

Intrathecal baclofen for neuropathic pain in spinal cord injury: A systematic review

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Abstract: Neuropathic pain is a debilitating spinal cord injury (SCI) complication often resistant to conventional treatments. Intrathecal baclofen, a γ -aminobutyric acid type B (GABA_B) receptor agonist, has been suggested to provide additional analgesic benefits. This systematic review evaluated the efficacy and safety of intrathecal baclofen for neuropathic pain in patients with SCI, as well as its effects on spasticity and quality of life. Following PRISMA 2020 guidelines, we searched major databases through January 2024 for trials and cohort studies of intrathecal baclofen in adults with SCI. Risk of bias was assessed using RoB 2 and ROBINS-I tools. A narrative synthesis was performed due to substantial study heterogeneity. Among 48 patients across four studies, three reported meaningful reductions in neuropathic pain following intrathecal baclofen, as reflected in validated pain scales such as the Numerical Rating Scale, Neuropathic Pain Symptom Inventory, Brief Pain Inventory, and Visual Analogue Scale. Greater improvements were observed in paroxysmal pain and dysesthesia than in continuous pain or allodynia. All studies reported significant reductions in spasticity, primarily assessed using the Modified Ashworth Scale. Functional outcomes and quality-of-life domains improved where reported. Adverse events were generally mild and transient, with no serious complications. Intrathecal baclofen is a promising adjuvant for SCI-related neuropathic pain, providing consistent benefits for spasticity and quality of life. However, limited evidence from small, heterogeneous studies necessitates larger, well-designed randomized controlled trials to confirm these findings.

Keywords: GABAB receptor, Intrathecal baclofen, Neuropathic pain, Spasticity, Spinal cord injury.

1. Introduction

Spinal cord injury (SCI) is a devastating neurological disorder causing long-term sensory, motor, and autonomic dysfunctions that profoundly affect patients' physical, psychological, and socioeconomic well-being [1, 2]. Globally, the prevalence of SCI has increased over the past three decades, with 250,000–500,000 new cases reported annually, mostly affecting individuals aged 20–35 years. Approximately 90% of cases are trauma-related, primarily due to motor vehicle accidents, falls, and violence [3, 4].

Neuropathic pain is one of the most common and disabling sequelae of SCI, reported in 11–95% of patients. It is characterized by burning, tingling, or electric-shock sensations and is frequently associated with severe pain intensity [5, 6]. This pain markedly reduces quality of life and functional independence [7]. Conventional treatments such as NSAIDs, opioids, antidepressants, and anticonvulsants often provide limited relief [8, 9].

Baclofen, a γ -aminobutyric acid type B (GABA_B) receptor agonist, is widely used to treat spasticity after SCI and has shown potential in alleviating neuropathic pain. It exerts presynaptic and postsynaptic

inhibitory effects by increasing K^+ conductance and reducing Ca^{2+} influx, thereby suppressing excitatory neurotransmitters such as glutamate and substance P [10, 11]. Experimental and clinical studies have demonstrated significant analgesic effects of intrathecal Baclofen in SCI-related neuropathic pain [12-14].

Despite these benefits, Baclofen may cause adverse effects, including rebound spasticity, erectile dysfunction, and withdrawal symptoms [11, 12]. Given these considerations, a systematic review is warranted to synthesize current evidence on Baclofen's efficacy and safety in managing neuropathic pain following SCI. Although previous systematic reviews have examined intrathecal Baclofen for SCI-related neuropathic pain, they often focused primarily on pain intensity outcomes. This review additionally evaluates spasticity, quality of life, and multidimensional patient-reported outcomes, providing a more comprehensive assessment of therapy efficacy and safety. Therefore, this study aims to systematically evaluate the effect of Baclofen on neuropathic pain in patients with spinal cord injury.

2. Materials and Methods

2.1. Protocol and Registration

This systematic review was conducted in accordance with the PRISMA 2020 statement. The review protocol was retrospectively submitted to the International Prospective Register of Systematic Reviews (PROSPERO) due to refinement of the review scope after initial planning. At the time of manuscript submission, the registration is under editorial review.

2.2. Eligibility Criteria

Studies were eligible if they met the following criteria:

1. Population: adults (≥ 18 years) with confirmed spinal cord injury (SCI). Studies including adolescents or children were excluded.
2. Intervention: administration of Baclofen (intrathecal) for neuropathic pain management.
3. Comparators: placebo, standard care, or non-Baclofen interventions.
4. Outcomes: neuropathic pain (e.g., NRS, NPSI, VAS), spasticity (MAS), functional outcomes, quality of life (e.g., BPI, WHOQOL-BREF), and adverse events.
5. Study design: randomized controlled trials (RCTs), prospective or retrospective cohort studies.
6. Language: English. No restrictions were applied to the publication year. Case reports, reviews, and animal studies were excluded.

2.3. Search Strategy

A comprehensive literature search was conducted in PubMed/MEDLINE, Cochrane Library, Scopus, EBSCOhost, and DOAJ from inception to 31 January 2024. The search strategy combined controlled vocabulary (e.g., MeSH terms) and free-text terms for spinal cord injury, Baclofen, and neuropathic pain using Boolean operators "AND" and "OR." Only English-language studies were included. Full search strategies for all databases are provided in Supplementary Material 1.

2.4. Study Selection

Studies were included if they involved adults (≥ 18 years) with confirmed SCI who received Baclofen for neuropathic pain, compared with control or non-Baclofen groups, and reported outcomes related to neuropathic pain, spasticity, and adverse events. Both RCTs and prospective or retrospective cohort studies were eligible. Two reviewers independently screened titles, abstracts, and full texts; disagreements were resolved by discussion or consultation with a third reviewer.

2.5. Data Extraction

Data extraction was performed independently by two reviewers using a standardized form. Extracted data included study characteristics (author, year, country, study design), participant

demographics (age, sex, injury level, injury duration), intervention details (route, dose, frequency, duration), comparator information, and outcomes (neuropathic pain, spasticity, functional outcomes, quality of life, and adverse events). Any disagreements were resolved through discussion or a third reviewer. Descriptive and quantitative data were summarized narratively and in tables. Missing or unclear data were reported as available; no imputation was performed.

2.6. Quality Assessment

Quality and risk of bias were assessed independently by two reviewers. RCTs were evaluated using RoB 2 and the Jadad Scale, while non-randomized studies were assessed using ROBINS-I and the Newcastle–Ottawa Scale (NOS), following the Cochrane Handbook for Systematic Reviews of Interventions [1]. Discrepancies were resolved by discussion or consulting a third reviewer. Publication bias was examined qualitatively using funnel plots.

2.7. Effect Measures

Neuropathic pain outcomes were assessed using changes in the Numeric Rating Scale (NRS), Visual Analog Scale (VAS), or the Neuropathic Pain Symptom Inventory (NPSI), and were reported as mean differences or percentage reductions from baseline, as provided by the included studies. A reduction of $\geq 30\%$ was considered clinically significant [2]. Spasticity was evaluated using the Modified Ashworth Scale (MAS), with a decrease of ≥ 1 point regarded as clinically meaningful [3]. Functional outcomes were assessed using Brief Pain Inventory (BPI) subdomains and expressed as mean scores or percentage improvements. Quality of life was measured using the WHOQOL-BREF or other validated instruments, with higher scores indicating better quality of life. Adverse events were recorded as the number and proportion of patients experiencing specific events.

2.8. Data Synthesis

Due to heterogeneity across study designs, interventions, outcome measures, and follow-up durations, a meta-analysis was not performed. A structured narrative synthesis was conducted:

- Studies were grouped by outcome domain.
- Neuropathic pain outcomes were synthesized across all eligible studies.
- Spasticity outcomes were synthesized only for intrathecal Baclofen due to route-specific effects.
- Functional outcomes and quality of life were described where reported.
- Missing or incomplete data were explicitly noted; attempts to contact authors were made when feasible.

Results were presented in structured tables summarizing study characteristics, interventions, outcomes, direction of effect, and magnitude of change. Figures illustrated overall trends. Narrative synthesis involved vote counting based on the direction of effect and summarizing ranges of effect sizes. Heterogeneity related to study design, Baclofen dosage, and follow-up duration was explored qualitatively. No formal subgroup or sensitivity analyses were performed due to the limited number of studies. Certainty of evidence was not formally assessed using GRADE.

2.9. Reporting Bias

Risk of reporting bias was assessed qualitatively as part of the overall risk of bias using RoB 2 (RCTs) and ROBINS-I (non-randomized studies). Judgements were based on selective outcome reporting and the availability of prespecified outcomes. Formal quantitative methods were not applied due to the small number of included studies (<10); conclusions regarding reporting bias were drawn cautiously.

3. Results

3.1. Study Selection

The database search identified 52 records (PubMed 42, Cochrane Library 5, EBSCOhost 5), as shown in Figure 1. No additional records were found in Scopus or DOAJ. After removing duplicates, 42 records were screened by title and abstract. Eight full-text articles were assessed for eligibility, and four studies met the inclusion criteria for qualitative synthesis (Figure 1). Four full-text articles were excluded due to: absence of neuropathic pain-specific outcomes ($n = 2$), non-SCI population ($n = 1$), and case-report design ($n = 1$).

3.2. Study Characteristics

The four included studies comprised one randomized controlled trial and three non-randomized studies (two prospective cohorts and one non-randomized controlled trial), with a total of 48 patients. The mean age was 49.3 years (range 21–67), with 87.5% male. All studies evaluated intrathecal Baclofen, with follow-up durations ranging from 24 hours to 6 months. Detailed intervention protocols are summarized in Table 1.

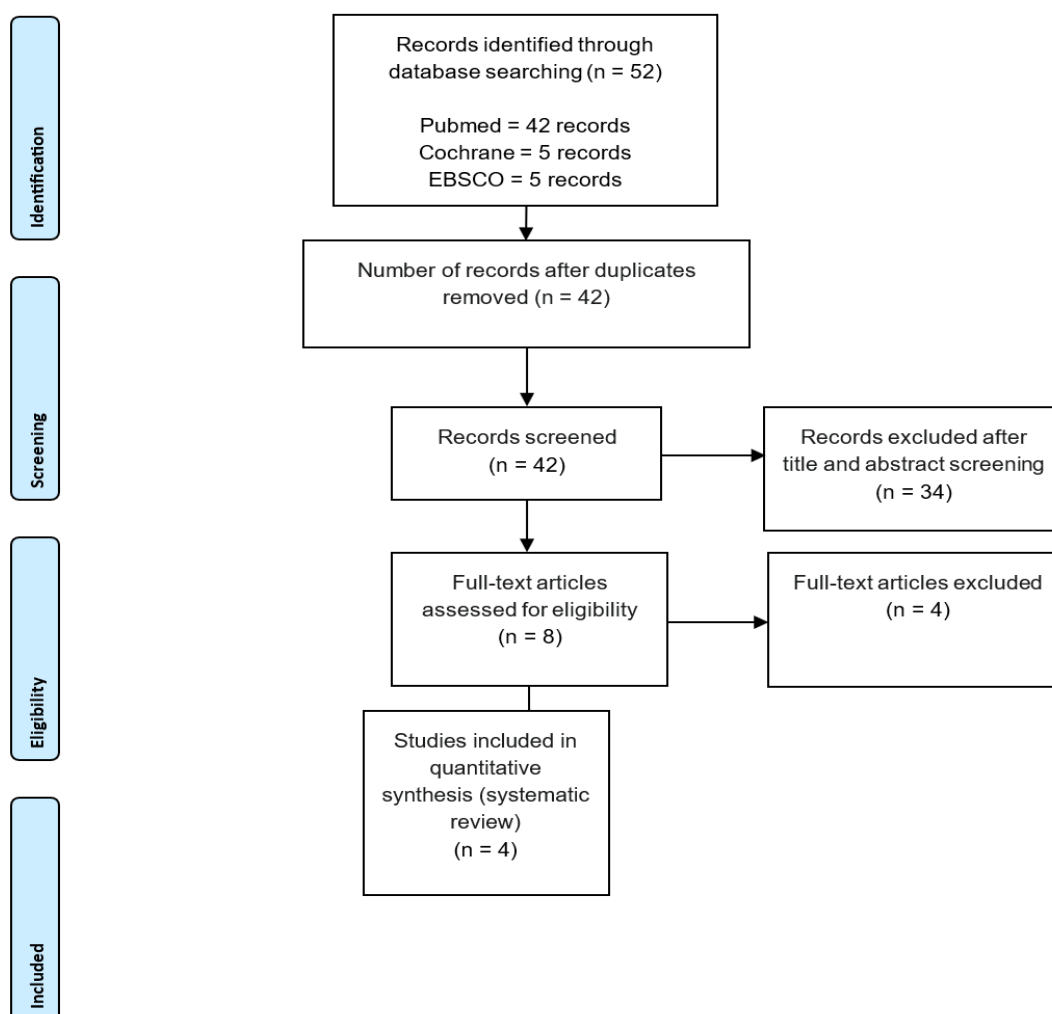


Figure 1. PRISMA flow diagram of study selection for intrathecal baclofen in spinal cord injury-related neuropathic pain.

Table 1.

Summary of included studies evaluating intrathecal baclofen for neuropathic pain in spinal cord injury patients.

Reference	Study Design	Total Patients	Baclofen Patients	Median Age	Baclofen Intervention	Follow-up	Adverse Events	Neuropathic Pain Outcomes	Other Outcomes
Kumru et al. [13]	Double-blind RCT	13	8	46 (29–67)	50 µg intrathecal bolus; repeat 100 µg if ineffective	24 h	Minimal, well tolerated	Significant improvement in NRS, NPSI, BPI; improved mood, mobility, QoL	Spasticity (MAS), QTT, and CHEPs improved 4 h post-administration
Kumru et al. [14]	Prospective Cohort	9	9	52 (29–65)	100–550 µg/day via intrathecal pump	6 months	Not reported	Significant reduction in NRS, NPSI; improvement in BPI and spasticity	Spasticity (MAS) improved throughout follow-up
Loubser and Akman [15]	Prospective Cohort	12	12	45.5 (21–63)	50 µg intrathecal injection	6–12 months	Not reported	Improvement in musculoskeletal pain; no significant neurogenic pain relief	MAS, VAS improved
Taira et al. [16]	Non-RCT	14	14	54 (46–66)	50–100 µg intrathecal bolus	24 h	Headache, urinary retention, gait disturbance	Pain relief in 3 SCI patients; reduced allodynia and hyperalgesia	Pain improved in 6 post-stroke patients

Note: NRS = Numeric Rating Scale; NPSI = Neuropathic Pain Symptom Inventory; BPI = Brief Pain Inventory; VAS = Visual Analogue Scale; MAS = Modified Ashworth Scale; QTT = Quantitative Thermal Testing; CHEPs = Contact Heat-Evoked Potentials.

^b “Significant improvement” defined as ≥30% reduction in pain score from baseline.

4. Results of Individual Studies

All four studies assessed neuropathic pain using validated instruments, including the Numeric Rating Scale (NRS), Neuropathic Pain Symptom Inventory (NPSI), Brief Pain Inventory (BPI), and Visual Analog Scale (VAS), as shown in Table 1-2. Three of the four studies reported reductions in neuropathic pain intensity following intrathecal baclofen administration, whereas one study found no significant improvement in neurogenic pain [15]. A randomized controlled trial reported that a single intrathecal baclofen bolus was associated with significant short-term reductions in neuropathic pain intensity across multiple domains, including paroxysmal pain, allodynia, and dysesthesia, with concurrent improvement in pain-related functional interference affecting mood, mobility, and enjoyment of life [13]. A prospective cohort study demonstrated sustained reductions in neuropathic pain intensity following continuous intrathecal baclofen infusion over six months, with greater improvement in paroxysmal pain and dysesthesia, while continuous pain and allodynia showed more variable responses [14]. A non-randomized clinical study reported partial pain relief following a single intrathecal baclofen bolus, with reductions in allodynia and hyperalgesia observed at 24 hours post-administration [16]. In contrast, one study reported no significant change in neurogenic pain intensity following intrathecal baclofen administration, although improvement in musculoskeletal pain was observed [15].

Table 2.
Effect of Baclofen on Neuropathic Pain.

Study	Effect on Neuropathic Pain
Kumru et al. [13]	Significant effect
Kumru et al. [14]	Significant effect
Loubser and Akman [15]	No significant effect
Taira et al. [16]	Significant effect

Note: a Neuropathic pain assessed using Numeric Rating Scale (NRS), Neuropathic Pain Symptom Inventory (NPSI), or Visual Analogue Scale (VAS) b "Significant effect" defined as $\geq 30\%$ reduction in pain score from baseline.

4.1. Spasticity Outcomes

All studies assessed spasticity using the Modified Ashworth Scale (MAS). Intrathecal Baclofen consistently reduced spasticity, with greater and sustained effects in studies using continuous infusion. Improvements were observed as early as 4 hours post-administration in the RCT and maintained throughout follow-up in the cohort study.

4.2. Functional and Quality-of-Life Outcomes

Two studies reported improvements across multiple functional domains, including general activity, mobility, mood, sleep, and social interaction, indicating broader clinical benefits alongside reductions in neuropathic pain and spasticity [13, 14].

4.3. Adverse Events

Reported adverse events were generally mild and transient: headache, pruritus, constipation, urinary retention, and gait disturbance. Continuous intrathecal administration was well tolerated with close monitoring. No serious complications were reported.

4.4. Certainty of Evidence

Certainty of evidence was not formally assessed using GRADE due to the small number and heterogeneity of included studies.

4.5. Risk of Bias Assessment

The randomized controlled trial demonstrated an overall low-to-moderate risk of bias [13]. In contrast, the non-randomized studies were judged to have a serious risk of bias, primarily due to

confounding and selection bias, with additional moderate concerns related to outcome measurement as shown in Figure 2-3 [14-16].

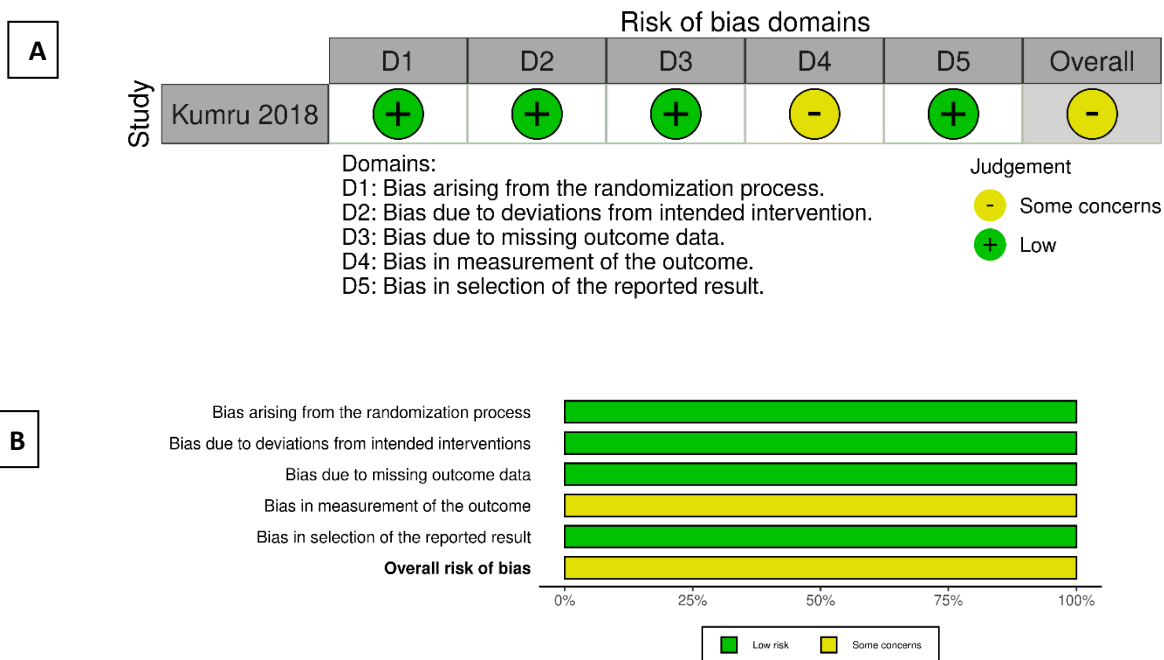
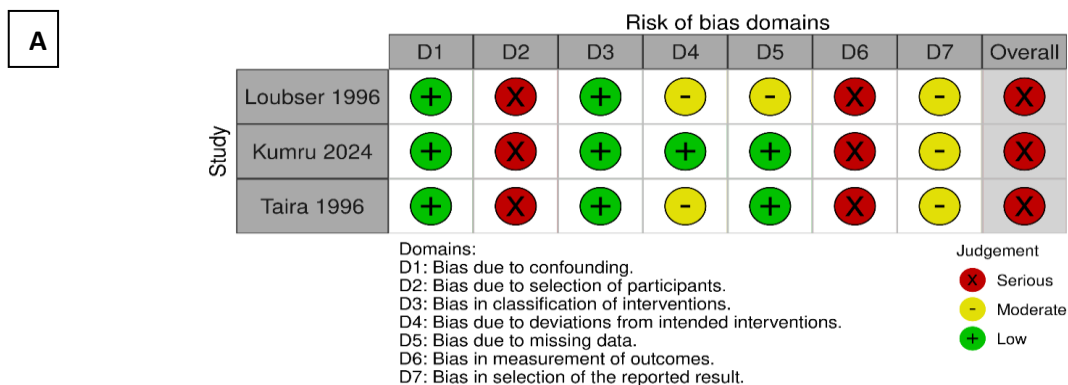


Figure 2. Risk of bias assessment using RoB 2 for randomized studies: (a) domain-specific risk per study; (b) proportion of studies with low, some concerns, or high risk of bias.

Source: Kumru et al. [13].



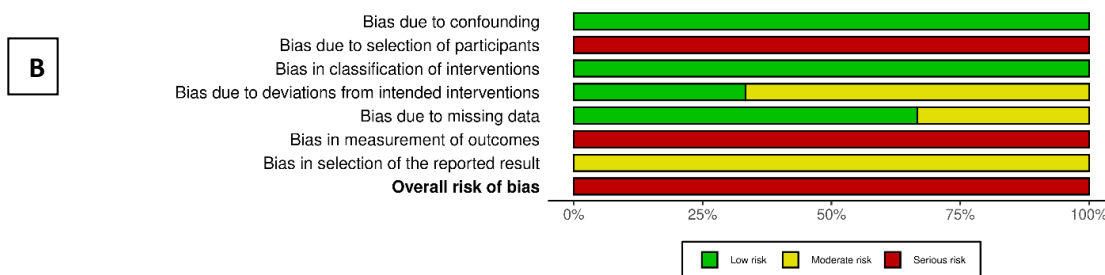


Figure 3.

Risk of bias assessment using ROBINS-I for non-randomized studies: (a) domain-specific risk per study; (b) proportion of studies with low, moderate, or serious risk of bias.

Source: Loubser and Akman [15], Kumru et al. [14] and Taira et al. [16].

4.6. Reporting Bias

Selective outcome reporting was low-to-moderate in the RCT and serious in non-randomized studies due to incomplete reporting. Formal quantitative assessment was not feasible due to the small number of studies (<10).

5. Discussion

The findings of this systematic review suggest that intrathecal baclofen may contribute to reductions in neuropathic pain intensity among patients with chronic spinal cord injury. However, these results should be interpreted cautiously due to the small number of studies and considerable heterogeneity in study design, dosing regimens, and follow-up durations. These findings suggest that intrathecal baclofen may provide greater relief for paroxysmal pain and dysesthesia, potentially accounting for the variability in patient responses seen across studies. Nevertheless, the clinical relevance of these findings remains uncertain, and further well-designed randomized trials are needed to establish definitive efficacy and safety profiles.

Baclofen is a γ -aminobutyric acid type B (GABA_B) receptor agonist widely used to manage spasticity secondary to spinal cord injury (SCI) and other neurological disorders. Intrathecal administration allows baclofen to achieve therapeutic concentrations in the cerebrospinal fluid at much lower doses than oral administration, thereby reducing systemic adverse effects. Beyond its established antispastic properties, intrathecal baclofen may offer additional benefits in alleviating neuropathic pain, a frequent and disabling complication following SCI, potentially making it a valuable adjuvant therapy to improve both motor function and overall quality of life [11].

This systematic review identified four primary studies evaluating intrathecal baclofen for neuropathic pain in patients with SCI. Across these studies, intrathecal baclofen consistently demonstrated reductions in pain intensity, as measured by the Numerical Rating Scale (NRS), Neuropathic Pain Symptom Inventory (NPSI), and Brief Pain Inventory (BPI), supported by data from the Visual Analogue Scale (VAS) and Modified Ashworth Scale (MAS). Despite these positive trends, variations in study design, dosing regimens, and follow-up durations warrant cautious interpretation and may have influenced the magnitude of observed effects.

A double-blind randomized controlled trial involving SCI patients with chronic neuropathic pain demonstrated that a single intrathecal baclofen bolus (50 μ g, followed by 100 μ g if the initial response was insufficient) resulted in significant reductions in NRS scores, along with improvements across multiple NPSI subdomains, including paroxysmal pain, allodynia, and dysesthesia.¹³ Functional interference due to pain also improved, as reflected by BPI domains such as general activity, mood, mobility, work capacity, interpersonal relationships, and enjoyment of life. While encouraging, the short-term nature of this study limits conclusions about sustained efficacy.

In a prospective cohort study, continuous intrathecal baclofen infusion (100–350 μ g/day) administered via pump over six months was associated with sustained reductions in NRS scores and

improvements in NPSI subdomains related to paroxysmal pain and dysesthesia [14, 15]. However, continuous pain and allodynia showed more variable responses, suggesting that individual patient characteristics or administration methods may influence outcomes. BPI assessments indicated improvements in general activity, mobility, mood, social relationships, and overall quality of life. These findings highlight potential multidimensional benefits, yet the small sample size limits generalizability.

Earlier studies reported variable effects of intrathecal baclofen on neuropathic pain, although consistent reductions in spasticity were observed, as indicated by improvements in MAS scores [16, 17]. Such heterogeneity may be attributed to small sample sizes, differences in patient populations, variability in pain characterization, and limitations in outcome assessment methods used in older studies.

Mechanistically, the analgesic effects of baclofen are mediated through activation of spinal GABA_B receptors, which inhibit excitatory neurotransmitter release, including glutamate and substance P, within nociceptive interneurons. Both presynaptic and postsynaptic actions reduce calcium influx and enhance potassium conductance, leading to neuronal hyperpolarization and reduced motor neuron excitability. In addition, baclofen modulates descending inhibitory pathways from the brainstem to the spinal cord, thereby increasing pain thresholds and attenuating symptoms such as allodynia and hyperalgesia [11, 18]. Such mechanisms may underlie the more pronounced relief in paroxysmal pain and dysesthesia observed in some patients, whereas continuous pain and allodynia appear less responsive.

Additional Benefits: Spasticity and Quality of Life

Beyond analgesic effects, intrathecal baclofen consistently reduced spasticity across all included studies. Decreases in MAS scores suggest that its antispastic properties contribute to functional improvements and enhanced rehabilitation outcomes [13, 14, 16]. Improvements in quality of life were also reported, with positive changes observed in multiple BPI domains, including general activity, mood, mobility, work capability, social function, and sleep quality [15, 18]. In patients receiving intrathecal baclofen for at least six months, WHOQOL-BREF assessments demonstrated satisfactory overall quality of life, with the highest scores in psychological domains and high levels of treatment satisfaction [15].

Consistent with these findings, intrathecal baclofen was associated with a 40% reduction in pain interference with general activity, a 35% improvement in mood, and a 38% reduction in sleep disturbance. These results highlight the multidimensional clinical benefits of intrathecal baclofen, addressing not only pain intensity but also psychological and social aspects of patient well-being [18].

5.1. Safety Profile

Adverse events associated with intrathecal baclofen were generally mild and transient. Reported side effects included pruritus, constipation, transient headache, and urinary retention [13, 14, 16]. No major complications were reported in the included studies [11]. Although generally well tolerated, careful monitoring remains essential to prevent toxicity or withdrawal-related complications, particularly with long term use.

6. Conclusions

Intrathecal Baclofen appears to be an effective adjuvant therapy for neuropathic pain in patients with spinal cord injury, particularly for paroxysmal pain, allodynia, and dysesthesia. Beyond analgesia, it consistently reduces spasticity, improves motor function, and supports rehabilitation outcomes. Evidence also indicates benefits across multiple domains of quality of life, including physical, psychological, and social aspects. Adverse events are generally mild and well-tolerated.

Despite limitations such as small sample sizes and varied study designs, intrathecal baclofen shows promise as a multifaceted therapy for neuropathic pain in SCI. Clinicians should weigh individual patient characteristics and monitor carefully for adverse effects. Further research is needed to clarify optimal dosing, long-term benefits, and patient-centered outcomes.

Data Availability Statement:

All data analyzed in this systematic review are derived from published studies. Further details are available from the corresponding author upon reasonable request.

Transparency:

The authors confirm that the manuscript is an honest, accurate, and transparent account of the study; that no vital features of the study have been omitted; and that any discrepancies from the study as planned have been explained. This study followed all ethical practices during writing.

Acknowledgements:

The authors thank the staff and colleagues who contributed to literature screening, data extraction, and methodological support for this review. Their expertise and guidance were invaluable in the preparation of this manuscript.

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