

Cost-Effectiveness of Sumatriptan in a Managed Care Population

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Abstract

We conducted an open-label study to determine whether sumatriptan is more cost-effective than other therapies used to treat migraine headache. We contacted by phone 220 sumatriptan users enrolled in QualMed, a health maintenance organization (HMO) in Spokane, Washington. Of these, 203 met the inclusion criteria and 164 (81%) completed our telephone survey. The main outcome measures were healthcare costs to the HMO and number of days free of migraine-related disability before and after sumatriptan treatment. Before sumatriptan treatment, 89% of patients reported severe migraine, compared with 63% after sumatriptan treatment. The number of monthly migraine disability days decreased from 6.5 days per month before sumatriptan to 3.9 days per month after sumatriptan. Healthcare utilization rates (ie, number of hospitalizations, emergency department visits, and physician visits) and costs were lower after the patients began taking sumatriptan. The number of different over-the-counter medicines and prescription medications (other than sumatriptan) taken for migraine disabilities decreased. Although total drug expenditures per month increased, the total migraine healthcare expenditure was 41% lower after sumatriptan was initiated. The cost-effectiveness ratio was 47% more favorable after patients started taking sumatriptan. Overall, patients reported fewer migraine-related disabilities, had lower migraine severity scores, and used fewer healthcare resources when taking sumatriptan. These changes resulted in a better cost-effectiveness ratio for migraine treatment. (Am J Man Care 1997;3:117-122)

From 5.3% to 19% of men and 11% to 28% of women in the United States suffer migraine headache,¹ with the highest prevalence occurring among persons aged 35 to 45. Migraine is almost three times more common in women than men. Although community-based epidemiologic studies yield high prevalence rates, many patients self-treat migraine headache, as may be true for many diseases.² For this reason, small changes in benefit design and disease or treatment awareness may lead to large changes in the actual number of patients treated within a medical system.

Patients with migraine can be high utilizers of healthcare services. In a study of patients with migraine enrolled in the United Health Care health maintenance organization (HMO)³ those who used the healthcare system generated almost twice as many medical claims and 2.5 times as many pharmacy claims as a comparison group of patients without migraine. The annual per-patient migraine healthcare cost was estimated at \$816 in a sample of patients enrolled in a clinical trial.⁴ Outside of clinical trials, patients with varying degrees of migraine severity who have open access to care may have different costs.

In March 1993, sumatriptan injectable was introduced for treating migraine. Sumatriptan is a selective serotonin agonist that can effectively treat acute migraine attack (with or without aura).⁵ This effectiveness offers the prospect of improved outcomes for patients with migraine.⁶ However, published literature to date offers mixed findings on the economic impact of sumatriptan. Is the increased cost of sumatriptan offset by reduced utilization of healthcare services (cost minimization)? Or does the improved effectiveness of sumatriptan justify the increase in cost (cost-effectiveness)? A recently published claims-based study⁷ indicated that the cost of migraine care increased after sumatriptan became available. A separate outcomes-based study found that quality-of-life indicators improved and the trend toward increasing utilization for migraine and non-migraine visits decreased with sumatriptan treatment.⁶

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A previously reported analysis of migraine claims data at QualMed in Spokane, Washington, indicated that in the first year after sumatriptan was added to the formulary, the per-patient cost of migraine management did not increase, despite increased expenditures for sumatriptan.⁸ This analysis was limited to a retrospective review of medical and pharmacy claims data. Since claims data were used, patient-reported data were not available to determine whether a difference in treatment effectiveness existed. Our present study expands on this earlier preliminary research by including patient-assessed endpoints. Our specific objective in conducting this study was to determine from a payer perspective whether sumatriptan is more cost-effective than alternative treatments for migraine.

... METHODS ...

We studied the impact of sumatriptan on healthcare costs and clinical effectiveness at QualMed, an independent-practice-association model HMO in Spokane, Washington, which had 58,000 enrollees in mid-1995. QualMed is part of Health Systems International, a healthcare company covering more than 1.5 million lives in the United States.

A total of 220 patients (identified through HMO pharmacy records) who received at least one sumatriptan injectable prescription through their QualMed prescription benefit between January 1, 1994, and December 31, 1994, were eligible for the study. (Oral sumatriptan was not available in the United States at the time of this study.) A patient's data were included in the analysis if he or she was older than age 18, had used sumatriptan at least once, and reported having migraine headaches.

We contacted all 220 patients by phone. The telephone survey instrument was designed to measure the hypothesized improvement in clinical effectiveness and reduction in migraine healthcare costs within QualMed. Patients were asked to recall the effectiveness of treatment and their healthcare utilization rates in the 12 months before and after they started using sumatriptan. Data were analyzed on an intent-to-treat basis and were included even from patients who stopped taking sumatriptan for any reason.

Trained telephone interviewers at the Social and Economic Sciences Research Center at Washington State University administered the telephone survey and entered the data using automated computer-assisted telephone interviewing equipment. The phone survey was conducted in July 1995 and consisted of 119 questions. Patients were called up to five times in an attempt to obtain a completed response.

Clinical Effectiveness

To assess clinical effectiveness, we asked patients to rate the severity of their migraine disability during a treated attack using a three-point scale, where 1 = mild, 2 = moderate, and 3 = severe. We also asked them to recall the number of disability days in a typical month because of migraine. The migraine disability period was defined in the survey as the time of disability including "everything related to a migraine attack, such as aura, nausea, head or other pain, and light and sound sensitivity."

Healthcare Costs

Patients self-reported their typical monthly migraine-related utilization rates before and after sumatriptan treatment. The validity of self-reported data compares favorably with that of data from medical records.^{9,10} The range of agreement between the two methods depends on the time since the event, salience of the event, and social desirability.¹ Previous studies indicate that underreporting of utilization occurs more often than overreporting.²

Each patient was asked to generalize their monthly healthcare utilization rate across the 12-month period before they started using sumatriptan. This estimate served as the baseline utilization rate. Patients were asked to recall the number of migraine-related services they used in a typical month before and after sumatriptan treatment for all services except hospitalization. Because hospitalization for migraine is rare, patients typically remembered these events, both before and after sumatriptan therapy. The number of hospitalizations recalled before sumatriptan was divided by 12 to calculate the monthly hospitalization rate. The number of hospital visits after sumatriptan was divided by the number of months the patient had used sumatriptan to calculate the monthly hospitalization rate. The utilization rate for sumatriptan was calculated using actual QualMed pharmacy claims, because these claims are not affected by the ICD-9 limitations of medical claims.

Each unit of healthcare utilization (ie, emergency department visits, physician visits, hospital visits, and medications) was valued using costs from QualMed that represent the actual cost to the HMO. The cost to QualMed for each healthcare service was multiplied by the utilization rate and summed across services to calculate the monthly migraine healthcare cost in a typical month for each patient, both before and after sumatriptan. Since the total elapsed time period in this study was approximately 2 years, no discounting or inflation rates were used. Costs are reported in 1995 dollars.

The study methodology was reviewed and approved by the Center for Health Services Research and Policy, QualMed Health Plan of Washington, Inland Northwest Division in Spokane, Washington, and the Washington State University Institutional Review Board in Pullman, Washington.

Statistical Analysis

We hypothesized that, after sumatriptan treatment, improved effectiveness outcomes and decreased utilization rates would occur for all categories except sumatriptan utilization. Using the Statistical Analysis System (SAS System Software, 1991, Version 6.08, Cary, NC), we used paired *t*-tests to analyze items with complete data. Probabilities of significant differences are reported for two-tailed tests. Because many of the endpoints in this analysis were hypothesized to be correlated, no correction was made for the multiple paired *t*-tests conducted.

Cost-effectiveness ratios before and after sumatriptan treatment were compared. The primary effectiveness variable was the number of days per month a patient did not experience a migraine-related disability. Total monthly migraine healthcare cost to QualMed was used in the numerator for the cost-effectiveness calculations.

... RESULTS ...

Of the 220 patients who purchased sumatriptan injectable according to HMO pharmacy claim records, 17 were excluded from the study because they were younger than age 18, had not yet used the sumatriptan they purchased, or reported having had no migraines. Of the remaining 203 patients, 168 were contacted by phone and 164 interviews were completed (81% response rate). The 119-question survey was completed in an average of 24 minutes. Patients were generally enthusiastic and cooperative. Only four patients declined to participate, one of whom reacted negatively to being contacted. An incorrect phone number was the most common reason for nonresponse.

The average age of the respondents was 44 years (range, 18 to 70 years), with 146 women and 18 men completing the survey. In general, patients were well educated, with 56.1% having progressed beyond high school.

Clinical Effectiveness

The mean (\pm standard deviation) migraine severity score before sumatriptan treatment was 2.89 ± 0.31 , with 89% of patients reporting severe headaches and 11% reporting moderate headaches (Table 1). The mean migraine severity score after

sumatriptan treatment was 2.55 ± 0.64 , with only 63% of patients reporting severe headaches and 29% reporting moderate headaches (Table 1). The 12% decrease in mean migraine severity after sumatriptan treatment was statistically significant ($n = 161$; $P < 0.01$).

While a decrease in migraine severity is a critical clinical outcome, a decrease in the number of days of disability because of migraine may be more important to patients. The number of monthly migraine disability days decreased by 40%, from 6.5 ± 5.9 days before sumatriptan to 3.9 ± 4.9 days after sumatriptan ($n = 158$; $P < 0.01$). The distribution of disability days before and after sumatriptan treatment is shown in Table 2.

Table 1. Migraine Severity Before and After Sumatriptan Treatment

	Before	After
Severe	144 (89%)	101 (63%)
Moderate	17 (11%)	47 (29%)
Mild	0 (0%)	13 (8%)

Chi-square = 34.41; $P < 0.001$.

Table 2. Frequency of Migraine Disability Days Before and After Sumatriptan Treatment

Monthly Disability Days	Before	After
0-1 days	22 (14%)	63 (40%)
2-3 days	43 (27%)	42 (27%)
4-5 days	28 (18%)	23 (15%)
6-10 days	36 (23%)	20 (13%)
>10 days	29 (18%)	10 (6%)
Total	158 (100%)	158 (100%)

Chi-square = 28.30; $P < 0.001$.

Healthcare Costs

After sumatriptan treatment, patients reported fewer migraine-related hospitalizations, emergency department visits, and physician visits and used fewer over-the-counter and prescription products other than sumatriptan for migraine (Table 3). The sumatriptan utilization rate was the only one to increase, from 0 prescriptions per month before sumatriptan treatment to 0.73 ± 0.82 prescriptions per month after sumatriptan treatment (Table 3). Total monthly healthcare costs for migraine decreased from $\$286 \pm 398$ to $\$168 \pm 215$, a 41% decrease ($n = 157$; $P < 0.01$, paired t -test). This net decrease in healthcare costs included the $\$14.61$ monthly increase in drug expenditures.

Cost-Effectiveness

Cost-effectiveness is a common economic measure used to compare alternatives and assess comparative value obtained for money spent.¹¹ In this study, cost was defined as monthly migraine healthcare cost and effectiveness was defined as the number of migraine disability-free days per month. Disability-free days per month were calculated by subtracting the number of migraine disability days from 30. The cost-effectiveness ratio using aggregate- or mean-level cost-and-effect data (cost-effectiveness ratio #1) was $\$12.18$ before sumatriptan and $\$6.43$ after sumatriptan (Table 4). This cost-effectiveness ratio is 47% more favorable after sumatriptan treatment.

Sensitivity analysis revealed that total healthcare costs after sumatriptan treatment would have to

increase by 89% over existing levels of $\$168$ to $\$318$ per month for all services or the effectiveness of sumatriptan would have to decrease by 47% to only 13.81 disability-free days per month before the two cost-effectiveness ratios would be equal. When individual healthcare service components are varied one at a time during the sumatriptan treatment period, the total cost or utilization rate would need to increase by 1324% for over-the-counter medicines, 459% for emergency department visits, 408% for hospitalizations, 343% for physician visits, or 528% for non-sumatriptan prescriptions (without an increase in effectiveness) before the two cost-effectiveness ratios would be equal.

Determining whether a statistical difference exists between the two aggregate-level cost-effectiveness ratios is not straightforward because both the numerator and the denominator have a variance. Researchers do not agree on the appropriate tests nor are tests readily available for aggregate statistical comparisons. Another approach to examining the meaningfulness of differences in cost-effectiveness ratios is to calculate individual cost-effectiveness ratios for each patient during each time period and compare the two distributions statistically. Patient-level cost-effectiveness ratios were calculated for each patient using data from both the before and after treatment periods (Table 4). The mean of the patient-level cost-effectiveness ratios (cost-effectiveness ratio #2) before sumatriptan was $\$14.51 \pm 26.95$ per disability-free day. The mean after sumatriptan was 43% lower ($\$8.20 \pm 18.09$). Using a

Table 3. Migraine-Specific Healthcare Utilization and Cost Before and After Sumatriptan Treatment ($n = 157$)

Service	Cost per Unit	Before		After		P
		Monthly Use Rate	Rate x Cost	Monthly Use Rate	Rate x Cost	
Hospital Visits	\$1950	0.04 ± 0.14	\$79.70	0.02 ± 0.06	\$29.46	0.01
Emergency Department Visits	\$200	0.36 ± 0.75	\$71.34	0.13 ± 0.41	\$26.75	<0.01
Physicians Visits	\$58	1.05 ± 1.13	\$60.77	0.58 ± 0.87	\$33.80	<0.01
Over-the-Counter Products	\$10	2.14 ± 2.48	\$21.40	1.05 ± 1.54	\$10.51	<0.01
Other Prescriptions	\$20	2.65 ± 2.19	\$52.99	1.19 ± 1.33	\$23.82	<0.01
Sumatriptan Prescriptions	\$60	0	0	0.73 ± 0.82	43.78	<0.01
Total Cost			\$286.20 ± 397.84		\$168.13 ± 215.38	<0.01

Data are mean ± standard deviation

Rates and monthly costs reported as per sumatriptan user per month. Rates are rounded

paired *t*-test, we found that the patient-level cost-effectiveness ratio (the cost per disability-free day) was significantly lower after sumatriptan treatment.

... DISCUSSION ...

In this QualMed population, patient-reported healthcare utilization decreased significantly after patients began taking sumatriptan for migraine. Self-reporting methodology was used because we believed it was the most efficient means of collecting patient-rated effectiveness and healthcare utilization data. The ICD-9 codes are 100% complete in the QualMed claims system because they are required for payment. However, the low number of migraine diagnoses found in the initial claims-based study⁸ at QualMed suggests that physicians may have been underreporting migraine as the cause for a visit or service and thus patients should be consulted. Recall bias and under- or overreporting healthcare utilization are possible limitations of studies using self-reported data. In our study design, if the magnitude and direction of patient bias are consistent in both the before and after treatment periods, the error caused by self-reporting is reduced. Considering these limitations, self-reporting methodology was considered acceptable and more practical for our research.

The response rate for this study was high by survey research standards, which increases the external validity of these findings. Of those patients successfully reached by phone, 97.6% completed the phone survey, a record high participation rate for the survey center. In attempting to extrapolate these findings to other migraine severity groups within QualMed, we could not accurately predict whether the same changes in cost-effectiveness ratios would be observed.

Previously published research has focused on the clinical improvement obtained with sumatriptan, often by measuring the severity of a specific migraine immediately after treatment. Our study found decreases in clinical severity scores similar to those seen in controlled clinical trials.^{12,13} The results of our research extend beyond the traditional clinical outcomes for sumatriptan and into economic outcomes, which have not been studied extensively in managed care organizations. A limitation of this expanded approach is that it does not assess quality of life or functional status. Although self-reported patient outcomes are probably

Table 4. Cost-Effectiveness Before and After Sumatriptan Treatment (n = 157)

	Before	After
Cost (mean migraine-related healthcare costs/month)*	286 ± 398	168 ± 215
Effect (mean migraine disability-free days/month)*	23.5 ± 5.9	26.1 ± 4.9
Cost-Effectiveness Ratio #1 (Cost per disability-free day aggregate level)	\$12.18	\$6.43
Cost-Effectiveness Ratio #2 (Cost per disability-free day, patient level)*	\$14.51 ± 26.95	\$8.20 ± 18.09
Total	157 (100%)	157 (100%)

Data are mean ± standard deviation.
P < 0.001, paired *t*-tested.

directly related to migraine disability days, the exact relationship is not known.

The results of this study can be used to extrapolate the cost-effectiveness ratios of sumatriptan in different patient populations. The appropriate unit costs for a different healthcare plan can be inserted into the cost model shown in Table 3. If the baseline migraine utilization rate is different, extrapolating the percent decreases seen in this population to other migraine groups will be more difficult. The validity of applying the same percent change in utilization to other severity groups is not known.

Some types of migraine-related healthcare utilization were not specifically captured in this study. Computed tomographic scans, magnetic resonance imaging, and other expensive diagnostic tests may be performed in patients with migraine to rule out other serious conditions, such as brain tumors. This utilization category was not adequately assessed in our study design because patients may not have attributed the diagnostic procedure to their migraine. New treatments, such as sumatriptan tablets, may lead to changes in the migraine population treated with sumatriptan. The tablets have a different cost per unit and may yield a different effectiveness and healthcare utilization rate.

Our study design is consistent with the current goals of many managed care organizations of continuous quality improvement and can be implemented with or without external assistance as a National Committee for Quality Assurance accreditation activi-

ty. By continuing to apply a migraine outcomes assessment in a defined population, a managed care organization can begin to identify patient groups in whom sumatriptan treatment positively affects migraine outcomes. Demming has said, "If I had to reduce my message to a single sentence I'd say it all had to do with reducing variation."¹⁴ Through continuous quality measurement and reduction in variation, the managed care organization can achieve the lowest total cost and the highest degree of customer satisfaction while ensuring its long-term viability.

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