

Artificial Intelligence in Spinal Cord Stimulation and Neuromodulation: A Narrative Review of Clinical Applications, Emerging Evidence, and Future Directions

CHITRA KOLLA¹, SHEETAL MADAVI², SOUVIK BANIK³, DHWANI SHETH⁴, BHAGYESH SAPKALE⁵

ABSTRACT

Spinal Cord Stimulation (SCS) is known as an established neuromodulatory therapy which is used for refractory chronic pain; however, its clinical outcomes remain heterogeneous due to limitations in patient selection, subjective outcome assessment, and trial-and-error programming strategies. Recent advances into Artificial Intelligence (AI) as well as Machine Learning (ML) have further introduced data-driven approaches for addressing such challenges through leveraging high-dimensional clinical, electrophysiological, imaging, and patient-reported datasets. The present narrative review article summarises emerging role of AI into SCS and neuromodulation, which is focused on AI-assisted selection of patients, intelligent programming, closed-loop adaptive systems, as well as clinical evidence. AI techniques which are inclusive of supervised and unsupervised learning, Deep Learning (DL), and Reinforcement Learning (RL), enable improved prediction of responders, phenotyping of chronic pain populations, and real-time optimisation of stimulation parameters. Early clinical and pilot studies suggest promising improvements into personalisation, therapeutic consistency; however, evidence still remains limited by small sample sizes, heterogeneity, also lack of large prospective trials. Ethical, regulatory, data-governance challenges like privacy, algorithmic bias, transparency, accountability further act as additional barriers for widespread adoption of AI into SCS as well as neuromodulation. Future research must focus on validation at multicenter-level, standardised-type of data frameworks, explainable AI along with adaptive regulatory pathways. AI-based SCS thus holds very significant potential into advancement of precision neuromodulation, provided responsible integration, rigorous clinical validation are adequately achieved. The current narrative review article uniquely integrates current and emerging applications of AI across full SCS pathway while also further critically highlighting evidence gaps, future directions for precision neuromodulation.

Keywords: Algorithmic bias, Closed-loop control, Data governance, Pain phenotyping, Predictive modeling

INTRODUCTION

SCS has evolved over several decades as an established modality within the broader field of interventional neuromodulation for chronic pain management [1]. AI as well as ML methods offer tools to address these shortcomings by extracting high-dimensional patterns from radiological imaging, electrophysiology, and clinical datasets for improving candidate selection, prediction of responders, and personalise programming [1,2]. ML has the potential to reduce the trial-and-error nature of SCS by combining clinical features with radiomics, intraoperative EEG, longitudinal device telemetry for producing predictive models along with clustering strategies that stratify likely benefit [3].

Beyond the usage into prediction, AI also enables closed-loop, adaptive neuromodulation architectures which can help further into adjusting stimulation in real time to physiologic signals, optimise stimulation waveforms, as well as support it can also help clinicians in decision-making, thus promising not only incremental gains in pain reduction but also improved device longevity and patient satisfaction [4,5]. Recent reviews are highlighting that progress into AI mainly depends upon larger, interoperable datasets, rigorous validation, as well as attention to transparency, interpretability, along with clinical integration of such AI tools [4-6]. In earlier generations of SCS developed approximately in late 1965 following gate control theory of pain, relied on tonic, open-loop stimulation along with manual, clinician-driven programming that was based largely on trial-and-error method [7]. As neuromodulation expanded throughout the year 1990s and early 2000s, increasing waveform complexity (burst, high-frequency stimulation) as well as multichannel leads resulted into generation of large volumes of clinical and device-related data

[7]. The limitation of conventional programming inclusive of inter-operator variability, subjective pain assessment, and inconsistent long-term outcomes were highlighted in further studies thereby it helped laying groundwork for data-driven optimisation approaches [7,8].

Early clinical as well as pilot investigations of AI-enabled SCS have demonstrated encouraging improvements into patient personalisation, programming efficiency along with therapeutic consistency, particularly through data-driven patient selection and adaptive stimulation strategies [9-11]. However, current evidence base remains preliminary which is constrained through small sample sizes, heterogeneous study designs, retrospective analyses, limited external validation with a notable absence of large, prospective, multicenter randomised trials evaluating about clinically meaningful outcomes [11-13]. These limitations thus highlight further need for rigorous validation before any widespread adoption of AI-guided neuromodulation in the clinical practice [11,12]. This narrative review article aims to comprehensively synthesise current and emerging applications of AI across entire SCS pathway from selection of patient and pain phenotyping to intelligent programming, closed-loop neuromodulation while also critically appraising existing clinical evidence, limitations as well as future directions toward precision neuromodulation.

Established and Emerging Clinical Indications of Spinal Cord Stimulation (SCS)

SCS is most usually used for Failed Back Surgery Syndrome (FBSS) as well as Complex Regional Pain Syndrome (CRPS) [14,15]. In FBSS, which is characterised having persistent or recurrent

neuropathic pain following lumbar spine surgery, randomised controlled trials along with long-term observational studies have demonstrated that SCS provides superior relief into pain, functional improvement, as well as Quality-of-Life (QoL) outcomes compared with repeat surgery or Conventional Medical Management (CMM) [15-17]. Similarly, in Complex Regional Pain Syndrome (CRPS) types I and II, SCS has also further shown sustained reductions in intensity of pain, improved limb function, along with decreased analgesic requirements, usually when implemented earlier in the disease course [14]. Additional narrative and integrative reviews support all of these findings thereby highlighting SCS as an effective option for refractory CRPS while further emphasising about importance of patient selection and multidisciplinary care for optimal outcomes [8,18].

Multiple randomised clinical trials as well as meta-analyses show that conventional SCS, when it is compared to CMM, is associated with very significant reductions in intensity of pain as well as can do improvements in quality of life and functional outcomes at mid-term follow-ups (e.g., ≥6 months) [12,15,19]. A systematic review and meta-analysis inclusive of eight randomised controlled trials with a total of 893 patients showed that conventional SCS, in combination with CMM, significantly reduces pain intensity and improves quality of life, functional outcomes, and disability scores compared with CMM alone [12]. While the evidence supporting traditional tonic SCS is high (level I-II) for painful neuropathy, evidence for high-frequency as well as other novel stimulation paradigms remains limited [12]. Moderate-quality evidence mainly supports SCS for achieving meaningful pain relief and functional gains in Persistent Spinal Pain Syndrome Type 2 (PSPS-T2) at six months when it is compared with sham or CMM, albeit having notable adverse event rates like lead migration, IPG-site pain, also infection [19].

Beyond such classical indications, SCS has further expanded into treatment of peripheral neuropathic pain, which is inclusive of painful diabetic neuropathy, postherpetic neuralgia, radiculopathy, as well as peripheral pain related to nerve injury [20]. Randomised trials, prospective cohort studies have shown that both conventional and high-frequency SCS can significantly reduce pain scores as well as improve sleep, functional outcomes in patients having refractory peripheral neuropathies [21,22]. A prospective cohort study showed significant improvements in pain, QoL outcomes following 10-kHz SCS implantation in patients having chronic limb neuropathic pain [21]. The SENZA-PDN randomised clinical trial showed marked superiority of 10-kHz SCS plus CMM over medical therapy alone in reduction of pain along with improving QoL in painful diabetic neuropathy [22].

Growing evidence supports its role in chronic ischemic pain, refractory angina pectoris, painful diabetic neuropathy, chemotherapy-induced peripheral neuropathy, as well as also in visceral pain syndromes [23,24]. Additionally, role of SCS is being investigated in few conditions like spinal cord injury related pain, pelvic pain syndromes, as well as disorders of autonomic regulation [25,26]. Collectively, such expanding indications highlight about versatility of SCS along with need for advanced approaches which are inclusive of AI-driven personalisation for maximising clinical benefit across various types of pain [25].

Limitations and challenges of conventional Spinal Cord Stimulation (SCS): Despite having such a widespread clinical use, SCS remains limited by inter-patient variability in therapeutic response, also patients with similar diagnoses, lead configurations often experience divergent outcomes because of differences in pain mechanisms, spinal cord anatomy, neural plasticity, as well as psychosocial factors which are inadequately captured by current selection criteria [18]. Key limitations of conventional SCS are described in [Table/Fig-1] [18,27,28].

Domain	Limitation	Underlying factors / Implications	Reference(s)
Inter-patient variability	Heterogeneous therapeutic response among patients with similar diagnoses and lead configurations	Differences in pain mechanisms, spinal cord anatomy, neural plasticity, and psychosocial factors are inadequately captured by current selection criteria	[18]
Patient selection	Limited predictive accuracy of existing selection criteria	Inability to integrate complex biological and psychosocial determinants of pain response	[18]
Programming strategy	Dependence on empirical, trial-and-error optimisation	Large parameter space increases patient burden and healthcare utilisation	[27,28]
Programming outcomes	Suboptimal stimulation settings	Inefficient optimisation limits therapeutic effectiveness	[27,28]
Long-term efficacy	Loss of therapeutic benefit over time	Neural adaptation, disease progression, electrode migration, and evolving pain phenotypes	[28]
System design	Static, open-loop stimulation paradigms	Inability to respond to dynamic physiological and pathological changes	[28]
Overall clinical impact	Limited precision and durability of SCS therapy	Highlights the need for adaptive, data-driven neuromodulation approaches	[28]

[Table/Fig-1]: Key limitations of conventional Spinal Cord Stimulation (SCS) [18,27,28].

Core Artificial Intelligence (AI) Techniques Applied to Neuromodulation

AI in healthcare refers to usage of computational systems which are capable of performing tasks that usually require human intelligence inclusive of pattern recognition, decision-making, and predictive analysis [29]. ML is known as a subset of AI in which algorithms try to learn from data for identification of patterns and thereby improve performance without being programmed explicitly [30]. DL refers to the use of multilayered neural network architectures to model complex, non-linear relationships in large datasets [31]. These DL models are built upon neural networks, which are called as computational structures inspired by biological neural systems as well as consist of interconnected nodes that process and transmit information [31]. Together such core AI concepts underpin modern healthcare applications, thereby also enabling advanced data interpretation, predictive modeling, as well as personalised clinical decision support in various type of medical domains [29,31].

AI techniques that are applied into neuromodulation usually include supervised and unsupervised learning [32]. Supervised learning algorithms are trained with the usage of labeled clinical outcomes for prediction of treatment response, optimisation of patient selection, as well as identification of prognostic biomarkers in SCS [33]. In contrast, unsupervised learning methods which are inclusive of clustering, dimensionality reduction are used for uncovering latent patterns within electrophysiological signals, neuroimaging data, as well as longitudinal device telemetry, thereby it also enables identification of distinct pain phenotypes, responder subgroups without predefined labels [33,34]. These approaches have showed great utility in stratifying patients, reducing heterogeneity in outcomes, as well as it helps informing personalised neuromodulation strategies [34].

The RL, advanced pattern recognition and predictive analytics represent as an emerging AI-paradigms into neuromodulation [8]. RL frameworks can be used for iteratively adjusting stimulation parameters based upon feedback from physiological signals as well as Patient-Reported Outcomes (PRO), thereby it also supports adaptive and closed-loop SCS systems [8,35]. Pattern recognition

techniques which are applied to electroencephalography, Evoked Compound Action Potentials (ECAP), and sensor-derived data facilitate real-time detection of pain states along with neural responses to stimulation [10]. When integrated along with predictive analytics, such methods enable forecasting of management durability, detection of impending loss of efficacy, along with optimisation of therapy [10]. Collectively, all of these AI techniques further provide methodological foundation for precision neuromodulation and support transition from static, open-loop systems toward an intelligent as well as adaptive pain therapies [10,35].

Patient-reported, Physiological, and Imaging Data for AI-Based Neuromodulation

In pain medicine and neuromodulation, effectiveness of AI models is usually dependent on quality as well as diversity of underlying data sources [36]. The PROs which are inclusive of pain intensity scores, functional assessments, QoL measures, along with symptom diaries remain central to various AI studies, as they provide longitudinal insight into treatment response as well as patient experience [5,10,36,37]. When systematically collected with the usage of digital platforms, PROs enable supervised learning models for correlating subjective pain trajectories along with stimulation parameters, clinical variables, thereby supporting outcome prediction also therapy optimisation [36,37].

Complementing PROs, objective physiological-multimodal datasets play an important role into AI-driven pain medicine [34]. Electrophysiological signals such as ECAPs, Electromyography (EMG), also further help to provide insights into real-time markers of neural engagement, motor responses to stimulation, which have been utilised in closed-loop and adaptive SCS [34]. Wearable and sensor-derived data which includes activity levels, sleep metrics, heart rate variability, gait parameters also thereby further offer continuous, ecologically valid measures of functional status to behaviour related to pain [38]. Integration of these signals with imaging as well as clinical datasets like spinal and brain MRI, radiomics, electronic health records, procedural data, helps AI models in capturing structural, functional, also clinical dimensions of pain [11,39]. All these heterogeneous sources of data form base for accurate predictive analytics, personalised neuromodulation strategies into contemporary pain medicine [11].

Integration of Artificial Intelligence (AI) in SCS

AI improves identification of SCS responders by integration of demographics, pain characteristics, psychological factors, prior treatment as well as functional scores [40]. Supervised ML methods outperform traditional selection thereby helps reducing failed implants [30,41]. Unsupervised approaches identify patient subgroups with distinct profiles, guiding stimulation modality and programming [6,42]. Predictive models considering longitudinal

PROs and trial data estimate pain relief, functional improvement, opioid reduction as well as risk of adverse events [13,43]. ML-driven parameter tuning personalises stimulation inclusive of amplitude, pulse width, frequency thereby it helps into enhancing therapeutic consistency while further reducing workload of clinicians [44]. ECAP-guided closed-loop SCS uses real-time feedback to maintain neural dosing, compensating for posture and electrode-tissue changes, sustaining analgesia as well as minimising manual reprogramming [11,45,46]. AI-Driven Applications in SCS are depicted in [Table/ Fig-2] [6,11,13,30,40-46].

Clinical Evidence for Spinal Cord Stimulation (SCS)

AI-based SCS trials, evidence gaps, and limitations: Emerging studies are now exploring towards usage of AI and ML for refining and personalising SCS therapy [10,11]. Early clinical research shows that AI models can help into prediction of patient responses to SCS with high accuracy which is done through integration of intraoperative EEG signals and clinical outcome measures, thereby suggesting improved patient selection and optimisation of stimulation settings could be achievable beyond conventional trial-and-error approaches [10,11].

However, evidence gaps are very significant. AI-enhanced SCS research is still in its early stage, with many published studies limited by small sample sizes, retrospective designs, also lack of external validation across diverse clinical settings [2,6,11,13]. Comprehensive, randomised controlled trials which evaluate clinical endpoints of AI-guided SCS implementation such as pain relief, quality of life, long-term outcomes are not available [12,43]. In addition, standardisation of data, regulatory challenges along with integration of real-time adaptive algorithms into implantable devices are unresolved limitations [12]. Collectively, while traditional SCS has an established evidence base supporting its efficacy, and AI approaches which further offer promising enhancements, robust clinical validation of AI-based SCS still remains an important need to be completed [11,12].

Ethical, Data Governance, and Regulatory Challenges in AI-Enabled SCS

The integration of AI into SCS and neuromodulation poses several ethical and data-governance challenges, usually related to data privacy, security, and ownership [47]. AI-driven SCS systems are dependent upon large volumes of sensitive patient data inclusive of electrophysiological signals, imaging datasets, as well as longitudinal PROs, thereby raising concerns regarding informed consent, secondary data use, along with cybersecurity vulnerabilities [47,48]. Inaccurate protection of such data may expose patients to breaches-misuse, mainly in cases where cloud-based platforms and continuous data streaming are involved [48]. Additionally, algorithmic bias also remains a very critical issue, as

AI application domain	Key AI approaches	Clinical utility	Impact on SCS outcomes	Reference(s)
AI-assisted patient selection	Supervised ML models (random forest, support vector machines)	Integration of demographic, pain-related, psychological, functional, and treatment history variables to predict responders vs non-responders	Improved prediction accuracy, reduced failed implants, decreased unnecessary healthcare expenditure	[30,40,41]
Pain phenotyping and stratification	Unsupervised ML (clustering, principal component analysis)	Identification of latent chronic pain phenotypes based on biological, psychological, and behavioural profiles	Mechanism-based patient selection, optimised choice of stimulation modality and programming strategy	[6,13,42]
Outcome prediction and risk stratification	Predictive models using longitudinal PROs and peri-procedural data	Estimation of sustained pain relief, functional improvement, opioid reduction, adverse events, and explantation risk	Early identification of poor responders, tailored follow-up, timely consideration of alternative therapies	[43]
Intelligent SCS programming and optimisation	Adaptive ML algorithms	Automated tuning of amplitude, pulse width, and frequency based on patient response and posture variation	Personalised stimulation, reduced trial-and-error programming, lower clinician workload, improved consistency of analgesia	[44]
Closed-loop and adaptive neuromodulation systems	AI-driven ECAP-based feedback control	Real-time sensing of dorsal column activation to guide stimulation delivery	Improved precision of neural dosing, sustained pain relief across activities, reduced need for manual reprogramming	[11,45,46]

[Table/Fig-2]: Artificial Intelligence (AI)-driven applications in SCS [6,11,13,30,40-46].

Domain	Key challenge	Description/ implications	References
Ethical considerations	Data privacy and security	AI-driven SCS relies on large volumes of sensitive data (electrophysiological signals, imaging, PROs), raising concerns regarding informed consent, secondary data use, cybersecurity risks, and potential data breaches, particularly with cloud-based platforms and continuous data streaming.	[47,48]
Ethical considerations	Algorithmic bias and equity	AI models trained on non-representative datasets may generate biased predictions, leading to inequitable outcomes across demographic or clinical subgroups and reduced generalisability of AI-enabled SCS systems.	[47,48]
Ethical considerations	Transparency and explainability	Limited interpretability of AI algorithms challenges clinician trust and responsible clinical decision-making, driving the need for explainable AI (XAI) frameworks in neuromodulation.	[49]
Data governance	Data ownership and governance	Ambiguity regarding ownership, access, and long-term use of continuously generated patient data necessitates robust governance frameworks to ensure ethical and compliant data handling.	[47,48]
Regulatory challenges	Device regulation and oversight	AI-enabled and adaptive neuromodulation systems challenge traditional medical device regulatory models, prompting the development of adaptive, lifecycle-based regulatory pathways.	[50]
Medico-legal issues	Accountability and liability	Uncertainty exists regarding responsibility among clinicians, manufacturers, and software developers when AI-driven systems autonomously adjust stimulation parameters, particularly in closed-loop SCS.	[50]
Implementation challenges	Need for standardised frameworks	Lack of standardised ethical, regulatory, and governance frameworks limits safe and equitable clinical translation, emphasising the need for rigorous validation and sustained human oversight.	[49,50]

[Table/Fig-3]: Ethical, data governance, and regulatory challenges in AI-enabled SCS [47-50].

AI models which are trained on non-representative datasets may produce inequitable outcomes across different demographic or clinical subgroups [47,48]. The lack into diversity in data used for training such AI platforms can compromise generalisability and increase disparities in management of pain. Consequently, there is growing emphasis on usage of explainable AI (XAI) for ensuring transparency, which can allow clinicians to interpret algorithm-driven recommendations while also use them in responsible manner into clinical decision-making [49].

From a regulatory, medico-legal point of view, the usage of AI-enabled neuromodulation systems is directly proving as a challenge to existing medical device oversight [50]. Regulatory bodies inclusive of United States Food and Drug Administration (US FDA) as well as international counterparts have begun developing adaptive regulatory pathways for usage of AI/ML-based medical devices, thereby highlighting continuous performance monitoring, real-world validation, lifecycle-based regulation for addressing such evolving AI-based algorithms [50]. However, there are few uncertainties also present regarding accountability and liability when AI-driven systems influence stimulation parameters, therapeutic decisions, usually in closed-loop, autonomous neuromodulation platforms [50]. To determine and define responsibility among clinicians, manufacturers, as well as software developers remains complex, usually in cases when algorithms modify behaviour over time [50]. Such regulatory-legal concerns along with ethical issues into transparency and bias highlight an unmet need for making of standardised governance frameworks, rigorous clinical validation, as well as sustained human oversight to ensure that AI-based SCS systems are safe, equitable, clinically trustworthy [49,50]. Ethical, data governance, and regulatory challenges in AI-Enabled SCS are described in [Table/Fig-3] [47-50].

Future Directions in AI-driven SCS

Future research in AI-based SCS and neuromodulation approaches should prioritise it's work in development of robust closed-loop adaptive systems that continuously integrate real-time electrophysiological feedback, PROs, as well as sensor-derived data which helps to enable truly personalised therapy [16,37]. Investigators must always focus on large, prospective, multicenter clinical trials for validation of safety, efficacy, and generalisability of AI-guided SCS as compared to conventional type of programming strategies [16]. Further efforts must also address transparency in algorithms, mitigation of bias, and explainable AI which can ensure trust in clinicians, equitable patient care, along with an ethical deployment [51]. Additionally, future research work must focus on developing standardised data frameworks and secure data-sharing models, evolving regulatory pathways, thereby it can help in responsible clinical translation while maintenance of human oversight in AI-based neuromodulation approaches [51,52].

CONCLUSION(S)

AI represents a transformative advancement in SCS by addressing key limitations of conventional, open-loop neuromodulation systems. It enables data-driven selection of patients, intelligent programming, as well as closed-loop adaptive control. AI is very useful to improve precision, durability, and consistency of pain relief across various types of clinical indications. However, current research evidence remains preliminary, having significant gaps in large-scale validation, standardisation, also regulatory integration. Ethical governance, algorithm transparency, human oversight are very essential aspects which are responsible into its implementation. Future multicenter trials, robust frameworks will be critical to help in translation of AI-based SCS into routine clinical practice in appropriate way.

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PARTICULARS OF CONTRIBUTORS:

1. Junior Resident, Department of Anaesthesia, Jawaharlal Nehru Medical College, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.
2. Professor, Department of Anaesthesia, Jawaharlal Nehru Medical College, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.
3. Junior Resident, Department of Anaesthesia, Jawaharlal Nehru Medical College, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.
4. Junior Resident, Department of Anaesthesia, Jawaharlal Nehru Medical College, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.
5. Undergraduate Student, Department of Medicine, Jawaharlal Nehru Medical College, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Chitra Kolla,
Junior Resident, Department of Anaesthesia, Jawaharlal Nehru Medical College,
Datta Meghe Institute of Higher Education and Research, Wardha-442001,
Maharashtra, India.
E-mail: chitrakolla135@gmail.com

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