The Laryngoscope
Lippincott Williams & Wilkins, Inc.

Endolymphatic Sac Decompression as a Treatment for Meniere's Disease

William F. Durland, Jr, MD; G. Mark Pyle, MD; Nadine P. Connor, PhD

Objectives/Hypothesis: **Endolymphatic sac decompression is a surgical treatment option for patients with medically intractable Meniere's disease. However, effectiveness is debated because published data show great variability. Outcome-based research studies are useful in incorporating the patient's perspective on the success of treatment. To further assess effectiveness of endolymphatic sac decompression, we performed a prospective study to examine both symptom-specific and general health outcomes.** ***Study Design:*** **Prospective, observational outcome study.** ***Methods:*** **Nineteen patients with endolymphatic sac decompression responded to symptom-specific questionnaires and the Medical Outcomes Short-Form 36 Health Survey (SF-36) before and after surgery. Follow-up ranged from 6 to 58 months with a mean duration of 50 months.** ***Results:*** **Overall measures of physical health were significantly improved following endolymphatic sac decompression ($P = .04$), whereas overall measures of mental health were unchanged ($P = .74$). Role Physical and Social Functioning scores were significantly improved following endolymphatic sac decompression ($P = .04$ and $P = .03$, respectively). Study patients scored significantly lower ($P < .05$) than SF-36 normative data in 6 of 10 categories before endolymphatic sac decompression but patient scores were not significantly different from normal scores in all but one category (General Health) following endolymphatic sac decompression. The mean number of vertigo episodes was significantly reduced from an average of 8.3 times per month to an average of 2.6 times per month following endolymphatic sac decompression ($P = .006$). Ninety-five percent of patients (18 of 19 patients) reported improvement in symptoms (frequency, duration, or intensity) of vertigo and 37% (7 of 19 patients) reported complete resolution of vertigo.** ***Conclusion:*** **Endolymphatic sac decompression significantly improved perception of physical health, as well as symptom-specific outcomes, in patients with medically intractable Meniere's disease.** ***Key Words:*** **Endolymphatic sac decompression, Meniere's disease, quality of life, vertigo.**

Laryngoscope, **115:1454–1457, 2005**

From the Division of Otolaryngology—Head and Neck Surgery, Department of Surgery, University of Wisconsin, Madison, Wisconsin, U.S.A.

Editor's Note: This Manuscript was accepted for publication May 4, 2005.

Send Correspondence to Nadine P. Connor, PhD, University of Wisconsin Clinical Science Center, Room K4/711, 600 Highland Avenue, Madison, WI 53792-7375, U.S.A. E-mail: connor@surgery.wisc.edu

DOI: 10.1097/01.mlg.0000171017.41592.d0

INTRODUCTION

Traditionally, patients with Meniere's disease refractory to medical management are offered several surgical options for further management of their symptoms. These options include labyrinthectomy, vestibular neurectomy, endolymphatic sac decompression (ELSD), and transtympanic gentamicin injection. However, the treatment options that appear to have the greatest effectiveness are those which are the most invasive or impair hearing, or both.[1] Recently, ELSD has become a favorable surgical option because it has a low surgical morbidity and it does not significantly impact hearing.[2] However, the effectiveness of this procedure has been debated, and the published data show great variability. For example, in one study of 676 patients, it was reported that fewer than 60% of patients had resolution of vertigo, a result that caused the authors to abandon endolymphatic sac shunting in favor of vestibular nerve section.[3] Other studies have reported high success rates with improvement in vertigo in up to 94% of patients and resolution of vertigo in up to 78% of these patients.[4–6] This variability in data has made it difficult for surgeons to consistently agree on the most appropriate therapy for patients with vertigo secondary to Meniere's disease.

Despite the debate, many otolaryngologists continue to perform ELSD. Previously, in an effort to further evaluate the role of ELSD in the management of Meniere's disease, we performed a retrospective study employing the Medical Outcomes Short-Form 36 Health Survey (SF-36).[7] The SF-36 is a widely used survey instrument that assesses perception of general health and quality of life over a wide variety of physical and mental health domains. In that prior study, we demonstrated that the SF-36 was a good measure of functional impairment and quality of life in patients with disabling vertigo secondary to Meniere's disease.[5] Furthermore, we demonstrated that patients undergoing ELSD for disabling vertigo secondary to Meniere's disease scored below national normative data before ELSD but were equivalent to normative data following ELSD. However, that study did not have sufficient statistical power to show a significant improvement in quality of life within the study group following ELSD. Furthermore, that study had a limited follow-up period. Because many otolaryngologists think that the improvements in vertigo following ELSD are short-lived, we wanted to provide long-term follow-up data. To address these issues, we designed a prospective observational

study with a larger sample size and with long-term follow-up. We compared preoperative and postoperative outcome measurements as determined by both the SF-36 and a brief symptom-specific health survey. In addition, we compared preoperative and postoperative outcome measurements to age- and sex-matched population norms.

MATERIALS AND METHODS

Twenty-six patients were enrolled in the present study. These were patients who underwent ELSD for medically intractable, disabling vertigo secondary to unilateral Meniere's disease and who agreed to participate. The diagnosis of Meniere's disease was based on a careful history, physical examination, audiometry, diagnostic imaging (magnetic resonance imaging), and vestibular testing. All patients met criteria for definite Meniere's disease as established by the 1995 American Academy of Otolaryngology—Head and Neck Surgery committee on hearing and disequilibrium.[6] In addition, these patients had failed traditional medical management including a low-salt diet and diuretic therapy. Many of these patients had also been treated with vestibular suppressants, steroids, or vasodilators. These patients chose to proceed with ELSD after a careful discussion of options including observation only, continued medical management, transtympanic gentamicin injection, ELSD, vestibular neurectomy, and labyrinthectomy. Our technique involved complete mastoidectomy and facial nerve and posterior semicircular canal identification, followed by skeletonization of the posterior fossa dura and complete decompression of the sac. Maximum bone removal in the infra-labyrinthine compartment was stressed. The lateral aspect of the sac was incised, and the sac and duct were probed. A Silastic sheet was trimmed and placed into the sac extending into the mastoid cavity. A subarachnoid shunt was not employed.

Patients were invited to complete the SF-36 during their preoperative workup. The SF-36 was chosen for its well-established acceptance as a valid, reliable measure of perception of physical and mental health across a large range of disease entities, including Meniere's disease.[5] The SF-36 assesses physical and mental health across several individual domains and produces both a physical and a mental component score. Scores range from 0 to 100, with higher scores indicating higher levels of functioning and associated quality of life. In addition to the SF-36 items, we also included items related to symptoms of Meniere's disease. Of the 26 enrolled patients, 19 completed the study by filling out the questionnaire postoperatively. One patient underwent a second treatment (transtympanic gentamicin injection) before filling out the postoperative survey and was excluded from the study. Follow-up ranged from 6 to 58 months with a mean duration of 50 months. The postoperative questionnaire was identical to the preoperative instrument and also included general questions regarding the patients' overall satisfaction with their surgical outcome. The preoperative and postoperative data were compared using Wilcoxon paired signed-rank tests.

RESULTS

Overall measures of physical health as measured by the Physical Component Score (PCS) of the SF-36 survey were significantly improved following ELSD ($P = .04$). Overall measures of mental health as measured by the mental component score (MCS) were unchanged ($P = .74$) (Table I and Fig. 1).

Individual scores including Role Physical (RP) and Social Functioning (SF) scores were also significantly improved following ELSD ($P = .04$ and $P = .03$, respectively) Individual scores including Physical Functioning (PF), Bodily Pain (BP), General Health (GH), Vitality (VT), Role Emotional (RE), and Mental Health (MH) were unchanged following ELSD ($P > .05$) (Table I and Fig. 1).

Before surgery, study patients scored significantly lower ($P < .05$) than age- and sex-matched U.S. normative data in 6 of 10 categories (RP, GH, PCS, VT, SF, and RE). However, following surgery, these same patients scored equivalently to age- and sex-matched normative data in all but one category (GH) (Table I and Fig. 2).

The mean number of episodes of vertigo was significantly reduced following ELSD from an average of 8.1 times per month to 2.6 times per month ($P = .006$) (Fig. 3).

Eighteen of 19 patients (95%) reported improvement in symptoms (frequency, duration, or intensity) of vertigo. Seven of 19 patients (37%) reported complete resolution of vertigo.

DISCUSSION

The management of disabling vertigo in patients with Meniere's disease remains controversial. Labyrinthectomy and vestibular neurectomy have long been the gold standard for management of disabling vertigo in patients with Meniere's disease because these procedures have proven to reduce or eliminate episodic vertigo in a high percentage of patients.[8] However, these procedures have a relatively high surgical morbidity and can lead to

TABLE I.
Short-Form 36 Health Survey Data.

	pF	RP	BP	GH	PCS	VT	SF	RE	MH	MCS
Preoperative score	84.8	33.3	75.1	62.3	44.5	51.1	66.0	66.7	74.2	46.7
Postoperative score	85.4	66.7	83.3	61.8	48.1	55.8	80.6	75.0	71.9	48.0
P value (preoperative vs. postoperative scores)	.81	**.04**	.27	.95	**.04**	.21	**.03**	0.36	0.49	0.74
U.S. population norms	84.6	82.7	73.1	71.8	50.0	61.8	84.1	83.6	75.3	50.0
P value (preoperative scores vs. population norms)	.97	**.00**	.74	**.04**	**.03**	**.04**	**.00**	**.04**	.80	.22
P value (postoperative scores vs. population norms)	.88	.05	0.08	**.04**	.45	.24	.51	.29	.43	0.44

Physical Functioning (PF), Role Physical (RP), Bodily Pain (BP), General Health (GH), Physical Component Score (PCS), Vitality (VT), Social Functioning (SF), Role Emotional (RE), Mental Health (MH), and Mental Component Score (MCS) data were obtained at the preoperative workup and after endolymphatic sac decompression (ELSD) (mean follow-up period, 50 mo). National normative data were obtained from the *SF-36 Health Survey: Manual and Interpretation Guide*.[7] Data obtained before and after ELSD were compared to each other and to age- and sex-matched norms using Wilcoxon paired signed-rank test. Boldface type designates statistically significant values ($P < .05$).

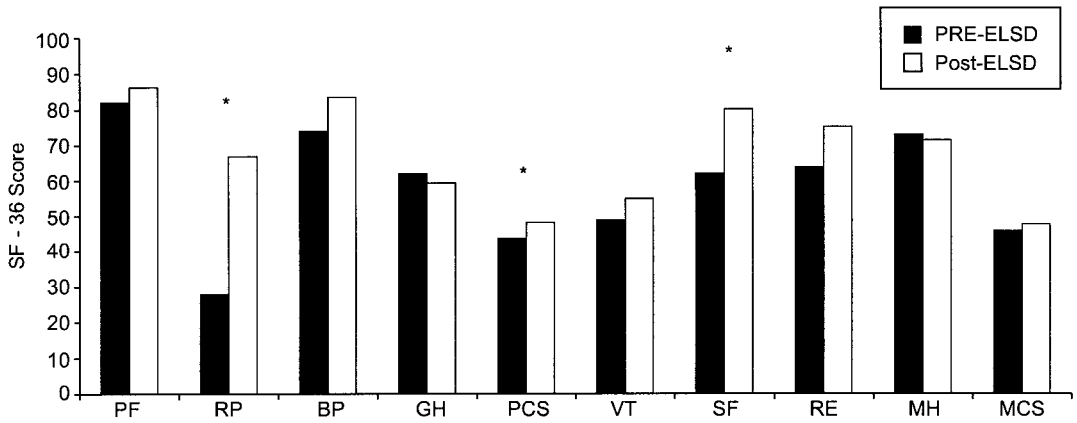

Fig. 1. Comparison of average preoperative and postoperative SF-36 individual scores. Scores range from 0 to 100, with higher scores indicating better functioning. The PCS (Physical Component Score), RP (Role Physical), and SF (Social Functioning) scores were significantly improved following ELSD ($P \leq .05$). BP, bodily pain; GH, General Health; VT, Vitality; RE, Role Emotional; MH, Mental Health; *$P \leq .05$.

complete hearing loss and permanent vestibular injury with resulting ataxia and imbalance.[9,10] Furthermore, these procedures are typically performed only at major medical centers by subspecialists; thus, they are less accessible to patients in small communities. Therefore, additional treatment modalities that can be performed more universally with lower morbidity have been sought.

Recently, treatments including chemical labyrinthectomy (transtympanic gentamicin titration) and ELSD have gained favor because they are less invasive and are associated with fewer risks and side effects. However, these treatment modalities have also been criticized. Although chemical vestibular deafferentation has shown promise in terms of efficacy (vertigo control rates comparable to transmastoid labyrinthectomy and vestibular neurectomy), it still carries a risk of hearing loss and permanent ataxia.[11,12] Endolymphatic sac decompression is appealing because it does not destroy the inner ear structures; as such, it preserves both hearing and balance. However, the effectiveness of this procedure has been seriously questioned. In a hallmark double-blind, placebo-controlled study published by Thompsen et al.[13] in 1981, patients treated with mastoidectomy alone (control group) had a similar outcome to patients treated with ELSD (improvement in 70% of patients in both groups). Although the interpretation of these data is debated,

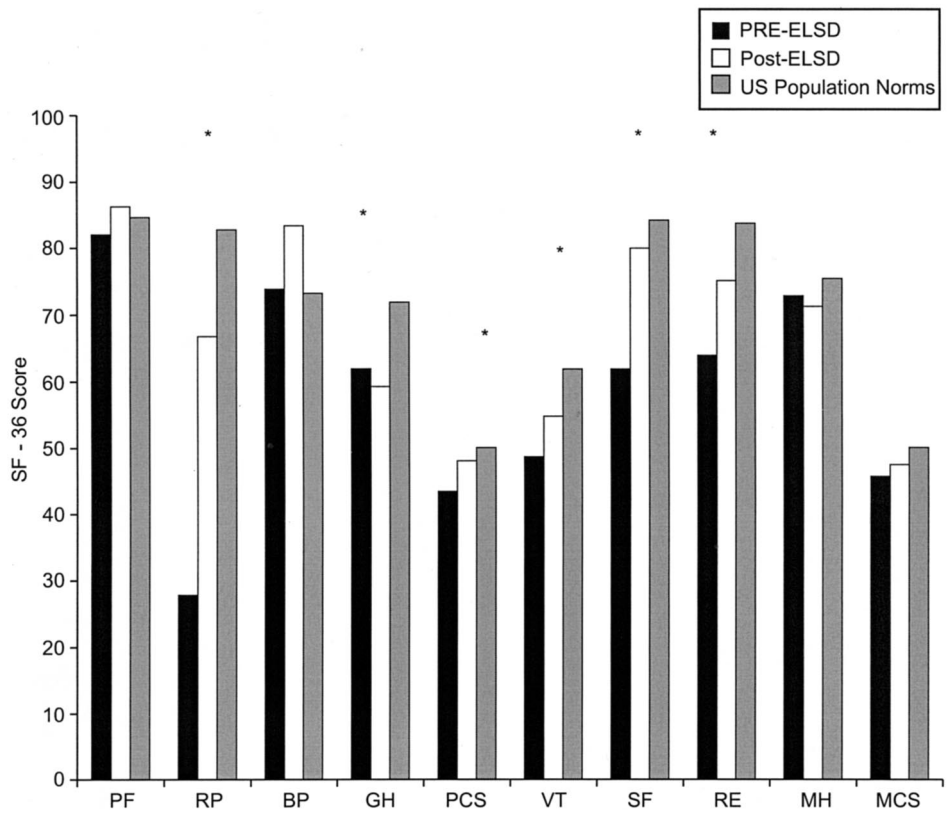

Fig. 2. Comparison of average preoperative SF-36 health survey scores, postoperative SF-36 scores, and age- and sex-matched U.S. population normative data. Scores range from 0 to 100, with higher scores indicating better functioning. Study patients scored significantly lower than U.S. population norms in 6 of 10 categories before endolymphatic sac decompression (ELSD) (Role Physical [RP], General Health [GH], Physical Component Score [PCS], Vitality [VT], Social Functioning [SF], and Role Emotional [RE]) ($P \leq .05$). These patients remained below the population norms in only 1 of 10 categories (GH) following ELSD. PF, Physical Functioning; BP, Bodily Pain; MH, Mental Health; MCS, Mental Component Score; *$P \leq .05$.

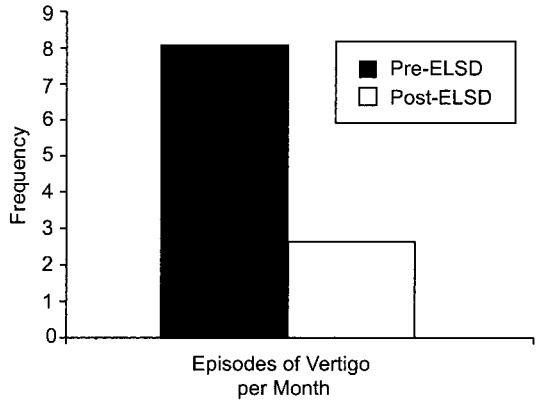

Fig. 3. Frequency of vertigo before and after endolymphatic sac decompression (ELSD). Study patients had significantly fewer episodes of vertigo following ELSD ($P < .006$). Mean follow-up was 50 months.

many authorities still use that study as a rationale for not performing ELSD.[14]

In an effort to avoid the long-term imbalance and hearing loss associated with "destructive" procedures (vestibular neurectomy, transmastoid labyrinthectomy, and chemical labyrinthectomy), "nondestructive" treatment options including ELSD continue to be offered to patients with disabling vertigo secondary to Meniere's disease. Support for such procedures has come from numerous studies showing a reduction in both the frequency and intensity of vertigo in patients following ELSD.[15-19] However, these studies have been criticized for their lack of a prospective study design, their limited follow-up period, and their lack of a control group. Furthermore, patients' overall quality-of-life outcomes have not been studied. To address these criticisms, we performed a prospective study measuring both symptom-specific and quality-of-life outcomes. We followed patients for a mean period of more than 4 years.

In our study, we found that patients with Meniere's disease who underwent ELSD for management of vertigo had improvements in quality of life, as well as a reduction in frequency, intensity, and duration of vertigo. Specific quality-of-life improvements included an improved ability to perform normal social activities without interference attributable to physical or emotional problems (higher SF score). In addition, patients had fewer problems with work and daily activities as a result of their physical health (higher RP score). Furthermore, following ELSD, our study group was functioning at the same level as age- and sex-matched control subjects in 9 of 10 categories on the SF-36 survey.

Patients did not have a statistically significant improvement in their emotional health as measured by the MH, RE, and VT scores. Preoperatively, our patients with Meniere's disease did not have scores different from normal control subjects in the MH subset. It is possible that the SF-36 may not be sensitive to the subtle emotional or depressive changes that may occur in Meniere's disease. In addition, patients did not report feeling that their general health was improved, nor did they have an improvement in bodily pain.

The main limitations of the present study include the small sample size (n = 19), the statistical dilemma of evaluating the data given that one patient underwent a second treatment (gentamicin titration) before filling out her postoperative questionnaire, and the lack of a control group. Despite the small sample size, we were able to show a statistically significant improvement in patients who underwent ELSD. As the number of patients who enroll in the present study increases, we will be able to generate data with even more statistical power. To address the fact that one patient underwent two treatments (ELSD followed by gentamicin titration) before filling out her postoperative survey, we performed statistical analysis both with and without the data from this patient. Our results did not differ with both analyses. Our prospective study supports the continued use of ELSD for patients with intractable vertigo secondary to Meniere's disease.

BIBLIOGRAPHY

1. Snow JB Jr, Kimmelman CP. Assessment of surgical procedures for Meniere's disease. *Laryngoscope* 1979;89:737–746.
2. Miller GW, Welsh RL. Surgical management of vestibular Meniere's disease with endolymphatic mastoid shunt. *Laryngoscope* 1983;93:1430–1440.
3. Glasscock ME III, Jackson CG, Poe DS, Johnson GD. What I think of sac surgery in 1989. *Am J Otol* 1989;10:230–233.
4. Kitahara M, Kitajima K, Yazawa Y, Uchida K. Endolymphatic sac surgery for Meniere's disease: eighteen years' experience with the Kitahara sac operation. *Am J Otol* 1987;8:283–286.
5. Smith DR, Pyle GM. Outcome-based assessment of endolymphatic sac surgery for Meniere's disease. *Laryngoscope* 1997;107:1210–1216.
6. Monsell EM, Balkany TA, Gates GA, et al Committee on Hearing and Equilibrium guidelines for the diagnosis and evaluation of therapy in Meniere's disease. *Otolaryngol Head Neck Surg* 1995;113:181–185.
7. Ware JE. *SF-36 Health Survey: Manual and Interpretation Guide* . Boston: The Health Institute, New England Medical Center Hospitals; 1993.
8. Berryhill WE, Graham MD. Chemical and physical labyrinthectomy for Meniere's disease. *Otolaryngol Clin North Am* 2002;35:675–682.
9. Thomsen J, Berner B, Tos M. Vestibular neurectomy. *Auris Nasus Larynx* 2000;27:297–301.
10. Langman AW, Lindeman RC. Surgical labyrinthectomy in the older patient. *Otolaryngol Head Neck Surg* 1998;118: 739–742.
11. Nedezelski JM, Schessel DA, Bryce GE, Pfleiderer AG. Chemical labyrinthectomy: local application of gentamicin for the treatment of unilateral Meniere's disease. *Am J Otol* 1992;13:18–22.
12. Mondain M, Mouchet F, Marlier F, et al Chemical labyrinthectomy: results and applications. *Ann Otolaryngol Chir Cervicofac* 1998;115:234–242.
13. Thomsen J, Bretlau P, Tos M, Johnsen NJ. Meniere's disease: endolymphatic sac decompression compared with sham (placebo) decompression. *Ann N Y Acad Sci* 1981;374:820–830.
14. Welling DB, Nagaraja HN. Endolymphatic mastoid shunt: a reevaluation of efficacy. *Otolaryngol Head Neck Surg* 2000; 122:340–345.
15. Rutka JA, Nedzelski JM, Barber HO. Results of endolymphatic sac surgery for Meniere's disease. *J Otolaryngol* 1984;13:70–72.
16. Spector GJ, Smith PG. Endolymphatic sac surgery for Meniere's disease. *Ann Otol Rhinol Laryngol* 1983; 92:113–118.
17. Savary P, Charissoux G. Surgical opening of the endolymphatic sac in Meniere's disease: our experience from 1962–80. *J Otolaryngol* 1984;13:73–75.
18. Brackmann DE, Anderson RG. Meniere's disease: treatment with the endolymphatic subarachnoid shunt—a review of 125 cases. *Otolaryngol Head Neck Surg* 1980;88:174–182.
19. Huang TS. Endolymphatic sac surgery for Meniere's disease: experience with over 3000 cases. *Otolaryngol Clin North Am* 2002;35:591–606.