Research Article

Efficacy of Spinal Cord Stimulation for Failed Back Surgery Syndrome in Elderly Patients: A Retrospective Study

Naoki Higashiyama ⓘ **, Shinya Tamura** ⓘ **, and Taku Sugawara** ⓘ

Department of Spinal Surgery, The Akita Cerebrospinal and Cardiovascular Center, Akita, Japan

Correspondence should be addressed to Naoki Higashiyama; higashiyama-naoki@akita-noken.jp

Objectives. Failed back surgery syndrome (FBSS) refers to a condition where symptoms such as low back pain, leg pain, and numbness persist or recur after lumbar surgery; it has been reported to occur in 10%–40% of patients who have undergone lumbar surgery. Spinal cord stimulation (SCS) has been reported useful for low back and leg pain due to FBSS. In this study, we studied the efficacy and safety of SCS for FBSS in older adults. *Methods.* Among FBSS patients who underwent an SCS trial between November 2017 and December 2020, those with at least 50% pain reduction during the trial phase who requested spinal cord stimulator implantation underwent implantation of a stimulator under local anesthesia. The patients were divided into two groups: patients aged <75 years (<75-year-old group) and patients aged ≥75 years (≥75-year-old group). The male/female ratio, symptom duration, operative duration, visual analog scale (VAS) scores before and after one year of surgery, responder rate (RR), complications one year after surgery, and stimulator removal rate were analyzed. *Results.* There were 27 cases in the <75-year-old group and 46 in the ≥75-year-old group, with no significant differences in male/female ratio, duration of pain, or operative time between the two groups. VAS scores for low back pain, leg pain, and overall pain one year after surgery were improved significantly from respective preoperative scores in both groups ($P < 0.001$). There were no significant differences in low back pain VAS, leg pain VAS, overall pain VAS, RR, complications one year after surgery, or stimulator removal rate between the two groups. *Conclusion.* SCS reduced pain effectively in both <75-year-old and ≥75-year-old groups with no differences in complications. Therefore, spinal cord stimulator implantation was considered a viable option for FBSS treatment in older adults because it can be performed under local anesthesia and is associated with a low incidence of complications.

1. Introduction

FBSS, a condition where symptoms such as low back pain, leg pain, and numbness persist or recur, has been reported to occur in 10%–40% of the patients who had lumbar surgery [1]. Conventional treatments for FBSS include drug therapy, physical therapy, cognitive behavioural therapy, conservative treatments such as nerve block, or repeated surgery such as lumbar decompression and fusion, but they do not produce satisfactory effects [2–6].

SCS is widely used for treating chronic intractable pain [7], and randomized controlled trials (RCTs) comparing SCS with conservative treatment and repeated surgery for low back pain and leg pain due to FBSS have shown the advantage of SCS [8–10]. While conventional paresthesia-based SCS with low-frequency stimulation is still commonly used, recently introduced stimulation methods, such as burst SCS [11, 12], 10 kHz high-frequency therapy [13, 14], high-dose SCS [15, 16], high-density SCS [17, 18], closed-loop SCS [19, 20], and differential target multiplexed programming [21, 22], have been reported to be equally or more effective than paresthesia-based SCS. Also, spinal cord stimulator implantation using anatomical placement in which electrodes are placed mainly in the T9/10 intervertebral space has comparable therapeutic efficacy with paresthesia-based SCS but shorter operative time [23].

In this study, we compared outcomes of percutaneous SCS implantation, a minimally invasive procedure under local anesthesia, between older patients with FBSS aged <75 years and those aged ≥75 years to clarify the efficacy and

safety. The primary outcome was the comparison of VAS scores for low back pain, leg pain, and overall pain before and one year after surgery and RR (percentage of patients whose pain decreased by ≥50%) between the <75-year-old and ≥75-year-old groups of patients who underwent spinal cord stimulator implantation.

2. Methods

It was a single-center retrospective study in FBSS patients who underwent permanent spinal cord stimulator implantation between November 2017 and December 2020 at the Akita Cerebrospinal and Cardiovascular Center. This study was conducted with approval from the ethical review board of the Akita Cerebrospinal and Cardiovascular Center (Akita, Japan). The ethical review board registration number for the study is 22-21. It has been registered in the UMIN Clinical Trials Registry (registration number: UMIN000050979).

2.1. Subject Selection. Eligible patients were older than 18 years, diagnosed with FBSS, had low back pain or leg pain persisting for at least three months, were nonresponsive to drug therapy, physical therapy, and conservative treatment such as epidural block injection, and had a 100-mm visual analog scale (VAS) score of at least 50 mm for low back or leg pain. The interval between the last block injection and SCS implantation in the included patients is at least one month. Before the trial, all subjects underwent the Hasegawa dementia scale-revised (HDS-R) and Minnesota Multiphasic Personality Inventory (MMPI) administered by a clinical psychologist. The HDS-R features a scoring system that ranges up to 30, whereby any score below 20 is indicative of suspicion of dementia. Additionally, ten clinical scales of the MMPI were assessed, with specific attention given to the detection of elevated levels of depression as manifested on the second scale. After patients with severe cognitive impairment or severe depression were excluded, only those psychologically appropriate for the treatment underwent an SCS trial. The patients who responded to a 7-day percutaneous trial with at least 50% pain reduction and requested stimulator implantation underwent permanent spinal cord stimulator implantation.

2.2. Implantation Method. A 2-cm skin incision was made around the medial side of the left L3 pedicle as the center under local anesthesia with 1% lidocaine combined with dexmedetomidine. The dexmedetomidine is a loading dose of 6.0 μg/kg administered over a period of 10 minutes, followed by a continuous maintenance infusion of 0.2 to 0.7 μg/kg/hour. However, the dose was individually determined based on the patient's clinical response and potential adverse event. Tuohy needles were inserted under fluoroscopic guidance until the tip reached the epidural space via the L1/2 interlaminar foramen, and two leads (Vectris™ SureScan MRI 1 × 8 Compact, Medtronic Inc., Minneapolis, MN, USA) were then inserted. The leads were placed using an anatomical placement technique without paresthesia

mapping. The first lead was placed median, and the electrode at the most cranial position was located in the center of the T8. The second lead was placed paramedian, and the electrode at the most cranial position was positioned at the cranial end of the T9 (Figure 1). Tuohy needles were removed, and the leads were anchored to the lumbodorsal fascia using mechanical anchors.

We planned to place an implantable pulse generator (IPG) (INTELLIS™, Medtronic Inc., Minneapolis, MN, USA) between the low end of the costae and the iliac crest or in the gluteal region (Figure 2). A 5-cm transverse incision was made to prepare a subcutaneous pocket. The leads guided subcutaneously were connected to the IPG, and lead resistance values were checked. Additional strain relief loops were created in the IPG pocket before connecting the leads. The purpose of strain relief loops is to prevent tension or pulling on the lead from damaging the connection or causing the lead migration. The leads were placed in the subcutaneous pocket, and the wound was closed. Immediately after surgery, therapy was initiated utilizing a bipolar electrode directed towards the T9/10 intervertebral space. All participants were programmed to receive a high-dose SCS protocol featuring a pulse width of 90 μsec, a rate of 1 kHz, and a subperception threshold amplitude to enable continuous stimulation. The subperception threshold amplitude was defined as 70–80% of the perception threshold, which was determined by gradually increasing the amplitude while in the supine position until paresthesias were observed.

2.3. Definition of Older Adults. Adults aged ≥65 years are defined as elderly in many countries; however, clear global criteria to define older adults have not been established. In Japan, where the population is aging more rapidly than in other countries, older adults have improved physical functions in recent years, and the Japan Geriatrics Society has proposed to define adults aged ≥75 years as being elderly [24]. Therefore, in this study, individuals aged ≥75 years were defined as being elderly, and comparisons were made between patients aged <75 years (the <75-year-old group) and those aged ≥75 years (the ≥75-year-old group).

2.4. Parameters Analyzed. The following parameters were compared between the <75-year-old and ≥75-year-old groups of patients who underwent spinal cord stimulator implantation: male/female ratio, symptom duration (since diagnosis), the operative time for permanent implantation, VAS scores for low back pain, leg pain, and overall pain before and one year after surgery, RR (percentage of patients whose pain decreased by ≥50%), complications at one year after surgery, and stimulator removal rate. As more than half of the participants in this study were aged 75 years or older, age-related comorbidities and functional decline made it difficult to adjust for age differences in functional assessments such as the Oswestry Disability Index (ODI), Short Form (12) Health Survey (SF-12), Short Form (36) Health Survey (SF-36), and EuroQol-5 Dimension 5-Level (EQ-5D-5L). In addition, older individuals may have difficulty
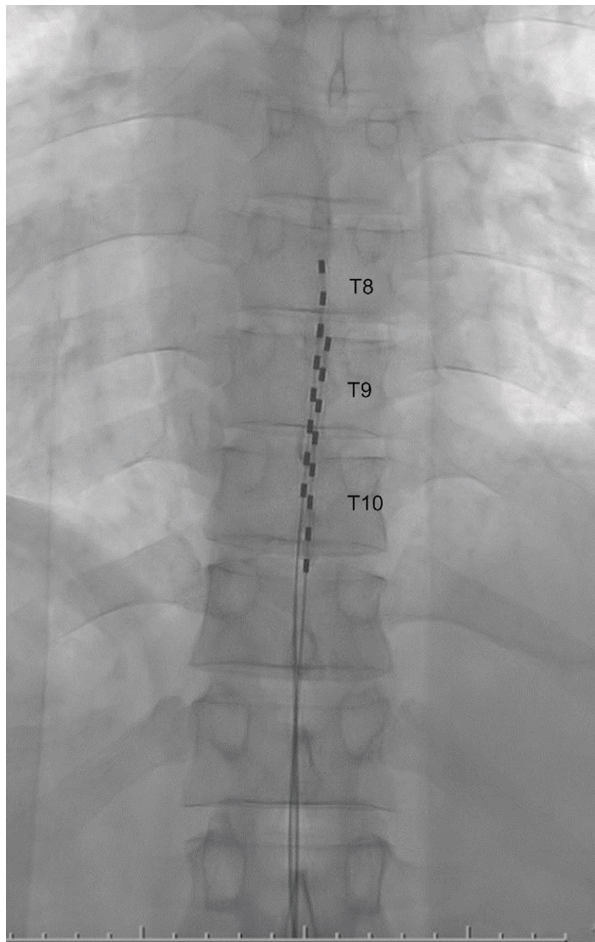
FIGURE 1: The first lead tip was placed at the midbody of T8, and the second lead tip was placed at the superior endplate of T9.

completing such functional assessment questionnaires due to potential cognitive impairment. Therefore, only pain intensity was reported as an outcome measure in this study.

2.5. Statistical Analysis. Fisher's exact test and t-test were used to compare categorical variables and preoperative/postoperative VAS scores. Mann–Whitney U test was used for intergroup comparisons of other variables. Differences with $P < 0.05$ were considered statistically significant. Kaplan–Meier curves were used to analyze the difference in explantation rates and adverse event rates over time between the <75-year-old and ≥75-year-old groups of patients who underwent spinal cord stimulator implantation. SPSS (IBM SPSS Statistics for Windows, Version 28.0.1; IBM Corp., Armonk, NY, USA) was used for data analysis.

3. Results

Seventy-three patients (33 men and 40 women) with a mean age of 74.8 ± 10.5 years underwent spinal cord stimulator implantation between November 2017 and December 2020. The number of patients, mean age, symptom duration, and operative duration were 27 patients (12 men and 15 women), 63.6 ± 8.2 years, 67.6 ± 93.2 months, and 55.2 ± 22.8 minutes,
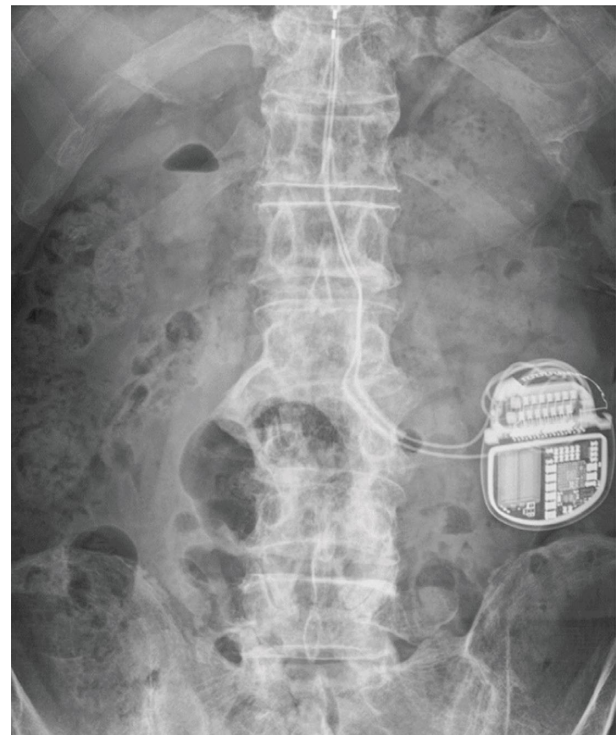

FIGURE 2: The implantable rechargeable neurostimulator was implanted between the 12th rib and the iliac crest.

respectively, for the <75-year-old group, and 46 patients (21 men and 25 women), 81.3 ± 4.4 years, 66.0 ± 81.9 months, and 57.7 ± 19.2 minutes, respectively, for the ≥75-year-old group. There were no significant differences between the two groups in the male/female ratio ($P = 1.000$), symptom duration ($P = 0.489$), and operative duration ($P = 0.163$) (Table 1).

As to treatment outcomes of the <75-year-old group, low back pain VAS scores before and one year after surgery were 78.6 ± 12.0 mm and 28.7 ± 19.9 mm, respectively, leg pain VAS scores before and one year after surgery were 76.4 ± 17.3 mm and 24.1 ± 15.8 mm, respectively, and overall pain VAS scores before and one year after surgery were 84.3 ± 10.9 mm and 30.0 ± 19.2 mm, respectively, for the ≥75-year-old group, and low back pain VAS scores before and one year after surgery were 78.0 ± 14.3 mm and 31.6 ± 20.2 mm, respectively, leg pain VAS scores before one year after surgery were 77.0 ± 14.2 mm and 24.1 ± 18.6 mm, respectively, and overall pain VAS scores before and one year after surgery were 85.8 ± 8.6 mm and 32.5 ± 20.9 mm, respectively. VAS scores for low back pain, leg pain, and overall pain one year after surgery were improved significantly from respective preoperative scores in both groups ($P < 0.001$). One year after surgery, the RRs for low back, leg, and overall pains were 81.5%, 81.5%, and 81.5% for the <75-year-old group and 80.4%, 82.6%, and 82.6% for the ≥75-year-old group. For the primary outcome measure, there were no significant differences between the <75-year-old group and the ≥75-year-old group in low back pain VAS scores before and one year after surgery ($P = 0.936$ and 0.391), leg pain VAS scores before and one year after surgery

TABLE 1: Subject demographics.

	<75 years old $n = 27$	≥75 years old $n = 46$	P value
Age mean (SD)	63.6 (8.2)	81.3 (4.4)	<0.001[†]
Gender n			
Female	15	25	1.000[*]
Male	12	21	
Duration of pain (months) mean (SD)	67.6 (93.2)	66.0 (81.9)	0.489[†]
Operative time (min) mean (SD)	55.2 (22.8)	57.7 (19.2)	0.163[†]
Previous spine surgery type			
Laminectomy	22	38	1.000[*]
Fusion	2	6	0.702[*]
Discectomy	3	2	0.352[*]
Level of operation			
L3/4 and above	4	5	0.718[*]
L4/5	12	24	0.630[*]
L5/S1	3	4	0.705[*]
Multiple levels	8	13	1.000[*]
Number of previous spine surgeries mean (SD)	1.6 (1.1)	1.3 (0.7)	0.392[†]

[*]Fisher's exact test, [†]Mann–Whitney U test.

($P = 0.995$ and $= 0.598$), overall pain VAS scores before and one year after surgery ($P = 0.775$ and $P = 0.511$), and RRs (all $P = 1.000$) (Table 2).

The following complications occurred within one year after surgery (cases in the <75-year-old group versus the ≥75-year-old group): lead migration (1 versus 3, $P = 1.000$), implant-related pain (1 versus 3, $P = 1.000$), infection (0 versus 1, $P = 1.000$), and metal allergy (1 versus 0, $P = 0.370$). No cerebrospinal fluid leaks and nerve injuries occurred. Implant-related pain was defined as pain associated with the component site of the device, such as pain around the IPG site or at the lead anchor site. Within one year after surgery, a total of five patients, two (7.4%) in the <75-year-old group and three (6.5%) in the ≥75-year-old group, underwent stimulator removal for implant-related pain (2 cases), infection (1 case), metal allergy (1 case), and loss of therapeutic effect (1 case). The complications and stimulator removal incidence rates did not differ significantly between the two groups ($P = 1.000$) (Table 3). Kaplan–Meier curves showed a nonsignificant difference in adverse event rates (log-rank $P = 0.617$) (Figure 3) and explantation rates (log-rank $P = 0.875$) (Figure 4) between the <75-year-old and ≥75-year-old groups of patients who underwent spinal cord stimulator implantation.

4. Discussion

The evidence available for the effectiveness of conventional drug therapy and repeated surgery for FBSS is weak [10]. On the other hand, SCS has been shown to alleviate pain more effectively than conservative treatment and repeated surgery [8–10] and has proven to be a safe and effective treatment strategy [25]. In this study, we also showed significant improvements in the low back and leg pain VAS scores one year after surgery.

The <75-year-old and ≥75-year-old groups in this study did not differ significantly in the male/female ratio, symptom duration, and operative duration. This study also showed no age-dependent differences in the treatment

TABLE 2: VAS scores and responder rate between baseline and 1-year postoperative follow-up. A responder was defined as achieving at least a 50% improvement in pain compared to baseline VAS scores.

	<75 years old $n = 27$	≥75 years old $n = 46$	P value
VAS mm (SD)			
Low back pain			
Baseline	78.6 (12.0)	78.0 (14.3)	0.936[†]
1 year	28.7 (19.9)	31.6 (20.2)	0.391[†]
Leg pain			
Baseline	76.4 (17.3)	77.0 (14.2)	0.995[†]
1 year	24.1 (15.8)	24.1 (18.6)	0.598[†]
Overall pain			
Baseline	84.3 (10.9)	85.8 (8.6)	0.775[†]
1 year	30.0 (19.2)	32.5 (20.9)	0.511[†]
Responder rate			
Low back pain	81.5%	80.4%	1.000[*]
Leg pain	81.5%	82.6%	1.000[*]
Overall pain	81.5%	82.6%	1.000[*]

[*]Fisher's exact test, [†]Mann–Whitney U test.

outcomes measured as VAS and RR. The data available in the literature about SCS outcomes in patients aged ≥75 years are limited, and there is a paucity of reports on whether age has effects on treatment outcomes. The issue remains controversial because studies report the absence of age-dependent differences in treatment outcomes [26–28], those reporting that the RR in pain relief decreased with age [29, 30], and those reporting that pain was removed more effectively in older patients [31, 32]. A recent retrospective study by Bondoc et al. in 189 patients has shown negative correlations of age with sensory and affective components of pain, suggesting that these pain components may be improved more effectively in older patients [32].

In recent studies using the stimulator removal rate to evaluate outcomes in patients who underwent SCS, the explant rate ranged from 5.96% to 11.6% [28, 33–37]. As to

Table 3: Adverse events and explant. Reasons for spinal cord stimulator explanation and adverse events in this study.

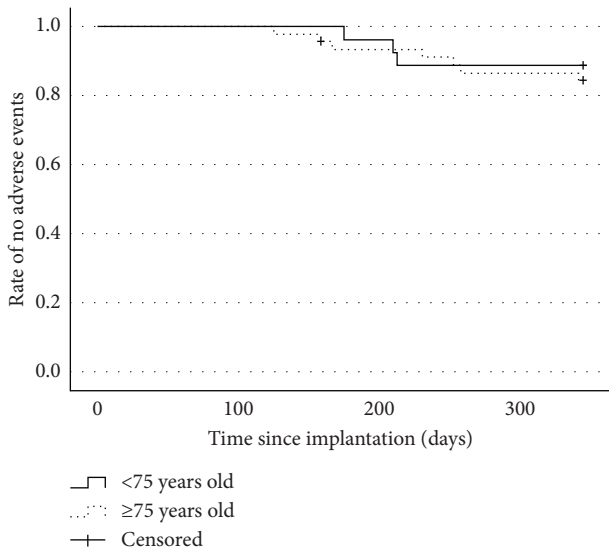|	<75 years old $n = 27$	≥75 years old $n = 46$	P value*
Adverse events n (%)	3 (11.1%)	7 (15.2%)	0.735
Lead migration	1	3	1.000
Implant-related pain	1	3	1.000
Infection	0	1	1.000
Metal allergy	1	0	0.370
Incidence of explant n (%)	2 (7.4%)	3 (6.5%)	1.000
Implant-related pain	1	1	1.000
Infection	0	1	1.000
Metal allergy	1	0	0.370
Loss of efficacy	0	1	1.000

*Fisher's exact test.

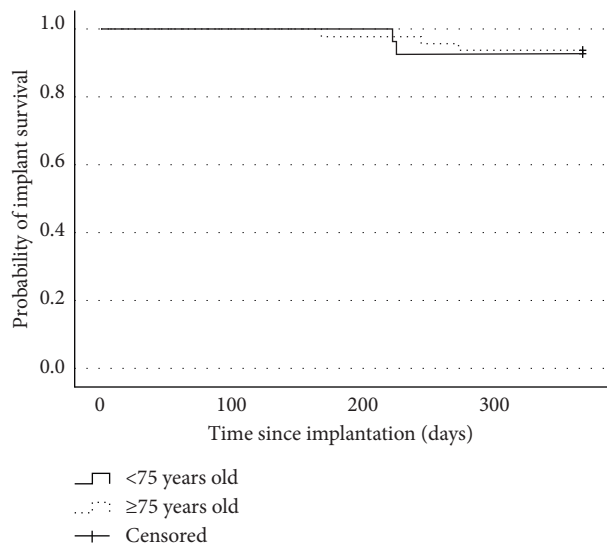Figure 3: Kaplan–Meier survival curve for the time to onset of adverse events (log-rank $P = 0.617$).

Figure 4: Kaplan–Meier survival curve for the time to explantation (log-rank $P = 0.875$).

whether age affects the incidence of stimulator removal, some studies have reported that age has no effects [28, 36], while others have reported that the incidence was higher in younger patients [33–35]. Hussain et al. have reported that 3104 of 52070 patients (5.96%) underwent removal of stimulators within two years after implantation, 72.8% of them did so in the first year, and the odds ratio for removal was lower in older patients [37]. The stimulator removal rates in the present study were comparable with previously reported rates and did not differ depending on age. Aside from age, factors reported to have effects on the stimulator removal rate include smoking [35, 37], depression [34, 37], psychiatric diseases [35], radiculopathy [36], female sex [34, 37], falls after implantation [28], and device manufacturer [28]. In recent studies in large samples, older patients had lower stimulator removal rates and better treatment outcomes; however, a meta-analysis of age-associated changes in pain has revealed that the pain threshold increases with age, and older adults have a decreased sensitivity to low-intensity pain [38], suggesting an association.

As to complications, lead migration is generally most common (15%), followed by lead fracture, malfunction, implant-related pain, and infection (5%–6%) [39]. Percutaneous SCS implantation has also been reported to be associated with lower rates of stimulator removal due to infection and reintervention due to medical-related complications compared with SCS implantation via laminectomy [40]. The use of a small incision technique and anatomical placement in this study to decrease the invasiveness and duration of surgery may have contributed to a lower incidence of infection than previously reported rates.

No global consensus about age to define older adults has been established. In this study, the <75-year-old group had a mean age of 63.6 years old and included many subjects who would be classified as older in other studies using a lower age to define older adults. This may explain why there were no differences in treatment outcomes and the device removal rate.

The diagnostic label "failed back surgery syndrome" may be considered unsatisfactory, inaccurate, and potentially problematic by medical professionals managing patients

with persistent pain after spine surgery. The International Association for the Study of Pain has recommended the use of the term "persistent spinal pain syndrome (PSPS) type 2" as a more appropriate diagnostic label than FBSS. The term PSPS encompasses the various potential symptoms of a syndrome of chronic pain (according to the usual criteria for determining pain persistence) or recurrent pain of spinal origin, paresthesias, numbness, stiffness, muscle spasms and weakness, and in some cases sphincter dysfunction [41].

Limitations of this study are the absence of functional outcome data, its retrospective nature, the small sample size, and the inclusion of a single center. Functional outcome is a crucial point in the treatment of patients with chronic pain as functional improvement is as important as pain reduction. It was evaluated 12 months after SCS implantation, and it would be of interest to follow patients over a longer period. Moving forward, it is desirable to conduct a prospective multicenter study on the relationships between age and SCS outcomes, along with other potential predictors.

5. Conclusion

In this study, the treatment outcomes and complications after SCS implantation did not differ between the <75-year-old group and the ≥75-year-old group. Since spinal cord stimulator implantation can be performed under local anesthesia and is associated with a low incidence of complications, therefore, SCS can be a highly effective treatment option for FBSS in older adults.

Data Availability

The data supporting the current study are available from the corresponding author upon request.

Ethical Approval

This study was conducted with approval from the ethical review board of the Akita Cerebrospinal and Cardiovascular Center (Akita, Japan).

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Authors' Contributions

Higashiyama contributed conception and design. Higashiyama, Tamura, Sugawara provided acquisition of data. Higashiyama contributed analysis and interpretation of data. Higashiyama drafted the article. Sugawara did study supervision.

Acknowledgments

References

[1] S. Thomson, "Failed back surgery syndrome – definition, epidemiology and demographics," *British Journal of Pain*, vol. 7, no. 1, pp. 56–59, 2013.

[2] R. G. Hazard, "Failed back surgery syndrome: surgical and nonsurgical approaches," *Clinical Orthopaedics and Related Research*, vol. 443, pp. 228–232, 2006.

[3] Z. Baber and M. A. Erdek, "Failed back surgery syndrome: current perspectives," *Journal of Pain Research*, vol. 9, pp. 979–987, 2016.

[4] J. H. Cho, J. H. Lee, K. S. Song et al., "Treatment outcomes for patients with failed back surgery," *Journal of Pain Research*, pp. E29–E43, 2017.

[5] K. Amirdelfan, L. Webster, L. Poree, V. Sukul, and P. McRoberts, "Treatment options for failed back surgery syndrome patients with refractory chronic pain: an evidence based approach," *Spine*, vol. 42, no. 14, pp. S41–S52, 2017.

[6] J. R. Daniell and O. L. Osti, "Failed back surgery syndrome: a Review Article," *Asian Spine J*, vol. 12, no. 2, pp. 372–379, 2018.

[7] D. A. Provenzano, J. A. Heller, and M. C. Hanes, "Current perspectives on neurostimulation for the management of chronic low back pain: a narrative review," *Journal of Pain Research*, vol. 14, pp. 463–479, 2021.

[8] R. B. North, D. H. Kidd, F. Farrokhi, and S. A. Piantadosi, "Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial," *Neurosurgery*, vol. 56, no. 1, pp. 98–107, 2005.

[9] K. Kumar, R. S. Taylor, L. Jacques et al., "Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome," *Pain*, vol. 132, no. 1, pp. 179–188, 2007.

[10] P. Rigoard, S. Basu, M. Desai et al., "Multicolumn spinal cord stimulation for predominant back pain in failed back surgery syndrome patients: a multicenter randomized controlled trial," *Pain*, vol. 160, no. 6, pp. 1410–1420, 2019.

[11] D. De Ridder, S. Vanneste, M. Plazier, E. van der Loo, and T. Menovsky, "Burst spinal cord stimulation: toward paresthesia-free pain suppression," *Neurosurgery*, vol. 66, no. 5, pp. 986–990, 2010.

[12] T. Deer, K. V. Slavin, K. Amirdelfan et al., "Success using neuromodulation with BURST (SUNBURST) study: results from a prospective, randomized controlled trial using a novel burst waveform," *Neuromodulation: Technology at the Neural Interface*, vol. 21, no. 1, pp. 56–66, 2018.

[13] L. Kapural, C. Yu, M. W. Doust et al., "Novel 10-kHz high–frequency therapy (HF10 therapy) is superior to traditional low–frequency spinal cord stimulation for the treatment of chronic back and leg pain: the SENZA–RCT randomized controlled trial," *Anesthesiology*, vol. 123, no. 4, pp. 851–860, 2015.

[14] L. Kapural, C. Yu, M. W. Doust et al., "Comparison of 10-kHz high–frequency and traditional low–frequency spinal cord stimulation for the treatment of chronic back and leg pain: 24– month results from a multicenter, randomized, controlled pivotal trial," *Neurosurgery*, vol. 79, no. 5, pp. 667–677, 2016.

[15] M. De Jaeger, L. Goudman, R. Brouns et al., "The long-term response to high-dose spinal cord stimulation in patients with failed back surgery syndrome after conversion from standard spinal cord stimulation: an effectiveness and prediction

study," *Neuromodulation: Technology at the Neural Interface*, vol. 24, no. 3, pp. 546–555, 2021.

[16] J. A. Hatheway, V. Mangal, M. A. Fishman et al., "Long-term efficacy of a novel spinal cord stimulation clinical workflow using kilohertz stimulation: twelve-month results from the vectors study," *Neuromodulation: Technology at the Neural Interface*, vol. 24, no. 3, pp. 556–565, 2021.

[17] F. Wille, J. S. Breel, E. W. P. Bakker, and M. W. Hollmann, "Altering conventional to high density spinal cord stimulation: an energy dose-response relationship in neuropathic pain therapy," *Neuromodulation: Technology at the Neural Interface*, vol. 20, no. 1, pp. 71–80, 2017.

[18] J. Sweet, A. Badjatiya, D. Tan, and J. Miller, "Paresthesia-free high-density spinal cord stimulation for postlaminectomy syndrome in a prescreened population: a prospective case series," *Neuromodulation: Technology at the Neural Interface*, vol. 19, no. 3, pp. 260–267, 2016.

[19] N. Mekhail, R. M. Levy, T. R. Deer et al., "Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial," *The Lancet Neurology*, vol. 19, no. 2, pp. 123–134, 2020.

[20] M. Russo, C. Brooker, M. J. Cousins et al., "Sustained long–term outcomes with closed–loop spinal cord stimulation:12–month results of the prospective, multicenter, open–label Avalon study," *Neurosurgery*, vol. 87, no. 4, pp. E485–E495, 2020.

[21] M. A. Fishman, A. Calodney, P. Kim et al., "Prospective, multicenter feasibility study to evaluate differential target multiplexed spinal cord stimulation programming in subjects with chronic intractable back pain with or without leg pain," *Pain Practice*, vol. 20, no. 7, pp. 761–768, 2020.

[22] M. Fishman, H. Cordner, R. Justiz et al., "Twelve-month results from multicenter, open-label, randomized controlled clinical trial comparing differential target multiplexed spinal cord stimulation and traditional spinal cord stimulation in subjects with chronic intractable back pain and leg pain," *Pain Practice*, vol. 21, no. 8, pp. 912–923, 2021.

[23] J. E. Pope, S. Schu, D. Sayed et al., "Anatomic lead placement without paresthesia mapping provides effective and predictable therapy during the trial evaluation period: results from the prospective, multicenter, randomized, Delivery study," *Neuromodulation: Technology at the Neural Interface*, vol. 23, no. 1, pp. 109–117, 2020.

[24] H. Arai, "Definition of older people: time to reconsider the definition?" *Nihon Ronen Igakkai Zasshi*, vol. 56, pp. 1–5, 2019.

[25] L. Kapural, E. Peterson, D. A. Provenzano, and P. Staats, "Clinical evidence for spinal cord stimulation for failed back surgery syndrome (FBSS): systematic review," *Spine*, vol. 42, no. 14, pp. S61–S66, 2017.

[26] K. A. Williams, M. Gonzalez-Fernandez, S. Hamzehzadeh et al., "A multi-center analysis evaluating factors associated with spinal cord stimulation outcome in chronic pain patients," *Pain Medicine*, vol. 12, no. 8, pp. 1142–1153, 2011.

[27] G. Colini Baldeschi and A. Carlizza, "Spinal cord stimulation: predictive parameters of outcome in patients suffering from critical lower limb ischemia. A preliminary study," *Neuromodulation: Technology at the Neural Interface*, vol. 14, no. 6, pp. 530–533, 2011.

[28] D. T. Graham, M. Lambert, Z. Mirzadeh, and F. A. Ponce, "Factors contributing to spinal cord stimulation outcomes for chronic pain," *Neuromodulation: Technology at the Neural Interface*, vol. 25, no. 1, pp. 145–154, 2022.

[29] I. Strauss, K. Taha, V. Krishna, and M. Hodaie, "Younger age predicts greater effectiveness of spinal cord stimulation for chronic pain," *Acta Neurochirurgica*, vol. 158, no. 5, pp. 999–1003, 2016.

[30] C. Odonkor, R. Kwak, K. Ting, D. Hao, B. Collins, and S. Ahmed, "Fantastic four: age, spinal cord stimulator waveform, pain localization and history of spine surgery influence the odds of successful spinal cord stimulator trial," *Pain Physician*, pp. E19–E30, 2020.

[31] R. V. Duarte, R. V. Duarte, S. Mann, T. R. Lawrence, and J. H. Raphael, "Analysis of psychological characteristics impacting spinal cord stimulation treatment outcomes: a prospective assessment," *Pain Physician*, pp. E369–E377, 2015.

[32] M. Bondoc, M. Hancu, M. DiMarzio et al., "Age as an independent predictor of adult spinal cord stimulation pain outcomes," *Stereotactic and Functional Neurosurgery*, vol. 100, pp. 1–7, 2022.

[33] J. L. Han, K. R. Murphy, S. M. Q. Hussaini et al., "Explantation rates and healthcare resource utilization in spinal cord stimulation," *Neuromodulation: Technology at the Neural Interface*, vol. 20, no. 4, pp. 331–339, 2017.

[34] J. Slyer, S. Scott, B. Sheldon, M. Hancu, C. Bridger, and J. G. Pilitsis, "Less pain relief, more depression, and female sex correlate with spinal cord stimulation explants," *Neuromodulation: Technology at the Neural Interface*, vol. 23, no. 5, pp. 673–679, 2020.

[35] M. C. Dougherty, R. W. Woodroffe, S. Wilson, G. T. Gillies, M. A. Howard III, and R. M. Carnahan, "Risk factors and survival analysis of spinal cord stimulator explantation," *Neuromodulation: Technology at the Neural Interface*, vol. 24, no. 1, pp. 61–67, 2021.

[36] J. M. Hagedorn, C. M. Lam, R. S. D'Souza et al., "Explantation of 10 kHz spinal cord stimulation devices: a retrospective review of 744 patients followed for at least 12 months," *Neuromodulation: Technology at the Neural Interface*, vol. 24, no. 3, pp. 499–506, 2021.

[37] N. Hussain, R. Boulos, T. M. Malik et al., "Identifying predictors for early percutaneous spinal cord stimulator explant at one and two years: a retrospective database analysis," *Neuromodulation*, vol. 7159, pp. 291–294, 2022.

[38] S. Lautenbacher, J. H. Peters, M. Heesen, J. Scheel, and M. Kunz, "Age changes in pain perception: a systematic-review and meta-analysis of age effects on pain and tolerance thresholds," *Neuroscience & Biobehavioral Reviews*, vol. 75, pp. 104–113, 2017.

[39] S. Eldabe, E. Buchser, and R. V. Duarte, "Complications of spinal cord stimulation and peripheral nerve stimulation techniques: a review of the literature," *Pain Medicine*, vol. 17, no. 2, pp. 325–336, 2016.

[40] A. Z. Blackburn, H. H. Chang, K. DiSilvestro et al., "Spinal cord stimulation via percutaneous and open implantation: systematic review and meta-analysis examining complication rates," *World Neurosurgery*, vol. 154, pp. 132–143, 2021.

[41] N. Christelis, B. Simpson, M. Russo et al., "Persistent spinal pain syndrome: a proposal for failed back surgery syndrome and ICD-11," *Pain Medicine*, vol. 22, no. 4, pp. 807–818, 2021.