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HEALTH SERVICES RESEARCH

Costs and Cost-Effectiveness of Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome

An Observational Study in a Workers' Compensation Population

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Study Design. Prospective cohort study.

Objective. We estimated the cost-effectiveness of spinal cord stimulation (SCS) among workers' compensation recipients with failed back surgery syndrome (FBSS).

Summary of Background Data. Randomized controlled trial (RCT) evidence suggests that SCS is more effective at 6 months than medical management for patients with FBSS. However, procedure costs are high and workers' compensation claimants often have worse outcomes than other patients.

Methods. We enrolled 158 FBSS patients receiving workers' compensation into three treatment groups: trial SCS with or without permanent device implant (n = 51), pain clinic (PC) evaluation with or without treatment (n = 39), and usual care (UC; n = 68). The primary outcome was a composite measure of pain, disability and opioid medication use. As reported previously, 5% of SCS patients, 3% of PC patients and 10% of UC patients achieved the primary outcome at 24 months. Using cost data from administrative databases, we calculated the cost-effectiveness of SCS, adjusting for baseline covariates.

Results. Mean medical cost per SCS patient over 24 months was $52,091. This was $17,291 (95% confidence intervals [CI], $4100–30,490) higher than in the PC group and $28,128 ($17,620–38,630) higher than in the UC group. Adjusting for baseline covariates, the mean total medical and productivity loss costs per patient of the SCS group were $20,074 ($3840–35,990) higher than those of the PC group and $29,358 ($16,070–43,790) higher than those of the UC group. SCS was very unlikely (<5% probability) to be the most cost-effective intervention.

Conclusion. In this sample of workers' compensation recipients, the high procedure cost of SCS was not counterbalanced by lower costs of subsequent care, and SCS was not cost-effective. The benefits and potential cost savings reported in RCTs may not be replicated in workers' compensation patients treated in community settings.

Key words: cost-benefit analysis, cost-effectiveness, failed back surgery syndrome, spinal cord stimulation, workers' compensation.

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Each year, US workers' compensation programs spend $26 billion in medical care and $29.9 billion in other benefits for work-related injuries.[1] Back pain accounts for more than 20% of this burden.[2] Most patients with back pain return to work quickly, but a minority have pain that persists despite medical and surgical therapies.[3] The term "failed back surgery syndrome" (FBSS) is often used to label pain that persists after spine surgery.[4]

Spinal cord stimulation (SCS) has been used for more than three decades to treat intractable pain. SCS devices and implantation methods vary, but all involve insertion into the epidural space of electrodes connected to an electrical pulse generator. Generally, a trial is performed and is followed by a permanent implantation only if successful in relieving pain. Case series have suggested that SCS is associated with pain improvement,[5] but there have been just two randomized controlled trials (RCTs) for FBSS.[6,7] The RCT that compared SCS with conventional medical management found that, at 6 months, a significantly higher proportion

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of patients randomized to SCS achieved more than or 50% improvement in leg pain (48% *vs.* 9%).[6] The lack of a sham control in the RCT makes it impossible to distinguish specific "active" mechanisms of SCS from nonspecific influences ("placebo effects").[8] The RCT economic evaluation[9] found significantly higher medical care costs in the first 6 months in the group randomized to SCS (difference of CA $15,395). Some researchers estimate that these initial costs of SCS will be recouped by approximately 36 months postprocedure because of a reduction in pain-related health service costs.[7,10,11] However, there are few prospective data on the long-term costs of care[12] and the cost-effectiveness of SCS remains uncertain.[13] US workers' compensation recipients were not included in the RCT and have worse outcomes from a variety of pain treatments[14]; therefore, the RCT results might not be applicable to this population.

In 2004, the Washington State workers' compensation program (Department of Labor and Industries [DLI]) began to cover SCS for injured workers with FBSS who met clinical criteria and agreed to participate in an independently conducted prospective cohort study. We previously reported the effectiveness results of this study, comparing patients who received trial SCS with or without permanent device implant, pain clinic (PC) evaluation with or without PC treatment, or usual care (UC; neither SCS nor PC evaluation).[15] We now report the cost-effectiveness results.

MATERIALS AND METHODS

The study methods and clinical outcomes were described previously.[15] In brief, 158 patients enrolled in the study. Inclusion criteria were: (1) Washington State workers' compensation claim for a back injury; (2) currently receiving work time loss compensation; (3) pain radiating into one or both legs for more than 6 months; (4) leg pain greater than back pain; (5) average leg pain in the last month rated more than 6 (0–10 scale); (6) no previous SCS surgery; (7) no current diagnosis of diabetes or cancer; and (8) ability to speak English or Spanish. Initially, additional inclusion criteria were age 18 to 55 years, claim duration less than 3 years, and 1 to 2 previously open lumbar spine operations during the claim. To increase enrollment, these criteria were broadened to age 18 to 60, claim of any duration, and 1 to 3 previous open lumbar spine operations during the claim.

SCS Group

Washington State physicians were informed of the study, and referred their patients who were candidates for SCS and appeared to meet the study inclusion criteria. Our research team conducted final screening, consent, and enrollment procedures.

PC and UC Groups

Patients potentially eligible for the PC group were identified from DLI administrative databases when they were approved for multidisciplinary PC evaluation. For the UC group, potentially eligible patients who had not been referred for SCS or PC were selected randomly from the DLI administrative database. For both groups, patients were sent a letter with study information and were telephoned by research staff for eligibility screening, informed consent, and enrollment.

Interventions

Decisions regarding treatments were left to patients and their health care providers. The physicians, working in academic and community settings, determined all SCS procedures, equipment and criteria for proceeding with a permanent implant. Similarly, in the PC group, the patients' health care providers decided whether the patient would be treated in the PC program and if so, the program length and content.

Analysis Sample

We defined treatment groups by the evaluation and treatment received during the year after enrollment. Primary analyses compared the SCS group (patients who received at least a trial of SCS; n = 51) with each of two comparison groups: PC group who received PC evaluation (n = 39) and UC group who received neither trial SCS nor PC evaluation (n = 68). This is similar to an intention-to-treat analysis advocated for RCTs[16] and adopted by the previous RCT of SCS *versus* medical management.[6] In secondary analyses, we compared costs and outcomes of the SCS subgroup who received a permanent SCS implant (n = 27) with those of the PC subgroup who received at least some PC treatment (n = 22).

At baseline, the three groups were similar in age, sex, and other characteristics. However, on average, the SCS group reported slightly more intense leg pain (mean score on a 0–10 scale = 7.7 *vs.* 7.3 [$P = 0.07$] in the PC group and 7.2 [$P = 0.02$] in the UC group), a longer duration of leg pain (median 48 months compared with 31 months [$P = 0.02$] in the PC group and 36 months [$P = 0.25$] in the UC group) and work time loss compensation (median 39 months compared with 24 months [$P = 0.01$] in the PC group and 30 months [$P = 0.26$] in the UC group). The SCS group reported slightly higher levels of pain-related physical disability (Roland Disability Questionnaire [RDQ] score 21.1 compared with 20.1 in the PC group [$P = 0.04$] and 20.0 in the UC group [$P = 0.01$]).[15] They were also more likely to have legal representation (49% compared with 26% [$P < 0.01$] in the PC group and 29% [$P < 0.01$] in the UC group).

Outcome Measures

Patients completed measures at enrollment and 6, 12, and 24 months. Physical functioning was assessed by the RDQ.[17] RDQ scores range from 0 to 24, with higher scores indicating greater disability. Patients rated the average intensity of their leg pain in the last month on a scale of 0 (no pain) to 10 (pain as bad as could be). Patients reported medications they took for back or leg pain more than five times in the past month and the number of days they used it. The primary outcome, defined in the protocol, was a composite measure that, consistent with the clinical goals of SCS, defined success as at least 50% reduction (relative to baseline) in leg-pain intensity, a two-point or greater improvement on the RDQ, and less

than daily opioid medication use. We also examined leg-pain intensity and RDQ scores separately to facilitate comparison with previous studies. The follow-up interview completion rate was 87% at 24 months.[15]

Economic Measures

Using administrative databases, we examined medical and productivity loss costs to DLI through 24 months postenrollment. DLI pays for injury-related medical costs, including medications, hospitalizations, and outpatient and home health care. DLI also reimburses patients for some expenses incurred in receiving care. We used actual reimbursements, not billed charges, to calculate the medical costs to the payer. We estimated the cost of SCS implantation, revision, replacement, and removal procedures by summing all reimbursements on the day of the procedure.

Productivity loss costs included work time loss compensation payments to workers unable to work because of injury. The benefit amounts to a maximum of 60% to 75% of the preinjury wage. Productivity loss costs also included "loss of earning power" payments to workers who returned to modified duties at a lower wage, as well as other reimbursements made to workers judged to have permanent loss of function. Administrative data on medical and productivity loss costs were available for all participants.

Cost-Effectiveness Analyses

All costs were converted into 2007 US dollars, using the consumer price index for medical care commodities (pharmaceuticals) and medical care services (other health care).[18] Costs after the first year of study enrollment were discounted at a rate of 3%.[19] We compared the unadjusted mean costs per patient for the three study groups using bootstrapping and bias-corrected accelerated confidence intervals (CI).[20] We also calculated the incremental cost-effectiveness of SCS *versus* PC and UC, by estimating the cost per successful outcome (*i.e.*, additional cost of SCS/additional percentage of SCS patients achieving the primary outcome) at 24 months. In secondary analysis, we calculated cost-effectiveness separately for the pain and disability components of the composite success measure.

We compared mean 24-month costs and cost-effectiveness adjusting for baseline covariates selected because they were not balanced between analysis groups at baseline or were independently associated with either the costs or effectiveness outcomes at 24 months. These covariates were medical and productivity loss costs in the year prior to enrollment and baseline patient age, 36-Item Short Form Health Survey version 2[21] Mental Health scale score, disability benefit in addition to workers' compensation, RDQ score, leg-pain intensity, duration of work time loss compensation, and legal representation.[15] Self-reported duration of leg pain was highly correlated with duration of work time loss compensation and was not included as a covariate in the adjusted analyses. For the covariate-adjusted analyses, we adopted Bayesian methods[22] to calculate 95% credible intervals (CrI). Costs were assumed to follow a gamma distribution. Covariate adjustment for the effect measure of therapeutic success was modeled using logistic regression. The final model was selected on the basis of the Deviance Information Criteria,[23] where more complex models were selected if they gave a reduction in Deviance Information Criteria of at least 3. Model convergence was achieved after 30,000 iterations and results were based on a further 60,000 iterations.

Because it is unclear how much the workers' compensation program would be willing to pay for a successful outcome, we used cost-effectiveness acceptability curves to depict the probability that SCS is the most cost-effective therapy at a wide range of thresholds ($0–250,000 per successful outcome).[24] Statistical analyses were conducted using Microsoft Excel 2000, STATA/IC 10.0 (College Station, TX), and WinBUGS 1.4.3 (Imperial College and MRC, United Kingdom).

RESULTS

Cost Analysis

At baseline, the three treatment groups had similar mean medical and productivity loss costs in the preceding year (Table 1). In the 24 months after enrollment, mean total medical cost per patient (Table 2) was $52,091 in the SCS group (all patients who had trial SCS, regardless of whether they had a permanent implant). This was $17,291 (95% CI, $4,100–30,490) higher than in the PC group and $28,128 ($17,620–38,630) higher than in the UC group.

Twenty-seven (53%) of 51 patients who had trial SCS went on to have a permanent SCS device implanted. The total cost

TABLE 1. Baseline Comparison of Medical and Productivity Loss Costs in the Year Prior to Study Enrollment

	SCS (n = 51)	PC (n = 39)	UC (n = 68)	*P**	
				SCS *vs.* PC	SCS *vs.* UC
Medical costs in past year, mean (SD)	$19,151 ($12,576)	$21,402 ($12,040)	$18,195 ($13,962)	0.39	0.70
Productivity loss costs in past year, mean (SD)	$24,286 ($10,962)	$26,170 ($13,376)	$22,403 ($9900)	0.46	0.33

**Group means compared with t tests.*

PC indicates private clinic; UC, usual care; SCS, spinal cord stimulation.

TABLE 2. Medical Costs and Productivity Loss Costs From Enrollment to 24 Months

	Mean SCS (n = 51)	Mean PC (n = 39)	Mean UC (n = 68)	Incremental costs SCS *vs.* Mean PC (95% CI)	Incremental costs SCS *vs.* Mean UC (95% CI)]
Initial SCS procedure*	$21,282				
SCS revision/removal	$1976				
Other hospital inpatient	$5197	$2839	$2952		
Other hospital outpatient	$1713	$1178	$1870		
Office visit†	$11,654	$21,875	$10,503		
Other‡	$5828	$3838	$4713		
Medications	$4441	$5070	$3924		
Medical costs—total	$52,091	$34,800	$23,964	$17,291 ($4100–30,490)	$28,128 ($17,620–38,630)
Productivity loss costs	$46,546	$49,540	$43,328	−$2994 (−$12,950–6960)	$3,218 (−$4,460–10,900)
Total costs	$98,637	$84,340	$67,292	$14,297 (−$3270–31,860)	$31,345 ($17,550–45,140)
Adjusted total costs§	$99,438	$79,364	$70,080	$20,074 ($3840–35,990; CrI)	$29,358 ($16,070–43,790; CrI)

**Including 51 SCS trial procedures and 27 permanent device implants.*

†Most commonly, physical therapist, physician, or vocational counselor office visits.

‡For example, ambulatory surgery center, emergency department, independent laboratory, and home care.

§Adjusted for baseline covariates: cost in the year prior to enrollment, age, 36-Item Short Form Health Survey mental health score, disability benefit from another source, RDQ score, leg-pain intensity, duration of work time loss compensation, and legal representation.

PC indicates private clinic; UC, usual care; SCS, spinal cord stimulation; CI, confidence intervals; CrI, credible intervals.

of the initial SCS trial (n = 51) and permanent implantation procedures (n = 27) was $1,085,394, equivalent to $21,282 per patient. Among the 27 permanent implantation patients, five had one or more revision/replacement procedures and five had permanent removal procedures billed to DLI by 24 months. The total cost of all revision/replacement and removal procedures was $100,753, equivalent to $1976 per patient. Among the 39 patients evaluated at PCs, 22 (56%) received some treatment at the PC. Among the 38 PC patients with follow-up data at 6- or 12-month interview, the most frequently reported treatments received were physical therapy (74%), occupational therapy (53%), and psychological therapy (39%). Among the 66 UC patients with follow-up data, the most frequently reported therapies received were physical therapy (39%), back brace or corset (35%), and spinal injections (33%).

There were no significant differences between groups in productivity loss costs (Table 2). Total unadjusted medical and productivity loss costs were highest in the SCS group, averaging $98,637 per patient over the 24 months (*vs.* $84,340 and $67,292 in the PC and UC groups, respectively). After adjusting for baseline covariates, the mean medical and productivity loss costs of the SCS group were $20,074 (95% CrI, $3,840–35,990) higher than those of the PC group and $29,358 ($16,070–43,790) higher than those of the UC group. There was no evidence that the SCS group had lower medical costs than the other two groups during the second year after enrollment (Figure 1).

Effectiveness and Cost-Effectiveness

Few patients achieved success on the primary outcome (Tables 3 and 4). As reported previously, at 24 months, 5% of SCS patients, 3% of PC patients, and 10% of UC patients reported at least two-point RDQ improvement, at least 50% leg pain reduction, and less than daily opioid use (differences not statistically significant).[15] Even after adjustment for baseline covariates, SCS was much more costly and only fractionally more effective than UC. Compared with UC, the incremental cost of SCS per patient achieving success on the primary outcome was very high ($334,704; Table 3).

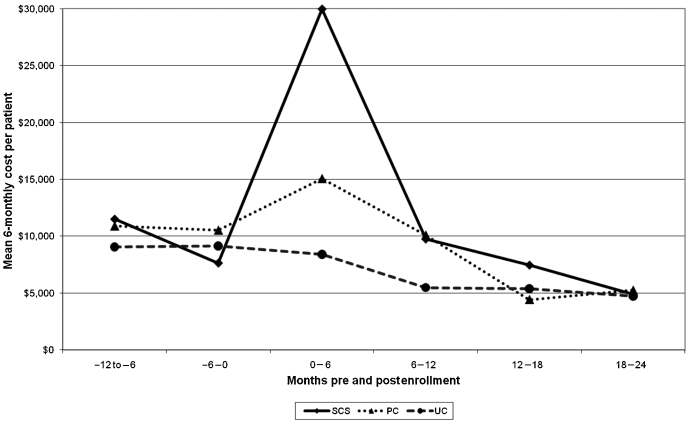

Figure 1. Medical costs in the 12 months prior to enrollment and during the 24 months after study enrollment.

TABLE 3. Cost-Effectiveness at 24 Months of SCS *Versus* Usual Care, Unadjusted, and Adjusted for Baseline Covariates

	SCS (n = 43*)	UC (n = 61*)
Incremental cost SCS *vs.* UC	$31,345	
% of patients achieving success on primary outcome	5%	10%
Incremental cost per patient achieving success on primary outcome ratio† (95% CrI)	UC less costly, more effective ($632,067—UC dominates)	
Adjusted§ incremental cost SCS *vs.* UC	$29,358	
Adjusted§ % of patients achieving success on primary outcome	10%	10%
Adjusted‡ incremental cost per patient achieving success on the primary outcome ratio (95% CrI)	$334,704 ($142,203–489,243)	

**Number of patients completing 24-mo follow-up for primary outcome.*

†Cost per additional patient who meets the primary success criterion (≥50% reduction in leg pain, a two-point or greater improvement on the RDQ, and less than daily opioid medication use).

‡Adjusted for baseline covariates: cost in the year prior to enrollment, age, 36-Item Short Form Health Survey mental health score, disability benefit from another source, RDQ score, leg-pain intensity, duration of work time loss compensation, and legal representation.

UC indicates usual care; SCS, spinal cord stimulation; CI, confidence intervals; CrI, credible intervals.

Compared with PC, the incremental cost of SCS per patient achieving success on the primary outcome, adjusted for baseline covariates, was also high ($131,146; Table 4).

The cost-effectiveness acceptability curve for the primary outcome (Figure 2A) suggests that SCS was very probably not (<5% probability) the most cost-effective treatment option at any threshold of willingness to pay because UC patients had much lower costs and very similar outcomes. Focusing on at least 50% improvement in leg pain at 24 months (16% of the SCS group, 15% of the PC group, and 21% of the UC group met this success definition)[15] did not alter the finding that SCS was very unlikely (<7% probability) to be a cost-effective therapy (Figure 2B). A nonsignificantly higher proportion of SCS patients achieved a modest improvement in physical function (≥2-point RDQ improvement) at 24 months (51% *vs.* 41% in PC and 44% in UC).[15] However, because of the high cost of care for the SCS patients, the probability that SCS is the most cost-effective type of care does not exceed 20% even if the payer is willing to pay $250,000 for a two-point improvement or greater in RDQ score (Figure 2C).

Subgroup Analysis: Patients Who Received Permanent SCS Implant *Versus* Those Who Had PC Treatment

At 24 months, a nonsignificantly higher proportion of patients who had a permanent SCS implant, as compared with patients who had at least some PC treatment, achieved success on the primary outcome and two of its components:

TABLE 4. Cost-Effectiveness at 24 Months of SCS *Versus* Pain Clinic, Unadjusted, and Adjusted for Baseline Covariates

	SCS (n = 43*)	PC (n = 34*)
Incremental cost SCS *vs.* PC	$14,297	
% of patients achieving success on primary outcome	5%	3%
Incremental cost per patient achieving success on primary outcome ratio† (95% CrI)	$846,977 (Undefined)‡	
Adjusted§ incremental cost SCS *vs.* PC	$20,074	
Adjusted§ % of patients achieving success on primary outcome	10%	3%
Adjusted§ incremental cost per patient achieving success on primary outcome ratio (95% CrI)	$131,146 (SCS dominates—$271,075)	

**Number of patients completing 24-mo follow-up for primary outcome.*

†Cost per additional patient who meets the primary success criterion (≥50% reduction in leg pain, a two-point or greater improvement on the RDQ, and less than daily opioid medication use).

‡Neither the cost nor the effect differences are significantly different from zero; in this instance, the 95% CI around the incremental cost-effectiveness ratio is not defined.

§Adjusted for baseline covariates: cost in the year prior to enrollment, age, 36-Item Short Form Health Survey version 2 mental health score, disability payments from another source, RDQ score, leg-pain intensity, duration of work time loss compensation, and legal representation.

SCS indicates spinal cord stimulation, PC, pain clinic; and CrI, credible intervals.

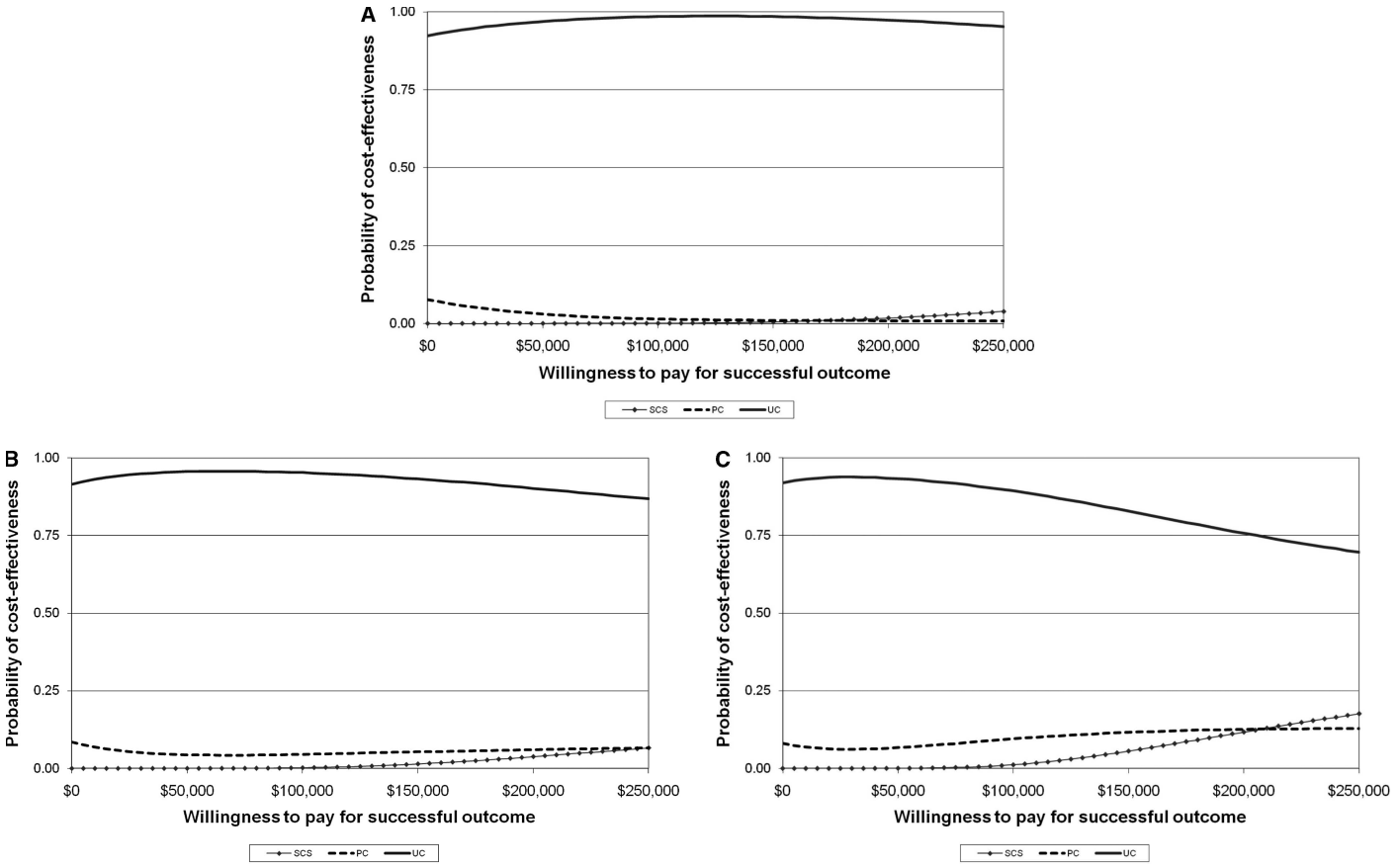

Figure 2. Cost-effectiveness acceptability curves (CEAC).* **A**, CEAC for the primary composite outcome. **B**, CEAC for the outcome of 50% improvement in leg pain. **C**, CEAC for the outcome of two point or greater improvement Roland score.

*indicates the CEAC depicts the probabilities that SCS, PC and UC are the most cost-effective type of care. In general, the more the health care payer is willing to pay for a successful patient outcome (moving to the right along the horizontal axis), the higher the probability that expensive, but more effective therapies are considered cost-effective. In figure 2A there is a very low probability that either PC or SCS is cost-effective (both curves are close to zero probability); UC is the most likely cost-effective intervention (>95% probability) throughout this range of willingness to pay. In each case, the CEAC is adjusted for baseline covariates: cost in the year prior to enrollment, age, 36-Item Short Form Health Survey version 2 mental health score, disability payments from another source, RDQ score, leg-pain intensity, duration of work time loss compensation, and legal representation.

at least 50% reduction in leg pain and two-point or greater improvement in RDQ score[15] (Table 5). The mean cost of care in the SCS permanent implant group was $18,810 higher (95% CI, −$672–38,292) than in the PC treatment group. The incremental cost per successful outcome was in excess of $100,000 for all three outcomes (Table 5), although the confidence intervals are very broad.

DISCUSSION

Among workers' compensation recipients with FBSS, the medical care and productivity loss costs (adjusted for baseline covariates) over 24 months for a patient who received a trial of SCS were, on average, $20,000 higher than those for a patient who received a multidisciplinary PC evaluation and more than $29,000 higher than those for a patient who received UC. Most of these additional costs reflect the costs of SCS trials and permanent implants, which were not counterbalanced by lower medical or productivity loss costs during the 24-month follow-up. As reported previously, the SCS group did not have significantly better pain, function, or opioid medication use outcomes at 24 months.[15] Therefore, we found no evidence that SCS is a cost-effective intervention for workers' compensation patients in this setting.

SCS devices are expensive and may lead to downstream costs, through adverse events and revision or removal procedures. These costs should be weighed against the potential benefits in terms of improvement in patient pain and function, reduced use of medications and health services, and reduced productivity losses. Technology appraisals of SCS have been limited by the paucity of RCTs and cost-effectiveness data.[25–27] In the United Kingdom, the National Institute of Health and Clinical Excellence recommended SCS as a treatment option for chronic neuropathic pain, but called for further "observational research to generate robust evidence about the durability of benefits."[25] Observational research is necessary because a therapy found to be cost-effective in tightly controlled RCTs may be less efficient when applied in the community, where patient characteristics and physician expertise vary.[28]

TABLE 5. Patients With a Permanent Spinal Cord Stimulation Implant *Versus* Patients Who Received Pain Clinic Treatment: Unadjusted Cost-Effectiveness at 24 Months

	SCS Permanent Implant (n = 27*)	PC Treatment (n = 22*)
Initial SCS trial and permanent implant	$34,641	–
SCS revision/removal	$3732	–
Total medical and productivity loss cost (mean)	$108,248	$89,438
% achieving success on primary outcome	9%	5%
% achieving ≥50% reduction in leg pain	30%	26%
% achieving ≥two-point improvement in RDQ score	61%	47%
Incremental cost per success on primary outcome (95% CI)	$520,315 ($17,728 — PC dominates)	
Incremental cost per success on leg pain outcome (95% CI)	$436,512 ($24,405 — PC dominates)	
Incremental cost per success on RDQ score outcome (95% CI)	$140,049 ($236 — PC dominates)	

**Number of patients with complete cost data at 24-month follow-up. 23 SCS permanent implant and 19 PC treatment group patients had complete primary outcome data at 24 months.*

PC indicates pain clinic; SCS, spinal cord stimulation; RDQ, Roland Disability Questionnaire; CI, confidence intervals.

Our findings differ from those of the RCT comparing SCS and conventional medical management for FBSS. In the RCT,[9] the per patient cost of SCS trial, permanent implantation and revision procedures (CA $18,175) was much lower than the equivalent cost observed in our study (US $23,258), despite a lower proportion of patients in our study proceeding from SCS trial to permanent implant. This large cost differential confirms previous work comparing SCS reimbursements between Canadian and US payers.[29] It emphasizes that cost-effectiveness results from international trials cannot be assumed to apply in the US health care system.

Several authors have used economic modeling to extrapolate trial results and predict the long-term efficiency of SCS for FBSS.[10,27,30] Kumar *et al*,[11] using data from one cohort study, estimated that medical costs in the second year after therapy would be much higher in conventional medical management patients (CA $7,291) than in patients treated with SCS (CA $1,092). Assuming that these costs remained constant in subsequent years, they estimated that SCS would be cost saving within 3 years. Our data, on the basis of actual reimbursements, do not replicate these estimates. Medical costs in all three treatment groups exceeded US $9500 during the second year after enrollment and costs were highest in the SCS group.

Compared with the RCT, fewer SCS patients in our study had a successful trial (53% in our study *vs.* 92%[6]), fewer achieved 50% reduction in leg-pain intensity at 6 months (18%[15] *vs.* 48%[6]), and fewer patients with successful SCS trials and permanent implants achieved 50% reduction in leg-pain intensity at 6 months (33%[15] *vs.* 51%[6]). The poorer outcomes of SCS observed in our study might be related to the patient population and setting. RCT participants are highly selected and often have better outcomes as compared with the wider patient population.[31,32] Furthermore, workers' compensation claimants have worse outcomes than other patients after a variety of pain therapies.[33,34] The effectiveness of SCS may also be dependent on physician expertise in patient selection and implantation procedures, and it is possible that physicians in the RCT were more technically proficient than those in our study.

Rigorous RCTs are the gold standard method of determining treatment efficacy; observational studies are graded to be of lower quality.[35] The primary limitation of observational studies is the potential for unmeasured differences between treatment groups to bias comparisons. It is possible that the lack of effectiveness and cost-effectiveness of SCS observed in our study is due to such unmeasured confounders. However, in some circumstances, observational study designs are recommended as a more feasible alternative to RCTs for health care payers wishing to provide access to a promising health technology while accumulating additional evidence.[36] Observational studies can determine whether RCT results are replicated in specific patient populations and settings,[28] whether short-term benefits reported in RCTs are durable over longer time periods, and the long-term risks and costs of care.[36]

Our small sample size was another potential limitation. Nevertheless, the large additional costs of SCS and the low success rates in the SCS group, regardless of the definition of success, resulted in a low probability that SCS was cost-effective in this setting. Our results suggest that US workers' compensation programs should not assume that the benefits of SCS and potential cost savings reported in the RCT would be replicated in their patient populations. The results also underscore the importance of conducting studies to assess a therapy's cost-effectiveness in actual practice settings, using actual cost data.

➢ Key Points

- ❑ Among workers' compensation recipients with FBSS, the mean cost of medical care over 24 months was $52,091 per patient who received trial SCS, $34,800 per patient who received a PC evaluation, and $23,964 per patient who received UC only.
- ❑ There was no evidence that the high cost of SCS was counterbalanced by lower subsequent medical or productivity loss costs during the 24-month follow-up.
- ❑ Our results suggest that workers' compensation programs should not assume that the benefits and potential cost savings of SCS reported in randomized trials would be replicated in their patient populations.

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