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Prospective Randomized Control Pilot Study to Compare the Role of Injection Cerebrolysin in Operated cases of Degenerative Cervical Myelopathy

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Study Design. Prospective randomized control trial.

Objective. The aim of this study was to analyze role of cerebrolysin in patients of degenerative cervical myelopathy (DCM) managed by surgical modalities.

Summary of Background Data. Cerebrolysin has been extensively researched with variable success in neurodegenerative pathologies. There has been only one study in published literature till date that has studied role of cerebrolysin in DCM in conservatively managed patients but none in the patients treated surgically. We present our pilot study which analyzes the role of cerebrolysin in patients of DCM managed by surgical modalities.

Methods. This prospective randomized control trial was conducted at a tertiary care institute in Mumbai. Sixty operated cases of DCM were randomly divided into 2 groups. The first group was given Injection Cerebrolysin 5 mL diluted in 100 mL Normal Saline over 30 minutes once a day for 21 days postoperatively. The second group was given placebo. Modified Japanese Orthopedic Association scores (mJOA) and visual analog scale (VAS) were used to document functional outcomes at 3 weeks, 3 months, 6 months, and 1 year. Recovery of hand function was separately accessed by improvement in hand power and sensations.

Results. Preoperative mJOA and VAS scores were comparable between 2 groups. Both groups showed significant improvement in both mJOA and VAS scores at 3weeks, 3 months, 6 months and 1-year follow-up ($P < 0.01$). In comparing the two groups, there was no difference in improvement of mJOA and VAS scores. However, cerebrolysin group showed significant improvement in hand function at 1 year compared to the placebo. Postoperative neurological recovery was better in the cerebrolysin group with 66.7% patients showing complete neurological recovery compared to 56.7% for placebo, but this was statistically insignificant. Two patients developed headache and one patient complained of dizziness in the cerebrolysin group, but these resolved without any intervention.

Conclusion. Use of cerebrolysin in postoperative cases of DCM is safe and results in improved hand function.

Key words: cerebrolysin, cervical, degenerative, myelopathy, neuroprotective.

Level of Evidence: 1

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Cervical spondylosis is a degenerative pathology of the spine which can lead to a reduction in the canal diameter.[1] This decrease can be caused either by anterior pathology (such as a herniated intervertebral disc, osteophyte, or a hypertrophic posterior longitudinal ligament), a posterior pathology such as hypertrophied osseoligamentous structures,orboth.[2,3] The reduced canal diameter compresses the spinal cord leading to a constellation of symptoms collectively termed degenerative cervical myelopathy (DCM).[2,3] DCM is associated with aging and usually presents after 50years of age, and although mild cases can be managed conservatively, moderate to severe disease, or progressive disease necessitates surgical intervention.[1,2,4–6]

Cerebrolysin is acquired by the enzymatic degradation of fat free pig brain containing 15% low-molecular-weight growth factors such as brain-derived neurotropic factor, insulin-like growth factors 1 and 2 and nerve growth factor (Figure 1) which cross the blood brain barrier (BBB).[7–9] It

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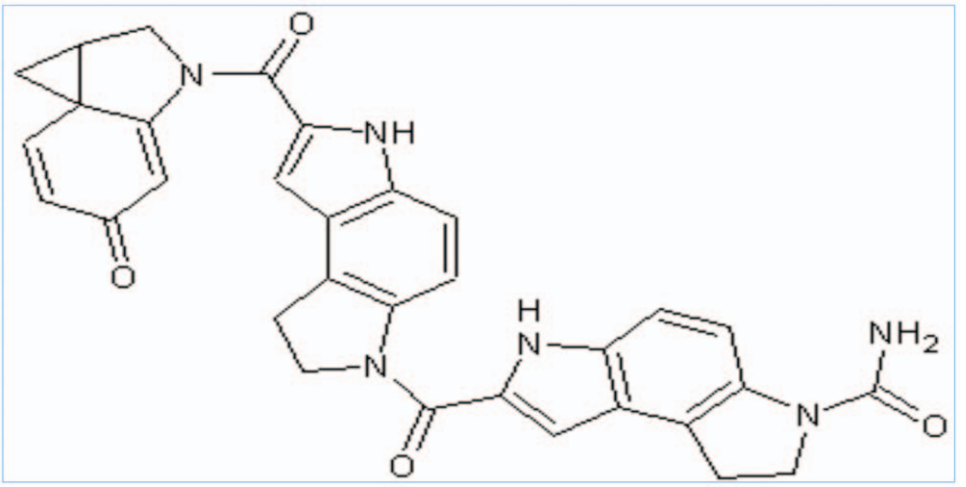

Figure 1. Molecular structure of cerebrolysin.

has neuroprotective, neurotropic, and neuroregenerative properties.[7–9]

Cerebrolysin has been extensively researched with variable success in neurodegenerative pathology.[8,9,10] The drug has been reported to be safe, with rare instances of allergy and no documented serious adverse reactions. Only a single study has evaluated the role of cerebrolysin in DCM in conservatively managed patients; however, none have investigated its use in those treated surgically.[11] In this report, we present our pilot study which analyzes the role of cerebrolysin in cases of surgically managed DCM.

METHODOLOGY

This prospective randomized study was conducted at a tertiary care hospital in India. Local IRB approval was granted (IRB approval number- EC/BYC/22112018/DRPD). The inclusion and exclusion criteria are given in Table 1. Patients with evidence of reduction in modified Japanese Orthopedic Association (mJOA)[1] scores < 15 with clinical or radiological signs suggestive of myelopathy were included in the study. Patients were enrolled by the primary investigator (PI) who took responsibility for completing the consent process and responding to patient queries.

TABLE 1. Inclusion and Exclusion Criteria for the Study

Inclusion Criteria	Exclusion Criteria
Clinical and radiological diagnosis of cervical myelomalacia (C3 to C7 levels) with mJOA < 15	Traumatic myelopathy
A maximum of four levels affected	Myelopathy in congenital stenosis of cervical canal
Age: 20–80 y	History of cervical spine surgery
Patients managed surgically	Cervical myelopathy due to fluorosis

mJOA indicates modified Japanese Orthopaedic Association scores.

The present study was designed as a pilot study and therefore an *a priori* sample size estimation was not done. The sample was included based on the availability of sufficient number of patients in each group. Patients were divided randomly into two groups of 30 by asking them to select one from a collection of shuffled and sequentially numbered, sealed envelopes containing the intervention written on pressure sensitive article. To reduce the effect of bias, the random allocation sequence was concealed from the PI. An independent investigator audit was carried out at the conclusion of the study.

All patients were operated by the same team of surgeons. The surgical approach was determined by the sagittal alignment, extent of pathology in terms of number of levels involved, and the modified K-line. Typically, patients with four or more levels involved and a positive K-line were approached posteriorly and those with three or fewer levels and a negative K-line were approached anteriorly.[3–5] Both the patients and the assessor were blinded to the management given. First group received Cerebrolysin (5 mL diluted in 100 mL 0.9% NaCl over 30 minutes) intravenously daily for 21 days postoperatively and the second group was administered a placebo for the same duration. The patients were not admitted for the entire duration and the drug/placebo continued to be administered at the site of the discharge destination (home/in-patient rehabilitation unit).

Data were collected by a blinded, independent observer with more than two decades of orthopedic surgical experience preoperatively, immediately after surgery and at 1 month, 3 months, 6 months, and 1 year postoperatively. The assessment consisted of clinical examination, Visual Analogue Scale (VAS) for pain, plain radiographs, computed tomography (CT), and magnetic resonance imaging (MRI) imaging (Figure 2) and functional evaluation using a modified mJOA. The recovery rate was calculated using the formula (postoperative score – pre-operative score) / (19 – preoperative score) $\times$ 100%. In terms of imaging, the pre and postoperative MRI was assessed to look at the features of myelopathy including signal changes in the cord, CT scan

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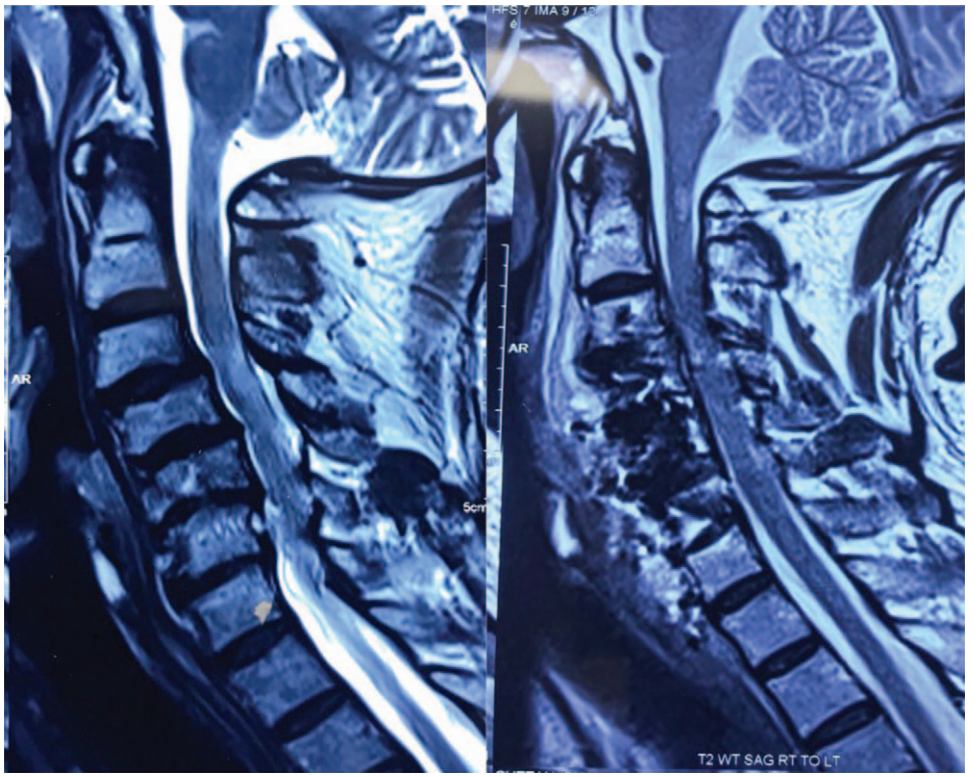

Figure 2. One year follow up magnetic resonance imaging showing reversal of signal changes after three levels ACDF in a patient treated with cerebrolysin. ACDF indicates anterior cervical discectomy and fusion.

was utilized in select cases (suspected OPLL) and x-rays were used to assess sagittal alignment and postoperatively to look at the status of the instrumentation.

The data were checked for normality using the Shapiro-Wilk test. The continuous variables (VAS and mJOA) were compared across groups (injection and no injection) and times (preoperative, postoperative, 12 weeks, 6 months, and 1 year) using Mixed model analysis of variance (ANOVA) (Figure 3) with post hoc analysis using Tukey Kramer test for pairwise comparisons. In case of any violations of assumptions, the groups were compared at each time using the Mann–Whitney test after Bonferroni correction for multiple comparisons. This was done as there is no non-parametric equivalent of mixed model ANOVA. The categorical variables (improvement in hand function/neuro improvement) were assessed across the groups using a chi squares test. All tests were performed at significance of $P < 0.05$.

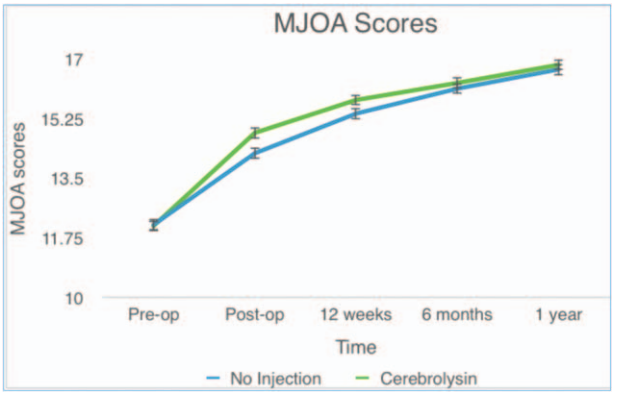

Figure 3. Mixed-effect analysis of variance regression modelling for mJOA score. mJOA indicates modified Japanese Orthopaedic Association scores.

RESULTS

Sixty patients were enrolled: 30 in Group 1 (Cerebrolysin, C) and 30 in Group 2 (placebo, P). There were no statistically significant differences in the baseline demographic data with a P value > 0.05 (Table 2). The mean age of patients in group C was 53.2 years and in group P was 56.2 years. There were 28 males and two females in group C, whereas group P had 26 males and four female patients. Five patients (two from group C and three from group P) gave a history of trauma. There were 10 smokers, and 17 patients (nine group C, eight group P) had imaging findings of underlying ossified posterior longitudinal ligament.

The mean duration of symptoms before surgery in group C was 4.2 ± 2.6 months, whereas in group P it was 3.96 ± 2.98 months ($P = 0.349$). Preoperative mJOA and VAS scores were similar ($P > 0.05$). Surgery was carried out via an anterior approach in 30 patients, posterior in 29 patients, and a combined approach in a single case (Table 3).

Both groups showed a significant improvement in both mJOA and VAS scores at 3 weeks, 3 months, 6 months, and 1-year follow-up ($P < 0.01$); however, there was no difference at any point between the groups. There was no significant interaction between the group and time and the main effects of group. However, there was a significant main effect of the time ($F = 258.07$, $df = 4, 232$, $P < 0.0001$). The post hoc analysis showed that the mJOA score increased

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TABLE 2. Baseline Demographic Data for Cerebrolysin (Group 1) and Placebo (Group 2) Groups. Both Groups Were Matched in the Demographic Data With *P* Value > 0.05

	Group 1	Group 2
Age	53.23 ± 13.30	56.20 ± 10.89
Sex	28 Males, 2 females	26 Males, 4 females
Smokers	6	4
History of trauma	2	3
Presence of OPLL	9	8
Mean Modified frailty index (11 factor)	2.1	1.9
BMI	22.11 ± 1.26	23.7 ± 2.07

BMI indicates body mass index; OPLL, ossification of posterior longitudinal ligament.

significantly for both the groups at all times of evaluation (Figure 3). The MCID was calculated for the MJOA score as the standard error of measurement (SEM) to be 5.10. The subjects who improved their scores by MCID at 1year in the no injection group were 10, whereas only eight subjects improved their scores in the injection group. The same analysis was not done for VAS scores because of the non-parametric nature of the data. Group C did show a significant improvement inhand functionat 1 year comparedto group P ($P = 0.03$) (Figure 2). Postoperative neurological recovery tended to be superior in group C with 66.7% patients showing complete neurological recovery compared to 56.7% in group P ($P = 0.318$). Two patients developed headache and one patient complained ofdizziness inthe cerebrolysin group, but these resolved without any intervention.

The present study was designed as a pilot study and therefore an a priori sample size estimation was not done. Post hoc power analysis was done on the mJOA score with alpha of 0.05 and the difference in the means of the groups at post operative time as 0.5 and pooled SD of 2.8. It was calculated to be 0.13. The Power to find group differences at subsequent times of evaluation was lower than this.

DISCUSSION

The term DCM describes myelopathy resulting from degenerative pathology in cervical spine.[3,12] The pathoanatomy of DCM includes static and dynamic causes, and can be congenital (such as a congenitally narrow canal) or acquired (such as spondylolysis or disc degeneration).[13,14] In many cases, age-related desiccation of the disc secondary to changes in proteoglycan composition initiates a cascade of degenerative changes.[13,14] This leads to a loss of disc height and increased uncovertebral and facet joint stress, causing osteophyte formation and buckling of the ligamen-tum flavum which reduces the cross-sectional area of the spinal canal and causes cord compression.[13–16] Dynamic factors cause exacerbation of compression during physiological and pathological motion of cervical spine.[17,18]

Present literature has focused on inflammatory pathways associated with DCM.[19] In rat models, Karadimas et al[20] found decreased capillary density in the compressed spinal cord as compared to controls. This corresponds to disruption of the blood–spinal cord barrier on the background of a reduction in cross-sectional area of the cord. In this setting, vascular insufficiency leads to local ischemia,

TABLE 3. Results for the Cerebrolysin (Group 1) and Placebo (Group 2)

	Group 1	Group 2	*P*
OPLL	No, 21 (70%)	22 (73.3%)	0.774
	Yes, 9 (30%)	8 (26.7%)	
Surgical approach	Anterior, 16 (53.3%)	14 (46.7%)	0.606
	Posterior, 14 (46.7%)	16 (53.3%)	
Complications	No, 27 (90%)	26 (86.7%)	1.000
	Yes, 3 (10%)	4 (13.3%)	
VAS Pre-op	7.3 ± 1.3	7.5 ± 1.10	0.512
Post-op	4.03 ± 0.99	3.90 ± 1.09	0.624
3 mo	3.36 ± 1.03	3.16 ± 1.08	0.468
6 mo	2.73 ± 1.01	3.0 ± 1.05	0.321
1y	1.80 ± 0.80	2.53 ± 0.89	0.002
mJOA Pre-op	12.13 ± 2.20	12.10 ± 2.84	0.960
Post-op	14.23 ± 2.31	14.83 ± 3.15	0.404
3 mo	15.4 ± 1.99	15.8 ± 2.53	0.500
6 mo	16.13 ± 2.11	16.3 ± 2.40	0.777
1y	16.7 ± 2.01	16.83 ± 2.33	0.814

mJOA indicates modified Japanese Orthopaedic Association scores; OPLL, ossification of posterior longitudinal ligament; VAS, visual analog scale.

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causing neuronal ionic imbalance and cellular dysfunction. This results in excitotoxic glutamate release causing an expanding area of neural injury.[21] At present, efforts are underway to evaluate the efficacy of surgery combined with pharmacological neuroprotective drugs which maximize the potential for postoperative recovery. This is where the role of Cerebrolysin comes into the picture because of its neuroprotective actions.[7–10]

Cerebrolysin contains 85% free amino acids and 15% biologically active low-molecular-weight peptides.[7,8] Chromatography of cerebrolysin shows 17 different amino acids including brain derived neurotropic factor, nerve growth factor, glial cell-derived neurotropic factor and ciliary neurotropic factor, each of which contribute to neurotropic, neuroprotective, and neuroregenerative actions.[7,8,22,23] The evidence for the mechanisms of action for Cerebrolysin suggests that it stimulates an increased efficiency of the aerobic neuronal metabolism, protein synthesis, neuronal differentiation, and inhibition of lipid peroxidation, while having anti-excitotoxic, antiapoptotic effects, and immune-active properties.[24,25]

Cerebrolysin has been studied in neurodegenerative conditions including Alzheimer disease, dementia and moderate to severe head injury with promising results.[8,9,10] Chang et al compared Cerebrolysin with placebo in stroke patients with motor deficits concluding that Cerebrolysin contributed to a significantly greater improvement in motor function.[26] Furthermore, Cerebrolysin has been shown to have a neuroprotective function in spinal cord injury in rats following administration via engineered nanoparticles of aluminum, silver, and copper. This may be because of its effect in decreasing spinal cord water content, leaking of plasma proteins and the quantity of injured neurons.[23] Iencean et al analyzed treatment outcomes in 37 cases of complete traumatic spinal cord injuries of which some patients received usual treatment protocols in SCI and others cerebrolysin.[27] This study concluded that Cerebrolysin has no complications when used as an immediate neuroprotective therapy and the initial results are promising, although longer-term follow-up is needed to document the extent of the benefits. Allam et al[11] evaluated the effects of Cerebrolysin as a conservative treatment in DCM patients, finding that if given over 4 weeks it is safe and effective in improving symptoms when compared with placebo, with no reported cases of neurologic deterioration over 6 months of follow-up.

The evidence for treating DCM suggests that conservative treatment is reasonable for stable patients with mild myelopathy and surgical management is recommended for progressive, moderate, or severe DCM.[3,4] An analysis of the effects of cerebrolysin in surgically treated cases of DCM is useful in maximizing the outcomes of decompression, and no study to date has examined the effect of Cerebrolysin on operated cases of DCM.

In this study, the cerebrolysin group showed a significant improvement in hand function at one year when compared to the placebo group ($P = 0.03$). This may be explained by the fact that hand function has been shown to be an independent predictor of outcomes in DCM.[28] Post-operative neurological recovery tended to be better in the cerebrolysin group, with 66.7% patients showing complete neurological recovery compared to 56.7% for the placebo group, ($P = 0.318$). However, it was not significant statistically. In the study by Allam et al,[11] the side effects of Cerebrolysin were dizziness in 4%, headache in 3%, and rash in 1%; all of which resolved spontaneously within the first week of treatment. We had two patients with complaints of headache and one patient with a complaint of dizziness, both of which resolved spontaneously without any intervention.

The major limitation of this study is that it is a single-center experience with a small sample size. The other limitation, specific to Cerebrolysin, is the long duration of intravenous therapy (21 days) that is needed. The efficacy of treatment over shorter period needs to be analyzed. We believe that the sex ratio may have been influenced by the current social determinants in the country where the study was conducted and gender roles which are still in vogue.[29] A study addressing some of these limitations and investigating a 10-days Cerebrolysin schedule is underway with initial results expected during 2021 (IRB approval number—EC/BYC/22112020/DRPD). Further studies on Cerebrolysin in other spine pathologies including dorsal myelopathy and SCI will further establish its efficacy as a neuroprotective agent in spinal pathologies.

CONCLUSION

Use of cerebrolysin in postoperative cases of DCM is safe and can result in improved hand function.

➢ Key Points

- ❑ Cerebrolysin has been extensively researched with variable success in numerous neurodegenerative pathologies.
- ❑ More importantly, the drug has been reported to be relatively safe, with only a few episodes of allergy and no serious adverse drug reactions.
- ❑ There has been only one study in the published literature till date that has studied the role of Cerebrolysin in DCM in conservatively managed patients but none in the patients treated surgically.
- ❑ This pilot study analyzes the role of Cerebrolysin in patients of DCM managed by surgical modalities.
- ❑ We concluded that the use of Cerebrolysin in postoperative cases of DCM is safe and results in improved neurological recovery.

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