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Surgical treatment for chronic ear disease improved the quality of life in patients receiving care at the Mobile Ear Clinic

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- Background** : *Chronic otitis media (COM) cholesteatoma and stapes fixation are common diseases that affect people of all age groups in Thailand. Studies show that surgical treatment can clinically improve the patient's hearing. There are no studies examining quality of life (QOL) of pre- the patients undergoing ear surgeries.*
- Objective** : *To assess whether ear surgeries in the mobile ear clinic can improve QOL.*
- Design** : *Prospective questionnaire study.*
- Setting** : *Mobile Ear Surgery Unit, Sakaeo Hospital.*
- Materials and Methods** : *Thirty - five patients undergoing ear surgeries for COM cholesteatoma and stapes fixation were recruited from 1 – 4 July 2008. Post-operative otoscopic examinations were administered on weeks 1, 2, 4 and 24. Audiograms were conducted on weeks 0 and 24. SF-36 questionnaire, a Thai version on quality of life questionairs was administered at weeks 0 and 24 to assess QOL of the patients.*

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- Results** : *The result showed a significant improvement in all dimension of QOL regarding: physical health (pre - surgery 52.8%, CI 45.7 - 59.8; post - surgery 72.8%, CI 66.1 - 79.5; $P < 0.001$), mental health (pre - surgery 56.9%, CI 50.2 - 63.6; post - surgery 76.3%, CI 70.4 - 82.3; $P < 0.001$), physical functioning ($P < 0.0001$), role - physical limitation ($P = 0.0001$), bodily pain ($P = 0.0046$), general health ($P < 0.0001$), vitality ($P = 0.0001$), social function ($P = 0.003$), role emotion limitation ($P = 0.0001$) and mental health ($P = 0.0007$).*
- Conclusion** : *Ear surgeries can significantly improve QOL in patients suffering with COM cholesteatoma and stapes fixation.*
- Keywords** : *Quality of life (QOL), SF-36, Tympanoplasty, Mastoidectomy, Stapedectomy, Audiogram, Mobile surgical ear.*

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- บทนำ** : โรคหูน้ำหนวกเรื้อรัง โรคหูรื้อรังร้ายแรง และโรคกระดูกหูพิการ เป็นโรคหูที่เกิดขึ้นกลางที่พบได้บ่อยและมีพบได้ในทุกช่วงอายุ การผ่าตัดเยื่อแก้วหู หูชั้นกลางและมาสตอยด์สามารถและการผ่าตัดใส่กระดูกหูเทียม ทำให้การได้ยินของผู้ป่วยดีขึ้น แต่ยังไม่เคยมีการศึกษาเกี่ยวกับคุณภาพชีวิตของผู้ป่วยที่ได้รับการผ่าตัดหูมาก่อน
- วัตถุประสงค์** : เพื่อศึกษาว่าการผ่าตัดโรคหูในหน่วยแพทย์เคลื่อนที่สามารถเพิ่มคุณภาพชีวิตของผู้ป่วย
- รูปแบบการวิจัย** : การวิจัยเชิงพรรณนา
- ผู้ป่วยที่เข้าทำการวิจัย** : ผู้ป่วยที่ได้รับการผ่าตัดโรคหูที่หน่วยผ่าตัดเคลื่อนที่ โรงพยาบาลสระแก้ว
- วิธีการวิจัย** : ผู้ป่วย 35 รายที่ได้รับการผ่าตัดรักษาหูน้ำหนวกเรื้อรัง หูน้ำหนวกเรื้อรังชนิดร้ายแรง และโรคกระดูกหูพิการในระหว่างวันที่ 1 - 4 กรกฎาคม 2551 จะได้รับการเชิญเข้าร่วมงานวิจัย และตรวจติดตามการรักษาในสัปดาห์ที่ 1, 2, 4 และ 24 ตรวจการได้ยินก่อนผ่าตัดและหลังผ่าตัดสัปดาห์ที่ 24 การเก็บรวบรวมข้อมูลนี้ใช้แบบสอบถามเกี่ยวกับข้อมูลพื้นฐานของผู้ป่วยและแบบสอบถามคุณภาพชีวิต (SF-36) ก่อนและหลังผ่าตัด เพื่อประเมินคุณภาพชีวิต
- ผลการศึกษา** : จากผลการศึกษาคุณภาพชีวิตที่ดีขึ้นอย่างมีนัยสำคัญในทุกด้าน สภาวะสุขภาพทางกาย (ก่อนผ่าตัด 52.8%, CI 45.7 - 59.8; หลังผ่าตัด 72.8%, CI 66.1 - 79.5; $P < 0.001$) สภาวะสุขภาพทางจิตใจ (ก่อนผ่าตัด 56.9%, CI 50.2 - 63.6; หลังผ่าตัด 76.3%, CI 70.4 - 82.3; $P < 0.001$), ความสามารถทางกายภาพ ($P < 0.0001$), ข้อจำกัดในบทบาททางกายภาพ ($P = 0.0001$), ความเจ็บปวดของร่างกาย ($P = 0.0046$), สุขภาพโดยทั่วไป ($P < 0.0001$), ความมีชีวิตชีวา ($P = 0.0001$), ความสามารถทางสังคม ($P = 0.003$), ข้อจำกัดในบทบาททางอารมณ์ ($P = 0.0001$) และสุขภาพทางจิต ($P = 0.0007$).
- สรุป** : การผ่าตัดรักษาโรคหูในหน่วยแพทย์ผ่าตัดเคลื่อนที่สามารถเพิ่มคุณภาพชีวิตของผู้ป่วย
- คำสำคัญ** : คุณภาพชีวิต, SF-36, การผ่าตัดปะแก้วหู, การผ่าตัดหูน้ำหนวกร้ายแรง, การผ่าตัดใส่กระดูกหูเทียม, การตรวจการได้ยิน, หน่วยผ่าตัดหูเคลื่อนที่.

Chronic otitis media (COM), cholesteatoma and stapes fixation are common bacterial ear diseases that affect 65 - 330 million people worldwide.⁽¹⁾ COM may flare up after having a cold or after water has entered the middle ear while bathing or swimming. Frequently, these flare-ups result in a painless some may be painful and foul smelling discharge which can be treated either by acetic acid with hydrocortisone, antibiotic ear drops or oral antibiotics such as amoxicillin.

However, persistent flare-ups may result in formation of granulation tissue polyps which will disturb ossicular function that are important to sound conduction from the outer ear to the inner ear. As a result of this, 39 - 200 million (60%) people suffer from hearing impairment⁽¹⁾ with a persistent or recurrent otorrhea due to a persistent perforation of the tympanic membrane.⁽¹⁾ The thickened granular mucosa, polyps, and cholesteatoma may develop in the middle ear will occur⁽²⁾ Oftenly cholesteatoma can cause other serious complications such as labyrinthitis, facial paralysis and brain infection.

Tympanoplasty is usually used to treat a ruptured eardrum or ossicular disruption with removal of the middle ear pathology whereas mastoidectomy is used to surgically remove the cholesteatoma either with or without any serious complication. In cases that perforation of the tympanic membrane has persisted for more than 3 months or in severe cases, myringoplasty or tympanoplasty are indicated.⁽³⁾ And surgical treatment can clinically improve the patient's hearing.⁽⁴⁾ On the other hand, stapedectomy is used to correct conductive hearing loss caused by a stapes fixation. It has been shown that any ear surgeries can effectively treat infection in the middle ear and improve the patient's hearing.^(4, 5)

Also, it has been shown that patients suffering from chronic ear disease will often lose their hearing⁽⁶⁾ which can significantly affect their social life as well as their performance at work. According to the National Academy on Aging Society and the policy institute of the Gerontological Society of America, hearing loss can have a profound impact on emotional, physical and social well-beings, especially when it is left untreated because it can lead to depression, dissatisfaction with life, reduced functional and cognitive health, and withdrawal from social activities. Even though chronic ear disease is not considered life threatening, We believe that it can dramatically affect the quality of life (QOL) in those inflicted with the disease. For instance, adults with chronic ear disease may avoid attending social functions or may not be able to effectively perform their duties at work because of their inability to properly communicate with other people due to hearing loss. In Thailand and other resource-limited countries, this will have a considerable effect on the household income for many families struggling to make ends meet since the majority of the workers belong to the blue collar level.

Since 1972, the Rural Ear Nose Throat Foundation of Thailand has established a mobile ear clinic in collaboration with rural hospitals to offer free ear treatments to people living in the rural areas who have low income and lack of opportunity to have the good ear service. Later, in 1997, Relief and Community Health Bureau, the Thai Red Cross Society established the Hearing Rehabilitation and Ear Surgery Unit project in collaboration with the Rural Ear Nose Throat Foundation to offer free ear care and surgeries to people living in the rural areas.

From this mobile ear clinic, a study conducted in adults in 1989 showed that both tympanoplasty (n = 125) and mastoidectomy (n = 10) effectively improved the patient's hearing by 68.8% regardless of the surgeon who performed the procedures.⁽⁷⁾ From another studies on adult patients recruited from the mobile ear clinic, they demonstrated that 80% (95%, CI 67 - 89.6%) of the tympanic membranes healed within 5 months after ear surgery.^(8,9)

Aside from the proven effectiveness of the ear surgeries for the treatment of COM, there have been many studies investigating the QOL in children.⁽¹⁰⁾ Also, the SF-36 is considered the gold standard for health surveys which are commonly used worldwide to assess QOL both in the mental and physical health fields.^(11 - 23) Although prior research conducted in Caucasian children have shown significant improvement in QOL after undergoing ear surgery for COM, we are unaware of

studies that have examined this in adults, especially in the Southeast Asian region. Hence we carefully and objectively assessed the QOL in Thai adult patients suffering from severe or recurring COM, cholesteatoma and stapes fixation for 3 months after having either tympanoplasty, mastoidectomy and/or stapedectomy by comparing data obtained from Thai SF-36 questionnaires pre- and post-surgery.

Materials and Method

Study Population

Four hundred patients were evaluated by otoscopic examination at the mobile ear clinic organized by the Thai Red cross Society and the Rural Ear Nose Throat Foundation at Sakaeo Hospital in Sakaeo province during 1 - 4 July 2008 with ear disease. The detail was display in figure 1. Thirty - five patients were recruited for surgery with either severe or persistent tympanic membrane perforations

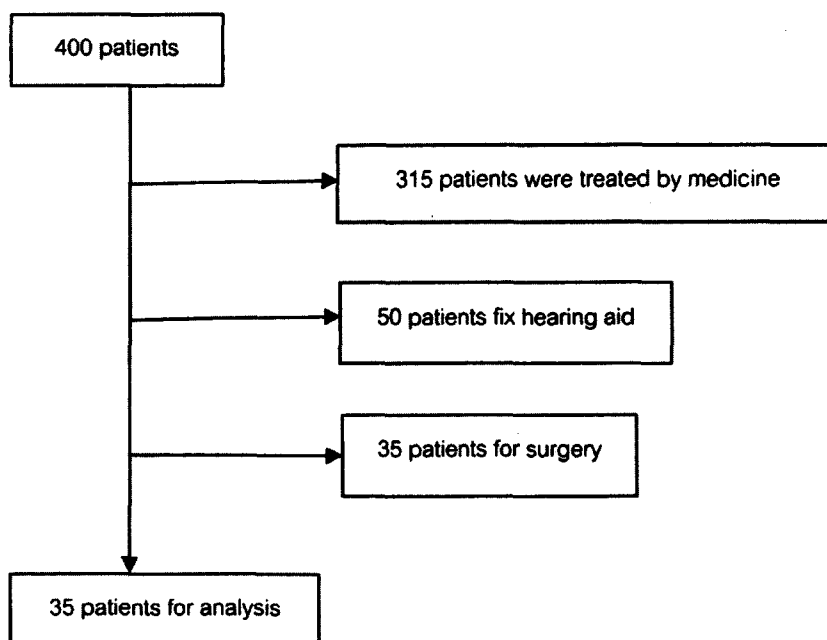


Figure 1. Exclusion and inclusion of patients.

lasting longer than three months. All patients who received ear surgery were studied. The exclusion criteria were: acute otitis externa, ear canal stenosis less than 4 millimeters in diameter, atelectasis of eardrum without cholesteatoma and tuberculous otitis media. Tympanoplasty, mastoidectomy and stapedectomy were performed by otolaryngologists at the Sakaeo Hospital.

Study design

This is a prospective questionnaire study evaluating the patients' QOL after having ear surgery such as tympanoplasty, mastoidectomy and stapedectomy for the treatment of COM, cholesteatoma and stapes fixation. The study was approved by the Chulalongkorn Institution Review Board and the Ethics Committee of the Faculty of Medicine, Chulalongkorn University. Informed consent was obtained from every patient before surgery was performed. In cases where children or adolescents were involved, consent was obtained from their guardians before any procedure was performed.

SF-36 questionnaire

A Thai version of SF-36 questionnaire, created by Ronnachai Kongsakon of Mahidol University was used with permission from the creator to collect the patients' demographic and surgical data at day 0 and week 24 after surgery from July to December 2008. The questionnaire consists of 36 items that measure 8 different parameters, namely: 1. Physical Functioning (PF) which consists of 10 items measuring the ability of the patients to perform a variety of tasks ranging from vigorous (i.e., running)

to basic (i.e., bathing or dressing oneself) activities; 2. Physical Limitations (RP) which consists of 4 items measuring the patients' limitations in work or other activities resulting from physical problems; 3. Bodily Pain (BP) which consists of 2 items measuring the patients' degree of pain and limitations in activity due to the pain; 4. General Health (GH) which consists of 5 items measuring the patients' self-evaluation of their overall health; 5. Vitality (VT) which consists of 5 items measuring the presence or absence of pep and energy; 6. Social Functioning (SF) which consists of 3 items measuring the degree to which physical or emotional problems interfered with the social activities; 7. Role-Emotional Limitation (RE) which consists of 4 items measuring limitations in work or in other activities due to emotional problems; and, 8. Mental Health (MH) which consists of 5 items measuring the feelings of nervousness and depression. In addition, in the first part of the questionnaire, the patients' health during the previous year was also assessed.

All participants were informed about the purpose and format of SF-36 questionnaire. The researchers thoroughly defined each scale of the questionnaire to the participants. The participants were interviewed by the researchers. We planned not to let them self-administered because we believed the reading skill among participants should be variable. And we planned to use the same method of data collection for all rather than interviewing some and let other self-administer. The participants rated each item on either a 1, 2, 3, 4, 5 or 6 - point Likert scale, (i.e., 1 = Yes, 2 = No; or, 1 = significant improvement; 2 = some improvement seen initially, and; 3 = No improvement; 4 = excellent, 5 = very good, 6 = good, 7 = average or so-so, and 8 = poor;

or 1 = none, 2 = very little, 3 = some initially, 4 = average, 5 = strong, and 6 = very strong). And the summary scores were computed for each scale by adding across items.

Clinical evaluation

The condition of the middle ear and the tympanic membrane was evaluated by otoscopic examination at weeks 0, 1, 2, 4, 14 and 24 in terms of infection control and the healing of neo-membrane. Audiogram was tested at weeks 0 and 24.

Statistical Analysis

The Data of QOL from two-time points, day 0 and week 24 post-surgery, were analyzed. Both the demographic and QOL data used descriptive analysis, percentages, mean and confidence interval (CI 95); Paired t-test was used to compare the QOL pre- and post-surgery. A p-value < 0.05 was considered statistically significant.

Results

A total of thirty - five patients participated in this study. There was slight formal preponderance males = 15 (42.9%) and females = 20 (57.1) in the study. The mean age was 44.4 (range 10 - 83; SD 17.9). Twenty nine patients underwent tympanoplasty. 3 children, 10 adult males and 11 adult females, 3 aged male and 2 aged females (> 60 of age). Two female adults had mastoidectomy with tympanoplasty whereas one female adult had only mastoidectomy while the other three adult females had stapedectomy. Even though most of the participants were adults, there were three children: one girl aged 11 and two boys aged 12 and 10. The results from the three

children and five elderly patients (> 60 of age) did not significantly impact the rest of the data and hence was included in the analysis.

From the demographic data presented in Table 1, the majority of our participants were married (n = 27; 77.15%) with primary school education (n = 20; 57.15%). In regards to occupation, most of our patients are manual laborers or blue collared workers: farmers (n = 12; 34.39%), construction workers (n = 9; 25.71%), merchants (n = 5; 14.29%) and governmental officers (n = 2; 5.71%). Seven out of 35 participants were unemployed; this indicated that there were a total of four unemployed adults whereas the three children were taken out of the equation. Thirty-one out of thirty-five had a good hygiene in terms of cleanness and daily self care. As for the frequency of respiratory tract infection, 31 patients (88.57%) stated that they had good hygiene which correlated with the number of colds they had per year. 16 patients (45.72%) stated that they had 1-2 colds per year while 10 (28.57%) had 3-4 colds per year. Only 2 patients (5.71%) stated that they had more than 30 colds per year whereas 1 patient (2.86%) had between 13 - 20 colds per year. Otherwise there were equal number of patients (n = 3; 8.57%) catching cold between 5 - 6 times and 7-12 times per year.

Table 2 shows the numbers of patients having tympanoplasty, mastoidectomy and stapedectomy. After tympanoplasty and tympanoplasty with mastoidectomy (n = 31), from Table 2, the closure rate of tympanic membrane (n = 31) was 90.3%. The percentage of ear dryness (n = 32) was 87.5%. The rate of hearing improvement (n = 35) was 74.3% (95%CI = 56.7 - 87.5%). Hearing was not improved for the patient who had mastoidectomy.

Table 1. Demographic characteristics of the study population from the mobile ear clinic located in the Sakaeo Province.

Characteristics	No. of cases (n = 35)	%
Male	15	42.9
Female	20	57.1
Age (yrs)	10 - 83	
Mean age (yrs) (SD)	44.4 (SD 17.9)	
Status		
Single	6	17.14
Married	27	77.15
Widowed	2	5.71
Divorced	0	
Education		
None	3	8.57
Primary school	20	57.14
Secondary school	5	14.3
Vocational	3	8.57
Diploma	2	5.71
Bachelor degree	2	5.71
Occupational		
None	7	20
Construction workers	9	25.71
Farmers	12	34.29
Governmental officers	2	5.71
Merchants	5	14.29
Hygiene		
Good	31	88.57
Poor	4	11.43
Frequencies of the Common Colds		
1 - 2 times / year	16	45.72
3 - 4 times / year	10	28.57
5 - 6 times / year	3	8.57
7 - 12 times / year	3	8.57
13 - 20 times / year	1	2.86
>30 times / year	2	5.71

SD: standard deviation

Table 2. Types of ear surgeries used and its clinical effects.

Type of surgery	n	%	Healing (%)	Improved Hearing (%)
Tympanoplasty	29	82.9	28 (87.09)	23 (65.73)
Mastoidectomy & Tympanoplasty	2	5.71	1 (3.21)	1 (2.86)
Mastoidectomy	1	2.53	0	0
Stapedectomy	3	8.86	0	2 (5.71)
Total	35	100%	90.3%	74.3%

As for the overall physical and mental health presented in Table 3, after 24 weeks of having tympanoplasty, mastoidectomy and stapedectomy, a significant improvement was shown ($p < 0.001$). When all 8 parameters were analyzed individually, it was shown that after 24 weeks of ear surgery, there was a statistically significant improvement in PF, RP, BP, GH, VT, SF, RE, and MH ($p < 0.05$).

No patient was lost to follow-up during the entire period of the study. In addition, there were no missing data for all time points.

Discussion

To the best of our knowledge, this study is the first of its kind in evaluating the quality of life after receiving ear surgeries such as tympanoplasty, mastoidectomy and stapedectomy, for the treatment of COM, cholesteatoma and stapes fixation. Since most of our patients are manual laborers or blue-collared workers with only primary education, it is pertinent to assess whether their illness interferes with their ability to work or decreases their daily income which in turn could affect the country's economy. There

Table 3. Overall comparison between physical and mental health using Thai SF-36 questionnaire before and after tympanoplasty mastoidectomy and stapedectomy for the treatment of chronic otitis media (COM) Cholesteatoma. and stapes fixation.

Parameter	Pre-surgery (Day 0) Mean (95%CI)	Post-surgery (Wk 24) Mean (95%CI)	P-value
1. Physical Health (PCS)	52.8(45.7 - 59.8)	72.8 (66.1 - 79.5)	<0.001
2. Mental Health (MCS)	56.9(50.2 - 63.6)	76.3(70.4 - 82.3)	<0.001
Total	55.8(49.2 - 62.5)	75.8 (69.8 - 81.8)	<0.001

PCS : Physical Cumulative Scale; MCS : Mental Cumulative Scale

Table 4. Using the Thai SF-36 questionnaire, each parameter was compared to before and after tympanoplasty mastoidectomy and stapedectomy for the treatment of chronic otitis media (COM) Cholesteatoma and stapes fixation.

Parameter	Pre-surgery	Post-surgery	P-value
	(Day 0)	(Wk 24)	
	Mean (95%CI)	Mean (95%CI)	
1.1 Physical Functioning (PF)	65.7(56.2 - 75.2)	84.7(78.0 - 91.4)	<0.0001
1.2 Role-Physical Limitation(RP)	42.1(27.9 - 56.4)	71.4 (59.6 - 83.2)	0.0001
1.3 Body Pain (BP)	53.9(43.7 - 64.0)	68.7 (59.0 - 78.3)	0.0046
1.4 General Health (GH)	46.5(37.8 - 55.2)	69.1 (60.8 - 77.5)	<0.0001
2.1 Vitality (VT)	56.3(50.4 - 62.2)	70.9 (65.0 - 76.7)	0.0001
2.2 Social Functioning (SF)	77.7(69.0 - 86.3)	90.8 (85.7 - 95.9)	0.003
2.3 Role-Emotional Limitation (RE)	42.8(27.7 - 57.9)	77.1 (65.8 - 88.6)	0.0001
2.4 Mental Health (MH)	61.3(54.8 - 67.7)	73.7 (68.0 - 79.4)	0.0007

is no financial assistance from the government when the breadwinner or the primary care provider for the family cannot work.

Our study has demonstrated that ear surgeries in adults and children can significantly improve the QOL for patients who have suffered from severe or recurring chronic ear disease as shown in Tables 2 and 3. This indicates that once the tympanic membrane having healed properly and hearing returned, the patients' mental and emotional well being greatly improved it allowed them to have better communication with others as well as increased their social activities. Similarly, physical scores also showed that ear surgeries were able to decrease physical symptoms, such as fever, otalgia, and otorrhea which also dramatically improved the patients' physical well being. Patients with good physical health were able to continue their work and take extra-curricular activities without any interruption or hindrance. This is in accordance to the World Health Organization's

(WHO) aim to achieve "Health for All by the Year 2000 and beyond" through the Ottawa Charter for Health Promotion: "Good health is a major resource for social, economic and personal development and an important dimensions of quality of life, i.e., political, economic, social, cultural, environmental, behavioral and biological factors can all favor health or be harmful to it."

Nevertheless, we noticed that the score for BP was slightly lower compared to the other parameters even though it still showed a significant impact on the patients' physical health. We attributed this because the body pain was caused by both pain related to ear diseases and pain related to the patients' occupation as most of them are hard laborers: construction workers and farmers. We noticed that the body pain existed before the surgery and subsided a bit after surgery which indicated that the ear surgery could not cure all types of pain.

On the other hand, this study showed that patients attending the mobile ear clinic could also have good clinical care as compared to developed countries⁽²⁴⁾ without affecting the healthcare costs or the current healthcare system in resource-limited settings. The mobile ear clinic may be a good model for other resource-constrained countries to adopt and modify according to their specific needs. In addition, from this study, the Thai SF-36 was useful in assessing health and QOL of patients with chronic ear disease. The data are in accordance with other studies conducted in children^(10, 24 -26) and may be valuable in assessing the effectiveness and impact of the ear surgeries on patients living in developing countries.

Another interesting finding from this study indicated that in order to have a successful treatment and follow-up, it was essential to have a good patient-doctor relationship. In our study, we did not see any patient lost to follow-up and attributed this to the good rapport that was established between the patient and the medical team of the mobile ear clinic. Home call by a nurse would remind the patients about how they should behave post-surgery, drug intake, swimming avoidance and the follow-up schedule. This result supports several published data^(27 - 32) seen in HIV studies showing patients' adherence to anti retroviral treatment (ART), increases in response to having a good patient-doctor relationship. As a consequence of this, HIV specialists are able to ensure that their patients will not develop HIV resistance strains due to sporadic intake of anti retroviral (ARV).

Regardless of these findings, our study is limited by its subjective nature and possible bias in the way the patients responded to the questions. For example, since the patients already knew the physical

benefits of the ear surgeries, it is possible that they were more prone to select answers that showed improvement. However, we have ruled this out as these results supported other studies conducted in children.^(10, 24 - 26)

Conclusion

We conclude that Thai adults and children who attended the mobile ear clinic significantly have their QOL improved after receiving ear surgeries such as tympanoplasty, mastoidectomy and stapedectomy, for the treatment of severe or recurring COM, cholesteatoma and stapes fixation.

Conflict of interests: KS is the Secretary General of the Rural Ear Nose and Throat Foundation. UB is the committee of Hearing Rehabilitation and Ear Surgery Unit project. The Thai Red Cross Society declares no conflict of interest. None of the authors have received any fee, salary, gift or indirect financial support from the Rural Ear Nose and Throat Foundation.

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