

# Evaluation of the Cost-Effectiveness of Electrical Stimulation Therapy for Pressure Ulcers in Spinal Cord Injury

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**ABSTRACT.** Mittmann N, Chan BC, Craven BC, Isogai PK, Houghton P. Evaluation of the cost-effectiveness of electrical stimulation therapy for pressure ulcers in spinal cord injury. *Arch Phys Med Rehabil* 2011;92:866-72.

**Objective:** To evaluate the incremental cost-effectiveness of electrical stimulation (ES) plus standard wound care (SWC) as compared with SWC only in a spinal cord injury (SCI) population with grade III/IV pressure ulcers (PUs) from the public payer perspective.

**Design:** A decision analytic model was constructed for a 1-year time horizon to determine the incremental cost-effectiveness of ES plus SWC to SWC in a cohort of participants with SCI and grade III/IV PUs. Model inputs for clinical probabilities were based on published literature. Model inputs, namely clinical probabilities and direct health system and medical resources were based on a randomized controlled trial of ES plus SWC versus SWC. Costs (Can \$) included outpatient (clinic, home care, health professional) and inpatient management (surgery, complications). One way and probabilistic sensitivity (1000 Monte Carlo iterations) analyses were conducted.

**Setting:** The perspective of this analysis is from a Canadian public health system payer.

**Participants:** Model target population was an SCI cohort with grade III/IV PUs.

**Interventions:** Not applicable.

**Main Outcome Measure:** Incremental cost per PU healed.

**Results:** ES plus SWC were associated with better outcomes and lower costs. There was a 16.4% increase in the PUs healed and a cost savings of \$224 at 1 year. ES plus SWC were thus considered a dominant economic comparator. Probabilistic sensitivity analysis resulted in economic dominance for ES plus SWC in 62%, with another 35% having incremental cost-effectiveness ratios of \$50,000 or less per PU healed. The largest driver of the economic model was the percentage of PU healed with ES plus SWC.

**Conclusions:** The addition of ES to SWC improved healing in grade III/IV PU and reduced costs in an SCI population.

**Key Words:** Electric stimulation; Economics; Pressure ulcer; Rehabilitation; Spinal cord injuries.

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**P**RESSURE ULCERS ARE one of the most common secondary complications in individuals with spinal cord injury (SCI). Between 14% to 33%<sup>1-6</sup> of individuals with SCI will be affected by a pressure ulcer (PU) at some point in their life. If left untreated, PUs may result in hypoproteinemia, increased malnutrition due to severe fluid and protein loss, osteomyelitis, sepsis, and death.<sup>7</sup> Among individuals with SCI, PUs can lead to functional limitations and 60% of individuals reported that the PUs disrupted their lives.<sup>8</sup> Despite efforts to prevent and treat PUs, the prevalence of PUs in SCI individuals continues to increase.<sup>8</sup>

Standard wound care (SWC) for managing PUs typically includes nonsurgical procedures, such as debridement, dressing, nutritional, physical therapies, and surgical procedures for the management of complications.<sup>9,10</sup> Another type of treatment, electrical stimulation (ES) treatment, involves the delivery of low-level current via surface electrodes to the area of the wound bed. ES is used as an adjunct to SWC treatment. ES is thought to affect protein synthesis, cell migration, antibacterial effect in the wound area, increase wound angiogenesis, and tissue oxygenation.<sup>11</sup> Typically, administered by nurse specialists, a number of studies have observed accelerated wound healing when ES was used alongside SWC.<sup>12-16</sup> A number of published studies have examined the efficacy of ES. Baker et al<sup>13</sup> compared 3 different ES protocols (asymmetric biphasic, symmetric biphasic, and microcurrent) with a control group (no ES). Individuals received treatment until the PU was healed up to 4 weeks. There were no statistical differences in initial and discharge ulcer areas or healing rates between all groups. When the secondary outcome: good responses (wounds that healed) versus poor responses (wounds that failed to close) was analyzed, statistically significant differences were observed between asymmetric biphasic treatment group, the microcurrent group, and controls. Another study investigated the efficacy of high-voltage pulsed current (HVPC) ES compared with controls for 20 days in 20 SCI individuals with pelvic PUs.<sup>12</sup> A statistically significant decrease in wound size was observed at day 5, 15, and 20 when compared with controls. Adegoke and Badmos<sup>14</sup> conducted a randomized controlled trial study of IDC on PU healing in SCI individuals. Individuals received interrupted direct current (IDC) stimulation or placebo for 4 weeks. IDC resulted in a 22.2% reduction in wound surface area compared with 2.6% for placebo at 4 weeks. Ahmad<sup>15</sup> used HVPC for 45, 60, and 120 minutes per day for 5 weeks, compared with sham HVPC for 45 minutes per day for 5

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## List of Abbreviations

CEAC	cost-effectiveness acceptability curve
ES	electrical stimulation
HVPC	high-voltage pulsed current
IDC	interrupted direct current
PU	pressure ulcer
QALY	quality-adjusted life years
SCI	spinal cord injury
SWC	standard wound care

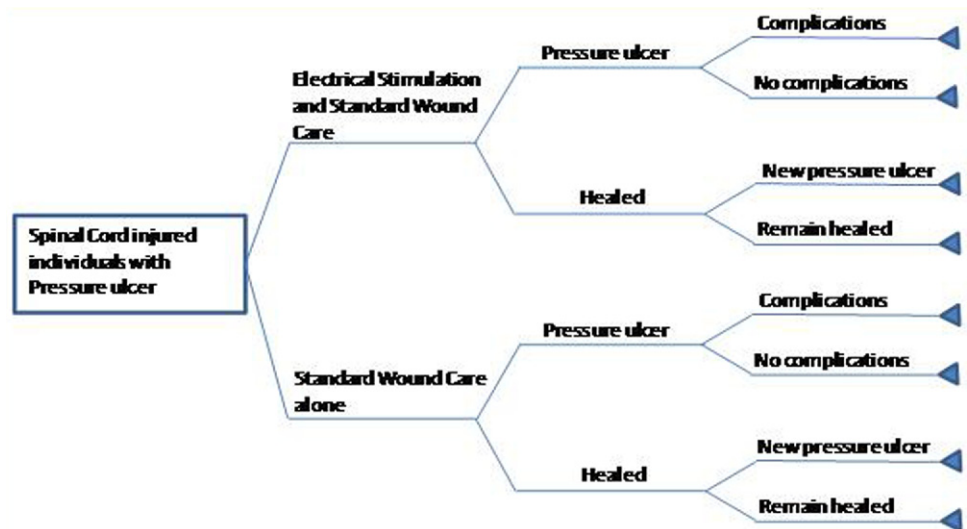


Fig 1. Decision tree representation.

weeks. A significant reduction in wound surface area was observed as early as 3 weeks with HVPC for treatment of 60 and 120 minutes per day compared with 45 minutes of HVPC or sham HVPC. Finally, a randomized study compared low frequency pulsed current ES plus SWC with SWC alone for 4 weeks (N=109 SCI individuals).<sup>16</sup> Mean healing rates at 4 weeks were significantly greater in the ES plus SWC group.

The economic impact of wound care is thought to be substantial. In a SCI population, treating a PU has been reported to cost upwards of \$9000 per month (Can \$).<sup>17</sup> In non-SCI populations, the cost of a PU has been estimated to be as much as \$70,000 (\$ US).<sup>18</sup> The introduction of new treatments for PUs adds to this cost burden. In this environment of limited resources and increasing costs, there is now the need to express outcomes not only in terms of clinical outcomes, but also in terms of their additional value or cost-effectiveness. Many countries around the world have developed frameworks for the formal conduct and assessment of economic evaluations, including Canada, the United Kingdom, Scotland, Australia, and most European countries. In those countries, economic value often translates into reimbursement of treatments.

Although ES is associated with improved wound healing, it does so at an added cost to the health system over SWC. Can improvements in healing PUs and avoiding downstream complications result in a savings to the system? And is the added cost worth it? Given that there is some observed benefit associated with ES but that use of ES represents an added cost to the system, the objective of this analysis was to determine whether ES is cost-effective. Our analysis examined the cost-effectiveness of adding ES to SWC to heal PUs in an SCI population.

## METHODS

### Perspective

The cost-effectiveness of adding ES to SWC was determined using a decision analysis model constructed from a Canadian provincial public/universal health care payer perspective.

### Model and Time Horizon

A decision analytic model was constructed using the Tree-Age Pro 2009 program.<sup>a</sup> In this model, individuals would receive ES for 3 months and would receive SWC to manage

PUs in the 1-year time horizon. Individuals could either progress to a healed PU state or they could remain unhealed. For individuals with a healed PU, there was a probability of experiencing another PU or a complication (fig 1).

### Effectiveness

The primary outcome of this analysis was the incremental cost per PU healed. Efficacy, relapses, complications, resources, and costs were included in this analysis. A literature review was conducted to select the clinical inputs for the model, including healing rates, recurrence rates, and complication rates supported by published studies were assumed to hold for the 1-year period used in our model. Efficacy rates (% of patients with completely healed PUs) for ES plus SWC in an SCI population were obtained from patients (n=29) with stage III/IV from a randomized controlled trial of individuals with 1 to 20cm<sup>2</sup>-sized PUs (n=34) for a duration of 3 months.<sup>19</sup> In this analysis, the 3-month efficacy rates were assumed to be at the rate at 1 year (table 1). Relapse was defined as recurrence of a PU after healing. The probability for a relapse was obtained from an American study characterizing veterans with an SCI.<sup>20</sup> This study was selected given the lack of published Canadian PUs relapse rates in the SCI population. Bates-Jensen et al<sup>20</sup> reported that 24 out of 64 veterans had a recurrence of a stage III/IV PU at the pelvic area in the 9-month follow-up period. The probability of recurrence at 9 months was assumed to be identical at 1 year. The rate of relapse was assumed to be identical between treatment arms.

Infections (50%) and osteomyelitis (50%) were the complications used in this model. The percentage of patients hospitalized for complications was based on the total rate of SCI hospitalization with skin disorders (3%)<sup>21</sup> divided by the incidence of PUs in a Canadian SCI population (29%).<sup>22</sup> Mortality was not incorporated into the decision tree because the duration of analysis was only 1 year.

### Resources and Costs

Canadian dollars (2009) were used in this analysis. Discounting was not applied given the 1-year time horizon for the decision analytic model. Only direct medical system costs were considered in this analysis. Costs for ES (equipment rental, electrodes, and specialist home visits) were calculated by

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