CLINICAL STUDY

Cost-Effectiveness Analysis of Percutaneous Sclerotherapy for Venous Malformations

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ABSTRACT

Purpose: To assess cost-effectiveness of sclerotherapy for venous malformations (VMs) to improve patient quality of life (QOL).

Materials and Methods: This prospective study enrolled 28 patients with symptomatic VMs who underwent sclerotherapy. EuroQol-5 Dimension (EQ-5D) and Short-Form 36 (SF-36) Health Survey were used to measure health-related QOL. Questionnaires were collected before and 1, 3, 6, and 12 months after sclerotherapy. Quality-adjusted life years (QALYs) were calculated using EQ-5D score as a measure of health utility. Medical costs obtained from the hospital accounting system and other costs of staff, drugs, materials, and angiographic equipment were calculated for each procedure. Cost-effectiveness was analyzed using incremental cost-effectiveness ratio (ICER) as the medical cost/gain of QALYs.

Results: Median EQ-5D scores improved from 0.768 (range, 0.705–1) to 1 (range, 0.768–1) after 6 months ($P = .023$) and 1 (range, 0.768–1) after 12 months ($P = .063$). The gain of QALYs at 12 months was 0.043. The mean medical cost was ¥281,228 ($2,337). The pain group (baseline bodily pain scale of SF-36 score < 70) showed greater improvement in median EQ-5D score, from 0.705 (range, 0.661–0.768) to 0.768 (range, 0.705–1) after 6 months ($P = .041$) and 0.768 (range, 0.768–1) after 12 months ($P = .049$). ICER at 12 months was ¥6,600,483 ($54,840) in the overall group and decreased to ¥3,998,113 ($33,218) in the pain group, $<$ ¥6,000,000 ($49,850), threshold for acceptance of a public health benefit in Japan, even accounting for 50% increase in costs.

Conclusions: Sclerotherapy was cost-effective for improving QOL for symptomatic VMs, especially for patients with moderate to severe pain.

ABBREVIATIONS

EQ-5D = EuroQol-5 Dimension, ICER = incremental cost-effectiveness ratio, QALY = quality-adjusted life year, QOL = quality of life, SF-36 = Short-Form 36, VM = venous malformation

Venous malformations (VMs) are the most common vascular malformations, with an estimated incidence of one to two per 10,000 births (1). VMs comprise dilated, abnormal vascular channels lined by mature endothelium (2). VMs may be present at birth and usually enlarge during childhood or in puberty (3). These lesions occur in the head and neck (40%), extremities (40%), or trunk (20%) (4). Some are localized to the skin or subcutaneous tissue, but others infiltrate into the deep tissues, including muscles, bones, and ligaments. As the lesion grows in size, patients may experience various symptoms, including pain, swelling, dysfunction, bleeding, and cosmetic disturbance.

Treatment options for VMs mainly comprise conservative therapy, such as compression or pain management, and invasive treatment, such as surgery (5) or

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percutaneous sclerotherapy (6). Historically, surgery has often been performed, and a recent report (7) indicated that high treatment satisfaction after surgery was achieved for mainly or partly circumscribed VMs. However, complete resection was seldom achieved for VMs infiltrating into deep tissues. Percutaneous sclerotherapy has been proposed as an alternative because the procedure is less invasive and more easily repeated (6). Although percutaneous sclerotherapy has been widely performed for symptomatic VMs, this therapy is not covered by the national insurance system in Japan.

According to the Japan Revitalization Strategy in 2014 endorsed by the Japanese government (http://www.kantei.go.jp/jp/singi/keizaisaisei/pdf/honbunEN.pdf), a new standard of coverage for new drugs and medical equipment is to be adopted in Japan, and cost-effectiveness will be considered in the evaluation. Thus, to be reimbursed, treatment offered will be required to not only be therapeutically effective but also cost-effective. Few previous reports have examined clinical economic evaluations based on cost-effectiveness analysis for the treatment of VMs, and those reports were limited to intracranial arteriovenous malformations (8–10). In addition, the reports evaluated the cost-effectiveness of surgery or stereotactic radiotherapy, not sclerotherapy. The purpose of this study was to assess the cost-effectiveness and improvement in quality of life (QOL) of percutaneous sclerotherapy for symptomatic VMs.

MATERIALS AND METHODS

Study Participants

An open-label, nonrandomized, single-arm, prospective observational study was conducted in four university hospitals in Japan. Patients who had been given a clinical diagnosis of VMs and referred for percutaneous sclerotherapy were eligible for this study. The inclusion criteria were as follows: (*a*) patients with localized symptomatic VMs (eg, pain, swelling, dysfunction); (*b*) patients with VMs located in the head and neck, extremities, or trunk of the body; and (*c*) patients who were scheduled for initial sclerotherapy or patients in whom sclerotherapy had already been repeated up to three times and $>$ 3 months had passed since the last therapy. Exclusion criteria were (*a*) cerebrospinal or visceral lesions, (*b*) age $<$ 10 years, (*c*) severe cardiopulmonary dysfunction, (*d*) severe infection, or (*e*) mental disorder. Enrolled patients were asked to complete questionnaires regarding health-related QOL; voluntary response to the questionnaires was regarded as agreement to participate in this study. The study protocol was approved by the institutional review board of each university hospital.

Study Design

All participants underwent percutaneous sclerotherapy after providing tacit agreement to participate. Detailed methods for sclerotherapy, such as the use of local or general anesthesia and the particular sclerosants used, were tailored for each patient based on operator preference. After treatment, follow-up questionnaires and other clinical information, such as existence or absence of the residual lesion or persistent symptoms, were collected at subsequent clinic visits. If a patient had difficulty visiting the clinic, questionnaires were collected by mail. Data on medical costs were also collected. Cost-effectiveness was analyzed in patients who completed the questionnaires until 12 months after treatment.

Combination with conservative treatment, such as analgesics, fomentation, and compression stockings, was allowed during the observation period. If the lesion remained or symptoms relapsed after the first procedure, repeat sclerotherapy was allowed after at least 2 months.

Measurement of Health-Related QOL

The secondary outcome of this study was improvement in QOL. The EuroQol-5 Dimension (EQ-5D), which is widely used to evaluate health status in clinical studies, was used as an indicator of health-related QOL (11,12). The EQ-5D has five dimensions: mobility, self-care, usual activities (work, study, housework, family or leisure), pain/discomfort, and anxiety/depression. Each dimension is subdivided into three categories: no problem, moderate problem, or severe problem. Health utility scores, ranging from 0 (death) to 1 (perfect health), can be calculated based on the combination of answers to these categories. The Short-Form 36 (SF-36) Health Survey version 2 (13,14) was also used to assess health-related QOL. The SF-36 comprises 36 question items to measure eight health scales: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. The range for each score is 0–100. The EQ-5D and SF-36 scores were measured at baseline and 1, 3, 6, and 12 months after initial sclerotherapy.

Measurement of Quality-Adjusted Life Years

Quality-adjusted life years (QALYs) offer a measure of health outcomes, including both quality and quantity of life. QALYs are determined by integrating health utility and time. Utility is an indicator of the level of human expectation or satisfaction. In measuring QALYs, utility ranges from 0 to 1, with 1 indicating perfect health, and various health states are indicated between 0 and 1. We used the EQ-5D score as a measure of utility. Because no control group was used in this study, gain of QALYs was defined as an increase in utility above baseline level (**Fig 1**) (15). We regarded conservative therapy as a control group for descriptive purposes and assumed that

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