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Clinical and Economic Impact of TENS in Patients With Chronic Low Back Pain: Analysis of a Nationwide Database

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Abstract: This study evaluated patients who were given transcutaneous electrical nerve stimulation (TENS) compared with a matched group without TENS prior to intervention and at 1-year follow-up. Patients who were treated with TENS had significantly fewer hospital and clinic visits, used less diagnostic imaging (31 vs 46 events per 100 patients), had fewer physical therapy visits (94 vs 107), and required less back surgery (7.5 vs 9.2 surgeries) than patients receiving other treatment modalities. Total annual costs for chronic low back pain patients without neurological involvement were lower in TENS patients ($17,957 vs $17,986 for non-TENS), even when the cost of the device was taken into account. [*Orthopedics.* 2013; 36(12):922-928.]

Chronic low back pain continues to be one of the conditions most commonly presenting to orthopedic surgeons, who, following primary practitioners, are the most common physicians patients seek.[1,2] It is the fifth most frequent indication for a physician visit.[2] Up to 85% of the population will experience an episode of nonspecific low back pain during their lifetimes, but the vast majority (more than 90%) will have a self-limited disease that resolves within 3 months.[1,3,4] However, due to the large number of patients presenting with this condition annually, it represented a substantial fiscal burden estimated to be $26 billion in 1998 and nearly $100 billion in 2007.[5,6]

Chronicity is less common, but the prevalence of chronic low back pain in the United States rose from 3.9% in 1992 to 10.2% in 2006.[7,8] These patients in particular may be drivers of cost because they often require substantial medical intervention and have high pharmacologic costs.[5,9] Low back pain is associated with substantial direct (eg, cost of medical care) and indirect (eg, lost productivity due to time off work) costs. A study of Swedish patient data by Ekman et al[10] demonstrated that direct costs represented only 15% ($2200) of the total annual cost, with 85% ($16,600) consisting of indirect costs.

Patients with chronic low back pain who do not also have neurological deficits represent a treatment dilemma with multiple nonoperative treatment modalities proposed.[11] However, combined guidelines from the American College of Physicians and the American Pain Society,[12] which were also adopted by the American Academy of Orthopaedic Surgeons in 2010,[13] have given nonoperative modalities a weak recommendation due to the poor level of evidence for the supporting studies. One potential treatment modality for chronic low back pain is transcutaneous electrical nerve stimulation (TENS). This functions by delivering a localized voltage of varying intensity and frequency, which has been shown to inhibit normal nociceptive fiber signaling.[14-16] The literature has reported mixed results regarding the efficacy of TENS. Recent meta-analyses by Brosseau et al[17] and Khadilkar et al[18] demonstrated no

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evidence for or against the use of this treatment modality. The primary reason for this lack of consensus is interstudy heterogeneity, which is due to a lack of a standardized treatment protocol (eg, different TENS device settings, duration of treatments, and adjuvant therapies).[19,20] However, no study has evaluated the clinical and economic effects of the use of TENS for the treatment of chronic low back pain without neurological symptoms using a nationwide administrative claims database.

The purpose of this study was to evaluate the clinical and economic effects among patients who were given TENS for chronic low back pain compared with a matched group of patients who were not given TENS, both prior to intervention and at 1-year follow-up. The primary outcome measures of this study were whether the use of TENS resulted in differences between (1) hospital and clinic visits; (2) use of diagnostic imaging; (3) use of physical therapy; (4) incidence of back surgery; and (5) treatment costs.

Materials and Methods

The costs and clinical effects of TENS for patients with chronic low back pain, compared with those who were not treated with TENS, were evaluated using a commercial and Medicare supplemental administrative claims database (MarketScan; Truven Health Analytics, Ann Arbor, Michigan). This database contained claims and eligibility records for approximately 30 million enrollees in distinct sets of files for commercially insured individuals (ie, working-aged adults and their dependents), and 3 million enrollees for Medicare supplemental insurance. Patients were selected if they had at least 2 ICD-9-CM coded claims for low back pain during a 3-month period anytime between January 1, 2008, and September 30, 2010. Patients were then divided into groups based on those who received TENS and those who did not receive TENS during the follow-up period (**Table 1**). For TENS patients, the date of the first TENS procedure was set as the study index date. The index date for the non-TENS patients was the date of the first claim for procedures other than TENS (eg, physical therapy, opioids, back surgery, or diagnostic imaging).

Patients in each group were matched using a 1:1 greedy propensity score matching algorithm to ensure patient groups were comparable regarding baseline clinical and demographic characteristics. Logistic regression models were used to calculate a predicted probability of group membership (eg, receiving TENS vs not receiving TENS), or propensity score, based on the observed predictors. The following variables were included in the logistic regression model: age, sex, geographic region of residence, indicators of individual comorbidities, medication use, back surgery, and surrogate low back pain baseline severity measures. These predictor variables were measured during the 12-month pre-index period. Following matching, there were 22,913 patients in each group (**Figure**). Patients with low back pain findings without neurological involvement were further selected using ICD-9 diagnosis codes to isolate patients with purely mechanical low back pain (as opposed to patients with neurological symptoms or those with congenital or acquired spinal disorders). After final selection, there were 16,593 patients available for analyses.

Primary outcomes (hospital and clinic visits; physical therapy use; incidence of back surgery; direct and indirect treatment costs) were compared across treatment groups by measuring the proportion of patients with an outcome for categorical variables (eg,

Table 1

Inclusion and Exclusion Criteria

TENS Group	Non-TENS Group
Inclusion Criteria	
1. At least 1 claim for a TENS device (HCPCS codes: E0720, E0730) between January 1, 2008, and September 30, 2010	1. No claims for TENS and received other therapy (including physical therapy, opioids, back surgery, or diagnostic imaging) between January 1, 2008, and September 30, 2010
2. At least 2 medical claims with an associated primary or secondary diagnosis of LBP within 90 days and at least 1 of the LBP claims within ±90 days of the TENS index claim	2. At least 2 medical claims with an associated primary or secondary diagnosis of LBP within 90 days and at least 1 of the LBP claims within ±90 days of the LBP other therapy (eg, physical therapy, opioids, back surgery, diagnostic imaging) index claim
3. At least 18 years of age as of the study index date	3. At least 18 years of age as of the study index date
4. Continuously enrolled in the health plan for 12 months prior to the index date and at least 24 months of continuous enrollment after the index date	4. Continuously enrolled in the health plan for 12 months prior to the index date and at least 24 months after the study index date
Exclusion Criteria	
Did not have a claim indicating cancer or neurodegenerative disease during the 12-month period prior to the study index date or during the follow-up period	Patient did not have a claim indicating cancer or neurodegenerative disease during the 12-month period prior to the index date or during the follow-up period post-study index date

Abbreviations: HCPCS, Healthcare Common Procedure Coding System; LBP, low back pain; TENS, transcutaneous electrical nerve stimulation.

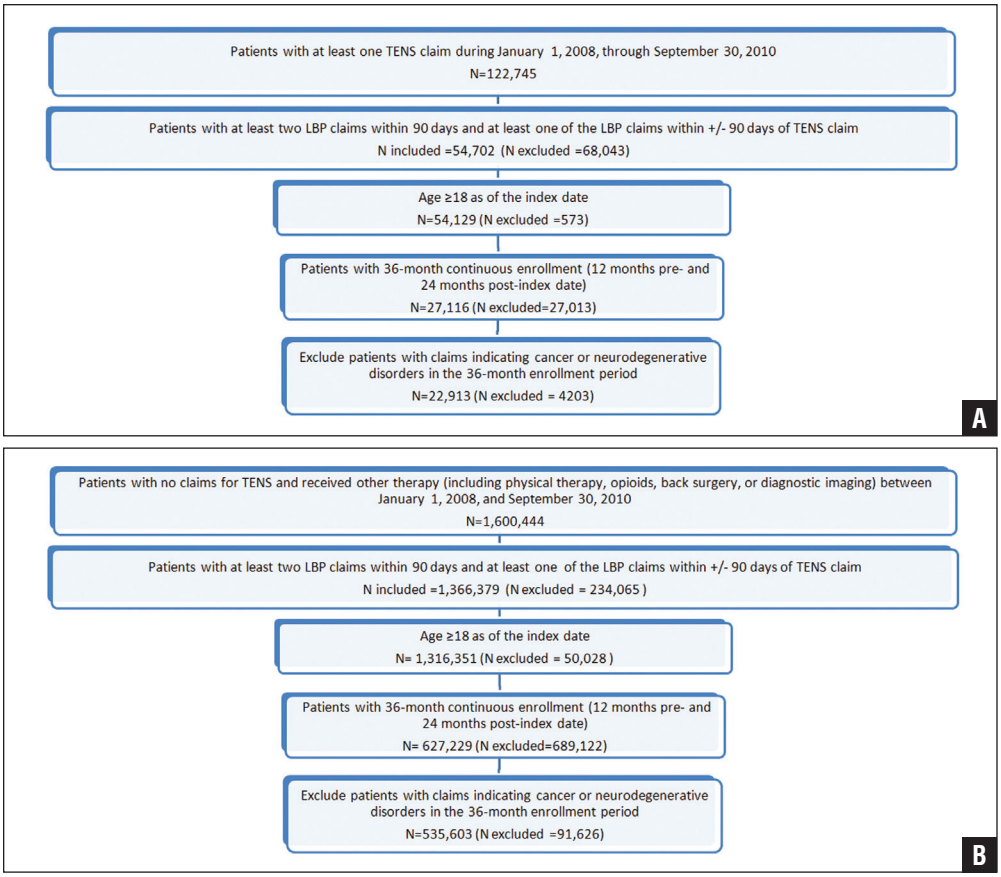

Figure: Flow diagrams of patient selection based on inclusion and exclusion criteria for patients who received transcutaneous electrical nerve stimulation (TENS) (A) and those who did not receive TENS (B). Abbreviation: LBP, low back pain.

percent of patients having outpatient or inpatient visits) or the means for continuous variables (eg, total medical costs). All outcomes were evaluated at baseline (prior to intervention) and at 1-year follow-up.

All statistical analyses were performed using SAS version 9.1 software (SAS, Cary, North Carolina). The chance of having a type I error used as a cutoff to determine statistical significance was set at alpha=0.05. Continuous study measures were assessed and reported with means and SDs. Categorical variables were reported using frequency distributions. Student's *t* test was used to test for statistical differences for continuous variables, chi-square test was used for categorical variables, and the nonparametric Wilcoxon rank sum test was used for ranked data.

RESULTS

Baseline demographic and clinical variables were compared between TENS and non-TENS patients. There were no significant differences between the 2 groups based on mean age, age category, sex, geographic region of residence, major medical comorbidities, Charlson Comorbidity Index, or psychiatric disorders (**Table 2**). The only significant differences observed were in the type of insurance (13.1% in the TENS group had supplemental Medicare insurance compared with 11.9% in the non-TENS group) and single episodes of low back pain (17.6% vs 16.4%, respectively) (**Tables 2-3**).

Chronic Low Back Pain Without Neurologic Compromise

Overall, patients with chronic low back pain without neurologic compromise who were treated with TENS had significantly lower proportions of inpatient and outpatient admissions and physician office visits than those who did not receive TENS (all $P<.001$). Patients who received TENS had higher medical equipment costs (eg, cost of the TENS unit), but lower total annual costs.

Resource use due to any cause between the 2 groups demonstrated that patients who received TENS had lower proportions of emergency department visits (26.9% vs 28.2%; $P=.048$), inpatient hospital stays (13.7% vs 15.9%; $P<.0001$), and physician office visits (98.9% vs 99.6%; $P<.0001$). These differences were maintained when patients were specifically evaluated for visits due to pain alone (**Table 4**).

Analysis of total annual costs demonstrated that patients who received TENS had significantly lower total costs, although the difference was modest ($17,957 for TENS patients vs $17,986 for non-TENS patients; $P<.0001$). Transcutaneous electrical nerve stimulation patients were observed to have significantly lower inpatient costs ($4074 vs $4772, respectively; $P<.0001$), but significantly higher outpatient costs ($10,489 vs $9643, respectively; $P<.0001$), primarily due to durable medical equipment costs, which incorporate the cost to purchase the TENS device (**Table 5**).

Overall Cohort

Diagnostic imaging use during the 1-year follow-up period was found to be significantly lower in TENS patients (mean, 31 events per 100 patients)

compared with non-TENS patients (mean, 46 events per 100 patients; *P*<.0001).

Physical therapy use at 1-year follow-up was significantly lower in TENS patients (mean, 94 events per 100 patients) compared with non-TENS patients (mean, 107 events per 100 patients; *P*<.0001). Of note is that the higher number demonstrates that several patients were prescribed physical therapy on more than 1 occasion.

Similar trends were seen in back surgery. An evaluation of the entire cohort demonstrated significantly less back surgery in TENS patients (mean, 7.5 episodes per 100 patients) compared with non-TENS patients (mean, 9.2 episodes per 100 patients; *P*<.0001).

Discussion

The purpose of this study was to evaluate resource use and costs in patients with chronic low back pain who received TENS compared with a matched group of patients with chronic low back pain who did not receive TENS. Few studies have evaluated the effect of TENS use or non-use on resource use and costs using a large administrative claims database.[21] The current authors observed that TENS was associated with significantly fewer inpatient visits and less diagnostic imaging, physical therapy, and back surgery. Overall, when all costs were considered, TENS use was cost neutral compared with TENS non-use, although the upfront costs for the unit itself were significantly higher.

Avoiding surgery when it is not clinically indicated is of utmost importance to orthopedic surgeons. However, this may be particularly difficult when patients erroneously believe that surgery in the setting of no neurologic compromise will effectively reduce their pain. Spinal fusion to treat chronic low back pain is controversial, with conflicting data on clinical and disability outcomes. In a randomized, controlled trial performed in Norway comparing surgical outcomes with physical therapy and cognitive intervention for 124 patients with chronic low back pain (symptom duration, more than 1 year) but no neurological symptoms, Froholdt et al[22] observed no difference in clinical outcome scores at 9-year follow-up (mean adjusted Oswestry Disability Index treatment effect, 1.9; 95% confidence interval, -7.9 to 11.6). The authors also observed that, compared with prior studies reporting 1- and 4-year follow-up, there was no significant difference in disability, pain, fear avoidance beliefs, trunk muscle strength, and return to work for lumbar fusion compared with structured exercise and cognitive behavioral therapy for treatment of chronic low back pain.[23-25] Therefore, the current study provides a potentially compelling treatment alternative and/or adjuvant for patients for whom back surgery is not indicated. The current authors observed that TENS was a noninvasive option that provided clinical and economic advantages compared with non-use of TENS. Interestingly, in the entire cohort, which included patients with neurological symptoms, TENS was observed to result in less back surgery.

The observed reduction in the use of medical imaging and opioids for TENS patients with chronic low back pain is in stark contrast to increases in imaging studies and opioid therapy during the past

Table 2

Comparison of Baseline Demographic Variables Following Matching

Demographic	Non-TENS (n=8286)	TENS (n=8307)	*P*
Mean age, y	50.0±13.5	50.3±13.5	.1095
Age range, %			
18-34	12.77	11.66	
35-44	20.49	21.27	
45-54	30.64	30.67	
55-64	24.69	24.05	
65-74	6.09	6.89	
75-84	4.34	4.49	
≥85	0.97	0.96	
Sex, %			.8416
Female	65.51	65.66	
Male	34.49	34.34	
Region of residence, %			.0834
Northeast	10.31	10.12	
Midwest	22.36	23.43	
South	47.09	47.26	
West	16.71	16.32	
Unknown	3.52	2.87	
Health plan type, %			.0236
Commercial	88.10	86.94	
Medical supplemental	11.90	13.06	
LBP episodes, %			<.0001
0	35.28	23.62	
1	16.36	17.61	
2	8.67	14.27	
3	7.14	11.06	
≥4	32.55	33.44	

Abbreviations: LBP, low back pain; TENS, transcutaneous electrical nerve stimulation.

Table 3

Comparison of Baseline Comorbidities Following Matching

Variable	Non-TENS (n=8286)	TENS (n=8307)	*P*
CCI component, %			
Myocardial infarction	1.18	1.17	.9284
Congestive heart failure	2.86	3.07	.4264
Peripheral vascular disease	4.31	4.14	.5920
Cerebrovascular disease	2.62	2.89	.2875
Chronic respiratory disease	9.29	9.26	.9371
Rheumatologic disease	4.15	4.08	.8187
Ulcer disease	0.72	1.05	.0263
Mild liver disease	2.82	2.35	.0531
Hemiplegia	1.52	1.60	.6761
Moderate or severe liver disease	1.89	2.09	.3573
Diabetes mellitus	13.47	13.03	.3996
Moderate or severe liver disease	0.76	0.76	.9886
Mean CCI score	0.6±1.1	0.6±1.1	.8682
CCI score distribution, %			.9233
0	67.60	67.88	
1	13.72	13.60	
2	11.14	11.18	
3	4.31	4.03	
≥4	3.23	3.30	
Chronic LBP-related comorbidity, %			
Coronary atherosclerosis	5.58	5.75	.6189
Anxiety	7.81	7.40	.3252
Major depressive disorder	6.22	6.50	.4515
Insomnia/sleep disorder	0.82	0.84	.8760
Kidney stones	2.78	2.73	.8652
Obesity	2.15	2.24	.6895
Myalgia	10.37	10.32	.9153

Abbreviations: CCI, Charlson Comorbidity Index; LBP, low back pain; TENS, transcutaneous electrical nerve stimulation.

Table 4

Overview of Resource Use Between Groups

Variable	% Non-TENS (n=8286)	% TENS (n=8307)	*P*
All-cause resource use			
Any emergency department visit	28.23	26.86	.0480
Any inpatient hospital stay	15.85	13.72	.0001
Any outpatient claim	100.00	100.00	
Any outpatient hospital visit	76.90	76.14	.2481
Any physician office visit	99.64	98.90	<.0001
Any use of durable medical equipment	11.24	99.99	<.0001
Pain-related resource use			
Any emergency department visit	6.79	5.02	<.0001
Any inpatient hospital stay	6.63	4.90	<.0001
Any outpatient claim	98.46	97.41	<.0001
Any outpatient hospital visit	37.55	34.92	.0004
Any physician office visit	93.24	83.03	<.0001
Any use of durable medical equipment	1.98	79.21	<.0001

Abbreviation: TENS, transcutaneous electrical nerve stimulation.

20 years. Based on an extensive review of the evidence, the guidelines issued jointly from the American College of Physicians and American Pain Society recommend against routine imaging for patients with nonspecific low back pain.[12] Although the current study could not definitively determine the circumstances for imaging in each patient, the observation that fewer imaging studies were done for TENS patients with chronic low back pain is an important factor contributing to lower overall health care costs. Likewise, in the current study, the small reduction in opioid use for TENS patients with chronic low back pain may be important as an overall public health measure in reducing the exposure of chronic low back pain patients to chronic opioid use and the related sequelae. According to the jointly issued American College of Physicians and American Pain Society guidelines, "Failure to respond to a time-limited course of opioids should lead to reassessment and consideration of alternative therapies or referral for further evaluation."[12] Alternative therapies such as TENS for chronic low back pain may provide clinicians with an option that requires less imaging and avoids opioid pain medication in this challenging population.

There were several limitations to this study. First, confounding factors may have occurred as a result of selection bias related to receiving the

TENS device. However, the 2 groups were well matched on baseline demographic variables and comorbidities. One potential confounder is that patients in the TENS group had a slightly higher number of low back pain episodes, which can be seen as a surrogate for slightly more severe disease. It is thus possible that the results of this study may have understated the benefits of TENS. One should note that medical conditions were identified based on administrative claims using ICD-9-CM diagnosis codes, which may be susceptible to clerical errors or erroneous reporting. Also, this study was not able to determine indirect costs (eg, missed workdays) because these are not captured in the database. However, because non-TENS patients had more inpatient and physical therapy visits, it can be hypothesized that they may have also had higher indirect costs. Despite these limitations, the authors believe that this study provides important insights regarding the use of TENS for the treatment of chronic low back pain that have not been previously reported.

Table 5

Overview of Resource Use Costs Between Groups

Resource	Mean±SD Cost, $ Non-TENS (n=8286)	Mean±SD Cost, $ TENS (n=8307)	*P*
All-cause resource use			
Total	17986±30,617	17,957±25,711	<.0001
Emergency department	409±1566	399±1530	.1335
Inpatient hospital	4772±20,984	4074±16,841	.0002
Outpatient services	9643±15,487	10,489±14,425	<.0001
Outpatient hospital	4177±10,604	3896±8163	.2027
Physician office	3636±3857	3752±4424	.0792
Durable medical equipment	116±597	545±785	<.0001
Pharmacy	3161±7987	2996±4455	.0345
Pain-related resource use			
Total	6193±17,127	6331±16,636	<.0001
Emergency department	65±562	55±722	<.0001
Inpatient hospital	2474±14,159	1948±13,321	<.0001
Back surgery	2066±12,244	1717±12,009	<.0001
Outpatient services	2998±7021	3680±7943	<.0001
Back surgery	101±1142	94±960	.3144
Outpatient hospital	1235±5442	1156±4744	.0005
Physician office	1324±2060	1312±2216	<.0001
Durable medical equipment	19±249	337±484	<.0001
Physical therapy	865±1594	793±1635	<.0001
Imaging	373±910	244±756	<.0001
Pharmacy	656±1574	647±1287	.002
Opioids	191±1101	680±2	.0973

Abbreviation: TENS, transcutaneous electrical nerve stimulation.

A few prior studies have attempted to evaluate the effect of TENS on costs and resource use,[21,26] but have usually had small sample sizes or limited geographic areas. Lin et al[21] attempted to evaluate the cost-effectiveness of several treatment modalities for chronic low back pain present in the American College of Physicians and American Pain Society guidelines[12] but noted that much of the currently available data are methodologically inconsistent and use lower levels of clinical evidence. Chabal et al[26] attempted to quantify the cost-effectiveness of TENS by surveying 276 patients with unspecified chronic pain who were being treated with TENS. They observed that physical therapy costs could be decreased by 69% with long-term TENS use. However, it is unclear whether these patients had chronic low back pain or other types of chronic pain. Furthermore, many of these conclusions were based on extrapolations of future expected resource use and thus may have been sensitive to bias. Dagenais et al[27] attempted to evaluate the cost-effectiveness of several treatments for chronic low back pain but identified few reports of high quality. This general lack of available data should be seen as an opportunity to further understand the interplay between efficacy and cost-effectiveness in the treatment of chronic low back pain that is likely due to heterogeneous causes.

On the basis of the current study, the authors believe that TENS may be a useful adjuvant in the management of chronic low back pain, which may be more difficult to manage than new-onset acute low back pain. Compared with

treatment without TENS, the authors' results demonstrate that TENS is associated with fewer inpatient, outpatient, physician office, emergency department, and physical therapy visits, less diagnostic imaging, and fewer episodes of back surgery and is less costly annually, although these savings may not be clinically compelling. Further studies are needed using a standardized methodology to determine the optimal treatment options for this challenging patient population.

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