Annals of Clinical and Medical Case Reports[R] ISSN 2639-8109 |Volume 16

Case Report Open Access

Repeated Intrathecal and Intravenous Autologous Bone Marrow-Derived Mesenchymal Stem Cell Administration in a Patient with Chronic Complete Tetraplegia due to Post-Tuberculous Syringomyelia: A Case Report and Literature Review

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Received: 02 Aug 2026
Accepted: 19 Aug 2026
Published: 22 Aug 2026
J Short Name: ACMCR

Keywords:

Mesenchymal Stem Cells; Spinal Cord Injury; Safety; Tuberculosis; Syringomyelia; Cell Therapy

Citation:

Hyun Soo Kim, Repeated Intrathecal and Intravenous Autologous Bone Marrow-Derived Mesenchymal Stem Cell Administration in a Patient with Chronic Complete Tetraplegia due to Post-Tuberculous Syringomyelia: A Case Report and Literature Review. Ann Clin Med Case Rep® 2026; V16(3): 1-7

1. Abstract

1.1. Background

Mesenchymal stem cells are increasingly administered off-label in chronic spinal cord injury, yet their use in patients with a history of central nervous system tuberculosis is barely documented. Because these cells are immunomodulatory, latent tuberculosis reactivation is a specific theoretical concern in such hosts. We describe the tolerability and 12-month course of repeated mesenchymal stem cell therapy in one such patient and review the current status of this treatment in chronic spinal cord injury.

1.2. Methods

We report a 46-year-old Korean man with chronic complete tetraplegia after tuberculous myelitis and meningitis, complicated by extensive syringomyelia and long-term ventilator use, who received four combined intrathecal and intravenous administrations of autologous bone marrow-derived mesenchymal stem cells over approximately five months. Adverse events, serial cerebrospinal fluid analysis, systemic laboratory indices across four time points over 12 months, structural magnetic resonance imaging, and the standardized neurological examination were reviewed, together with the patient-reported clinical course. A structured review of clinical studies of mesenchymal stem cell therapy in chronic spinal cord injury was performed to place the case in context.

1.3. Results

The four administrations were completed without any serious adverse event. A transient self-limited fever followed one administration, and no febrile illness, antimicrobial course, or antituberculosis treatment was required over 12 months. Inflammatory markers, blood counts, hepatic enzymes, and coagulation indices remained stable, with no systemic sign of tuberculosis reactivation, inflammation, or tumour formation. One of four cerebrospinal fluid samples showed a lymphocytic pleocytosis for which mycobacterial testing was not obtained; the others showed a persistent protein elevation attributable to the pre-existing subarachnoid pathology. The standardized neurological examination and structural imaging were unchanged. The patient reported subjective changes, including a downward extension of trunk sensation, a qualitative change in fingertip sensation, a sense of greater strength in the shoulders and arms, an approximately 30 percent reduction in leg pain, and improved tolerance of upright sitting; these were not confirmed by the standardized examination and are not evidence of a treatment effect.

1.4. Conclusions

In this patient with a remote history of central nervous system tuberculosis, repeated intrathecal and intravenous mesenchymal stem cell administration was completed without a serious adverse event over 12 months of inpatient rehabilitation, with no systemic sign of tuberculosis reactivation and no clinical event requiring further infective work-up, although a lymphocytic pleocytosis in one cerebrospinal fluid sample was not characterized. The patient reported improvements in sensory, motor, autonomic, and pain domains, which were not corroborated by the standardized examination. Cerebrospinal fluid findings suggest a subarachnoid block may have limited delivery of the intrathecal fraction to the cervical cord; because the treatment also included an intravenous fraction, the reported changes are compatible with a systemic paracrine mechanism that does not require cells to reach the lesion, a hypothesis proposed here for future study. The case adds to the limited documented experience for patients and clinicians weighing this option and underlines that

mycobacterial testing of the cerebrospinal fluid should accompany such treatment in patients with prior central nervous system tuberculosis.

2. Introduction

Chronic spinal cord injury produces permanent loss of motor, sensory, and autonomic function below the level of the lesion, and no treatment reliably restores neurological function once the injury is established. Cell-based therapies have been investigated as a means of modifying this course, and mesenchymal stem cells are the most widely studied. Mesenchymal stem cells are readily obtained from bone marrow, expandable in culture, and act mainly through paracrine and immunomodulatory mechanisms rather than by replacing lost neurons, and they have been delivered by intravenous, intrathecal, and intramedullary routes in a large number of clinical studies.

Most of these studies enrolled patients with traumatic injury. Post-infectious spinal cord injury, and in particular injury following central nervous system tuberculosis, is far less well represented. This distinction is not trivial. Tuberculous involvement of the spine and meninges can cause arachnoiditis, syringomyelia, and progressive myelopathy, and it leaves the patient with a history of mycobacterial infection that may persist in a latent form. Because mesenchymal stem cells are immunomodulatory and can suppress local T-cell responses, their administration to a host with prior tuberculosis raises a specific and legitimate safety question, namely whether the treatment could reactivate latent infection. Reports addressing this question in the spinal cord injury setting are scarce.

A patient considering this off-label treatment therefore has little published information on which to base a decision, especially if that patient shares the additional complexity of a post-tuberculous cord injury. We report the tolerability and the detailed 12-month clinical course, including the patient-reported outcomes, of repeated intrathecal and intravenous mesenchymal stem cell administration in such a patient, with particular attention to the safety question raised by the tuberculosis history, and we place the case in the context of the current evidence on this treatment in chronic spinal cord injury. The standardized examination did not change, and no claim of neurological restoration is made; the contribution of the report is to the safety literature and to the limited body of documented experience available to patients and clinicians weighing this option.

3. Case Description

3.1. History and Baseline Status

A 46-year-old Korean man had long-standing complete tetraplegia. In 1999, during military service, he developed dyspnea and was diagnosed with tuberculous pleuritis, which was treated with antituberculous medication. In 2000 he developed low back pain and lower-limb weakness; tuberculous spondylitis and myelitis were diagnosed and treated surgically on two occasions. In 2001 he was diagnosed with tuberculous meningitis, which was later declared cured. From 2010 he developed progressive weakness attributed to syringomyelia extending from the first cervical to the tenth thoracic level, and he underwent syringo shunt operations in 2011 and 2012. Since 2012 he has required mechanical ventilation via tracheostomy for most of each day, tolerating only short periods off the ventilator, and he has been maintained on comprehensive inpatient rehabilitation. His history included type 2 diabetes mellitus, diabetic polyneuropathy, and a cardiac arrest with recovery in 2022. He was fully alert and cognitively intact on clinical assessment and, because his next of kin were estranged, provided consent independently.

On serial rehabilitation assessment, manual muscle testing showed trace power in shoulder, elbow, and wrist groups and no power in finger and lower-limb groups, corresponding to a motor level at the fourth cervical segment. The sensory level was at the fifth thoracic segment bilaterally, with absent perianal sensation, absent deep anal pressure, and no voluntary anal contraction; the injury was clinically complete, with no motor or sensory function in the lowest sacral segments. Reflexes were exaggerated with negative Babinski and Hoffmann signs; bulbocavernosus, cremasteric, and anal reflexes were preserved, consistent with a chronic upper motor neuron lesion. He was totally dependent for all activities of daily living and managed with a suprapubic cystostomy, and this status had been documented as stable for years.

3.2. Intervention

Autologous bone marrow-derived mesenchymal stem cells (Hearticellgram, Pharmicell Co., Ltd., Seongnam, Republic of Korea) were manufactured by the standard, marketing-authorized process from posterior iliac crest marrow, expanded in medium containing fetal bovine serum and gentamicin, and released at passage 5, with each dose containing approximately 90 million cells. Release testing included viability, immunophenotype, and standard sterility and mycoplasma testing. This product holds marketing authorization for intracoronary administration in acute myocardial infarction and was used off-label with respect to indication, route, and dosing frequency. With no approved therapy available for his chronic deficit, the patient sought cell therapy and gave written informed consent for off-label treatment. He received four administrations over approximately five months; at each session 3 mL was given intrathecally by lumbar puncture and 15 mL intravenously. Coagulation indices measured before the procedures were within normal limits. Concurrent medications during the observation period included metformin, an anxiolytic as needed, an intermittent course of hydroxychloroquine, periodic intravenous hydration, and a herbal preparation; physiotherapy was maintained throughout.

3.3. Safety and Adverse Events

The primary focus of this report is tolerability, and the four administrations were completed without any serious adverse event. After the second administration the patient developed a transient fever with malaise that resolved without sequelae, without respiratory deterioration, and with inflammatory markers near baseline; a self-limited fever is the most frequently reported reaction to intrathecal mesenchymal stem cells and is discussed below.

Self-limited vesicular lesions on the fingers were noted after treatment and were documented as resolved on subsequent skin examination. No procedure-related headache requiring intervention and no neurological deterioration were recorded. Critically, given the tuberculosis history, no febrile illness, no course of antibiotics, and no antituberculous treatment were required at any point during the 12-month observation period, and there was no clinical sign of tuberculosis reactivation.

3.4. Serial Cerebrospinal Fluid Findings

Cerebrospinal fluid obtained at each intrathecal procedure showed a persistently elevated protein concentration across all four samples (572.6, 811.7, 885.7, and 778.8 mg/dL; reference 15 to 45), with xanthochromia and spontaneous partial clotting on the later samples and normal glucose. This pattern is consistent with a spinal subarachnoid block related to the prior tuberculous arachnoiditis and two shunt operations, and it reflects the pre-existing cord pathology rather than a new process; flow was not directly measured. Cell counts were low in the first three samples (3, 0, and 2/mm3). The fourth sample showed a lymphocyte-predominant pleocytosis (30 cells/mm3, 90% lymphocytes) in a specimen that was also blood-stained (560 red cells/mm3) and clotted. At that red-cell count, peripheral blood contamination would introduce only about one white cell, so the pleocytosis is a genuine cerebrospinal fluid finding rather than an artefact. It is also separate from the protein elevation, since a subarachnoid block concentrates protein but does not generate white cells and the first three samples with equally high protein showed no pleocytosis.

Confirmatory mycobacterial studies of this sample, namely culture, acid-fast smear, and nucleic acid amplification, were not performed at the time, because the pleocytosis was identified on the routine cell count only after the encounter and the clotted, blood-stained residual sample was not suitable for reliable mycobacterial assay. The patient had no systemic features of active tuberculosis, being afebrile apart from the earlier transient episode, with normal inflammatory markers and no clinical deterioration. The significance of this omission, and the lesson it carries, are addressed in the Discussion.

3.5. Systemic Laboratory Course

Systemic laboratory indices were monitored across four time points over 12 months (Table 1). Inflammatory markers, including C-reactive protein, the erythrocyte sedimentation rate, and procalcitonin, remained within or near their reference ranges throughout. Blood counts were stable, without leukopenia, without cytopenia, and without emergence of immature cells; hepatic enzymes, coagulation indices, and glycated hemoglobin were also stable. There was no laboratory signal of systemic inflammation, hematological toxicity, or tuberculosis reactivation over the period sampled. Creatinine-based renal indices were not interpreted, because muscle loss in chronic tetraplegia makes them unreliable, and tumour surveillance was limited to a single tumor-marker value.

3.6. Imaging

Sagittal T2-weighted magnetic resonance imaging of the cervical spine showed a longitudinal intramedullary cystic cavity with cord atrophy, consistent with chronic syringomyelia. On comparison of the pre-treatment study with follow-up imaging approximately 12 months later, and on independent re-review, there was no significant interval change in the syrinx and no new intramedullary mass or abnormal signal (Figure 1). No new structural lesion, and in particular no mass suggesting tumour formation, was identified.

Time 1: corresponds to the day of the second administration, Time 2 to the day before the fourth administration, and Times 3 and 4 to approximately three and seven months after the fourth administration. A baseline before the first administration was not available.

Analyte	Reference	Time 1	Time 2	Time 3	Time 4
C-reactive protein (mg/dL)	<0.6	<0.6	0.63	<0.6	Not assayed
Erythrocyte sedimentation rate (mm/h)	0 to 9	8	4	8	Not assayed
Procalcitonin (ng/mL)	<0.5	0.022	<0.02	0.021	Not assayed
White blood cell count (x10^3/uL)	4 to 10	6.68	5.01	5.55	6.34
Lymphocytes (x10^3/uL)	1.5 to 4	3.82	2.74	3.23	3.16
Hemoglobin (g/dL)	13 to 17.5	13.2	12.2	13.3	12.6
Platelets (x10^3/uL)	140 to 400	204	147	176	183
Aspartate aminotransferase (U/L)	<=40	12	13	14	15
Alanine aminotransferase (U/L)	<=41	13	12	21	13
Prothrombin time (INR)	0.93 to 1.14	1.14	1.10	1.09	Not assayed
Glycated hemoglobin (%)	<6.4	5.5	5.5	5.9	Not assayed

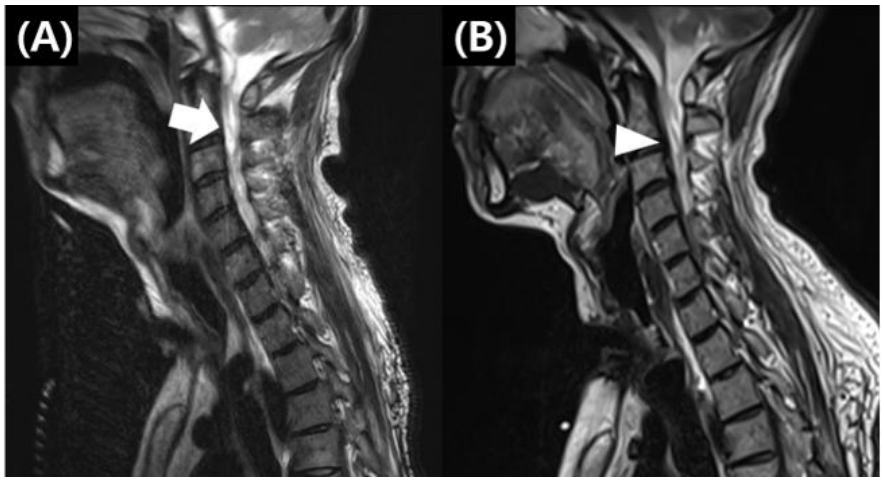

Figure 1: Sagittal T2-weighted magnetic resonance imaging of the cervical spine before treatment (A) and approximately 12 months after the first administration (B). A longitudinal intramedullary cystic cavity (syrinx) with cord atrophy is present in the cervical cord; the arrow (A) and the arrowhead (B) indicate the same upper cervical segment of the syrinx on the two studies. No significant interval change in the syrinx, and no new intramedullary lesion, was identified on independent re-review.

3.7. Patient-Reported Clinical Course

Over the follow-up period the patient reported several subjective changes, which are recorded here because they concern the domains most relevant to patients considering this treatment. He described a qualitative change in sensation at the fingertips and a downward extension of trunk sensation from around the level of the nipples to approximately the level of the navel, in a region that had previously been without sensation. He reported a sense of returning strength in both shoulders and arms and an approximately 30 percent reduction in the long-standing pain in his legs. During the short periods each day when he was off the ventilator, he reported, for the first time, a perception of his own breathing effort. He also reported that he could remain seated in his wheelchair for more than two hours without the dizziness or breathlessness he had previously experienced on being upright, a change consistent with improved orthostatic and autonomic tolerance. These reports were volunteered over more than one visit. None of them was accompanied by a change in the standardized neurological examination, which showed the same motor level, sensory level, clinically complete status, and complete dependence for activities of daily living throughout, or by a change on imaging. Their interpretation is considered in the Discussion.

4. Discussion and Literature Review

This patient received a treatment for which patients in his situation have little published guidance, and the value of the case lies principally in what it adds to the safety literature, which is considered first and in the greatest depth, followed by the specific question raised by his tuberculosis history and the interpretation of his reported improvements.

4.1. Safety Profile of Mesenchymal Stem Cell Therapy and Intrathecal Delivery

Mesenchymal stem cells have been evaluated in many clinical studies in spinal cord injury, using cells from bone marrow, umbilical cord, or adipose tissue and delivered by intravenous, intrathecal, or intramedullary routes [1,2]. Repeated dosing is common, on the reasoning that any paracrine effect is transient [3]. Across this literature, the safety signal is consistent. Systematic reviews conclude that mesenchymal stem cell therapy in spinal cord injury has a favourable short-to-medium-term safety profile, with no significant treatment-related adverse events within the studied time frames, while noting that long-term data remain limited [2,4]. A systematic review and meta-analysis dedicated to adverse events in cell therapy for chronic spinal cord injury reached the same conclusion, finding mostly minor and transient events [4].

The events observed in this patient align closely with that published profile. In a study of 37 patients who received repeated intrathecal mesenchymal stem cell injections, the most common adverse events were mild injection-site discomfort (4.11%), fever (3.42%), and headache (2.05%), with no severe adverse events and no procedure-related mortality [5]. The transient fever after this patient's second administration and the elevated cerebrospinal fluid protein seen throughout therefore fit the recognized, benign reaction pattern of the treatment rather than indicating a complication, and a meta-analysis of intrathecal delivery for neurological disorders similarly found no excess of serious adverse events relative to controls [6]. The intrathecal route is not without local risk, and in a phase I trial of intrathecal delivery the most common adverse events were headache and musculoskeletal pain, although no serious adverse events occurred [7], indicating that serious events are rare. The uneventful completion of four administrations in this patient, with no serious adverse event and no neurological deterioration over 12 months, is consistent with this body of evidence.

4.2. Mesenchymal Stem Cells in A Host with Prior Tuberculosis

The most specific safety question raised by this case concerns the tuberculosis history, a question that is rarely documented because patients with prior central nervous system tuberculosis are almost entirely absent from the cell-therapy literature. Mesen-

chymal stem cells suppress T-cell responses, and because control of latent Mycobacterium tuberculosis depends on cell-mediated immunity, their administration could in principle reactivate latent infection. This concern is explicit in the literature: reviews of mesenchymal stem cells and tuberculosis note that their immunosuppressive function could worsen active disease or reactivate latent infection, while also observing that systemic autologous mesenchymal stem cells have been used, apparently safely, as an adjunct in drug-resistant tuberculosis [8]. Evidence from transplantation is partly reassuring, in that mesenchymal stromal cell infusion in recipients of allogeneic stem cell transplantation did not increase the frequency or severity of viral reactivation relative to conventional immunosuppression [9].

Over the 12 months following the four administrations, this patient showed no clinical, laboratory, or spinal imaging sign of tuberculosis reactivation: no fever beyond the single transient episode, stable inflammatory markers, no antituberculosis treatment, and no new lesion on imaging. The patient remained in continuous inpatient rehabilitation throughout this period, and at no point did he develop the neurological deterioration, recurrent fever, meningism, or clinical change that would ordinarily prompt repeat cerebrospinal fluid sampling or a targeted infective work-up. The fourth-sample pleocytosis was a genuine lymphocytic response, and in a patient with prior tuberculous meningitis it keeps mycobacterial reactivation on the differential alongside a reactive response to repeated injection, the latter reported after intrathecal mesenchymal stem cells and attributed to residual culture components such as bovine serum. Direct mycobacterial testing of that sample was not performed, and this is a limitation of the report; because no subsequent clinical event called for further investigation, the pleocytosis resolved from clinical view without being characterized, and a transient mycobacterial process at the target site during treatment therefore cannot be formally excluded.

The clearest practical contribution of this case is didactic. It shows that a lymphocytic pleocytosis can arise during intrathecal cell therapy in a host with prior central nervous system tuberculosis, and it supports a simple rule for such patients: the cerebrospinal fluid should be tested directly for mycobacteria by culture, acid-fast smear, and nucleic acid amplification whenever a pleocytosis appears, irrespective of systemic signs, and further administration deferred until reactivation has been excluded. Within this limitation, the combination of a stable 12-month course during continuous inpatient rehabilitation and the absence of any clinical event requiring further work-up provides a real, if incomplete, measure of reassurance for a host in whom reactivation was a legitimate concern.

4.3. Reported Improvements and Their Interpretation

The changes the patient reported fall into sensory, motor, autonomic, and pain domains, and these are biologically plausible targets of the treatment rather than arbitrary. A reported downward extension of the trunk sensory level, if genuine, would be the kind of segmental sensory change that controlled studies have most often detected after cell therapy, since sensory gains are reported more consistently than motor gains [2]. Autonomic dysfunction, including orthostatic intolerance, is a common and disabling consequence of cervical spinal cord injury, and improvement in autonomic and related domains has been described after bone marrow cell therapy [10]. An open-label study of intrathecal co-administration of bone marrow mesenchymal stem cells and Schwann cells in patients with complete injury reported acceptable safety and possible functional gains during 12-month follow-up [11]. That the patient's reported changes fall in these domains is therefore consistent with the direction of the published evidence, although it does not establish that the treatment caused them.

These reports must nevertheless be interpreted with caution. A single, uncontrolled, unblinded observation cannot separate a genuine physiological effect from expectation, from the several concurrent treatments and intensive rehabilitation, or from ordinary variation, and the patient's standardized neurological examination and imaging did not change. A further consideration is specific to this patient. The serial cerebrospinal fluid findings indicate a pre-existing subarachnoid block, most likely from the prior tuberculous arachnoiditis and shunt operations, which raises the possibility that cells delivered into the lumbar space did not distribute rostrally to the cervical cord; structural imaging, which was unchanged, cannot resolve this, since demonstrating patency would require flow-directed methods that were not performed.

The intrathecal route was chosen deliberately and was not redundant with the intravenous one. Established protocols for chronic spinal cord injury place cells close to the cord in order to maximize local exposure, and a Korean phase III trial delivered autologous mesenchymal stem cells both into the intramedullary area at the injured level and into the subdural space for this purpose [12]. The combined intrathecal and intravenous schedule used here follows the same intention, with the intrathecal fraction aimed at local delivery to the cord and the intravenous fraction providing systemic exposure. The subarachnoid block identified retrospectively was not known before treatment, and structural imaging would not have revealed it; the intrathecal attempt at local delivery was therefore clinically reasonable at the time, even though the block may in the event have limited rostral distribution of that fraction.

This delivery finding does not nullify the reported improvements, because mesenchymal stem cells are understood to act in the chronic phase chiefly through paracrine and immunomodulatory signaling rather than through engraftment at the lesion [1,3]. Systemically infused cells release trophic and immunomodulatory mediators into the circulation, and effects on distant tissues have been attributed to these secreted factors rather than to the physical arrival of cells at a specific site. A block that limited rostral distribution of the intrathecal fraction would therefore not preclude a systemic paracrine effect from the intravenous fraction, and the patient's reported changes in sensory, autonomic,

and motor domains are compatible with such a mechanism. This is offered as a hypothesis rather than a demonstrated pathway; it cannot be tested in a single case and does not convert the subjective reports into proof of benefit. It does, however, provide a coherent account in which the reported improvements and the delivery findings are not contradictory.

4.4. Limitations

The principal limitations follow from the preceding discussion. This is a single, uncontrolled, unblinded observation; the reported improvements were subjective and were not confirmed by the standardized examination or by imaging; and the systemic paracrine mechanism proposed for those reports is a hypothesis that a single case cannot test. Cerebrospinal fluid evidence of a subarachnoid block limits conclusions about delivery of the intrathecal fraction to the cervical cord. Several investigations that would have strengthened the account were not performed, including cerebrospinal fluid mycobacterial studies, an interferon-gamma release assay, chest imaging, flow-directed cerebrospinal fluid imaging, and objective autonomic testing to correlate with the reported changes. No pre-treatment cerebrospinal fluid or blood sample was available, so the baseline is unknown. Follow-up of 12 months is adequate for detecting subacute tuberculosis reactivation and short-to-medium-term adverse events but not for excluding late effects such as tumour formation. Two of the authors have a relationship with the manufacturer, as declared below. Within these limits, the case documents the tolerability of the treatment and provides a record of the clinical course for patients and clinicians considering this option.

5. Conclusions

In a patient with chronic complete tetraplegia due to post-tuberculous syringomyelia, four repeated intrathecal and intravenous administrations of autologous bone marrow-derived mesenchymal stem cells were completed without any serious adverse event over 12 months, during which the patient remained in inpatient rehabilitation and was continuously observed. No systemic clinical, laboratory, or spinal imaging sign of tuberculosis reactivation, inflammation, or tumour formation appeared, and at no point did a clinical event arise that would have required further infective investigation, with the acknowledged limitation that a lymphocytic pleocytosis in one cerebrospinal fluid sample was not characterized by mycobacterial testing. The transient fever and the elevated cerebrospinal fluid protein fit the recognized, benign reaction pattern of intrathecal cell therapy. The patient reported improvements in sensory, motor, autonomic, and pain domains that were not confirmed by the standardized examination and do not by themselves establish a treatment effect. Although a subarachnoid block may have limited delivery of the intrathecal fraction to the cervical cord, the treatment also included an intravenous fraction, and the reported changes are compatible with a systemic paracrine mechanism that does not depend on cells reaching the lesion directly, a hypothesis for future controlled study. The case adds to the limited documented experience for patients and clinicians weighing this off-label treatment, and it supports two practical measures when intrathecal cell therapy is undertaken in a host with an altered subarachnoid space and prior central nervous system tuberculosis: assessment of cerebrospinal fluid flow before treatment, and direct mycobacterial testing of the cerebrospinal fluid if a pleocytosis arises.

6. Declarations

Ethics and consent: This article is a retrospective report of the clinical course of a single patient. Written informed consent to the off-label treatment was obtained from the patient before it was given, and written informed consent for publication of this report and any accompanying images was also obtained. The patient was fully competent to provide consent.

7. Conflicts of Interest

HSK is the Chief Executive Officer of Pharmicell Co., Ltd., the manufacturer of the autologous mesenchymal stem cell product (Hearticellgram) used in this report. HK is a physician at Dr. Kim’s Stem Cell Clinic, which is owned and directed by HSK. The product was used off-label with respect to indication, route, and dosing frequency. The authors declare that these affiliations did not influence the interpretation of the data presented, and no efficacy claim is made.

8. Funding

This work was funded by Pharmicell Co., Ltd.

9. Authors’ Contributions

HK conceptualized the report, collected the clinical, laboratory, and imaging data, performed the literature review, and drafted the manuscript. HSK provided clinical expertise, supervised the therapeutic intervention, and critically reviewed the manuscript. Both authors read and approved the final manuscript.

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