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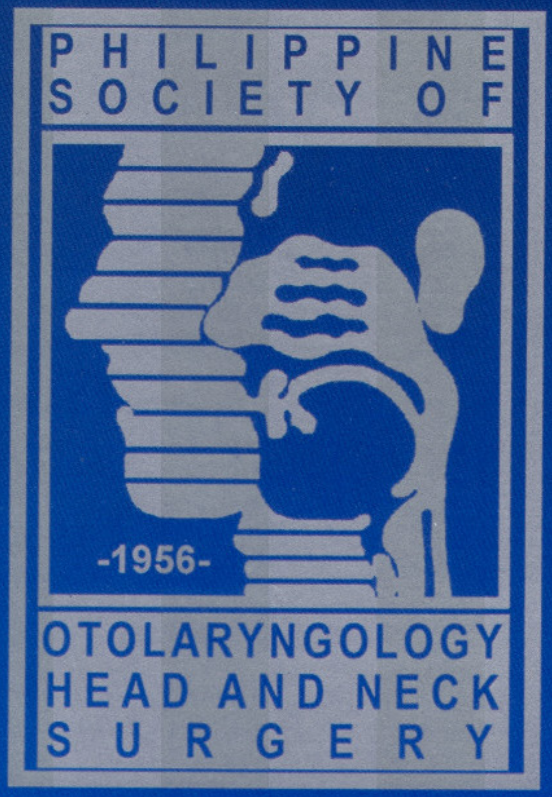

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THE EFFECTIVENESS OF A MODIFIED NASOGASTRIC TUBE AMONG MANDIBULAR TRAUMA PATIENTS*

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ABSTRACT

OBJECTIVES: To compare the effectiveness of a modified Nasogastric tube (mNGT) with the conventional NGT (cNGT) in terms of patient preference, global assessment of superiority, and failure rate.
DESIGN: Prospective Randomized Cross-over Trial
SETTING: Tertiary Government Hospital
PATIENTS: 26 mandibular trauma patients requiring more than 4 weeks of post-operative tube feeding
RESULTS: Primary outcome measures computed and compared using the z-test for a single proportion showed that the modified NGT was the preferred choice of 25/26 or 96.15% of patients at the end of the 3 week study period. When asked to respond to the question "Overall, which of the treatments do you think is better?", 21/26 or 80.77% of subjects ranked mNGT higher as against 1/26 or 3.85% in favor of cNGT and 4/26 or 15.4% with equivocal response ($p<0.001$). The failure incidence densities of mNGT (ID=3/266 person-days) and cNGT (ID=3/280 person-days) were not statistically different and had a computed risk ratio=1.05. No adverse events, as defined in the study methods, were observed for the entire 3 week duration of the study.
CONCLUSION: The mNGT is more effective than cNGT with regard to patient preference and global assessment of superiority. Failure Incidence rates were comparable and showed no statistically significant difference.

INTRODUCTION

Nasogastric intubation is a simple, non-surgical, time tested, and widely accepted method of providing enteric feeding to those who are restricted or are unable to feed orally[13]. Any clinician having to deal with prolonged nasogastric intubation can attest to patients' complaints regarding the general discomfort and inconvenience that invariably accompany this common procedure. In addition several authors have identified other specific adverse effects of nasogastric intubation such as sinusitis, nasal pain, obstruction and discharge, dysphagia, Eustachian tube dysfunction, among others[1,2,3,4,6,7,12]. Studies on how to alleviate some or all of these adverse effects have focused mainly on the technique of insertion and on what to watch out for, prevent, or avoid in patients requiring NGT. Despite a comprehensive electronic and manual search of the current literature, no studies were found having anything to do with physically modifying the NGT and only one study by Gonzales et al in 1996 explored the feasibility of using an orogastric tube as an alternative to the conventional NGT[5].

Inspired by the "NGT-innovation" designed by a laryngectomized patient with a stubborn oro-cutaneous fistula, a group of ENT residents in a tertiary gov't hospital developed and refined an inexpensive detachable Nasogastric tube attachment that was met with initial success during a limited open trial[14]. The proponents of this device theorized that the modification, which basically shortened the conventional NGT, would do away with much of the aesthetic and functional difficulties associated with the long external (exposed) portion of the standard Nasogastric tube (6). In pursuit of the objective of improving the lot of patients who have to undergo prolonged intubation, this comparative trial was thus designed with the intent of showing that the modified NGT is an improvement over the conventional NGT, in the estimation of the people who actually have to undergo the ordeal.

Research Question:

Among adult post-operative mandibular trauma patients who will be requiring 4 or more weeks of tube feeding, is the modified detachable NGT more effective than the conventional NGT in terms of treatment preference, global superiority,

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and NGT failure incidence?

OBJECTIVES

General Objective:

To compare the effectiveness of a modified nasogastric tube with the conventional NGT.

Specific Objectives:

1. To compare the proportions of patients preferring mNGT and cNGT (primary effectiveness variable using the patients' choice of treatment to be continued and their global assessment of the superiority of treatments.
2. To compare the risk of failure (incidence density) of mNGT and cNGT (secondary effectiveness variable)
3. To determine some of the reasons behind the subjects' preference for mNGT or cNGT.
4. To monitor the occurrence of adverse events

METHODS

A consecutive series of 26 adult (18y/o or more) post-operative mandibular trauma patients admitted at the ENT Department of a Tertiary Gov't Hospital from January to September 2000 requiring more than 4 weeks of tube feeding were recruited for the study after satisfying the following criteria:

1. Written informed consent (Appendix A)
2. No Chronically or severely obstructed nasal passages
3. No injured nasal vestibule and nasal mucosa
4. Ability to follow up during the 3 week study period
5. Physical and psychological ability to comprehend or answer questions related to the outcome measurement

At the time of securing the subjects' informed consent, all subjects were uniformly made aware of the objectives and the procedure of the study, as well as the task that would be required of them during the exit interview. A detailed description of the modified NGT is found at Appendix B.

The patients were then randomized into 2 treatment groups with the first group initially undergoing cNGT insertion for the first week (run-in period and adaptation week) then subjected to mNGT insertion for the second week then back to cNGT insertion for the 3rd week. Group 2 patients initially underwent mNGT insertion for the first week followed by cNGT during the 2nd week and then back to mNGT for the 3rd week. The procedure for cNGT and mNGT insertion was standardized for all patients (Appendix C & D). All the subjects were discharged from the hospital within 5 days after surgery, properly instructed by the hospital's dietary personnel regarding the amount and frequency of feeding. Subjects and/or their watchers were further instructed (hands-on) on the use of the cNGT and mNGT attachment in a uniform fashion by one of the study personnel.

Subsequent NGT insertions were done at the OPD by the same study personnel during their scheduled weekly follow-up sessions. A washout period of 2 hours between treatments was instituted. Subsequent weekly NGT insertions were performed on alternate nostrils as per the recommendations of Batol el. al (1990) to prevent development of NGT-induced sinusitis. Monitoring and recording of NGT failure events (Appendix E-Case Report Form) defined as either dislodgment of the NGT or mechanical failure to feed via NGT which necessitated reinsertion of replacement/repair of the NGT were done during the weekly follow up periods. Adverse events possibly related to the modification such as vestibulitis/vestibular injury, undue nasal pain, undue epistaxis were monitored.

At the end of the three-week study period, the subjects were made to undergo a structured exit interview wherein they were asked to carry out the following tasks:

1. to indicate their unforced comparison or global assessment as to which of two treatments they found better (mNGT, cNGT, or EQUIVOCAL),
2. to indicate their reasons (if any) for their choice
3. and finally to indicate their final choice of treatment they would want to undergo for their 4th week of Nasogastric intubation (forced choice).

Additional data regarding the subject's perception of the superiority of one treatment over another in terms of aesthetic considerations, ease of feeding, and overall comfort in activities of daily living were gathered via close-ended questions (mNGT, cNGT, or EQUIVOCAL).

Statistical Analyses

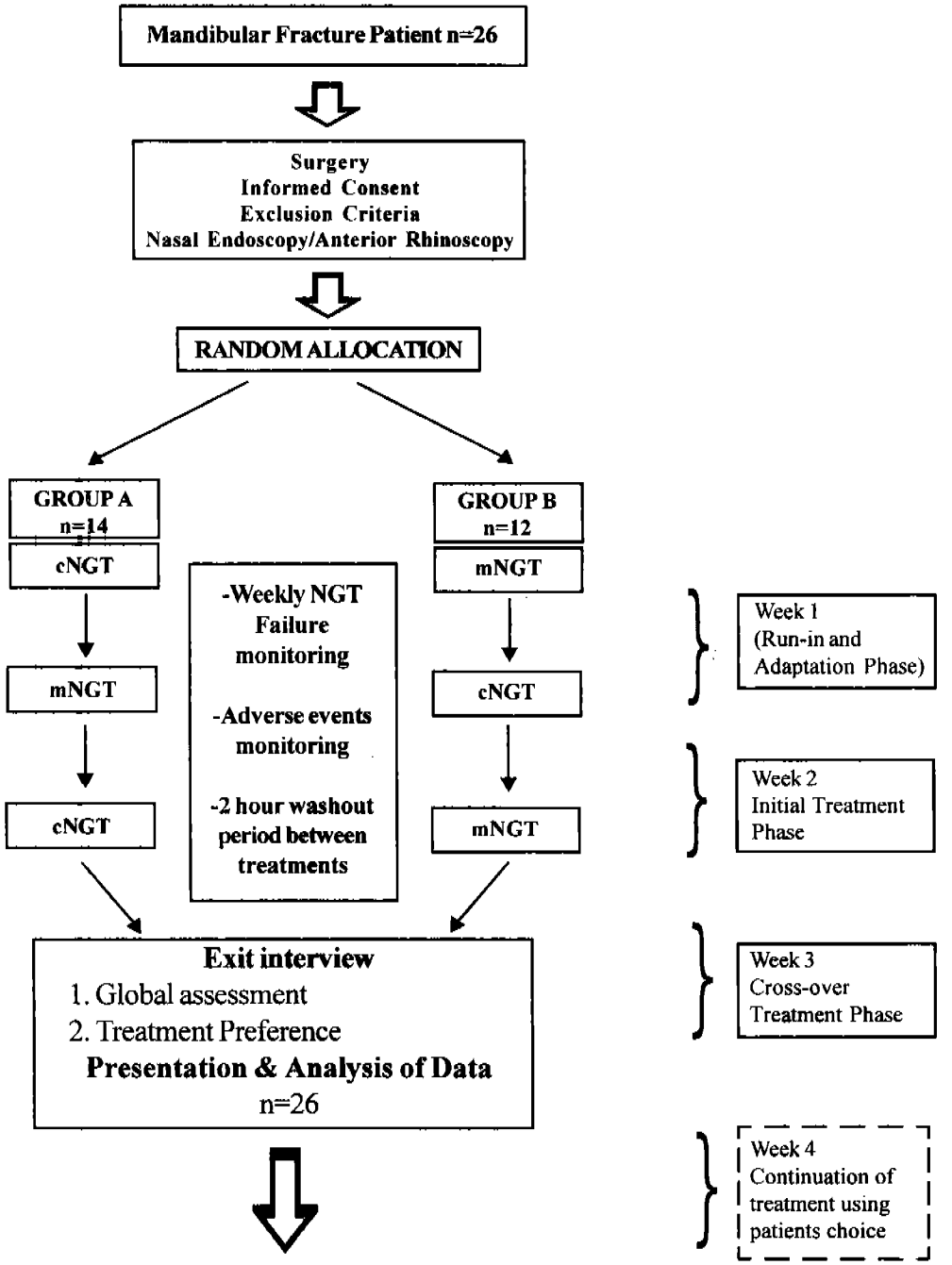
For the primary effectiveness variable, the frequency and percentages of subjects making the final choice (forced choice) of either the mNGT or the cNGT as their treatment for the 4th week were computed and the frequencies statistically compared using the z-test for a single proportion. Supplementary analysis of the patients' global assessment of the treatments as indicated by responses to the close-ended question: "which of the treatments do you think is better?" (unforced

comparison) was carried out using the non-parametric Sign Test. (Appendix G)

For the secondary effectiveness variable involving failure incidence, the total person-days the subjects were treated using mNGT or cNGT were used for the denominators of the incidence density measures and the total number of failures observed from each treatment period were used as the numerators. The resulting failure incidence densities (risk of NGT failure) were analyzed using the risk ratio and the Exact Test for Comparing Incidence densities (Appendix H).

Adverse events and interview data gathered from open-ended interview questions designed to gain insights as to the reasons behind the subjects' final preference were tabulated, presented, and analyzed using descriptive statistics (percentages, frequencies) where applicable. Supplementary tables comparing the responses of subjects to close-ended questions regarding possible factors influencing their treatment preference are also presented at Appendix I.

METHODOLOGY FLOW CHART



RESULTS

TABLE 1
Subjects

Total Number of Subjects	26
Age	
Range	19-45
Mean	30.3+/-8.96
Median	26
M:F ratio	25:1

All randomized subjects were able to complete the 3 weeks duration of the study.

TABLE 2
Patients' "forced" decision as to what type of treatment they will undergo after the exit interview.

"FORCED" DECISION OF PREFERRED TREATMENT	Number n=26	%	HYPOTHESIS TESTING RESULTS α=.05 one-tailed
Modified NGT	25	96.15	Null hypothesis (p=.5) rejected: The proportion of subjects choosing mNGT is significantly greater than 0.5
Convention NGT	1	3.85	

TABLE 3
Unforced comparison responses to the close-ended exit interview question "Overall which of the treatments do you think is better?"

GLOBAL ASSESSMENT OF TREATMENT SUPERIORITY	Number n=26	%	P (Sign Test)
Modified NGT	21	80.77	<.001
Conventional NGT	1	3.85	
Equivocal Response	4	15.4	

TABLE 4
Failure rate observed for each type of treatment during the entire 3 weeks of the study

TREATMENT	# of FAILURE EVENTS (a)	PERSON -DAYS (t)	INCIDENCE DENSITY (a/t)	RISK RATIO	Exact test (for competing incidence rates)
mNGT	3	266	0.01128	1.06	No significant difference
cNGT	3	280	0.01071		

TABLE 5
Weekly frequency of NGT failure events for each type of treatment

FREQUENCY OF FAILURE EVENTS							
WEEK 1		WEEK 2		WEEK 3		WEEK 4	
cNGT n=14	mNGT n=12	cNGT n=12	mNGT n=14	cNGT n=14	mNGT n=12	cNGT n=40	mNGT n=38
3	3	0	0	0	0	3	3

No adverse events (as defined in the methodology) were observed during the entire study period.

TABLE 6
Subject responses when asked, "Why did you choose mNGT?"

CLASSIFICATION OF SUBJECTS' RESPONSES TO OPEN ENDED QUESTION	NUMBER	%
1. Less fear of dislodgment	14	66
2. Ease with performance of daily activities (including work)	17	81
3. Aesthetically better	21	100

The lone subject who indicated the conventional NGT as her preferred treatment cited her fear of ingestion of the entire modified tube and the difficulty she experienced with feeding as reasons for her choice. This subject also had a failure experience with the modified NGT during the run in period when the rubber cap of the attachment was left behind in the mouth of the tube.

DISCUSSION

History and Development of the Modified NGT

Sometime in the last quarter of 1999, Mr. M underwent total laryngectomy and partial resection of the tongue base with pectoralis major flap reconstruction for advanced laryngeal cancer. In the succeeding weeks that followed, Mr. M developed a persistent pharyngocutaneous fistula and had to be placed on extended nasogastric intubation. He surprised his doctors when he showed up during a scheduled follow-up with his NGT cut short almost up to the nasal ala. He explained to his doctors that he felt inconvenienced by the long dangling portion of the standard tube and proceeded to describe how he used a 3cc disposable syringe as an attachment for feeding and how this modification made life a bit easier for him.

Mr. M's stroke of genius served as a long-overdue reminder to his doctors to pay closer

attention to quality of life issues that often take a back seat to the physician's belief or perception of what is best for a patient. The doctors of the institution where Mr. M was following up were no strangers to clinical research aimed at improving the delivery of Nasogastric intubation, with two previous published papers on "NGT Induced sinusitis" (1990) and "Orogastric intubation: A variable Alternative to the NGT" (1996) under its belt. Armed with the lessons learned from these previous studies, the proponents of the modified NGT refined and developed the modification introduced by Mr. M, initially testing it on a limited number of patients for up to two weeks at a time.

The results of the pilot study were very encouraging, prompting the development team to embark on a comparative trial that would help settle their contention that the mNGT was indeed better for patients. Realizing that the task of trying to prove a new method was better than a time-tested, widely accepted one was by no estimation trivial, much time and discussion was spent on designing a study that would stand up against scrutiny on internal validity and applicability issues.

Emphasis on "Patient's Preference"

From the very start, the authors agreed that the prime moving force of the study should be the measurement of the "patient's preference", as opposed to the "physician's preference" of the treatment of interest. While it was realized that overly relying on patient's preference for a treatment carried with it the risk of masking a long term deleterious effect, the authors determined that there was no other way to directly measure such preference but to administer the two treatments successively to the patients and after wards ask them to indicate which was better as this approach would give an overall view, taking into consideration both efficacy and tolerability[15].

Choice of Study Design

The prospective randomized cross-over design was utilized as this study design places a premium on making the delivery of the two treatments as equal as possible, while at the same time recognizing the existence and possible influence of 'carry-over effects". The elements of a cross-over design were carefully adhered to in the conduct of this study.

A (randomized) one-week run-in period immediately post-operatively was instituted since it was recognized that the first few days of nasogastric intubation are usually the worst in terms of patient discomfort. The run-in period also served to achieve baseline conditions in that by the time the "initial treatment" was started, the postoperative swelling and discomfort that accompanies mandibular fracture surgery would have stabilized and the patient would have adapted to the condition of having a tube in place.

A two-hour washout period was also instituted. The relatively short washout period was mainly dictated by practical and ethical issues concerning making the patient wait for a longer period before crossing over to the next treatment in as much as the subjects were already discharged from the hospital by the time he was due for the first NGT reinsertion. In addition, the authors did not think that having a short washout period would have a significant effect on the PRIMARY outcome measure since the baseline condition of the patient also involved having an NGT already in place for a week.

To limit any additional carry-over or interaction effect of exposing the nose to prolonged trauma and alter baseline conditions, NGT insertion was done on alternate nostrils, after ensuring that both noses were not initially injured and had no severe structural deformities that would render insertion on one side more difficult than the other.

Choice and Method of Primary Outcome Measurements

Several types of outcome measures are possible for a cross-over design, the most commonly employed being the difference in the means of some quantitative measure. In this study, the primary outcome measured was the proportion (percentage) of patients preferring one treatment over another. The authors felt that coming up with a numerical scoring system was unrealistic and impractical because of the very subjective nature of the outcome being measured.

There are two primary outcome tables presented in this paper (table 2 and 3), the global assessment of superiority (or the "unforced comparison" tables) and the "forced decision" proportions. The measurements of these outcomes were taken using a structured interview, which asked the patients their global assessment of the treatments first before making them choose what treatment they would actually prefer to be subjected in the immediate future. This maneuver of separately presenting two very similar outcome measures was carried out in cognizance of the fact that what a person might prefer in retrospect may not be the same as what he would want at the present. Disadvantages of preference studies include problems of too many patients having "no opinions" (thereby rendering statistical analysis doubtful) or "forcing" patients to indicate a preference that may have no real clinical significance. In presenting two primary outcomes, the reader is afforded a deeper insight and wider perspective as regards overcoming the above-mentioned

disadvantages. The strength of the "forced choice" outcome is that it speaks for itself. It is also reassuring that both outcomes support the same conclusion that mNGT is more preferred by patients than the conventional NGT.

The Role of Secondary Outcome Measures (NGT failure rates/adverse event rates)

The ideal condition for a treatment to be considered more (or less) effective is one wherein it is both preferred by patients and physicians, the assumption being that physicians' preferences are often based on very different criteria which are usually more objective and more clearly defined. These more objective measurements are discussed below.

The results of NGT failure monitoring in this study reveal a state of no difference between the treatment and control periods (table 4). This measure is an important effectiveness indicator because it serves as direct conformation of the primary function of the NGT of providing a route of feeding. It is interesting to note that all failure events occurred during the one week run-in period (table 5). Could this be interpreted as indication of the success of the run-in period in stabilizing the patient's conditions and achieving the desired baseline? The temporal and numerical similarity of the failure events between the two treatments further support that the modified NGT serves the purpose of feeding the patient just as well as the conventional NGT.

Adverse events monitoring (which was defined as being mutually exclusive with NGT failure monitoring) yielded no events for the two treatment periods. As a measure of treatment effectiveness, the results support (or at least do not contradict) the conclusion derived from the results of the "patients' preference" measure.

Due to the paucity of failure events, should a longer study period have been instituted so as to capture more realistic failure rates? The authors felt that extending the study period to the full 5 or 6 weeks of Nasogastric intubation that are usually required for mandibular trauma patients would result in many drop-outs as well as withdrawals from a treatment.

The Advantages and Disadvantages of MNGT

At the start of the study, the theoretical advantages of the modified NGT over the conventional NGT were seen to revolve around the issues of better aesthetic appearance, a lower dislodgment rate from accidental pulling on the tube, less discomfort because it affords better mobility to the patient, less pain because it would have has less chances of pulling, and therefore a higher preference rate.

The theoretical disadvantages considered included higher vestibulitis rates because of more manipulations being done near the vestibule (during feeding), increased cost and maintenance requirements, and less convenient feeding preparations.

To further explore the above mentioned risk factors, patients were asked during the exit interview as to the reasons behind their choice of treatments. Their responses were classified and presented in table 6 and generally bear out the above stated theories. In addition, four close-ended questions were asked of the subjects pertaining to aesthetics, nasal pain, ease of feeding, and comfort after they made their "forced" final choice. The results likewise support the theories put forward (Appendix F) with the exception that there were no cases of vestibulitis observed.

CONCLUSION

The modified NGT is more effective than the conventional NGT with regard to actual patient preference and patient's global assessment of treatment superiority. Failure incidence rates were comparable and showed no statistically significant difference. No adverse events, as defined in this study, were noted during the entire three-week study period.

RECOMMENDATIONS

The authors felt that the randomized cross-over design used in this study is the best method that would put primary importance on the clinical outcome that is most relevant to a patient in the clinical setting-his own preference for a certain treatment.

However, the authors recognize that physician and other non-patient factors that might also play an important role (i.e. added cost, device preparation, device maintenance issues, quality control issues, unrecognized adverse events) in determining whether the modified NGT is indeed the better alternative of the two treatments could be answered more directly using a parallel study design. Increasing the sample size and/or the study duration, or employing a multiple period cross-over design would surely result in more powerful conclusions and more accurate estimates of adverse event rates and failure rates.

Logistic regression analysis of the predictors or factors that are relevant to the patient's ultimate choice of treatment will also probably aid in refining the design of the apparatus as well as determine which domains surrounding the central

issue of long-term nasogastric intubation deserves more attention.

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APPENDIX

APPENDIX A
INFORMED CONSENT

THE EFFECTIVENESS OF A MODIFIED DETACHABLE NASOGASTRIC TUBE AMONG MANDIBULAR TRAUMA PATIENTS

I, _____, residing at _____
hereby consent to participate in the study "THE EFFECTIVENESS OF A MODIFIED DETACHABLE NASOGASTRIC TUBE AMONG MANDIBULAR TRAUMA PATIENTS"

I have been made to understand the following conditions:

1. That the study protocol / methodology was explained to me in such a manner that I understood the objective of the study which is mainly to compare the effects of and determine my preference between the conventional NGT and the modified NGT.
2. That while the conventional NGT is currently the standard device used for nasogastric intubation, the modified NGT is newly developed deviced which has undergone preliminary safety testing on actual hospital subjects during its development and that it's use may or may not result in the improvement of my condition as compared to the conventional NGT.
3. That I agree to undergo physical examination (nasal endoscopy and / or anterior rhinoscopy) which are considered necessary for diagnosis and evaluation. I understand that the above mentioned examination will be free of charge. However, such benefit will not cover other laboratory work-up which will be ordered by the attending physician.
4. That I have been given the opportunity to ask questions concerning this project and that the doctors have been willing to answer these inquiries to my satisfaction.
5. That I can, at any time of my choosing, for whatever reason, without prejudice to my person, withdraw from the study.
6. That if I develop adverse effects due to the study treatment, the sponsoring institution will shoulder medical expenses for the appropriate management of such adverse effects.
7. Be it known that this consent was freely and voluntarily given without influence, force or intimidation from any person after I have fully understood the procedure of the treatment which I will receive.

_____ Signature

_____ Witness

_____ Signature

_____ Witness

(Filipino version not included)

APPENDIX B

THE INSTRUMENT

Materials

The prototype was assembled using the following readily available and inexpensive materials:

1. Tuberculin Syringe (TERUMO)
2. Nasogastric Tube, French 16

Procedure

The detachable NGT had 2 parts:

1. Segment A of the NGT, the part inserted through the anterior nares to the stomach, and
2. Segment B of the NGT, the detachable part of the NGT which would be connected to Segment A during feeding. Segment A had an adaptor for Segment B to facilitate feeding and a plug to seal Segment A when not feeding.

These different parts were easily made by the following a few simple steps.

Steps in Making Segments A and B

1. The Nasogastric tube was cut into two parts at the approximate distance* from the anterior nares to the stomach.

Figure 1

*The distance from the anterior nares to the stomach is approximately the distance from the tip of the nose to the ear and then from the ear to the xiphoid process.

The part that would be inserted into the nostril was termed Segment A. The other part was termed Segment b, the detachable segment. Figure 2.

FIGURE 1. Step 1 in Making the detachable NGT. The Nasogastric tubewas cut into two parts at the approximate distance* from the anterior nares to the stomach. The distance from the anterior nares to the stomach is approximately the distance from the tip of the nose to the ear and then from the ear to the xiphoid process.

2. Segment A was further modified by fitting an adaptor and a plug made from parts of the tuberculin syringe. The barrel and plunger of the tuberculin syringe was used to make the adaptor and the plug, respectively.

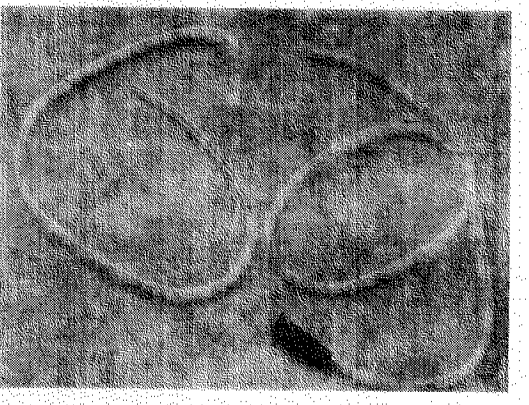

FIGURE 2. Segment A and B. The part that would be inserted into the nostril was termed Segment A (at the left side of the picture). The other part was termed Segment B - thedetachable segment (at the right side of the picture).

a. Making the Adaptor

The adaptor was a 1.5 cm segment of the syringe barrel with the flanges. This was made by cutting the barrel at the 1.0ml mark. Figure 3a. The cut end of Segment A was then inserted into the cut end of the adaptor, halfway through the barrel. Figure 3b.

b. Making the Plug

The plug was a 1.5cm segment of the plunger with the rubber plug. This was made by simply cutting the plunger. Figure 4a. The cut end was heated and pressed to a flat surface forming a circular flat end. Figure 4b. This flattened end would serve as a grip for removing and inserting the plug. Figure 4

The assembled dNGT would be used as follows. The whole length of Segment A would be inserted through

FIGURE 3a: Step 2 in Making the dNGT-Making the Adaptor. The adaptor was a 1.5cm segment of the syringe barrel with the flanges. This was made by cutting the barrel at the 1.0ml mark(at the left side of the picture). The cut barrel at the right side of the picture) is the adaptor.

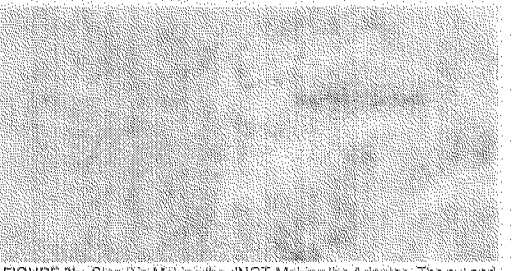

FIGURE 3b: Step 2 in Making the dNGT-Making the Adaptor. The cut end of segment A was then inserted into the cut end of the adaptor, halfway through the barrel.

the anterior nares to the stomach. The flange of the adaptor would rest at anterior nares and secured in place with a tape. During feeding, Segment B (the detachable part) would be inserted into the adaptor and connected to Segment A. Figure 5a. After feeding, Segment B would be detached. The plug would then be used to seal Segment A. Figure 5b.

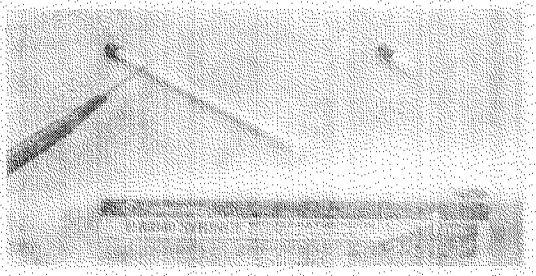

FIGURE 4a: Step 2 in Making the dNGT-Making the Plug. The plug was a 1.5cm segment of the plunger with the rubber plug. This was made by simply cutting the plunger (at the left side of picture). The cut plunger (at the right side of the picture) is the plug.

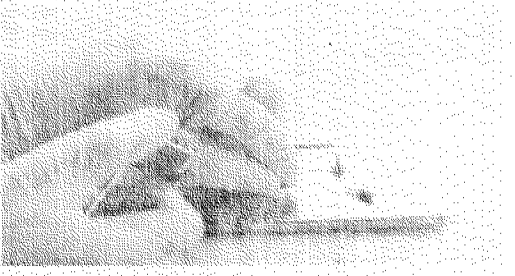

FIGURE 4b: Step 2 in Making the dNGT-Making the Plug. The cut end was heated and pressed to a flat surface forming a circular flat end. This figure shows the cut end being pressed on a flat surface after it was heated with a lighter. The cut plug (at the right side) is the finished plug.

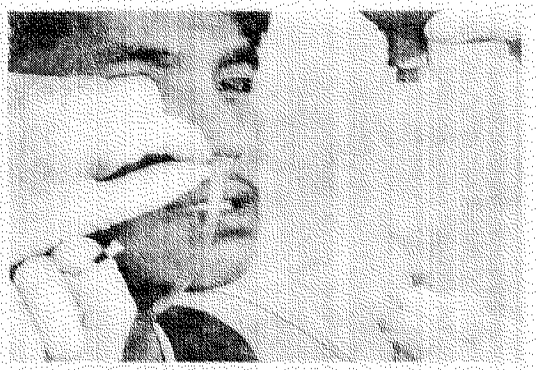

FIGURE 5a: Using the dNGT during Feeding. The whole length of Segment A would be inserted through the anterior nares to the stomach. The flange of the adaptor would rest at anterior nares and secured in place with a tape. During feeding, Segment B (the detachable part) would be inserted into the adaptor and connected to Segment A.

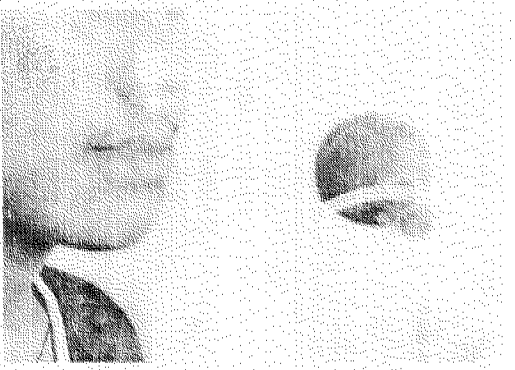

FIGURE 5b: Using the dNGT when not Feeding. After feeding, Segment B would be detached. The plug would then be used to seal Segment A.

APPENDIX C

TECHNIQUE FOR INSERTION OF NASOGASTRIC TUBE

CONVENTIONAL NASOGASTRIC.

1. Informed consent was secured. Complete history and physical examination was done. The purpose, method, as well as the potential benefits and hazards were thoroughly explained to the patient. The technique, with emphasis on the areas where patient cooperation is required, was also explained.

2. With the patient in the sitting position, the length of tube to be inserted was measured from the nose to the ear, and then from the ear to xyphoid process. Area was marked.

3. A well lubricated (using K-Y jelly) 16 Fr. 80 cm. Long feeding tube was inserted into a patent naris, introduced along the floor of the nose, and then advanced into the nasopharynx. As it reached the oropharynx, the patient was asked to swallow and each time the tube was advance 3-5 inches until the marking was at the level of the naris, which indicated that the tube was in the stomach. If coughing or gasping persisted, the tube was immediately pulled back. The tube was in the stomach if gatric contents could be aspirated and/or a swooshing sound was heard through a stethoscope placed over
the stomach when air was injected into the tube.

4. Once tube placement has been confirmed, it was secured in place at the bridge of the nose with a non-allergenic tape.

The above procedure was adapted from the following published articles:
1. Dees, G: Difficult Nasogatric Tube Insertions. Emergency Medicine Clinics of North America, 1989:7:1:177-182
2. Wrenn, Keith: The Lowly Nasogastric Tube: Still Appropriate After All These Years: American Journal of Emergency Medicine, 1993:11:1:84-89
3. Gonzales, AL, et al: Patients' Acceptability of Nasogatric Tube (NGT) versus Orogastric Tube (OGT): The Philippine Journal of Otolaryngology-Head and Neck Surgery, 1996

APPENDIX D

TECHNIQUE FOR INSERTION OF NASOGASTRIC TUBE

MODIFIED NASOGATRIC TUBE:

1. Informed consent was secured. Complete history and physical examination was done. The purpose, method, as well as the potential benefits and hazards were thoroughly explained to the patient. The technique, with emphasis on the areas where patient cooperation is required, was also explained.

2. With the patient in the sitting position, the length of tube to be inserted was measured from the nose to the ear, and then from the ear to xyphoid process. Area was marked.

3.Feeding tube was cut at the marked level. A connector was attached to the tube that is to be inserted.

4. Lubricated tube (using K-Y jelly) was inserted into a patent naris, introduced along the floor of the nose, and then advanced into the nasopharynx. As it reached the oropharynx, the patient was asked to swallow and each time the tube was advanced 3-5 inches until the marking was at the level of the naris, which indicated that the tube was in the stomach. If coughing or gasping persisted, the tube was immediately d back.
The external tube is connected and placement was checked. The tube was in the stomach if gatric contents could be aspirated and/or a swooshing sound was heard through a stethoscope placed over the stomach when air was injected into the tube.

5. Once tube placement has been confirmed, it was secured in place at the bridge of the nose with a non-allergenic tape.

The above procedure was adapted from the following published articles:
1. Dees, G. Difficult Nasogatric Tube Insertions. Emergency Medicine Clinics of North America, 1989:7:1.177-182
2. Wrenn, Keith The Lowly Nasogastric Tube: Still Appropriate After All These Years: American Journal of Emergency Medicine, 1993:11:1:84-89
3. Gonzales, AL, et al: Patients' Acceptability of Nasogatric Tube (NGT) versus Orogastric Tube (OGT): The Philippine Journal of Otolaryngology-Head and Neck Surgery, 1996

CONVENTIONAL NASOGASTRIC TUBE INSERTION

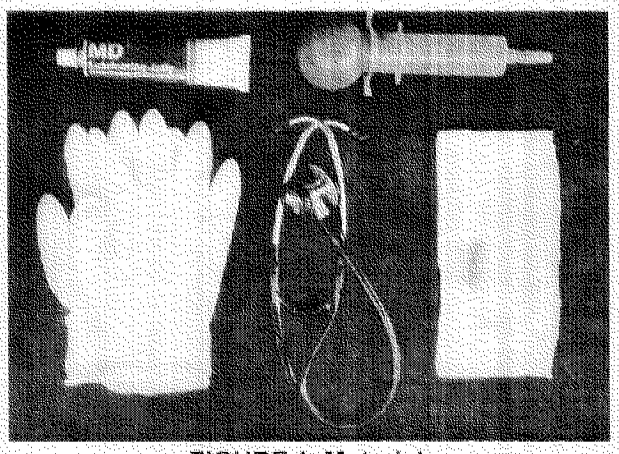

FIGURE 1: Materials

FIGURE 2: Measurements

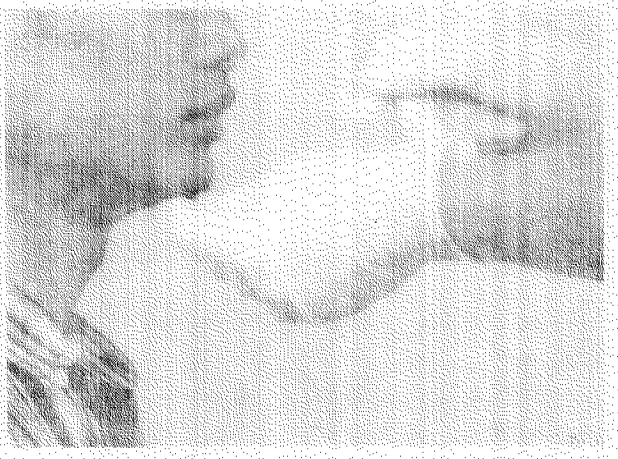

FIGURE 3: Insertion

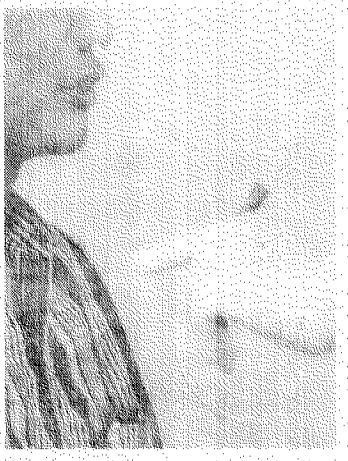

FIGURE 4: Confirmation

FIGURE 5:
Conventional NGt

APPENDIX E

CASE REPORT FORM **patient # _____**

Name: _____ Age: ___Sex ___Date recruited: _____

Address _____ Tel#_____

Diagnosis: _____

Operation done: _____

TREATMENT GROUP

1st week (baseline)
no. of failures **no. of adverse events** _____NGT
specify:_____ **specify:** _____

2nd week
no. of failures **no. of adverse events** _____NGT
specify:_____ **specify:** _____

3rd week
no. of failures **no. of adverse events** _____NGT
specify:_____ **specify:** _____

TOTAL FAILURES

mNGT ☐

cNGT ☐

GLOBAL ASSESSMENT

☐ **mNGT**
☐ **cNGT**
☐ **equivocal**

PREFERENCE

☐ **mNGT**
☐ **cNGT**

EXIT INTERVIEW

1. Overall, which do you think is better?
   Sa kabuuan alin ang mas maganda para sa iyo?
   (IF RESPONSE IS EQUIVOCAL, PROCEED TO QUESTION #3)
   cNGT_____ mNGT_____ equivocal/pareho lang _____
   Remarks:
2. Why? (do you think it's better---answer in #1)

3. Which of the two do you want to be inserted now?
   cNGT_____ mNGT _____

Interview Date

APPENDIX F

Supplementary Questionare handed to the patient after the exit interview

Name: _____

Age: _____ Sex: _____

1. Which is more aesthetically acceptable?
   Alin ang mas maganda tingnan?
   cNGT _____ mNGT _____ equivocal/pareho lang _____

2. Which tube is easier to use when feeding?
   Alin ang mas madali gamitin sa pagkain?
   cNGT _____ mNGT _____ equivocal/pareho lang _____

3. Which has more occurence of nasal pain?
   Sa aling klase ng NGT mas matindi ang naramdaman na pananakit ng ilong?
   cNGT _____ mNGT _____ equivocal/pareho lang _____

4. Which is more comfortable to use?
   Alin ang mas komportable gamitin?
   cNGT _____ mNGT _____ equivocal/pareho lang _____

MODIFIED NASOGASTRIC TUBE INSERTION

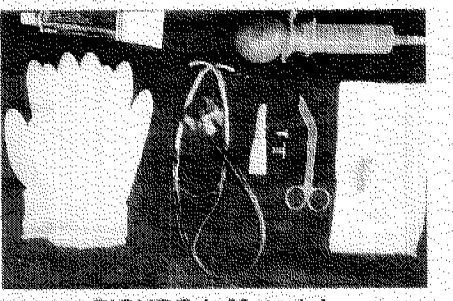

FIGURE 1: Materials

FIGURE 2: Measurements

FIGURE 3:
Attachment of the Connector

FIGURE 4:
Attachment to the Connector

FIGURE 5:
Confirmation

FIGURE 6:
Modified NGT

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HEAD AND NECK ABSCESSES: CASE SERIES IN A TERTIARY HOSPITAL*

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BENJAMIN S.A. CAMPOMANES JR., MD, FPSO-HNS***

ABSTRACT

OBJECTIVES: The aim of this study is to profile the cases as to areas involved, bacteriology and clinical course based on different treatment options and to evaluate the results of existing management protocol

DESIGN: Case series

SETTING: Tertiary medical center

PATIENTS: 112 patients with head and neck abscesses treated from January to October 2000.

RESULTS: Abscesses usually involved the dentoalveolar area (44%), peritonsillar abscess (20%), subperiosteal abscess (12%), neck areas (8%), parotid glands (4%), nasal septal abscess (3%), retropharyngeal (2%), submandibular (2%), nasolabial (2%), mandibular (1%), submental (1%), preauricular sinus abscess (1%). The most common pathogens isolated were Pseudomonas sp. (28%) and Staphylococcus aureus (16%), Branhamella catharralis (16%), Klebsiella (12%) non-hemolytic streptococcus (12%) α- hemolytic streptococcus (12%), Proteus vulgaris (4%) and Proteus mirabilis(4%). There was no culture growth in 24%. Treatment of head and neck abscesses consists of good physical diagnosis, empiric antibiotic therapy that covers gram-negative and β-lactamases-producing organisms as well as gram-positive organisms and anaerobes, and surgical intervention in the form of incision and curettage, when indicated.

CONCLUSION: There are different sites involved in head and neck abscess, with a variety of bacteriology. Initial empiric antimicrobial therapy should include β-lactamase-stable drugs that are effective against gram-positive, anaerobic, and gram-negative pathogens. Surgical intervention when indicated assured of a successful result.

KEYWORDS:

INTRODUCTION

Abscesses in the head and neck are very common problems encountered in the practice of otorhinolaryngology- head and neck surgery, especially in a third world country like the Philippines. A review of these cases was done to determine the causes, the bacteriology and the clinical course based on the different treatment options available. It is the aim of this paper to profile the cases as to areas involved, bacteriology and clinical course based on different treatment options and to evaluate the results of existing management protocol.

METHODS

A review of the medical records of patients with head and neck abscesses admitted to the East Avenue Medical Center, Department of Otorhinolaryngology-Head and Neck Surgery during the period of January to October 2000. The variables under study included the demographic profile, sites of the abscesses, bacteriologic cultures, initial signs and symptoms, treatment options (medical vs. surgical), complications and treatment outcomes (length of hospital stay, condition at time of discharge, and mortality rate.

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RESULTS

In the review of records, 112 patients with head and neck abscesses were included in the study. Sixty-one patients (54%) were male and the fifty-one patients (46%) were female. The mean age was 30 years (SD= 5.5), with a range from nine months to 67 years. The age distribution is shown in Table 1.

Table 1. Showing the age distribution of 112 patients with head and neck abscess

	AGE	NO. OF PATIENTS	(%)
Pediatric	0-14	36	32
Eary Adult	15-40	63	56
Late Adult	41-59	9	8
Elderly	60	4	4

The abscesses classified as to site, is seen in table 2. The most common site of the occurence was dentoalveolar area at 44%, followed by peritonsillar abscess at 20%, and subperiosteal abscess 2°to Chronic Otitis Media at 12%. The other sites were less common: neck (8%), parotid (4%), nasal septum (3%), retropharyngeal(2%), submandibular (2%), nasolabial (2%), mandibular (1%), submental area and preauricular sinus both at 1%.

Table 2. Showing the anatomic site of head and neck abscess in 112 patients

Anatomic site	Total	(%)
Dentoalveolar abscess	49	44
Subperiosteal abscess	22	20
Neck area	14	12
Parotid	9	8
Nasal Septum	5	4
Retropharyngeal	2	2
Submandibular	2	2
Nasolabial	2	2
Mandibular area	1	1
Submental area	1	1
Preauriular sinus	1	1
Total	112	100

Table 3 shows the initial signs and symptoms when the patient is usually seen at the emergency room or the outpatient department. About 62% of the patients had moderate to high-grade fever. Majority of the patients had an initial symptom of toothache (40%). Patients with dentoalveolar abscess tend to complain of the symptoms as early as 5 days prior to consult in patients before having the other symptoms of trismus (40%), chin swelling (36%) and face swelling (27%).

Table 3. Showing the initial signs and symptoms of 112 patients with head and neck abscess

Signs and Symptoms	No. of Patients	(%)
Fever	70	62
Toothache	45	40
Trismus	45	40
Pain	40	36
Chin swelling	40	36
Face swelling	30	27
Odynophagia	22	20
Dysphagia	22	20
Difficulty of breathing	4	4

Treatment modalities are shown in Table 4. In patients in the pediatric age group with dentoalveolar abscess, incision and drainage with dental extraction was done in 28% of cases. Patients that presented with subperiosteal abscess due to chronic otitis media had all underwent incision and drainage and mastoidectomy. Only 3% of patients with peritosillar abscess had needle aspiration and interval tonsillectomy, inspite of the history of recurrent episodes in half of the patients. All patients received intravenous antibiotics on admission. A combination of Penicillin G and Metronidazole was given to patients with dentoalveolar abscess. Patients with neck abscess mainly due to skin infection received Cloxacillin. Patients with serious infections like subperiosteal abscess with chronic otitis media received Ceftriaxone, Ceftazidine, imepenen and piperacillin. A patient with retropharyngeal abscess that died received Ciprofloxacin, Amikacin, Rifampicin, PZA, Streptomycin.

Patients with serious infections were referred to the infectious service of the medicine department. Patients received intravenous antibiotics on an average of 7 days. The range of hospital day stay was 4 – 19 days (ave. 5.8 days).

Surgical intervention on patients that underwent I & D had 95% success rate of obtaining yellowish purulent material, of the 22 patients with peritonsillar abscess, 10 underwent needle aspiration with no pus found in 7 patients, a success rate of 35%. All other patients received antibiotics alone. About 20% of all patients had repeated I & D.

Table 4. Showing the treatment modalities of 112 patients with head and neck abscess

Treatment modalities	DAA	Peri tonsillar	Retro-pharyngeal	Neck/ Mand.	Nasal	Naso-labial	Parotid	SPA	Total	(%)
Antibiotics only	8	12	0	4	0	2	3	0	29	26
Antibiotics +DE	10	0	0	0	0	0	0	0	10	9
I & D	0	0	2	9	4	0	2	0	17	15
I & D+DE	32	0	0	0	0	0	0	0	32	28
NA	0	7	0	0	0	0	0	0	7	6
NA+IT	0	3	0	0	0	0	0	0	3	3
I & D + M	0	0	0	0	0	0	0	14	14	13
Total	50	22	2	13	4	2	5	14	112	100

DE = Dental extraction
I & D = Incision and Drainage
NA = Needle aspiration
IT = Interval tonsillectomy
M = Mastoidectomy
SPA = Subperiosteal abscess

Bacteriology

Only twenty-five patients out of 112 had bacteriologic culture examination. Shown in Table 6, the most frequently identified organism was Pseudomonas (28%), Staphylococcus aureus (16%), Branhamella catharralis (16%), Klebsiella (12%), non-hemolytic streptococcus (12%), α - hemolytic streptococcus (12%), Proteus vulgaris (4%), and Proteus mirabilis (4%). There was no growth in 24%. Majority of patients have multiple causative organism with one patient having heavy growth of Pseudomonas had +2 on Acid fast bacilli stain.

Table 5. Microbiologic profile in 112 patients.

Organism	No. of Cases	(%)
Pseudomonas aeruginosa	7	28
Staphylococcus aureus	4	16
Branhamella catharralis	4	16
Klebsiella	3	12
Non-hemolytic Ste.	3	12
*α-hemolytic Strep.	3	12
Proteus vulgaris	1	4
Proteus mirabilis	1	4
No growth	6	24

Patient Outcome and Complications

Majority of patients that had incision and drainage due to big abscesses and received IV antibiotics, had resolution of initial signs and symptoms of fever and swelling within 2-3 days; trismus after about 4-5 days. The two patients who had retropharyngeal abscesses required incision and drainage under general anesthesia. One patient had a repeat of the incision and drainage after one week. The mortality rate was 2% or 4 patients out of 112. The first case had deep neck abscess; the second was an immunocompromised patient with retropharyngeal abscess; the third had dentoalveolar abscess with sepsis and the fourth was a patient with subperiosteal abscess due to chronic otitis media that had intracranial complication of brain abscess.

DISCUSSION

This paper covers a broad spectrum of head and neck infections and also included a big age group, which however yielded, Clinically important information concerning the disease process of head and neck abscess. In a study of Ungkanont et al[2] they emphasized the importance of imaging modalities like CT-SCAN, to differentiate abscesses vs. cellulitis/adenopathy. The financial difficulties of the patients prevented the request for additional examinations. The patients with retropharyngeal abscess had soft tissue radiographs of the lateral neck, in which it confirmed the diagnosis and findings of narrowing at the second cervical vertebra, posterior pharyngeal soft tissue thicker than 7 mm that is abnormal. At the sixth vertebra, tissue thicker than 22 mm in the adult or 14 mm in children was considered abnormal[6].

Pseudomonas aeruginosa, a gram negative aerobe was the most common isolate, and this is commonly found in patients with altered host defenses[8], As the leading gram-negative isolate it may cause 30% of all infections[8].

Most commonly used antibiotics are not effective in the treatment against pseudomonas. Prevention of colonization, control of underlying disease are important factors in the treatment of this disease, Aminoglycosides (Amikacin,Gentamycin) are effective[8].

This relatively high incidence of gram-negative organisms (28%) has implications for the choice of empiric antibiotic therapy during head and

neck infection. Antibiotics covering gram-positive, anaerobic, gram-negative, and β-lactamase-producing organisms should be selected for empiric therapy pending more specific culture and sensitivity results.

Penicillin alone is inadequate. In this review majority of the patients responded to combination of Penicillin G with Metronidazole those who could afford other antibiotics received Clindamycin IV. Fairbanks[5] lists clindamycin as the drug of choice for peritonsillar abscess.

Other patients had only superficial abscesses, Incision and drainage with antibiotics were enough. Patients with dentoalveolar abscess, they had incision and drainage with dental extraction.

All of the patients who died were immunocompromised: two underwent tracheostomy so airway was secured however patient succumbed to sepsis and the other had extension of infection to the mediastinum; one patient with subperiosteal abscess with chronic otitis media eventually had brain abscess which was the cause of the patients demise, the one with dentoalveolar abscess had extension of the infection to the deep neck and eventually sepsis was noted

CONCLUSION AND RECOMMENDATION

Head and neck abscesses are fairly common in the practice of otorhinolaryngology-head and neck surgery, and it affects a wide variety of anatomic sites. It is highest in the early adulthood (15-40 years old). The most common isolate was Pseudomonas aeruginosa (28%), followed by gram positive Staphylococcus aureus (16%) equal to Branhamella catharralis, while 24% had no growth. Initial empiric antimicrobial therapy should include β-lactamase-stable drugs that are effective against gram-positive, anaerobic, and gram-negative pathogens. Surgical intervention when indicated assured of a successful result.

In this review many of the diseases are preventable diseases that can be cured immediately without any hospital stay if early identification was done. One of the mortality was due to dentoalveolar abscess, a person dying from an infected tooth. Public health education can never be too emphasized, specifically on proper hygiene and when to go to a physician for treatment.

Figure 1. Showing the patient with Subperiosteal abscess with chronic otitis media, after incision and drainage.

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DELAYED SPLIT DELTOPECTORAL FLAP RECONSTRUCTION OF IRRADIATED FULL-THICKNESS DEFECT OF THE CHEEK*

ARVIN L. DE JESUS, MD**
GIL M. VICENTE, MD***

ABSTRACT

OBJECTIVE: This article aims to relate our experience with the delayed longitudinally-split deltopectoral (DP) flap used on our patient with an irradiated through-and-through defect of the cheek.
DESIGN: Case Report
SETTING: Tertiary Government Hospital
PATIENT: Fifty-four-year-old-male
RESULT: A fifty-four-year-old-male with full-thickness defect of the right cheek resulting from previous surgery is presented. He underwent wide external beam radiation pre- and postoperatively. The defect was reconstructed using a delayed longitudinally split deltopectoral flap. Four months after the operation, the patient is doing well and is satisfied with the reconstruction.
CONCLUSION: The delayed longitudinally split deltopectoral flap is found to be a simple, safe, reliable and cosmetically acceptable technique for reconstruction of an irradiated full-thickness defect of the cheek. The authors recommend the modified flap for similar cases.

INTRODUCTION

Most cancers of the maxilla can be surgically removed. The defect is usually closed primarily or with a simple technique of repair.[1] However, advanced tumors especially those involving the skin may create large through-and-through defects of the buccal mucosa and cheek. These defects are challenging reconstructive problems because of the simultaneous need for intraoral lining and external coverage.[1,2]

As the combined approach of radiation and operation becomes popular as treatment for maxillary carcinoma with involvement of the skin, we are faced with the need to reconstruct in an irradiated field. Any form of reconstruction must deal with an environment of fibrotic tissue and inadequate blood supply. In this situation, undisturbed tissue must be brought in from nonradiated region in the form of a graft or pedicle flap.[7] In addition, the reconstruction must be functional, reliable and cosmetically acceptable.[2]

Most authors found the medially based deltopectoral (DP) flap introduced by Bakamjian[8] as the most useful for cheek reconstruction.[2,3,4,7,8,11] This flap is widely accepted because of its reliability, availability and effective length.[2] The flap is relatively free of hair and less bulky.[10]

Through the years, the flap has been expanded from the anterior to the posterior deltoid line and eventually down the arm with the addition of various paddles. However, such complications as flap necrosis, marginal separation and fistula formation have been reported.[5] Hence, further modifications of flap design and delay procedure are suggested for a specific clinical condition.

Theoretically, longitudinal splitting of a DP flap is safe, as regards the vascularity of the tip of the flap.[10] Daniel et *al* [5] reported the use of "split" DP flap for immediate reconstruction of both cheeks and lower lip. This was proven to be an effective technique. There was no reported case that this type of DP flap modification was used for reconstruction of full-thickness defect of the cheek with history of radiation.

This article aims to relate our experience with the delayed longitudinally-split deltopectoral (DP) flap used on our patient with an irradiated through-and-through defect of the cheek.

*Presented, PSO-HNS Poster Session on Surgical Innovation, November 30, 2000, Punta Baluarte, Calatagan, Batangas
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SURGICAL TECHNIQUE

The skin of the right cheek was marked. The mass and the indurated skin were excised with two-centimeter margins. This resulted to a circumferential full-thickness defect measuring 5 x 6 centimeters (Figure 1). The remaining walls and mucosa of the maxillary antrum as well as the nasal cavity and septum were free of tumor remnants. The defect was packed with antibiotic-laden gauze.

The landmarks for the DP flap were identified and marked. The base of this rectangularly shaped flap was situated parasternally over the first three or four intercostal spaces. The upper margin was a straight line along the lower border of the clavicle, extending from the region of the sternal head to the acromioclavicular joint prominence on the shoulder. The inferior margin was placed at about two or three fingerbreaths above

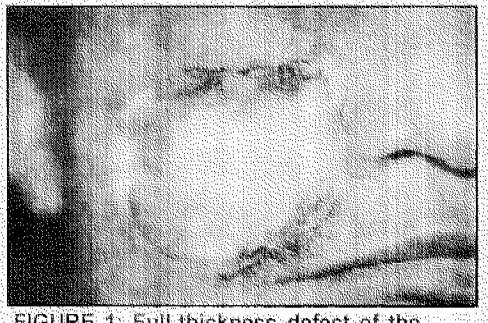

FIGURE 1: Full-thickness defect of the cheek following resection of the skin and tumor.

FIGURE 2: Outline of deltopectoral flap to be raised

the nipple and was passed to the deltoid region at the apex of the anterior axillary line. The tip was curvilinear (Figure 2). Preparation of the DP flap for delayed reconstruction was done by complete sharp incision along the margins of the flap. The incision was carried down to the fascia covering the pectoralis muscles. The flap was elevated using knife dissection. The dissection was continued medially. After completely elevating the flap, the skin paddle was returned to the donor site. Light dressings were employed. One week later, the margins of the defect were examined histologically for any residual tumor.

On the twentieth postoperative day, the patient underwent second- stage reconstruction.

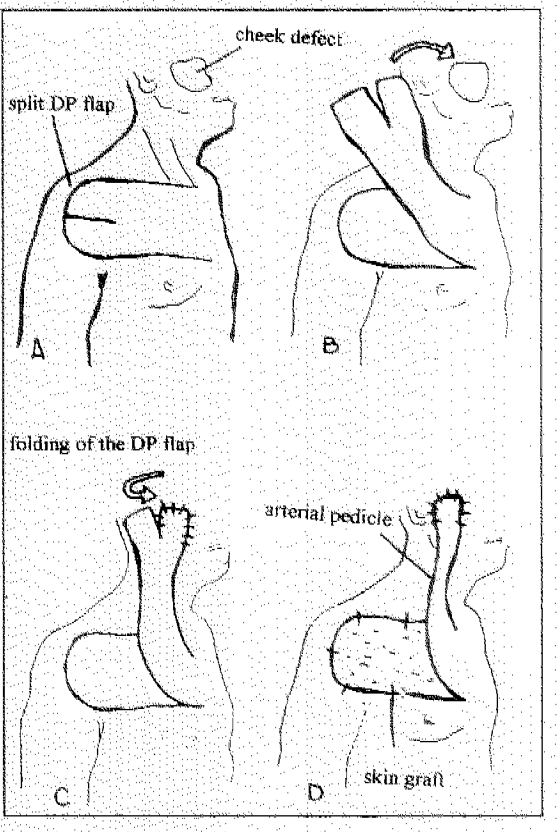

FIGURE 3: A folding of longitudinally split DP flap.
A. Incisions defining the margins of the DP flap
B. Elevation of the split DP flap
C. Closure of the mucosal lining using the first skin paddle
D. Closure of the outer covering using the second half of the paddle

The flap was elevated by sharp dissection along the plane deep to the fascia covering the pectoralis major and deltoid muscles. Dissection was continued medially near the origin of the perforating branches of the internal mammary vessels. The tip of the flap was split longitudinally into two equal parts and folded on itself (Figure 3). The first skin paddle was sewn to the posterior intraoral margin and laid in place providing intraoral lining. The second half of the skin paddle was sutured to cover the external defect (Figure 4). A few more sutures continue the seam, ending at a fistulous outlet where the flap enters the cheek. Proximally the carrier portion of the pedicle was tubed with its epithelial surface outermost as it spans over the neck to reach the cheek defect (Figure 5). The donor site was covered with split-thickness skin graft from the anteromedial aspect of the right thigh. Prior to closure, the operative sites were irrigated with iodine and sterile saline. A nasogastric tube was introduced through the nostril opposite to the side of operation. The neck was kept in a slightly flexed position and in the direction of the defect by placing check sutures from the chin to the shoulder. Dressings were applied to give moderately firm compression

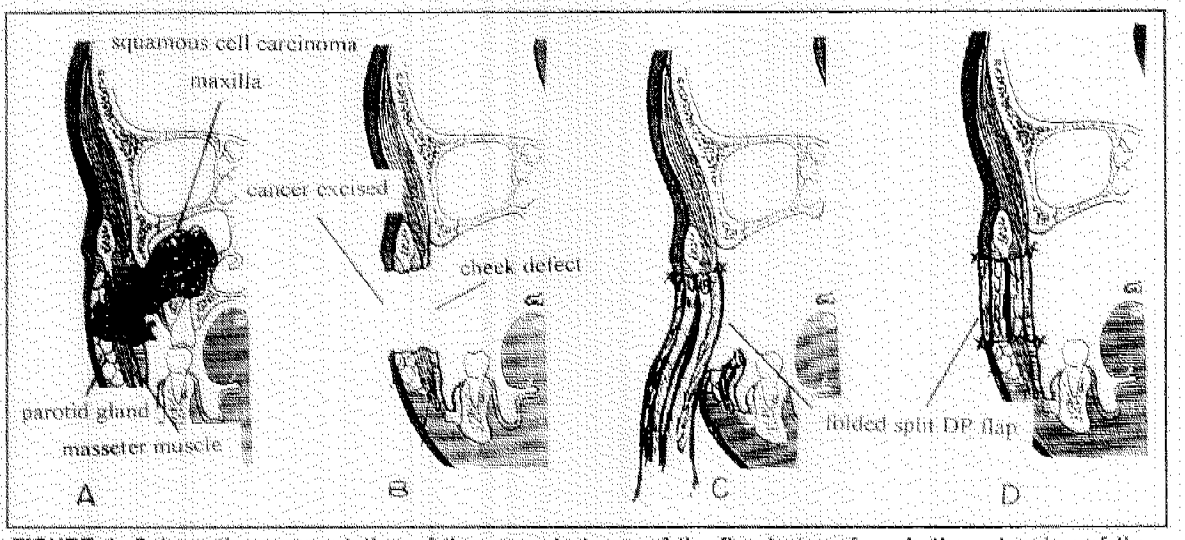

FIGURE 4: Schematic representation of the several stages of the flap in transfer. A. the extension of the tumor, B. the direction of the defect after resection of the mass, C. Folded split DP flap sutured to the cheek defect, D. the subsequent return of the bridge or pedicle with closure of the inner and outer lining of the cheek.

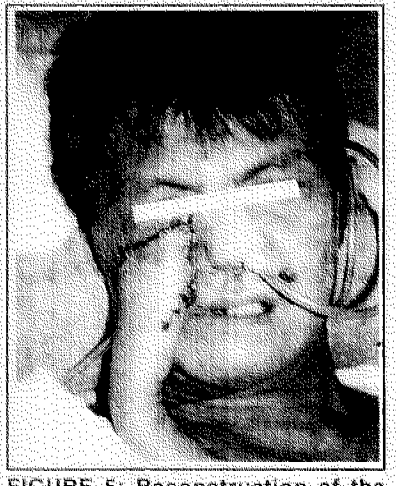

FIGURE 5: Reconstruction of the cheek defect showing the arterial pedicle. The donor site is covered with split-thickness skin graft.

FIGURE 6: Transection of the pedicle.

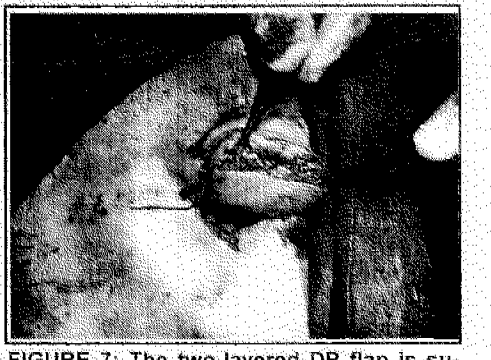

FIGURE 7: The two-layered DP flap is sutured in position to close the orocutaneous fistula providing the intraoral lining and outer covering of the cheek.

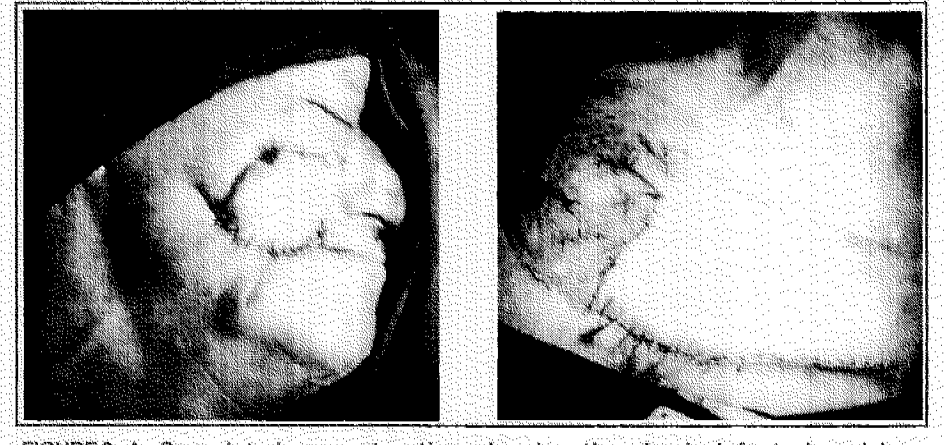

FIGURE 8: A. Completed reconstruction showing the cheek defect closed by the split DP flap
B. The unused portion of the DP flap is returned to the right chest wall.

in the area of the maxillary defect.

The pedicle of the flap was transected two weeks later (Figure 6). The two-layered DP flap was sutured in position to close the orocutaneous fistula providing the intraoral lining and outer covering of the cheek(Figure 7). The unused portion of the flap was returned to its original position on the chest wall. This left the anterior aspect of the shoulder as the only area covered with grafted skin, where it was relatively inconspicuous and functionally harmless (Figure 8).

PRESENTATION OF THE CASE

JC is a 54-year-old male who was admitted for the first time in our institution because of a 3-year history of a mass in the right maxillary area. The patient was a known case of squamous cell carcinoma of the right maxilla. Radiotherapy at 40 Gray via external beam radiation was given to the patient for 20 days. He underwent partial maxillectomy in a provincial hospital. Postoperative radiation therapy was delivered to the primary area (40 gray external beam radiation). However, a few months after the operation, the patient noted recurrence of the mass in the maxilla. He was subsequently referred and admitted in our institution.

The patient underwent wide excision of the maxillary mass with revision maxillectomy. This resulted to a circumferential full-thickness defect of the cheek measuring 5 x 6 centimeters. Incisional outlining with elevation of the skin paddle of DP flap for delayed reconstruction was done. Margins of resection were examined histologically for presence of tumor residual. On the third week, elevation and closure of the cheek defect was done using the longitudinally split DP flap. Split-thickness skin graft from the anteromedial aspect of the thigh was applied to the donor site. Minimal infection had developed on the fifth postoperative day. Debridement was done. Additional antibiotics were given resulting to subsequent resolution of the infection. The pedicle of the DP flap was amputated on the third week. There were no evidences of flap failure, leaks or fistula formation. He was discharged improved four weeks later. Four months after the operation, the patient is doing well and is satisfied with the reconstruction.

DISCUSSION

Various techniques for the reconstruction of full-thickness cheek defects have been used.[1,2,3] Earlier cases were managed by migrated random flaps for external coverage with split- thickness skin grafts for mucosal lining.[3] However, occasional occurrences of partial flap necrosis were noted because of the unreliability of the vascular supply. McGregor *et al* [4] suggested that a flap be used to secure a watertight intraoral closure while a skin graft could be used to complete external coverage. Intraoral lining can also be obtained with simultaneous use of two flaps.[2,5]

The use of temporal flap heralded the concept of axial vessel in cheek reconstruction.[2,3,6] It is one of the most versatile flaps for reconstruction.[6] The only disadvantage of using this flap is that it leaves an area of visible disfigurement on the forehead. The development of microvascular techniques has made feasible the transfer of tissue to a second site in a single procedure.[2] However, it should only be used in highly selected instances when less complicated and more reliable flaps cannot be used.

The choice of reconstructive techniques has evolved with our understanding of the vascular anatomy of the flaps.[2, 5] These accounts for the markedly different characteristics of length-width ratio needed for delay flap design and other factors in the use of flaps. Modification of flap design and delay procedure is suggested for specific situations.[5,9,10,11]

Clinically, DP flap comprises 3 confluent skin vascular territories. It is primarily an axial-vasculature flap (the large pectoral area), with variably sized random-vasculature flap extension (the deltoid area). At the upper part of the watershed (the deltopectoral groove) is a small area supplied by a direct cutaneous vessel, the terminal branch of the thoracoacromial artery (Figure 9). For the DP flap to survive, the three vascular regions must

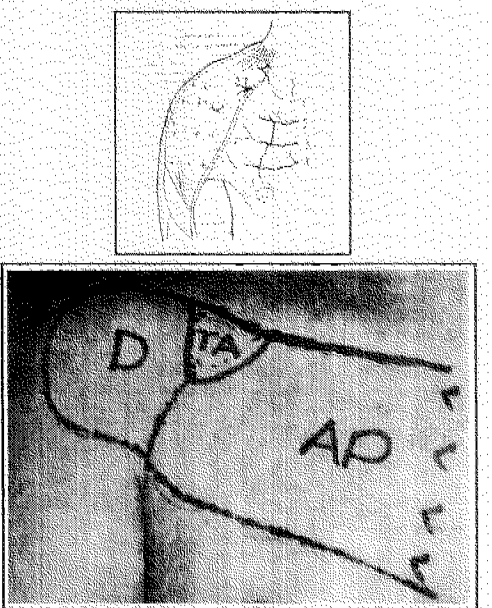

FIGURE 9: Vascular anatomy of DP flap (left) The vascular anatomy of the thoracic region. (right) Anatomical subdivision of the DP flap into three vascular areas by three different sets of vessels: anterior thoracic perforators (AP); thoracoacromial artery (TA); deltoid musculocutaneous arteries (D)

be "fused" and rendered solely dependent upon the anterior thoracic perforators.[5,10]

For reconstruction purposes, one can expect that the distal portion of the flap will be increasingly tailored to fit the facial defect. Many authors previously used folded flaps to cover facial defects.[2,4,5,6] Bunkis *et al*[2] employed folded random pedicle to close the mucosal cheek defect. The forehead flap was turned upon itself by Kavarana[6] for buccal defect. This left the patient with an obvious donor-site deformity. Others tried folding the tip of the DP flap by increasing the length of the flap leading to ishemic necrosis of the part beyond the kink.[10]

It is important to know that the terminal part of the flap requires special attention to details, such as the avoidance of infection and hematoma formation and the prevention of kinking, tension and angulation. Folding the tip further aggravates the diminished blood supply of the lateral cutaneous portion by compromising the medial arterial pedicle. McGregor *et al*[4] suggested L-shaped extension of the tip for a bigger defect but like the forehead flap, this could result to an obvious donor-site deformity.

Studies have demonstrated that a decrease in width would not decrease the surviving length of the flap provided the vascular base was not violated.[5,10] Longitudinally splitting the tip of the DP flap will not compromise the vascular anatomy of the length of the flap. We can fold the skin paddles on themselves to cover the two linings without affecting the medial arterial pedicle.

For cases with irradiated field, delaying the flap is also advisable.[7] The flap can be totally elevated with preservation of its arterial pedicle and returned to its bed.[9,10,11] The standard rationale is, of course, to improve blood flow through the intended base of the flap, stimulated in one or more stages by cutting off to critical levels the circulation into and out of the flap via parts other than its base.

In summary, the use of the delayed longitudinally split DP flap is remarkably safe. It diminishes the danger of compromised vascular supply by conditioning the random part of the flap and maintaining the arterial pedicle intact. Complications like infection and marginal separation may arise which can be prevented by proper postoperative management of the flap. Other potential hazards like kinking of the pedicle or tension may be avoided by adequate immobilization of the head by check sutures of the chin to the shoulder.

CONCLUSION

The modified longitudinally split delayed DP flap is a simple, safe, reliable and cosmetically acceptable technique for reconstruction of irradiated through-and-through defects of the cheek. The authors recommend this procedure for similar cases.

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INTERMAXILLARY FIXATION USING MODIFIED WIRING TECHNIQUE

PETER B. MIGUEL, MD**
FERDINAND G. PAMINTUAN, MD, FPSO-HNS***

ABSTRACT

Intermaxillary fixation (IMF) is the procedure for immobilization and stabilization of fractures involving mandible and maxilla. There are several methods of doing IMF. It varies depending on the indications and status of the dentition and preference of the surgeon. The most common and preferable way is by using Erich arch bars. Despite its effectiveness, there are problems with its availability and increasing price. This study presents a modified way of doing IMF that is comparable to Erich arch bars in its safety, efficiency, but lower in cost and readily available.

INTRODUCTION

Fractures or traumatic injuries to mandible and maxilla requires initial stabilization prior to definitive procedure. Other mandibular fractures can be treated with immobilization and stabilization methods of Intermaxillary fixation (IMF) alone[1]. The most common method of IMF is using stainless steel arch bars being fixed at upper and lower dentition then splinting the mandible against the maxilla by placing the arch bars with stainless steel wire. It is common knowledge among ENT specialist that placement of arch bars and metal wires is tedious, time consuming and not without complications. Recently scarcity of arch bars and consequently price increase was noted in the local setting. Therefore, this study was conceived to devise an alternative surgical approach for intermaxillary fixation that is safe, effective, lower in cost .

Description of the Procedure

Iron Ore bead selection

The iron ore beads used for this instrument is hematite. Hematite is Iron oxide (Fe_2O_3)[5]. It is relatively common iron ore with characteristic color of a blackish gray, nontransparent and with metallic luster[3]. This iron ore is highly resistant to rust and corrosion. Its durability is highly noted with hardness of 6.5 and density of 5.2 – 5.3 g/cm^3 [5]. This is found to be free of toxic effects to humans. Hematite is commercially used as polishing rouge, in red paints, and fashioned into necklace, beads or pendants[4,5,6].

Wire selection

A wire is needed to anchor the hematite beads. A size 2-0 stainless steel wire with a length of 5 inches per hematite bead is used. This surgical wire is the standard wires for various internal fixation procedures. Its tensile strength is paramount for internal maxillary fixation procedures. A separate 6-0 stainless steel wire measuring 8 inches is needed to secure the beads together. This is readily available in all dental, medical supply store and almost always available inside the operating room.

Instrument Preparation

This instrument is a simple bead that measures 5mm in circumference. It has a through and through hole from midcenter of one side to the midcenter of the opposite side. The hole is measured at 1mm diameter. A 5 inches stainless steel wire is inserted to the hole. The inserted wire

*Presented, PSO-HNS Poster Session on Surgical Innovation, November 30, 2000, Punta Baluarte, Calatagan, Batangas
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is then woven at the area halfway between holes (Figure 1A) The wire is woven to form an instrument like a pin with a head (Figure 1B) At this point the instrument is ready for IMF.

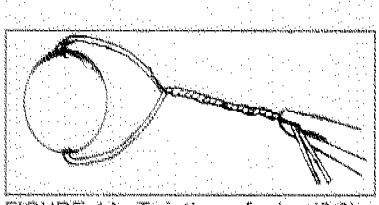

FIGURE 1A: Twisting of wire (2-0) to make a ball with a pin

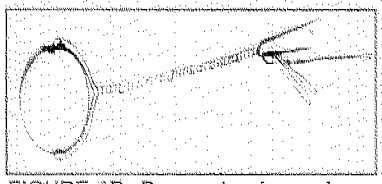

FIGURE 1B: Pre-made pin ready for use

Surgical Technique

Intermaxillary fixation can be carried out using general or topical/local anesthesia. After determining the number of preformed iron ore bead to be used, e.g. mandibular teeth, it will be interconnected by a string (6-0 wire) as one beaded string (Figure 2). The preformed wired iron ore bead which is handy and of light-weight material is inserted at the interdental space at lingual aspect exiting at the buccal side or lateral aspect (Figure 3).

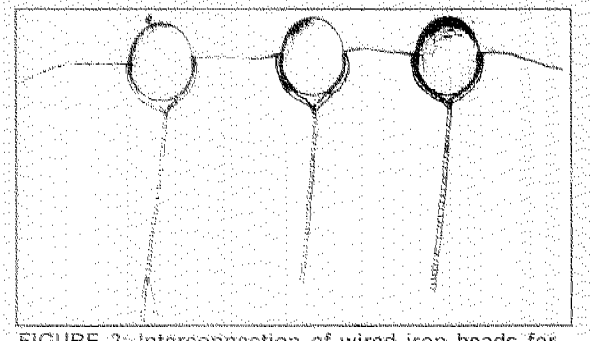

FIGURE 2: Interconnection of wired iron beads for protection

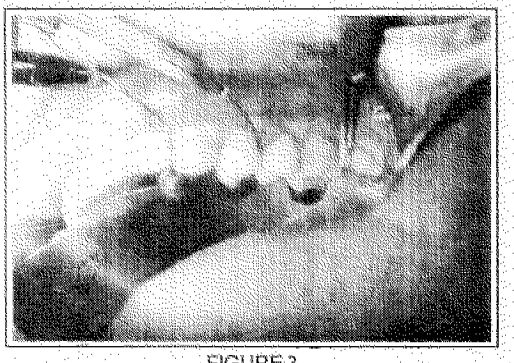

FIGURE 3

This is then pulled out to snug fit at the pit formed by interdental-gingivo-alveolar space. It is inserted in every other interdental space. Upon placement of wired iron bead in the upper and lower jaw, the assistant surgeon will fix the proper dental occlusion then approximate the mandible and maxilla against each other. At this point tightening is done by ligating/winding the wire that exit along the maxillary interdental space against the wire that exits at the mandibular interdental area in a diagonal manner using hemostat (Figure 4). The excess wire is cut off using wire cutter or heavy Mayo scissor and the remaining end is bent inwards to avoid trauma to buccal mucosa.

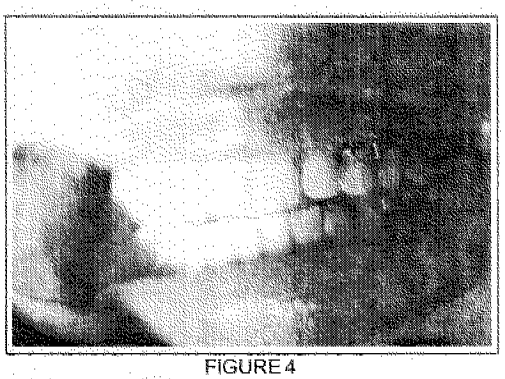

FIGURE 4

Lastly, the two ends of the stainless steel 6-0 string that interconnects each iron ore ball will be anchored at the buccal side/ lateral aspect to ensure that any accidental fall-off of wired iron ball to aerodigestive tract will be prevented (Fig. 5).

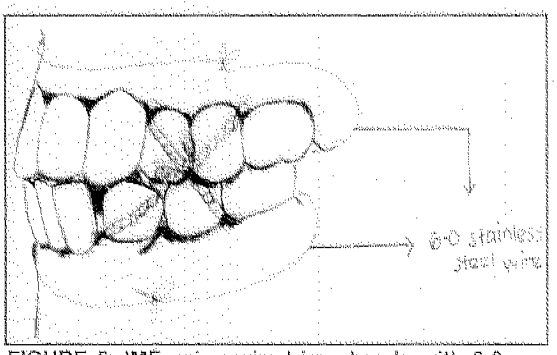

FIGURE 5: IMF using wired iron beads with 6-0 wire for anchor

DISCUSSION

The basic principles of definitive fracture management include reduction and firm immobilization of the fracture fragments and avoidance of infection at the fracture site. There are several ways to do IMF. Intermaxillary Fixation with Erich arch bars is the most common immobilization procedure done in mandibular and maxillary fractures[3]. Erich arch bars are used when a full complement of teeth are present[3]. For usual

fixation, Erich arch bars is measured then cut accordingly. It is then fixed to the upper and lower jaw by wiring it to the pre molars first on one side followed by the opposite side. Securing it is done by wiring it to other set of teeth (Fig. 6). Until both

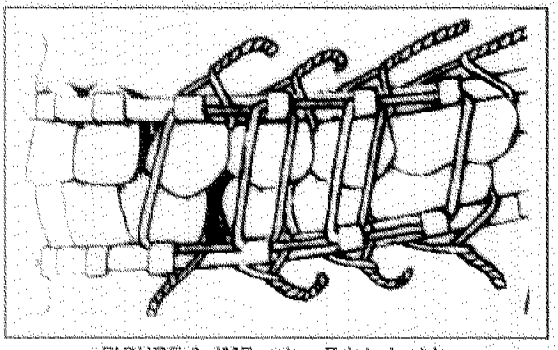

FIGURE 6: IMF using Erich Archbar

the upper and lower jaw is fixed with the Erich arch bar, immobilization of mandible against maxilla is not accomplished. Stabilization is done upon application of rubber bands or wires in the small hooks within the Erich arch bars. Other ways of doing IMF such as Ivy loops, Molar wafers, Jalenco arch bars and pre fabricated acrylic splints has its own limitations and usually unavailable in our setting.

The above preformed wired iron ball underwent trial in four cases of maxillo facial trauma in our institution. In all cases of mandibular and maxillary fracture, intermaxillary fixation is notably easy to perform because it is prepared as a pin prior to the procedure. During the fixation itself the technique is like pinning the interdental space from inside out which took only few seconds to perform. Interlocking of all the wires in diagonal fashion against upper and lower jaw took an average of 5 minutes. The entire procedure of IMF were done in 10 minutes as compared to IMF using Erich arch bars which is being done in 30-45 minutes by an average ENT/oral surgeon. During the entire procedure there was minimal trauma to the gingiva and other parts of oral cavity because wired iron ore ball is inserted only at the interdental space. Safety measures like the 6-0 wire that anchors the whole set of upper or lower wired balls is part of the design to prevent accidental fall-off to the aerodigetive tract. Fixation is also being done with out the use of archbars thus eliminating an extra cost aside from the fact that Erich arch bars is hardly available nowadays in our locality. Also, the prevailing price of it is at P 1500.00 / foot. While the iron ore (hematite) is readily available at beads shop with current price approximately P5.00 / bead. Furthermore, the lenth of dental wire to be used is much shorter with the average length of 5 inches per iron ball thereby rendering the whole procedure as cost effective.

CONCLUSION

The wired iron ore bead is an innovative oral surgery instrument that is useful and easy to use. Based on the results acquired this locally designed instrument has proven to be safe, effective, efficient and much cheaper than the conventional and commercially available instrument. Lastly, this can be an alternative to standard IMF procedure using an Erich arch bars.

Limitations of the Study

This surgical procedure cannot be done to edentulous mandible or maxilla. Moreover, in cases of intermittent TMJ movement is necessary, this method of wiring is not of choice.

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Guidelines for Authors

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All manuscripts and other editorial matter should be addressed to Charlotte M. Chiong, MD, Editor-in-chief, The PJO-HNS, PSO-HNS Office, Medical Plaza Ortigas, San Miguel Avenue, Ortigas Center, Pasig City.

Philippine Journal of Otolaryngology- Head And Neck Surgery
Volume 16 Number 4 , 2001

EDITORIAL

Working a Mission, Visioning a Future

It is an arduous task to keep the Philippine Journal of Otolaryngology-Head and Neck Surgery continue to get published despite all the financial difficulties. The previous editor in chief Dr. Lito Acuin started the work on a quarterly publication but given the increasing cost of printing, the journal fee that each fellow of the Philippine Society of Otolaryngology-Head and Neck Surgery (PSO-HNS) contributes annually can hardly support adequately this ambitious goal. We are grateful to Schering-Plough for bankrolling the first two issues of Volume 16, 2001 but the last issue had to be shouldered by the society and the P150 pesos contribution from all fellows can in reality only print one issue. We have to give credit to the past president Dr. Edgardo Rodriguez for supporting the printing despite the financial constraints related to the journal.

The mission of the PJO-HNS is to publish contemporary and clinically relevant researches in otolaryngology-head and neck surgery especially for the purpose of improving patient care and public health. As the official publication of the PSO-HNS, all researches presented in the annual interesting case, descriptive, analytical, surgical instrumentation and surgical innovation contests become eligible for possible publication. The winners in these contests are given top priority but there are equally relevant researches that are considered though thay have not been presented nor won in any of these contests. We have seen an increasing number of entries to these contests in recent years considering the fact that the number of accredited training institutions have increased four fold in the past ten years (from 6 in 1989 to 24 in 2002) and while a lot more papers could be selected for presentation in any of these fora the journal has limited funding to support publication of most of these papers.

In behalf of the editorial board, I wish to thank Solvay Pharma Philippines Inc. especially Mr. Marcus P. M. Wondergem for supporting the publication of this issue. As a pharmaceutical partner it has an unparalleled record of supporting the PJO-HNS for the most number of years (11 in all), for the most number of issues (11 out of 26) so far. It is with help like this that we are able to continue to work out this mission however difficult and vision a future filled with hope for a better PJO-HNS. Mabuhay!

CHARLOTTE M. CHIONG,MD
Editor-in-chief

SOLVAY PHARMA Inc
PHILIPPINES

April 14, 2003

Dear Doctors,

Allow us at Solvay Pharma to welcome-in the 1st issue of the PSO Journal for 2003! It gives us great pleasure to participate in this endeavor that promotes the continuing medical learning of the Philippine ENT community. Given our history in the Philippine pharmaceutical market, we have always considered the pursuit of higher learning in improving patient management and doctor practice as integral components to improving the country's general health environment.

We realize that it is not only through products that we could help improve the quality of patient life and care in the country; just equally important is the need for us to serve as conduits for doctors to further develop and heighten their knowledge and expertise. It is this two-fold belief that gives us the impetus to partake in programs with such goals.

Lastly, we would like to acknowledge the great efforts put forth by the officers of the Philippine Society of Otolaryngology- Head and Neck Surgery in continuing this tradition of sharing knowledge among its members.

On behalf of the Solvay Philippines family, allow me to wish the PSO-HNS a successful year and we all look forward to adding many more opportunities that would extend this very fruitful partnership!

Sincerely yours,

MARCUS P.M. WONDERGEM
President and CEO

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NEWBORN HEARING SCREENING USING THE EVOKED OTOACOUSTIC EMISSION: THE PHILIPPINE GENERAL HOSPITAL EXPERIENCE

MARIA RINA T. REYES-QUINTOS, MD*
PURA FLOR D. ISLETA, MD **
CHARLOTTE M. CHIONG, MD***
GENEROSO T. ABES, MD****

ABSTRACT

The evoked otoacoustic emission (EOAE) test is a universally well-known and established procedure for screening the hearing of babies during the newborn period. It has been documented in foreign literature that the prevalence of hearing loss is significantly higher in high-risk neonates. In the Philippine General Hospital, 301 high-risk neonates and 105 non high-risk neonates were screened for hearing loss using the EOAE during a period of one year from March 2000 to March 2001. The initial failure rate in the high-risk population was 33% and 11% in the non high-risk population. Very few infants were brought back for follow-up to the High-Risk Clinic to confirm the possibility of hearing loss in those with a fail or "refer" result. These issues should be addressed so that early rehabilitation for those found to have hearing loss can be implemented.

Keywords: Otoacoustic emission, newborn hearing screening, hearing loss, high-risk neonate

INTRODUCTION

Screening for hearing loss in the newborn period using either the EOAE or the automated/auditory brainstem response (AABR) test has raised the standard of care for the newborn in many hospitals in the United States, Europe and Asia. This is because studies show that hearing loss is a common disability in the newborn period[1] and that early diagnosis of hearing loss and early habilitation of the hearing impaired is possible with the rapidly advancing technology[2]. Early diagnosis and habilitation lead to improved speech and language development, educational attainment and psychological health of the individual[3], which later on may translate to a better financial situation and reliable manpower for the country. Although hearing loss is understandably more common in the high-risk population[4], 50% of children with severe hearing loss have no high-risk factors[5]. This is the reason why the American Academy of Pediatrics Joint Committee on Infant Hearing in 1990 advocated the early identification of hearing loss in children[6] and the National Institutes of Health (NIH) of the United States in 1993 also issued a consensus statement recommending **universal screening** for all infants prior to discharge[7]. Before implementing such a program, it is recommended and prudent to screen a smaller population first where the disease under scrutiny is more prevalent. This will give us an idea of the practicalities involved in starting a newborn hearing screening program in that particular hospital setting, the personnel that need to be involved and the mechanics of the procedure.

In this study we aim to determine the hearing screening initial failure rate in the high-risk and non high-risk population in the PGH NICU for a period of 1 year.

METHODS

The hearing of high-risk infants referred by the Department of Pediatrics, Section of Neonatology from March 2000 to March 2001 were screened prior to discharge by trained personnel using the evoked otoacoustic emission (EOAE) device (*Audiopath* manufactured by Welch Allyn). This particular

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instrument is fully automated with a fixed testing protocol and Pass/Refer template which can detect at least a mild hearing loss. At the same time, newborn babies, who had no risk factors (non high-risk) were also referred by their concerned pediatricians (primarily due to prematurity) and they were also screened. The neonates were tested while they were sleeping or resting quietly. There were a total of 455 neonates screened. Three hundred and one had high risk factors while 150 did not. A high-risk infant was defined as an infant with any one of the following high-risk factors (Table 1): family history of hereditary childhood sensorineural hearing loss, in utero infections (TORCH), craniofacial anomalies, birth weight less than 1500 g, hyperbilirubinemia requiring exchange transfusion, use of ototoxic medication, bacterial meningitis, Apgar score of 0-4 at 1 min or 0-6 at 5 min, mechanical ventilation of 5 days or longer, stigmata associated with a syndrome known to include sensorineural and or conductive hearing loss. A "pass" result was recorded for an ear which showed a signal-to-noise ratio of 10 dB with an averaged noise floor value of –20 dB before the maximum number of samples collected equals 500 and a failure or "refer" result was recorded when the 10 dB signal-to-noise ratio was not achieved. All the high-risk infants who "referred" on initial screening were advised to follow-up for a repeat screening (re-screen) at least 1 month after discharge.

TABLE 1
High Risk Registry: JCIH 1994

- Family history of hereditary childhood sensorineural hearing loss.
- In utero infection (e.g., TORCH).
- Craniofacial anomalies.
- Birthweight < 1500 g.
- Hyperbilirubinemia at serum level requiring exchange transfusion.
- Ototoxic medication including but not limited to the aminoglycosides used in multiple courses or in combination with loop diuretics.
- Bacterial meningitis.
- Apgar scores of 0-4 at 1 min or 0-6 at 5 min.
- Mechanical ventilation for greater than or equal to 5 days.
- Stigmata or other findings associated with a syndrome known to include sensorineural and / or conductive hearing loss.

RESULTS

A total of 455 infants were referred for screening. Three hundred and one of these neonates had the high-risk factors and 150 did not. For the high-risk population, 100 infants (33%) "referred" for both ears, (155) 52% "passed" the screen for both ears, and 15% "passed" in only one ear (and "referred" on the other) (Table 2).

TABLE 2
EOAE "Pass" and "Refer" rates in the High-Risk Population

Both ears "Referred"	100	33%
Both ears "Passed"	155	52%
"Pass" / "Refer"	46	15%
Total	301	

For the non high-risk population, 116 infants (77%) "passed" the screen for both ears, 16 (11%) "referred" and 18 (12%) "passed" in only one ear (Table 3).

TABLE 3
EOAE "Pass" and "Refer" rates in the Non High-Risk Population

Both Ears "Referred"	16	11%
Both Ears "Passed"	116	77%
"Pass" / "Refer"	18	12%
Total	150	

Out of the 180 newborns with at least one ear "referring" only 15 (8%) followed up in the High Risk Clinic. In 12 of these neonates who "referred" for both ears initially, 9 (75%) "passed" for both ears on re-screen, 1 (8%)"passed" for one ear only and 2 (15%) still "referred" for both ears. Three neonates of the 15 who followed up at the High Risk Clinic "referred" in only one ear and on retest 100% "passed" for both ears (Table 4). None of the non high-risk newborns who referred in at least 1 ear followed-up in the High Risk Clinic for re-screening.

TABLE 4
OPD Re-screen results in 15 Infants who Initially "Referred" in at Least One Ear

Initial Screen Result	Re-screen Result	Total
Both Ears "Refer"	Both Ears "Pass"	9
	Both Ears "Refer"	2
	"Pass"/"Refer"	1
"Pass"/"Refer"	Both Ears "Pass	3
		15

DISCUSSION

The use of the EOAE for screening for hearing loss in the newborn period is recognized and accepted worldwide. It has a sensitivity of almost 100% and a specificity of greater than 93%. Prevalence of hearing loss in the newborn period

has been documented to be about 1-3:1000 and in the high-risk population it is 2-4:100. Foreign literature has documented a 5-27% overall initial failure rate using the EOAE in newborn hearing screening. In our study, the initial failure rate in the high-risk population is 33% and 11% in the non-high risk population. It must be remembered that the EOAE test just like other hearing tests can be affected by environmental noise, internal noise (chewing and jaw movements, noisy breathing) and debris and fluid in the ear canal and middle ear respectively resulting in false positive results[8]. The 9 out of 12 babies who "referred" on both ears on initial screening and then "passed" on both ears on follow up gives us an idea that the prevalence rate is probably lower than calculated. Reasons for the high failure rate in this study include, first, the Philippine General Hospital is a tertiary hospital where the disadvantaged and very sick children are born. The population itself, then, is comprised of neonates who are malnourished and underweight so that even after they are discharged it may take them some time to regain their health. Second, the Neonatal Intensive Care Unit (NICU), which keeps more than 40 babies at one time, is a noisy place. The machines responsible for monitoring these babies constantly make noise, the babies themselves cry and the NICU staff also adds to the noise while doing their work. These are the factors that may be responsible for the increased failure rate in the PGH NICU. The number of babies who followed-up for repeat screening was very disappointing. A registered nurse was tasked to call and/or telegram patients for follow –up and despite these arrangement, very few returned for re-screen. This may be because the PGH is a tertiary government hospital and patients come from far flung areas, have no permanent residence and have no access to modern telecommunication devices. Out of the 180 babies who "referred" in at least one ear only 15 (8%) of the babies followed-up. The success of any screening program that will be implemented is dependent upon the babies who are followed-up, confirmed to have hearing loss and then habilitated. Screening is useless if those who are suspected to have hearing loss are lost to follow-up.

CONCLUSION

The newborn hearing screening initial failure rate using the EOAE in the high risk and non-high risk population are 33% and 11%, respectively. The high failure rate and the poor turn out for re-screening to confirm the presence of hearing loss should be addressed so that immediate habilitation can be implemented.

RECOMMENDATIONS

1. It is recommended that newborn hearing screening be done during the high-risk infant's first follow-up (after discharge) until such time when high failure rates in the PGH NICU can be minimized.
2. Building a soundproof room in the NICU where the infants can be wheeled in for the hearing screening will be beneficial in decreasing environmental noise and decrease the initial failure rate.
3. The importance of newborn hearing screening prior to discharge must be disseminated to encourage parents to bring their children for follow-up.
4. Finding other means to screen for hearing loss so that infants who live far from the metropolis and without access to this new technology may have the re-screen done in their place of residence.

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