Journal of Advances in Medical and Pharmaceutical Sciences

Volume 26, Issue 4, Page 6-13, 2024; Article no.JAMPS.113633
ISSN: 2394-1111

Evaluating the Therapeutic Efficacy of L-Lysine Aescinat Supplementation on Neurological Outcomes in Patients with Spinal Fractures and Traumatic Spine Injuries: A Prospective Cohort Study from Tbilisi, Georgia

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JAMPS/2024/v26i4678

Open Peer Review History:
This journal follows the Advanced Open Peer Review policy. Identity of the Reviewers, Editor(s) and additional Reviewers, peer review comments, different versions of the manuscript, comments of the editors, etc are available here: https://www.sdiarticle5.com/review-history/113633

Original Research Article

Received: 15/12/2023
Accepted: 19/02/2024
Published: 20/02/2024

ABSTRACT

This prospective study aimed to comprehensively investigate the impact of L-Lysine aescinat supplementation on the neurological outcomes of patients recovering from spinal fractures and traumatic spine injuries. A total of 32 patients were recruited and categorised into two groups: Group A (n=16), receiving L-Lysine aescinat supplementation, and Group B (N=16), serving as the

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control group without L-Lysine aescinat administration. The primary objective was to assess changes in the Karnofsky performance scale, a functional and well-being neurological assessment tool especially for those undergoing operations or with chronic illness, over a follow up period of one month in order to determine if L-Lysine aescinat had an immediate effect on recovery in the post-operative period. Urinary dysfunction was noted, alongside the location of the fracture, type of surgery and if there were any significant comorbidities.

Keywords: Therapeutic efficacy; L-Lysine supplementation; neurological outcomes; spinal fractures; traumatic spine injuries.

1. INTRODUCTION

Spinal fractures and traumatic spine injuries represent significant challenges in orthopaedic and neurosurgical practice, often leading to neurological deficits and compromised quality of life. Recent research has explored the potential neuroprotective effects of L-Lysine aescinat, an essential amino acid, in various clinical settings. This study sought to elucidate the therapeutic impact of L-Lysine aescinat supplementation on neurological outcomes in postoperative patients recovering from spinal fractures and traumatic spine injuries. A number of different patients were studied, with a variety of different fractures and surgeries to create a wider breadth of a population sample [1,2].

L-Lysine is an essential amino acid, the body does not make it, so it has to be taken from diet. A small number of studies so far have focused on the effect of L-Lysine aescinat in chronic back pain, but this is the first of its kind to focus on the implementation of L-Lysine aescinat in the post-operative period for spinal surgery in the Caucasus region [3,4,5]. A number of studies recommend a course of l-lysine aescinat in the period before surgery, but it has not yet been examined if there is a positive effect on outcomes for those who take it after the surgery has taken place [6,7].

In the group which received the l-lysine aescinat (Group A), a number of different fractures were diagnosed, alongside each surgery the patient received. Dens fixation, also known as odontoid fixation, is a surgical procedure performed to stabilise the odontoid process of the second cervical vertebra (C2). The dens is a bony protuberance that projects upward from the body of the second cervical vertebra and plays a crucial role in the stability and mobility of the cervical spine. This surgery was performed in 2 patients in Group A. Transpedicular fixation is the surgical procedure used to stabilise the spine by placing screws through the pedicles of the vertebrae. In the case of Th11-Th12-L2-L3 transpedicular fixation, the procedure involves stabilising the spine at the levels of the 11th thoracic (Th11), 12th thoracic (Th12), 1st lumbar (L1), and 2nd lumbar (L2) vertebrae. This was performed on 6 patients in Group A. Laminectomy is a surgical procedure that involves the removal of the lamina, the bony arch on the posterior aspect of the vertebrae. This procedure is often performed to relieve pressure on the spinal cord or nerves, as by removing part or all of the lamina, there is more space in the spinal canal, therefore reducing pressure on the nerves [8-10]. This was performed again on 6 patients within Group A. A "360 fixation" in spinal surgery typically refers to a comprehensive approach that involves stabilisation of the spine from both the anterior and posterior aspects. One patient within Group A received this surgery.

2. METHODS

To be able to see the effects of l-lysine aescinat supplementation on spinal surgery recovery, we performed clinical trials on parallel groups, a control group and the assessment group that received the l-lysine aescinat supplement. These surgeries all took place at Caucasus Medical Centre, Tbilisi, Georgia in the period of 16 months. The age range of patients was from 28-84. Urinary incontinence status was noted prior to surgery. Patients who met the criteria were selected and placed into either the assessment group or the control group. We assessed 16 Patients in Group A, all of whom received l-lysine aescinat supplementation intravenously at a standardised dose of 5ml/50ml NaCl once per day, for 7 days postoperatively, initiated 72h after surgical intervention. The patients in Group B, the control group, received standard postoperative care without L-lysine aescinat supplementation. Both groups underwent regular follow-up assessments, with comprehensive neurological examinations and Karnofsky score

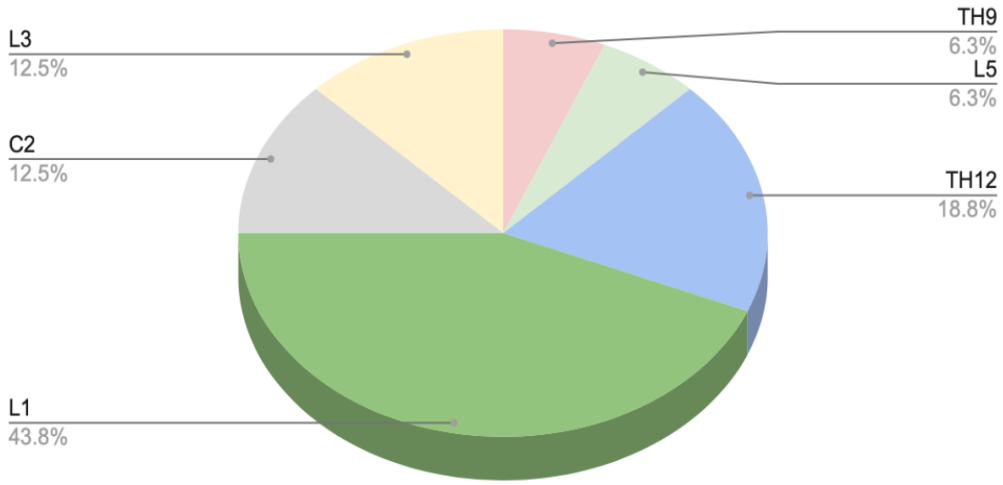

Fig. 1. Location of spinal fracture of patients within Group A

Table 1. Table to show the Karnofsky performance score scale

KP (Karnofsky Performance) Score	Description
100	Normal, no complaints, no evidence of disease
90	Able to carry on normal activity, minor signs/symptoms of disease
80	Normal activity with effort, some signs or symptoms of disease
70	Cares for self, unable to carry on normal activity or to do active work
60	Requires occasional assistance, but is able to care for most of their personal needs
50	Requires considerable assistance and frequent medical care
40	Disabled; requires special care and assistance
30	Severely disabled; hospital admission is indicated although death not imminent
20	Very sick, hospital admission necessary, active supportive treatment necessary
10	Moribound, fatal processes progressing rapidly
0	Dead

evaluations conducted before surgery, on the 5th day post-operatively and a month after the surgery. Karnofsky score was used as the evaluation of choice due to its ease in communication with the patient, the comprehensiveness of its assessment and the ability to longitudinally track the patients scores. The examinations performed to assess Karnofsky score were as follows: These assessment methods were used again on the 5th postoperative day, and a month post-operatively.

3. RESULTS AND DISCUSSION

The two patients' information from above, shows that both were experiencing impairment, S.G. especially, with low Karnofsky scores preoperatively and that both made a significant postoperative recovery in the 5 days after surgery, with no further improvement in the month following.

The trend found in this group of patients in Group A, was that the Karnofsky score kept improving, following both 5 days and then again to the 1 month post-operatively in this patient subsect on average. Therefore L-lysine aescinat might have a greater effect on patients who have undergone this specific type of surgery in comparison to others.

In TH11-12-13 transpedicular fixation, the Karnofsky scores again increase on average

both at the 5 day post-operative mark, and the month following, representing again that L-lysine aescinat may have a greater effect on this type of surgery, and its recovery, than that of dens fixation.

At the 5 day post operative mark, patients in Group A exhibited a mean Karnofsky score improvement. At the 1 month follow-up, the mean Karnofsky score improvement in Group A reached 90%.

The observed improvements in Karnofsky scores among patients supplemented with L-lysine aescinat suggest a potential neuroprotective role for this amino acid in the postoperative care of spinal fractures and traumatic spine injuries. In dens fixation however, all improvements were recorded within the 5 days post-operative time frame, with no further improvement of Karnofsky scores in the month that followed. This is a topic that requires further investigation in order to see if there is limitation on the effects of l-lysine aescinat and if it is only beneficial in the short term in this specific type of surgery. The other surgeries that were studied show an average improvement both after 5 days and further improvement in the month that followed, which could demonstrate a significant effect in neurological recovery in these types of surgery with the addition of L-lysine aescinat. L-lysine aescinat is known for its involvement in collagen synthesis and tissue repair, and its role in neurological recovery warrants further investigation. The study's limitations, including the relatively small sample size and the need for a placebo-controlled design if investigated again, should be acknowledged. The specific mechanisms underlying the observed improvements in neurological outcomes require in-depth exploration, as well as other factors which could have a significant impact on outcomes such as pain medication taken, focusing on one rather than multiple types of surgeries, and following the patients over a longer period of time.

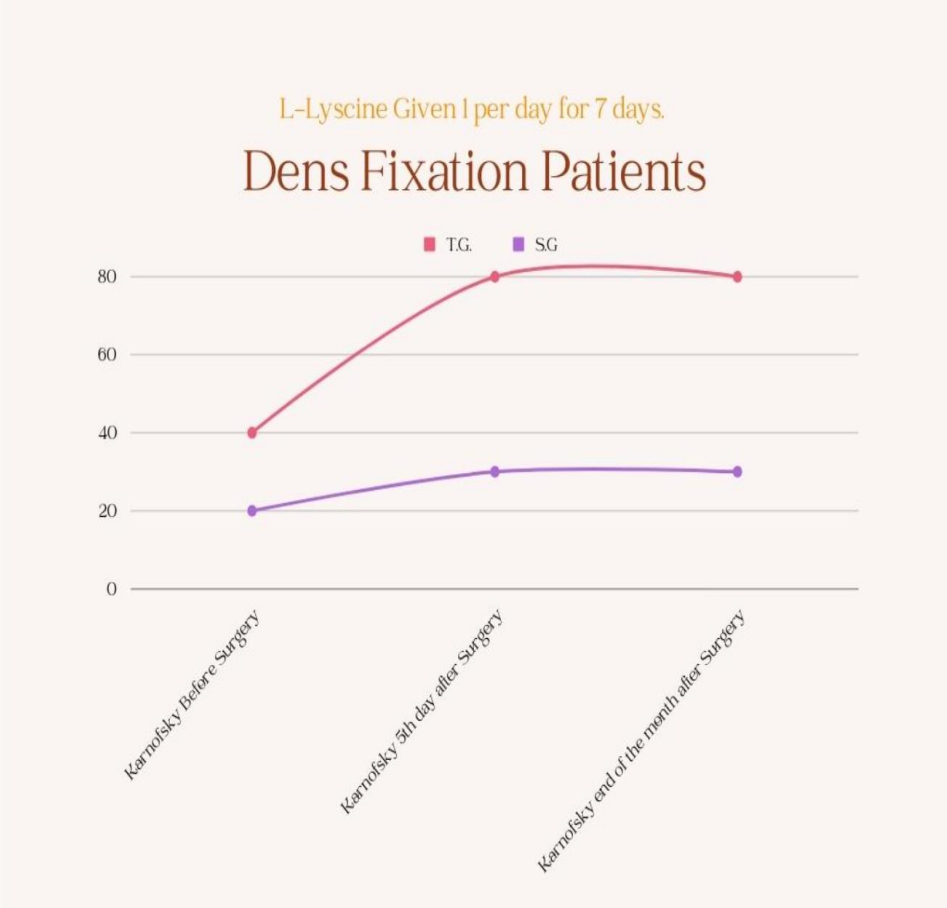

Fig. 2. Showing the results of Group A dens fixation patients Karnofsky scores

Table 2. Baseline characteristics and results of karnofsky scores in Group A - the group which received the L-lysine aescinat supplement

patient	diagnosis (FRACTURE)	Surgery	Karnofsky before surgery	Karnofsky 5th day after surgery	Karnofsky end of month after surgery	Age (years)	Comorbidities	Dosage of L-lysine	Urinary disfunction before the surgery	Urinary function 5th day from surgery
I.G	TH9	laminectomy, redresation, fixation, stabilisation	10	20	40	65	DM	1x1 7d	yes	Foley
B.G	L5	360 fixation	20	30	40	36	no	1x1 7d	yes	Foley
N.Z	TH12	redresation-stabilisation 3 vertebras	20	30	30	56	no	1x1 7d	yes	Foley
K.L	TH12	redresation-stabilisation 3 vertebras	10	20	40	35	no	1x1 7d	yes	preserved
M.S	L1	th11-th12-l2-l3 transpedicular fixation	20	50	50	78	no	1x1 7d	yes	Foley
G.P	L1	redresation-stabilisation 3 vertebras	10	30	50	46	no	1x1 7d	yes	Diapers
N.S	TH12	redresation-stabilisation 3 vertebras	10	10	40	34	no	1x1 7d	yes	Diapers
N.T	L1	th11-th12-l2-l3 transpedicular fixation	40	60	60	75	no	1x1 7d	no	Preserved
T.G	C2	dens fixation	40	80	80	44	no	1x1 7d	yes	Preserved
B.M	L3	redresation-stabilisation 3 vertebras	30	70	80	45	no	1x1 7d	yes	Preserved
D.H	L1	th11-th12-l2-l3 transpedicular fixation	10	20	30	42	no	1x1 7d	yes	Preserved
S.G	C2	dens fixation	20	30	30	84	osteoporosis	1x1 7d	yes	Preserved
S.R	L3	redresation-stabilisation 3 vertebras	20	30	40	28	no	1x1 7d	yes	Preserved
D.T	L1	th11-th12-l2-l3 transpedicular fixation	10	20	30	57	no	1x1 7d	yes	Foley
G.T	L1	th11-th12-l2-l3 transpedicular fixation	20	50	70	49	no	1x1 7d	no	Diapers
KH.T	L1	th11-th12-l2-l3 transpedicular fixation	10	30	50	81	osteoporosis	1x1 7d	no	Foley

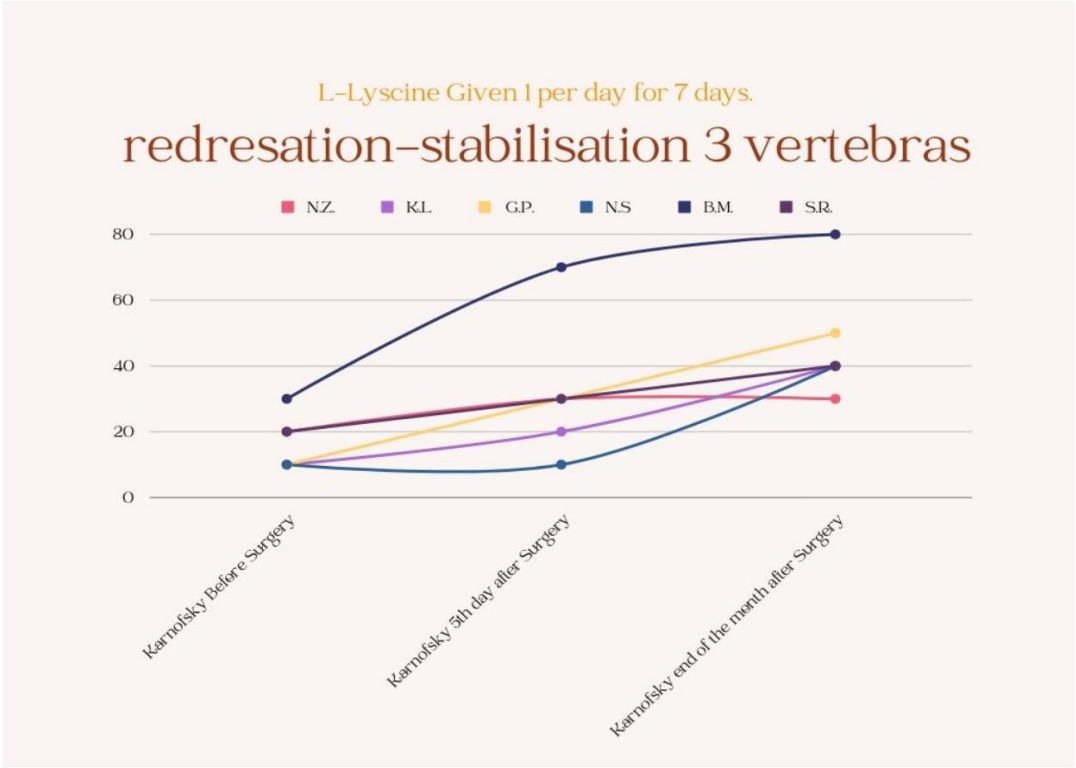

Fig. 3. Showing the results in Group A patients who had redressation-stabilisation of 3 vertebrae and their Karnofsky score outcomes, preoperatively, 5 days postoperatively and a month postoperatively

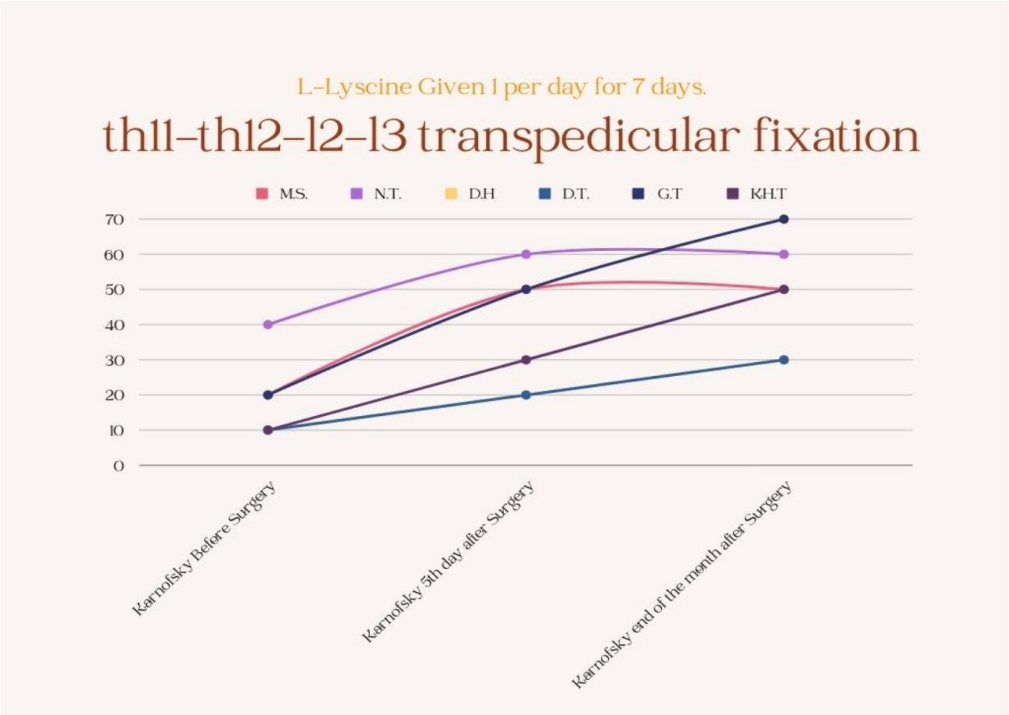

Fig. 4. Showing the results in Group A patients who had th11,12,13 transpedicular fixation and their Karnofsky score outcomes, preoperatively, 5 days postoperatively and a month postoperatively

4. CONCLUSION

In order to draw more definitive conclusions on the effects of L-lysine aescinat on surgical outcomes, a larger sample size, with a number of different controls would be hugely beneficial. This prospective study provides encouraging evidence supporting the beneficial effects of L-lysine aescinat supplementation on neurological outcomes in patients recovering from spinal fractures and traumatic spine injuries, however it does with limitations of small sample size and that several factors can influence surgical outcomes which could also be included in the statistical significance of the results observed. The improvement in Karnofsky scores over the period from pre-operative to the 5 day mark represents a huge increase in levels of impairment experienced by the patient, and underscores the potential neuroprotective role of L-lysine aescinat in immediate postoperative care. Future research should focus on elucidating the underlying mechanisms, conducting larger randomised controlled trials, and exploring the optimal dosage and duration of L-lysine aescinat supplementation in the patients who are undergoing spinal surgery.

CONSENT

As per international standards or university standards, patient(s) written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standards or university standards written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Shin JC, Kim KN, Yoo J, Kim IS, Yun S, Lee H, Jung K, Hwang K, Kim M, Lee IS, Shin JE. Clinical trial of human fetal brain-derived neural stem/progenitor cell transplantation in patients with traumatic cervical spinal cord injury. Neural plasticity; 2015.
2. Chio JC, Punjani N, Hejrati N, Zavvarian MM, Hong J, Fehlings MG. Extracellular matrix and oxidative stress following traumatic spinal cord injury: physiological and pathophysiological roles and opportunities for therapeutic intervention. Antioxidants & Redox Signaling. 2022;37(1-3):184-207.
3. Lanzino G, Torner J, Meissner I, Piepgras DG, Huston J, Kallmes DF, Cozzie E, Brown Jr RD. Unruptured Intracranial Aneurysms: Natural History and Treatment Outcome in Patients with Ischemic Cerebrovascular Disease—A Subgroup Analysis from the International Study of Unruptured Intracranial Aneurysms: 914. Neurosurgery. 2009;65(2):405.
4. Pickart L, Vasquez-Soltero JM, Margolina A. The effect of the human peptide GHK on gene expression relevant to nervous system function and cognitive decline. Brain Sciences. 2017 ;7(2):20.
5. Saito F, Nakatani T, Iwase M, Maeda Y, Murao Y, Suzuki Y, Fukushima M, Ide C. Administration of cultured autologous bone marrow stromal cells into cerebrospinal fluid in spinal injury patients: a pilot study. Restorative neurology and neuroscience. 2012;30(2):127-36.
6. Casha S, Zygun D, McGowan D, Yong VW, Hurlbert RJ. Neuroprotection with minocycline after spinal cord injury: results of a double blind, randomized, controlled pilot study: 929. Neurosurgery. 2009; 65(2):410-1.
7. Dyakonova EN, Fedin AI, Makerova VV. The use of L-lysine aescinat in the treatment of microcirculatory disturbances in patients young and middle age with violation of the intracranial venous outflow. Zhurnal Nevrologii i Psikhiatrii imeni SS Korsakova. 2016;116(9):42-50.
8. Dobran M, Iacoangeli M, Di Somma LG, Di Rienzo A, Colasanti R, Nocchi N, Alvaro L, Moriconi E, Nasi D, Scerrati M. Neurological outcome in a series of 58 patients operated for traumatic thoracolumbar spinal cord injuries. Surgical Neurology International. 2014;5 (Suppl 7): S329.
9. Westerveld LA, Van Bemmel JC, Dhert WJ, Oner FC, Verlaan JJ. Clinical outcome after traumatic spinal fractures in patients with ankylosing spinal disorders compared with control patients. The Spine Journal. 2014;14(5):729-40.
10. Scivoletto G, Farchi S, Laurenza L, Tamburella F, Molinari M. Impact of

multiple injuries on functional and neurological outcomes of patients with spinal cord injury. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine. 2013;21:1-7.

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