO-HNS Clinical Practice Guidelines on the treatment of sinusitis with antibiotics for 3-4 weeks.

TABLE 10
Agreement with PSO-HNS Clinical Practice Guidelines on the Duration of Treatment of Chronic Sinusitis

CATEGORY	STRONGLY AGREE N (%)	AGREE N (%)	UNSURE N (%)	DISAGREE N (%)	STRONGLY DISAGREE N (%)	TOTAL N (%)
CONSULTANTS	4 (6%)	18 (29%)	2 (3%)	3 (5%)	-	27 (43%)
RESIDENTS	6 (10%)	24 (39%)	2 (3%)	2 (3%)	1 (2%)	35 (57%)
TOTAL	10 (16%)	42 (68%)	4 (6%)	5 (8%)	1 (2%)	62 (100%)

A total of 24 consultants (39%) and 32 residents (52%) agree that if there is obstruction in the ostiomeatal complex, surgery is recommended (see Table11).

TABLE 11
Agreement with PSO-HNS Clinical Practice Guidelines on Surgery For Osteomeatal Complex Obstruction

CATEGORY	STRONGLY AGREE N (%)	AGREE N (%)	UNSURE N (%)	DISAGREE N (%)	STRONGLY DISAGREE N (%)	TOTAL N (%)
CONSULTANTS	6 (10%)	18 (29%)	2 (3%)	1 (2%)	-	27 (43%)
RESIDENTS	6 (10%)	26 (42%)	3 (5%)	0	-	35 (57%)
TOTAL	12 (20%)	44 (71%)	5 (8%)	1 (2%)	-	62 (100%)

The attitude of the consultants and residents towards the guideline can be seen in Table 12. Twenty-six consultants (41%) and 31 residents (50%) agree that the guidelines were made in accordance with accepted methods for making clinical practice guidelines. 91% of the respondents find the CPG applicable and 96% of them found it practical and useful in one's practice. 22 consultants (35%) and 31 residents (50%) agree with all the contents of the guideline. 3 respondents (5%) were unsure and 6 respondents (10%) did not agree with the contents of the guidelines.

TABLE 12
Acceptability of the PSO-HNS Clinical Practice Guidelines on the Treatment of Sinusitis

ACCEPTABILITY	STRONGLY AGREE N (%)		AGREE N (%)		UNSURE N (%)		DISAGREE N (%)		STRONGLY DISAGREE N(%)		TOTAL N (%)
	Cons	Res	Cons	Res	Cons	Res	Cons	Res	Cons	Res	
IN ACCORDANCE	4 (6%)	3 (4%)	22 (35%)	28 (45%)	1 (2%)	3 (5%)			-	1 (2%)	62 (100%)
APPLICABLE	4 (6%)	5 (16%)	22 (35%)	30 (48%)	-	1 (2%)			-	1 (2%)	62 (100%)
PRACTICAL	4 (6%)	8 (13%)	22 (35%)	26 (42%)	1 (2%)	1 (2%)			-	-	62 (100%)
AGREE WITH ALL THE CONTENTS	4 (6%)	6 (10%)	18 (29%)	25 (40%)	2 (3%)	1 (2%)	3 (5%)	2 (3%)	-	1 (2%)	62 (100%)

Twenty-two consultants and 22 residents (70%) use the guideline because of personal preference. 2 consultants (3%) and 9 residents (15%) use it because their department uses it (see Table13).

TABLE 13
Compliance of Guidelines

REASON FOR COMPLIANCE	CONSULTANT N (%)	RESIDENTS N (%)	TOTAL N (%)
REQUIREMENT IN THE DEPARTMENT	2 (3%)	9 (15%)	11 (18%)
PERSONAL PREFERENCE	22 (35%)	22 (35%)	44 (70%)
OTHERS ARE USING IT	1 (3%)	-	1 (3%)
OTHER REASON	2 (3%)	4 (6%)	6 (9%)
TOTAL	27 (44%)	35 (55%)	62 (100%)

Seventy percent of the respondents agree that the guideline needs to be revised for updates (see Table 14).

TABLE 14
Revision of Guidelines

YES N (%)	NO N (%)	TOTAL N (%)	CATEGORY
22 (35%)	5 (9%)	27 (44%)	CONSULTANTS
22 (35%)	13 (21%)	35 (56%)	RESIDENTS
44 (70%)	18 (30%)	62 (100%)	TOTAL

TABLE 15
Dissemination of Guideline

CATEGORY	YES N (%)	NO N (%)	TOTAL N (%)
CONSULTANTS	8 (13%)	19 (31%)	27 (44%)
RESIDENTS	13 (21%)	22 (35%)	35 (56%)
TOTAL	11 (34%)	41 (66%)	62 (100%)

Table 15 shows that 66% of the respondents agree that the PSO-HNS Clinical Practice Guidelines are not being disseminated to other specialties.

DISCUSSION

The Philippine Society of Otolaryngology-Head and Neck Surgeons (PSO-HNS) created a Clinical Practice Guidelines which aim to delineate operational definitions of Otitis Media with effusion (OME), Chronic Suppurative Otitis Media (CSOM), Rhinitis, Sinusitis, Tonsillitis, and Obstructive Adenoidal Hypertrophy, which intend to provide evidence-based guidelines for the care of these disorders. ENT practitioners and resident trainees are the providers of care for which these guidelines are intended for.[6]

According PSO-HNS Clinical Practice Guidelines on the treatment of Sinusitis, Acute Sinusitis is defined as an episode of sinonasal infection usually lasting for more than seven days characterized by purulent nasal discharge with no significant residual damage. Chronic Sinusitis is defined as persistent sinus disease usually lasting for more than three months with or without medical treatment characterized by purulent residual mucosal damage.

The presence of the following signs and symptoms are suggestive of Acute Sinusitis: purulent nasal discharge, purulent post-nasal discharge, cough, periorbital pain, headache, facial pain, tooth pain, earache, sore throat, foul breath, increased wheeze, fever, nasal obstruction, anosmia or decreased sense of smell.

The 1992 Symposium on Sinusitis and the 1997 AAO-HNS Rhinosinusitis Task Force Committee was used by the PSO-HNS CPG to suggest that anterior and/ or posterior rhinoscopic findings of purulent nasal discharge usually arising from the middle meatus and, occasionally from the superior meatus, strongly suggest acute sinusitis. The use of sinus x-rays as well as CT scan are not recommended for patients with acute sinusitis.

The initial treatment of Acute Sinusitis includes antibiotics for 7-14 days. Choices of antibiotics include Beta lactams, macrolides and sulfas. Topical decongestants may be used for 3-5 consecutive days in patients with severe nasal obstruction. Mucoevacuants, saline and steam inhalation may be used. In patients with allergic background, topical corticosteroids and antihistamine may be given as supported by RCTs by Meltzer 1994; Mohaimeid 1993; Day 1990; Bunnag et al 1992; Gastpar et al 1994.

Chronic Sinusitis may be diagnosed by the following signs and symptoms which usually last for more than 3 months: purulent nasal discharge, purulent post-nasal discharge, cough, periorbital pain, facial pain, headache, toothache, earache, sore throat, foul breath, increased wheeze, fever, nasal obstruction, anosmia or decreased sense of smell.

The presence of nasal polyps is frequently associated with chronic sinusitis. The routine use of sinus X-rays is recommended for patients with chronic sinusitis. Screening CT scan is cost-effective in patients with chronic sinusitis in whom medical therapy fails.

Chronic sinusitis is usually a mixed infection and it should initially be treated with antibiotics for 3-4 weeks. If there is no response to therapy after 7 days, re-evaluation for other causes must be done. If obstruction to the ostiomeatal complex is suspected, CT scan may be done and surgery is recommended.

In general, almost all the ENT-HNS Specialists were aware of the existence of PSO-HNS Clinical practice Guidelines in the Treatment of Sinusitis. They also agree on all the contents of the guidelines including the signs and symptoms, diagnosis and treatment of Acute and Chronic Sinusitis. Majority of them also comply with the guideline because of their own personal preference. The guidelines were found to be in accordance with accepted methods for making clinical practice guidelines, applicable in the management of sinusitis and practical. They also agree that PSO-HNS Guideline was not being disseminated to other specialties.

The best way to update the guidelines would be to systematically search and appraise the published and unpublished medical literature using criteria for including and evaluating studies, synthesize their results, and use them in revising and augmenting the evidence-based recommendations from which the guidelines were developed.[7] The task force should also consult other stakeholders (i.e. pediatricians, family physicians, etc.) who treat such patients, as well as, those who may be responsible in paying the patients expenditure (e.g. HMO). Guideline makes explicit recommendations, often on behalf of health organizations, with a definite intend to influence what clinicians do. A good guideline, which is based on solid scientific evidence and explicit process on judging the value of alternative practices, allows one to review at one sitting multiple options and outcomes, and are more accessible and useful to prospective users.

SUMMARY

Clinical Practice Guidelines make recommendations with intent to influence what clinicians do. Majority of the consultants and residents agree on the contents of the guidelines and that many of the contents were evidence-based. Majority based their clinical decision on the treatment of Sinusitis on the PSO-HNS Clinical Practice Guideline. However, majority also agree that the guideline needs to be updated since new evidences on the treatment of sinusitis have come up. The guideline also needs to be disseminated since treating patients with sinusitis not only involves otolaryngologists but also other health care providers.

APPENDIX 1

Good day! We are conducting a survey on the acceptability and compliance of ENT-HNS Specialists in the CPG-Guided Treatment of Sinusitis. Please be assured that your answers will be kept confidential. There are no correct or incorrect answers, and your opinion is most important to us. The survey is completely voluntary and will take a few minutes of your time. Thank you very much.

Sincerely yours,

QUESTIONNAIRE ON THE ACCEPTABILITY AND COMPLIANCE OF ENT-HNS SPECIALIST IN THE TREATMENT OF SINUSITIS

Initials: _____

Institution: _____1. Government _____2. Private

_____ a. Teaching institution
_____ b. Non-teaching institution

Category: _____ 1. Fellow
_____ 2. Diplomate
_____ 3. Resident
_____ 4. Non-fellow
_____ 5. EENT

Place of Practice: _____

1. Are you aware of existing guidelines on the management of Sinusitis?
_____ Yes If you answered yes to question no. 1, go to question no. 2.
_____ No If you answered no to question no. 1, stop here.

2. Which of the following guidelines have you come across?
_____ PSO-HNS Clinical Practice Guidelines on Otitis Media, Rhinitis, Sinusitis and Tonsillitis
____ Others (Pls. Specify _____)

(Please encircle your answer)
3. I agree that Acute Sinusitis is defined as an episode of sinonasal infection usually lasting for more than seven days characterized by purulent nasal discharge with no significant residual mucosal damage.

Strongly Agree Agree Unsure Disagree Strongly Disagree

4. I agree that Chronic Sinusitis is defined as a persistent sinus disease usually lasting for more than three months with or without medical treatment characterized by purulent nasal discharge with significant residual mucosal damage.

Strongly Agree Agree Unsure Disagree Strongly Disagree

5. Which of the following signs and symptoms should be elicited during history taking in patients with Acute Sinusitis?

_____ purulent nasal discharge
_____ purulent post-nasal discharge
_____ Cough
_____ Periorbital pain
_____ Head ache
_____ Facial pain
_____ Tooth pain
_____ Earache
_____ Sore throat
_____ Nasal obstruction
_____ Anosmia or decreased sense of smell

6. Anterior/ posterior rhinoscopic findings of purulent nasal discharge usually arising form the middle meatus strongly suggest Acute Sinusitis.

Strongly Agree Agree Unsure Disagree Strongly Disagree

7. The routine use of sinus x-rays is not recommended for patient with Acute Sinusitis.

Strongly Agree Agree Unsure Disagree Strongly Disagree

8. The use of CT scan is not recommended for patients with Acute Sinusitis.

Strongly Agree Agree Unsure Disagree Strongly Disagree

RECOMMENDATIONS ON THE TREATMENT OF ACUTE SINUSITIS IN ADULTS

9. Which of the following is recommended for treatment of Acute Sinusitis?

_____ Amoxicillin
_____ Augmented Penicillin
_____ 1st generation cephalosporins
_____ 2nd generation cephalosporins
_____ Sulfonamides
_____ Others (Pls. Specify)

10. In acute sinusitis, topical decongestants may be given to patients with severe nasal obstruction.

Strongly Agree Agree Unsure Disagree Strongly Disagree

11. Mucoevacuants, saline and steam inhalation may be used.

Strongly Agree Agree Unsure Disagree Strongly Disagree

12. Topical steroids and antihistamines may be given in patients with allergic background.

Strongly Agree Agree Unsure Disagree Strongly Disagree

RECOMMENDATIONS ON THE DIAGNOSIS OF CHRONIC SINUSITIS

13. The presence of nasal polyps is frequently associated with Chronic Sinusitis.

Strongly Agree Agree Unsure Disagree Strongly Disagree

14. The routine use of sinus x-rays is recommended for patients with Chronic Sinusitis.

Strongly Agree Agree Unsure Disagree Strongly Disagree

15. The use of CT scan is recommended in-patient with Chronic Sinusitis in whom medical therapy fails.

Strongly Agree Agree Unsure Disagree Strongly Disagree

RECOMMENDATIONS ON THE TREATMENT OF CHRONIC SINUSITIS IN ADULTS

16. Chronic sinusitis should be initially treated with antibiotics for 3-4 weeks.

Strongly Agree Agree Unsure Disagree Strongly Disagree

17.If there is obstruction in the ostiomeatal complex (OMC) surgery is recommended.

Strongly Agree Agree Unsure Disagree Strongly Disagree

18. These guidelines were properly made in accordance with accepted methods for making clinical practice guidelines.

Strongly Agree Agree Unsure Disagree Strongly Disagree

19. These guidelines are applicable in the management of Sinusitis.

Strongly Agree Agree Unsure Disagree Strongly Disagree

20. These guidelines are practical and useful in one's practice.

Strongly Agree	Agree	Unsure	Disagree	Strongly Disagree

21. I agree with all the contents of the PSO-HNS Clinical Practice guidelines

Strongly Agree	Agree	Unsure	Disagree	Strongly Disagree

22. I comply with these guidelines because (Pls. check your answer)
    - _____ It is required in our department
    - _____ It is my choice
    - _____ Others are using it
    - _____ Others (Pls. Specify)

23. Do you think this guideline needs revision? Why?
    - _____ Yes
    - _____ No

24. Are you aware if this guideline is being disseminated to other specialists?
    - _____ Yes
    - _____ No

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TRAPEZIUS OSTEO-MYOCUTANEOUS FLAP FOR ORO-MANDIBULAR RECONSTRUCTION REVISITED: SCAPULAR SPINE ANATOMY AND ITS APPLICATION*

EDGARDO S. ABELARDO, MD**
ARMANDO M. CHIONG JR., MD, FPSO-HNS***
CECILE DURAN, MD**
CHRISTOPHER BERMUDEZ, MD**
KENNETH BARITUA, MD**
DEREK MARTIN PETEZA, MD**

ABSTRACT

OBJECTIVE: To determine the optimal amount of the spine of the scapula available for bone graft in oro-mandibluar reconstruction among adult Filipinos and present its clinical application on a series of trapezius osteo-myocutaneous flap.
DESIGN: A cross-sectional descriptive study.
SETTING: The study was conducted at anatomy dissection laboratories at 2 medical schools in Metro Manila. The surgeries were done at a tertiary government hospital.
SUBJECTS/PATIENTS: Twenty adult cadavers, which resulted to 40 scapular bones, were dissected. Three cases of oro-mandibular defects resulting from benign inflammatory condition, avulsive trauma, and post-oncologic ablation were reconstructed using trapezius osteo-myocutaneous flap.
METHODS: Anatomic studies involved cadaver dissection of scapular spines and measurement of their length, width, and height. Clinical studies include oro-mandibular reconstruction using pedicled composite flap consisting of skin, trapezius muscle, and spine of the scapula to replace the mandibular defect and cover the intra-oral lining.
RESULTS: The amount of scapular spine available among Filipinos for mandibular reconstruction is about 12cm x 3cm x 2cm. All of the grafts in the series survived. No extrusion nor bone resorption were noted. The success rate is due to the reliable blood supply of the trapezius composite flap which promotes rapid osteointegration and resistance to infection. The use of titanium reconstruction plates permitted early mobilization. Minor complications noted were contamination and fistula formation but these were subsequently controlled with appropriate antibiotics.
CONCLUSION: The amonut of scapular spine available among Filipinos for mandibular reconstruction is about 12cm x 3cm x2cm, which is shorter by 1.5 to 2cm in length as reported in foreign journals. The trapezius-scapular spine osteo-myocutaneous flap, whose blood supply is based on the transverse cervical artery, is a reliable and versatile procedure in immediate oro-mandibular reconstruction.

INTRODUCTION

The search for an optimal method for oro-mandibluar reconstruction remains elusive. Reconstruction of the mandibular arch is regarded by many head and neck surgeons as one of the most challenging procedure confronting the specialty. The use of a vascularized composite bone graft has proven to be more reliable than free graft. Trapezius osteo-myocutaneous flap offers an advantage over other osteomyocutaneous flaps in that the scapula, being a flat bone, receives greater perfusion from the periosteum and the trapezius muscle, having a reliable blood supply through the transverse cervical artery, would result into a greater chance of osteointegration and lesser bone resorption[1].

One major consideration in this method is the amount of bone available since there is no reliable method in assessing the size of the spine

*Third Place, PSO-HNS Descriptive Research Contest, December 02, 2002, Westin Philippine Plaza Hotel, Manila
**Resident, Department of Otorhinolaryngology-Head and Neck Surgery, East Avenue Medical Center
***Consultant, Department of Otorhinolaryngology-Head and Neck Surgery, East Avenue Medical Center

of the scapula preoperatively. Moreover, the maximal amount of scapula spine might not necessarily be the optimal amount available for graft. Panje, one of the first surgeons who introduced this surgical technique, observed that further examination of bone graft failures following mandibular reconstruction revealed that all of the failures occurred in patients who had a composite island trapezius spine flap that contained a segment of bone greater than 6cm in length[2]. This is delimiting conclusion and a very conservative estimate of the size available for graft. If the bone graft is indeed to 6cm, the feasibility of this technique in anterior mandibular defects might be doubtful. We will try to show in this study that one can extend the length of the spine to be harvested beyond 6cm without compromising the viability of the composite graft.

Literature search revealed varied estimates in the length of the spine which could be harvested, ranging from 10 to 14cm[2,3,4,5,6]. Considering the smaller built of Asians, this paper aims to give the head and neck surgeon an estimate of the size of the scapular spine in an adult Filipino available for trapezius osteo-myocutaneous flap.

OBJECTIVE

General Objective

To determine the optimal amount of the spine of the scapula available for bone graft in oro-mandibular reconstruction among adult Filipinos and present its clinical application on a series of trapezius osteo-myocutaneous flap.

Specific Objectives

To determine the maximal length, height, width of scapular spine among adult Filipinos cadavers.

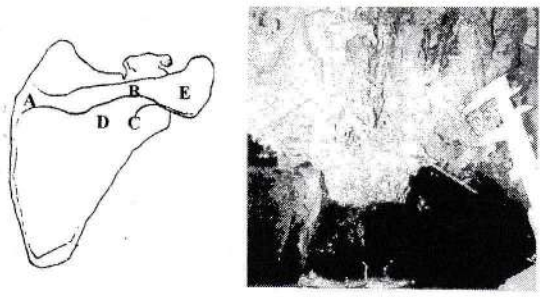
To determine the maximal viable length of the scapula available for bone graft in oro-mandibular reconstruction.

MATERIALS AND METHODS

Anatomic Studies

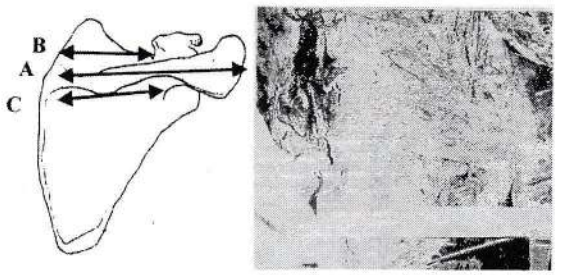
Twenty adult cadavers with no gross deformities, consisting of 10 males and 10 females, were included in the study. Age of death of the specimen materials ranged from 20 to 45 years old.

Scapular spines were skeletonized and the dimensions of each spine were measured. The landmarks were the medial border of the spine (A), the scapular notch (B), the base of the scapular notch (C), a 1cm strut from the scapular notch (D), and the acromion (E).

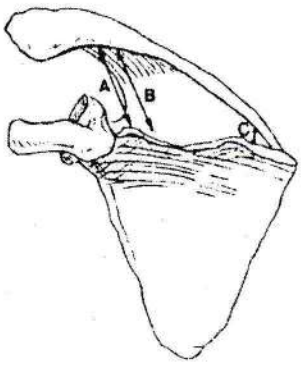


The length, width, and height of the spine were measred as follows:

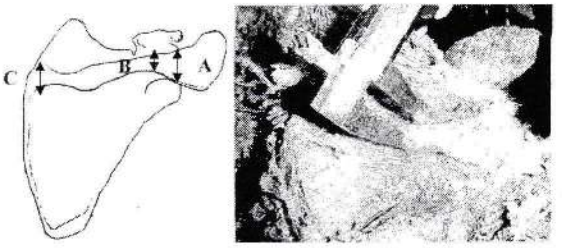
Length A - total length (medial border to acromion)
B - medial border to scapular notch
C - medial border to base of scapular spine



Height A - at area of scapular notch
B - at 1cm strut
C - at medial border



Width A - at area of scapular notch
B - 1cm strut
C - medial border



Statistical Analysis

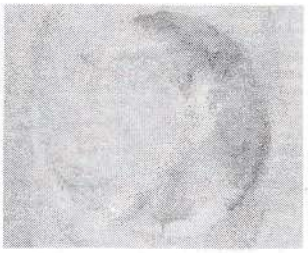
Average and standard deviations of the measurements were taken.

CLINICAL STUDIES

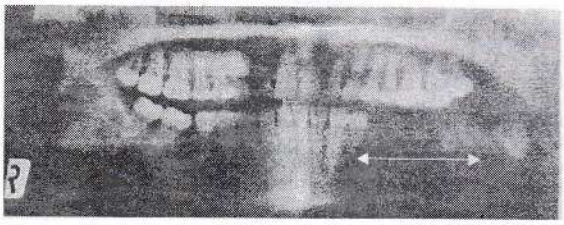
Case 1

A 29-year old female, from bulacan, came in due to progressively enlarging mandibular mass on the left of seven years duration. The mass was hard and fixed measuring about 8cm x 5cm. Intraoral examination revealed an ulcerating alveolar mass. Panoramic x-ray of the mandible showed a radiolucency extending from the ramus to the parasymphyseal area on the left side. Fine needle aspiration biopsy revealed ameloblastoma. Segmental mandibulectomy from left ramus to the symphysis was done. A 5 x 2cm oral mucosa defect and an 8cm mandibular bone defect were reconstructed using trapezius osteomyocutaneous flap. The scapular spine flap used measured about 8cm. Multiple osteotomies were made and the anterior mandible was contoured and fixed using 2.7mm titanium reconstruction plate and screws. The patient was discharged after two weeks. The patient could tolerate soft diet after 4 weeks post-op. Repeat panoramic x-ray two months post-op showed good osseo-integration. Follow-up after a year showed acceptable facial deformity and minimal functional disturbance.

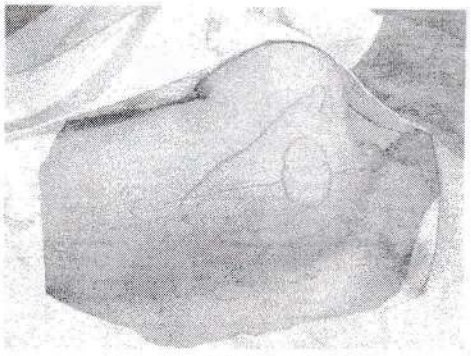
Pre-op - enlarging mandibular mass, left



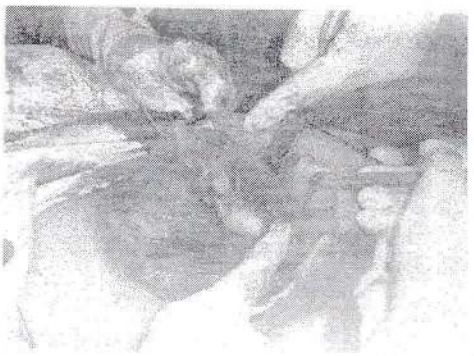
Ulcerating mandibular alveolar mass, left



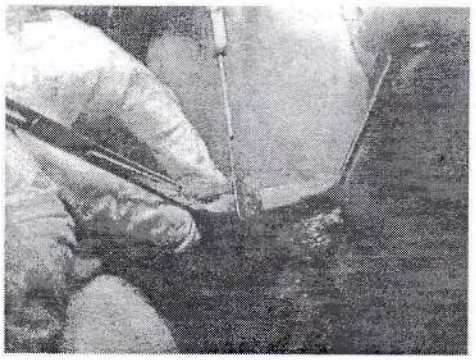
Panoramic radiography showing radioluscent area, mandible, left



Trapezius OMC flap design



Excision of mandibular mass, left



Multiple osteotomies on scapular spine

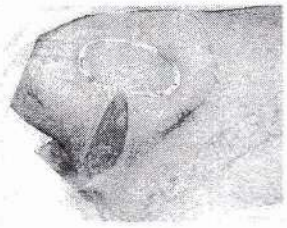
Post op - 2 weeks

Case 2

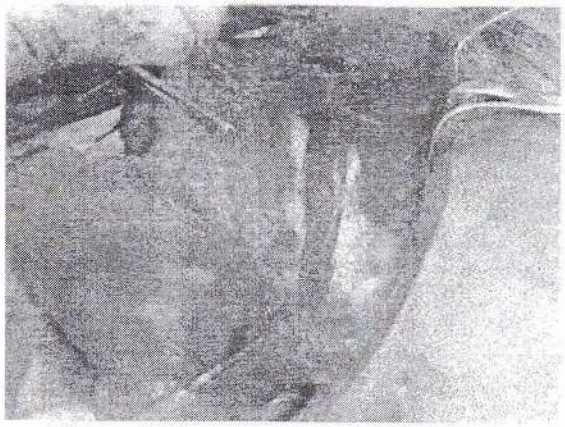
A 42-year old male, from Batasan Pambansa, Quezon City, was brought to the emergency room due to complex mandibular fracture, comminuted, with severe bone loss, extending from ramus, right, to contra-lateral parasymphyseal area due to gun shot injury. The point of entry of the bullet was at the right mandibular area adjacent to the angle and the point of exit was at the left cheek. The anterior two-thirds of the tongue and the anterior portion of the floor of the mouth were avulsed. After debridement and control of infection, oro-mandibular reconstruction was done using trapezius osteo-myocutaneous flap. The harvested scapular measured 13cm. The muscle and the skin served as the intra-oral lining in the floor of the mouth. The bone graft was osteotomized, contoured, and fixed on the condyle on the right and to the parasymphyseal area on the left using a 2.7mm titanium reconstruction plate and screws. Infection was noted few days after surgery but was

subsequently controlled by appropriate antibiotics. The patient was discharged after 3 weeks but was initially maintained on naso-gastric tube feeding. Two months post-op, repeat x-ray showed good osseo-integration of the graft. The patient could tolerate oral feeding and had intelligible speech. He had slight difficulty in mouth opening and uderwent rehabilitation for strengthening of suprahyoid muscles.

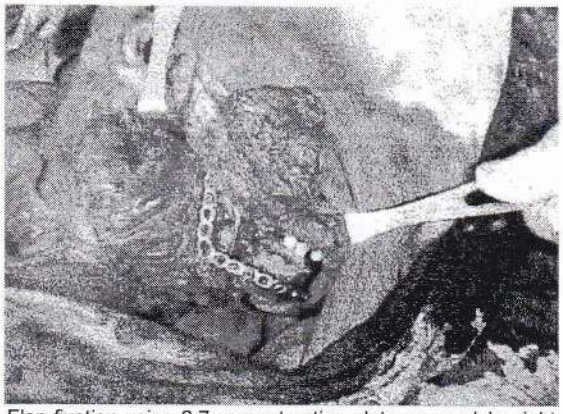
Gunshot wound, point of exit: left cheek



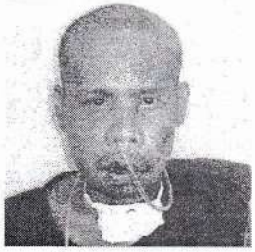
Trapezius OMCF donor site



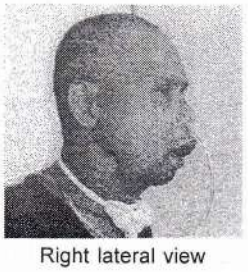
Composite flap with scapular spine harvested



Flap fixation using 2.7 reconstruction plate on condyle, right



Post op - 1month

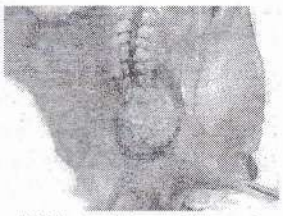


Right lateral view

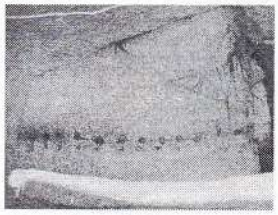
Case 3

A 65-year old female, from Laguna, consulted the Out-Pateient Deaprtment due to an ulcerating mass on the left buccal area of two years duration. Punch biopsy of the mass showed squamous cell carcinoma. The patient underwent a wide excision of the buccal lesion leaving a 5cm x 2cm intra-oral defect and segmental mandibulectomy from angle to parasymphyseal area on the left. Radical neck dissection on the ipsilateral side and modified radical neck dissection on the contra-lateral side were likewise done. Oro-mandibular reconstruction was done using a trapezius osteo-myocutaneous flap. The harvested spine of the scapula measured 9cm. The bone graft was fixed using a 2.7mm reconstruction plate. The skin served as intra-oral lining and was sutured to the adjacent mucosa. One week post-op, a fistula on the neck with yellowish discharge was noted but was subsequently controlled with use of proper antibiotics and external pressure. Oral feeding was started after a month. The patient was discharged well.

Pre op, SCCA buccal mucosa, left

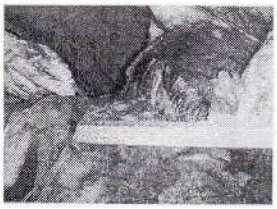


Wide excision of buccal mass

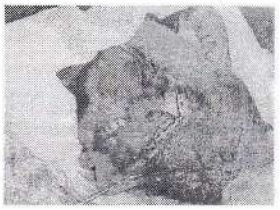


Trapezius OMCF donor site

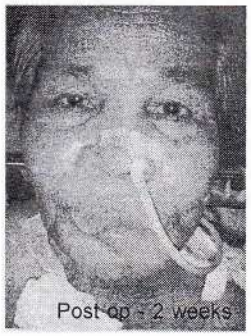
Trapezius composite flap elevated



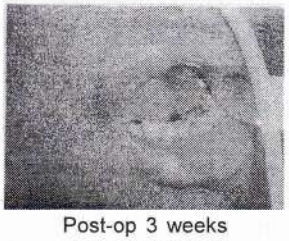
9cm of scapular spine harvested



Reconstruction using titanium plates, angle left



Post-op - 2 weeks



Post-op 3 weeks (intra-oral lining)

RESULTS

The difference between the dimensions of the spine of the male and female cadaver was not statistically significant. (Table 1)

The average length of the scapular spine from the medial border to the tip of the acromion was 11.91cm (SD 1.10), to the scapular notch was 9.94cm (SD 0.91), and to the base of the scapular spine was 7.47cm (SD 1.12). The average height at the area of the scapular notch was 3.15cm (SD 0.33), at 1cm strut area was 2.97cm (SD 0.29), and at the most medial border was 0.56cm (SD 0.10). The average width at the area of the scapular notch was 2.08cm (SD 0.11), at 1cm strut was 1.49cm (SD 0.08), and at the most medial border was 0.71cm (SD 0.07). (Table 2)

The upper border of the scapula was on the level of 7th cervical vertebrae and 1st thoracic vertebrae and the lower border was on the 6th and 7th thoracic vertebrae. the spine of the scapula was on the level of 2nd and 3rd thoracic vertebrae. (Table 3)

All of the three cases of trapezius osteomyocutaneous flap survived. Repeat panoramic x-ray two months post-op showed no extrusion nor bone resorption. Minor complications noted were contamination and fistula formation but these were subsequently controlled with appropriate antibiotics. Six months post-op showed acceptable facial symmetry and minimal functional disturbance.

DISCUSSION

The scapula, being a flat bone, receives relatively more blood supply from the periosteum. This diaphyseal character of the spine of the scapula accounts for its greater osseointegration to the recipient mandibular defect and minimal bone resorption. Epiphyseal-metaphyseal composite rib grafts, on the other hand, have not been successful due to late resorption of the rib bone[1]. The scapular spine is a triangular piece of bone at the dorsal surface of the body scapula. Its most lateral portion, the acromion, turns forward and articulates with the clavicle. The spine separates the scapular body into supraspinous and infraspinous. The lateral border curves forward and is known as scapular notch where the neuro-vascular bundle pass.

The difference between the dimensions of the spine of the male snd female cadaver was not statistically significant.

The upper border of the scapula was on the level of 7th cervical vertebrae and 1st thoracic vertebrae and the lower border was on the 6th and 7th thoracic vertebrae. The spine of the scapula was on the level of 2nd and 3rd thoracic vertebrae. These data could guide the surgeon in locating the scapula and the spine using the vertebrae as landmarks.

The use of locally available bony tissue to replace the resected mandible has long been established. In 1979, Demergasso and Piazza first proposed the use of trapezius-osteomyocutaneous flap. Literature search showed varied amount of spine of scapula available for harvest[7]. Whether to harvest the entire spine or to leave the acromion is still a matter of debate. Panje, the first head and neck surgeon to propose in American literature the use of trapezius osteomyocutaneous flap, used 12 x 2.5cm spine of scapula, leaving the acromion attached to the body of the scapula[2]. Krespi showed 7cm of spine could be used, excluding the acromion; 12cm when acromion is included; and could be extended to 15 to 18cm if the medial border of the scapula is included[3]. Dufrense illustrated 10-14cm spine to be harvested, leaving behind the spine[4]. Gregor utilized 14cm of spine, including the acromion, and noted minimal morbidity[5]. Maves studied the surgical anatomy of 24 cadavers and noted the following dimensions: 13.55cm-total length, including the acromion; 3.96cm-height at the area of scapular notch, and 2.22cm-width at the area of the scapular notch[6].

When harvesting the spine of scapula, it is sectioned between the supraspinous and infraspinous fossa ventrally and sectioned in these three points: acromio-clavicular joint (when the entire spine is harvested), at scapular notch (when the acromion is preserved), or 1cm medial to scapular notch (when a portion of spine is preserved to act as cantilever to the acromion. If the entire spine is used, 11.9cm is potentially available for harvest. This is shorter by 1.5cm compared to those reported in foreign literature. However, the functional morbidity discourages some surgeons to use the entire spine. When the acromion is left and the spine is taken off at the area of the scapular notch, 9.9cm is potentially available. The loss of 2cm is accounted by the average size of the acromion. Others may opt to be more conservative to guarantee a minimal post-op trapezius dysfunction, leaving a 1cm strut of intact lateral spine reduces the available bone graft to 7.5cm.

The height and width of the available bone graft are also of concern to reconstructive surgeons. The average height is maximal at area of the scapular notch measured at 3.2cm and least at the medial part. Excluding the acromion, the width of the spine is thickest at the area of the scapular notch measured at 2.1cm and thinnest at the medial border at 0.7cm.

According to Riolo, the average distance between the posterior angles of the mandible is 17cm. Moreover, the ascending ramus is 5cm. Total length of the mandible, from condyle to contralateral condyle is about 27cm[8]. Mandibular defects, especially those involving the anterior portion, could be reconstructed using the scapular spine. Defects from the mental area to contralateral mental area or mental area to contralateral angle could adequately be replaced by the spine. however, reconstruction of larger defects will be limited by the amount of the scapular spine available as described in this study.

In this case series presented, the amount of scapular spine harvested extended beyond the 6cm limit, as proposed by Panje[2], but none of our grafts failed. This is consistent with the findings of

other authors who used 10-14cm of scapular spine[3,4,5]. The longest we used was in case 2 where we harvested 13cm of the spine and left almost a small amount of the acromion. Still, the graft had good osteo-integration. the limit then to the amount of graft that can be used is the total amount of spine available. The question of viability of the bone can be dismissed due to the reliable blood supply of the composite graft. A study done by Gallardo et al on the identification of the vascular pedicle of trapezius muscle among adult Filipino cadavers showed transverse cervical artery provides the dominant supply to the pedicled trapezius island myocutaneous flap which could be located at the junction of the medial 3/5 and lateral 2/5 along the line drawn between the spine of the 7th cervical vertebrae and the acromio-clavicular joint. A reliable blood supply offers resistance to infection and extrusion and rapid osseo-integration to recipient bed.

CONCLUSION

The use of the spine of the scapula in mandibular reconstruction restablishes basal bone continuity, adequate alveolar bone height, and acceptable lower facial aesthetics and approximates normal oral function. The amount of scapular spine available among Filipinos for mandibular reconstruction is 12cm x 3cm x 2cm, which is shorter by 1.5 to 2cm in length as reported in a foreign journal. The trapezius-scapular spine osteo-myocutaneous flap, whose blood supply is based on the transverse cervical artery, is a reliable and versatile procedure in immediate oro-mandibular reconstruction.

RECOMMENDATIONS

A greater number of sample size in the case series and longer follow-up are recommended to further validate the conclusions. Furthermore, functional impairment on the donor site like limitation of arm movement should be explored in the succeeding studies.

TABLE 1
Demographic Data

	Female n=10	Male n=10	p-value
Length (total)			p>0.05
Range	8.95-13.15	10.8-13.8	
Mean	11.43	12.39	
Height (at the scapular notch)			p>0.05
Range	2.45-3.88	2.7-3.45	
Mean	3.2	3.09	
Width (at the scapular notch)			p>0.05
Range	1.8-2.2	1.95-2.25	
Mean	2.03	2.12	

TABLE 2
Scapular Spine Measurements

	LA	LB	LC	HA	HB	HC	WA	WB	WC
1	12.31	11.21	7.42	3.65	3.5	0.6	2.1	1.45	0.74
2	11.02	9.2	6.68	3.53	3.3	0.55	2.04	1.5	0.7
3	12.65	10.81	8.95	3.88	3.6	0.62	2.15	1.55	0.75
4	12.21	9.89	7.5	3.72	3.45	0.65	2.1	1.5	0.74
5	11.81	9.8	7.1	3.12	2.9	0.45	2.05	1.48	0.7
6	10.05	8.68	5.8	2.45	2.35	0.4	1.95	1.42	0.66
7	13.15	10.45	7.42	3.39	3.1	0.7	2.2	1.59	0.8
8	13.12	11.7	8.05	3.22	3	0.72	2.15	1.6	0.8
9	12.61	10.1	7.6	3.8	3.5	0.6	2.1	1.45	0.75
10	11.9	10	6.9	3.68	3.45	0.55	2.1	1.4	0.66
11	10.7	8.6	6.21	2.65	2.5	0.5	1.8	1.38	0.54
12	12.5	9.9	7.2	3.3	3.1	0.62	2.1	1.5	0.68
13	10.82	8.91	6.22	2.72	2.55	0.45	1.95	1.43	0.62
14	9.8	8.15	5.9	3.17	2.98	0.4	1.8	1.35	0.5
15	10.18	8.35	6.1	2.99	2.85	0.43	1.99	1.4	0.68
16	10.42	8.98	5.9	2.88	2.7	0.44	2	1.43	0.7
17	11.3	10	7	3.17	2.99	0.49	2.1	1.45	0.72
18	12.2	10.1	7.21	3.22	3.05	0.55	2.15	1.5	0.75
19	8.95	8.22	5.45	2.75	2.6	0.4	1.8	1.39	0.52
20	10.9	9.4	6.72	2.9	2.8	0.45	1.95	1.4	0.69
21	10.8	9.05	6.45	3.2	3	0.42	1.95	1.4	0.68
22	12.11	10.11	6.85	2.7	2.55	0.6	2.1	1.48	0.7
23	12.95	11.2	7.8	3.1	2.98	0.65	2.15	1.55	0.75
24	12.35	10.55	7.55	3.2	3	0.6	2.11	1.5	0.69
25	12.55	11	7.6	3.35	3.1	0.62	2.2	1.55	0.7
26	12.68	10.8	7.4	3.1	2.95	0.66	2.22	1.6	0.75
27	11.6	9.55	7.25	3.2	3.05	0.5	2.1	1.5	0.69
28	12.2	9.8	6.85	3.15	3	0.59	2.2	1.52	0.72
29	13.8	10	9	3.2	3.05	0.7	2.25	1.72	0.85
30	13.5	10.2	9.1	3.3	3.15	0.68	2.2	1.65	0.78
31	13.5	10	9.5	3.25	3.05	0.7	2.2	1.6	0.8
32	13	10.8	10	3.1	3	0.62	2.1	1.55	0.75
33	12	10.25	8.25	2.75	2.65	0.55	2.12	1.5	0.7
34	12.5	11.5	9.5	2.8	2.7	0.59	2.15	1.52	0.75
35	12.5	10.25	7.5	3.3	3.15	0.66	2.1	1.5	0.75
36	13	11.25	9.5	3.45	3.05	0.68	2.2	1.55	0.81
37	11.5	10.25	8.25	2.9	2.75	0.52	1.98	1.45	0.68
38	11.8	10.2	8	2.95	2.85	0.52	2	1.45	0.68
39	11.5	9.1	7.6	2.8	2.7	0.5	2	1.46	0.7
40	12	9.2	7.5	3	2.8	0.59	2.1	1.49	0.7

Legends:

Length *A (LA) - total length (medical border to acromion)*
B (LB) - medial border to scapular notch
C (LC) - medial border to base of scapular spine

Height *A (HA) - at area of scapular notch*
B (HB) - at 1 - cm strut
C (HC) - at medial border

Width *A (WA) - at area of scapular notch*
B (WB) - 1 cm strut
C (WC) - medial border

TABLE 3
Relationship of the scapula with cervical and thoracic vertebrae

	Upper border	Lower border	Scapular spine
1	T1	T7	T3
2	T1	T7	T3
3	C7	T6	T2
4	T1	T7	T3
5	C7	T6	T2
6	T1	T7	T3
7	T1	T7	T3
8	C7	T6	T2
9	T1	T7	T3
10	T1	T7	T3
11	T1	T7	T3
12	T1	T7	T3
13	C7	T6	T2
14	C7	T6	T2
15	T1	T7	T3
16	T1	T7	T3
17	T1	T7	T3
18	T1	T7	T3
19	C7	T6	T2
20	C7	T6	T2
21	C7	T6	T2
22	C7	T6	T2
23	C7	T6	T2
24	C7	T6	T2
25	C7	T6	T2
26	T1	T7	T3
27	C7	T6	T2
28	T1	T7	T3
29	T1	T7	T3
30	C7	T6	T2
31	T1	T7	T3
32	C7	T6	T2
33	C7	T6	T2
34	C7	T6	T2
35	C7	T6	T2
36	C7	T6	T2
37	T1	T7	T3
38	T1	T7	T3
39	T1	T7	T3
40	C7	T6	T2

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