ejpmr, 2023, 10(12), 536-541

SJIF Impact Factor 6.222

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Case Study

ISSN 2394-3211

EJPMR

EFFECT OF *QURS-E- ASBI* IN THE MANAGEMENT OF DIABETIC PERIPHERAL NEUROPATHY- A CASE SERIES

Sadaf*[1], Md. Rizwanullah[2], Prof. Tabassum Latafat[3]

[1]Assistant Professor, Department of Moalajat, University College of Unani, Tonk, Rajasthan, India.
[2]Assistant Professor, Department of Ilmul Jarahat (Surgery) University, College of Unani, Tonk, Rajasthan, India.
[3]Chairperson, Professor, Department of Moalajat, Ajmal Khan Tibbiya College, AMU Aligarh, UP, India.

***Corresponding Author: Sadaf**

Assistant Professor, Department of Moalajat, University College of Unani, Tonk, Rajasthan, India.

Article Received on 19/10/2023 **Article Revised on 09/11/2023** **Article Accepted on 29/11/2023**

ABSTRACT

Background: Diabetic Peripheral Neuropathy (DPN) is one of the most significant microvascular and troublesome complications of Diabetes Mellitus, leading to great morbidity and mortality. It imposes a considerable burden on patients' quality of life and the healthcare system. Unfortunately, current therapies that reduce symptoms of Diabetic Peripheral Neuropathy do not prevent the progression of the disease. Therefore, the search for safe and effective drugs for its management is quite necessary. Unani Medicine is the thrusting area of research to control or reduce the complications of Diabetes. **Methodology:** In the present study, 10 patients of Diabetes Mellitus Type 2 with Diabetic Peripheral Neuropathy (DPN) were enrolled based on clinical symptoms and confirmed by VPT, done with the help of Diabetic Risk Profiler. Patients were given *Qurs-e-Asbi* in the dose of 500mg twice a day for 45 days and were followed fortnightly for assessing improvement in VPT and clinical symptoms. **Results:** *Qurs-e-Asbi* is found to be significantly effective in reducing both subjective (pain, numbness, weakness, tingling) and objective (VPT) parameters, with a p-value < 0.01. **Conclusions:** *Qurs-e-Asbi* can be effectively used in managing Diabetic Peripheral Neuropathy.

KEY WORDS: Qurs-e- Asbi, Diabetic Peripheral Neuropathy, Diabetic Risk Profiler.

INTRODUCTION

Diabetes mellitus is a major metabolic disorder. Nearly half a billion people are living with Diabetes worldwide. International Diabetes Federation estimated that over four million people aged between 20-79 years died from Diabetes and Diabetes related complications in year 2019. The number of diabetic patients is expected to increase to 578 million (10.2%) by year 2030 and 700 million (10.9%) by year 2045.[1] Almost 50% of the people suffering from diabetes are expected to develop Diabetic peripheral neuropathy.[2,3] Diabetic neuropathy includes manifestations in the somatic or autonomic parts of the peripheral nervous system. It has been defined as a demonstrable disorder which may be evident either clinically or sub-clinically. It may occur in the setting of diabetes without other causes for peripheral neuropathy. The most important etiologic factors which may be associated with DPN are poor glycemic control, visceral obesity, diabetes duration, height, hypertension, age, smoking, hypoinsulinemia and dyslipidemia.[4] The most common clinical signs are diminished perception of vibration distally, 'glove and stocking' impairment of all other modalities of sensation and loss of tendon reflexes in the lower limbs. The symptoms include paraesthesia in the feet (and, rarely, in the hands), pain in the lower limbs (dull, aching and/or lancinating, worse at night, and felt mainly on the anterior aspect of the legs), burning sensations in the soles of the feet, and cutaneous hyperaesthesia.[5] Therefore DPN leads to a number of impairments and functional limitations, including foot ulceration and subsequent lower extremity amputation. The global prevalence of diabetic foot complications varies between 3% and 13%, with a global average of 6.4%. Lower limb amputation in people with diabetes is 10 to 20 times more common than those without diabetes.[1]

In Unani system of medicine, Diabetic Peripheral Neuropathy is not mentioned precisely as a complication of *Ziabetes* (Diabetes), but *Ibn-e-Sina* (Avicenna) (980-1037 Al)) has mentioned gangrene and collapse of sexual function as a specific complications of Diabetes. In classical Unani literature the term 'Waja (pain) is broadly classified according to the nature and character of pain into 15 types. Avicenna suggested that the true cause of pain is change of physical condition *Sue Mizaj* (Change in temperament) of the organ irrespective of injury. This concept closely mimics with modern theory of pain which recognizes that often pain can occur in the absence of injury. Avicenna extended the Galen's descriptions of

pain from 4 types to 15 types and he also coined the term *'Waja'*.[6]

A large number of single and compound Unani drugs have been described which possess *Muqawwi-e-Asab* (Nervine tonic) ,*Muharrik-e-Asab* (Nervine Stimulant) properties.*Qurs-e- Asbi* is one of such compound formulation mentioned in National Formulary of Unani Medicine (Part II, Volume 6). Its constituents are given below.[7]

Ingredients	Quantity
Ood Saleeb (*Paeonia emodi*)	500g
Jadwar Shireen *(Delphineum denudatum*	500g
Malkangni *(Celastrus paniculata*	250g
Samagh Arbi *(Acacia Arabic)*	QS

Methodology

This small preliminary study evaluates the safety and efficacy of *Qurs-e-Asbi* in the management of Diabetic Peripheral Neuropathy. Patients with Type 2 Diabetes Mellitus, Random Blood Sugar ≤ 200 mg/dl, aged between 30-60 years, presenting with any symptoms (pain, numbness, weakness, tingling) and a history of Diabetes Mellitus for atleast 3 years were selected from the Moalajat OPD/IPD of Ajmal Khan Tibbiya College Hospital, AMU Aligarh. The patients were clinically examined, and the Vibration Perception Test (VPT) was performed using the Diabetic Risk Profiler. Patients with VPT values > 15 Volts were included in the study after obtaining informed written consent. Patients with unstable systemic illnesses and complications other than neuropathy were excluded. Similarly, patients with other causes of neuropathy were also excluded based on history and clinical examination (symptoms included signs and symptoms of Vitamin B12 deficiency). Blood sugar was kept under control during the study. *Qurs-e-Asbi*, 500 mg (2 tablets) twice a day, was administered for 45 days, and assessments were conducted fortnightly to track amelioration or progression in symptoms and VPT. Patients were also queried for any adverse drug reactions. The final clinical efficacy was measured using subjective and objective parameters (VPT) at the end of the study.

Observations

Table No.1 Distribution of patients according to Gender,Age,Disease Duration& Mizaj		
Gender	Male	6
	Female	4
Age (Years)	35-40	2
	40-45	3
	45-50	5
Duration of Diabetes	<5 Years	8
	>5 years	2
Mizaj	Damvi	3
	Balghami	4
	Safravi	2
	Saudavi	1

Table No.2 Distribution of Patients according to Subjective Parameters				
Symptoms	**Before Treatment**		**After Treatment**	
	No.of Patients	**%age**	**No. of Patients**	**% Age**
Pain	**8**	**80**	**2**	**20**
Numbness	**6**	**60**	**1**	**10**
Weakness	**6**	**60**	**1**	**10**
Tingling	**5**	**50**	**1**	**10**

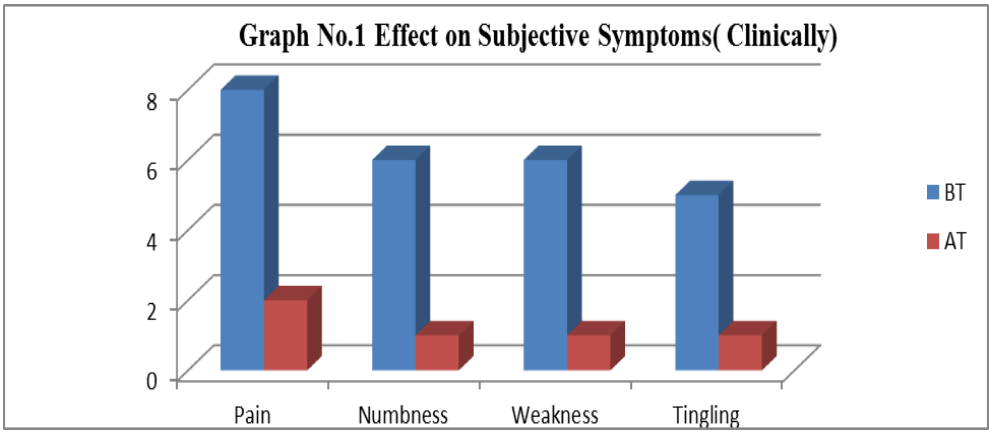


Table 3: Statistical Assessemnt on Subjective Prameters.

	BT (Mean ± SD)	AT(Mean ± SD)	P value
Pain	0.8±0.42	0.2±0.42	<0.0051
Numbness	0.6±0.51	0.1±0.31	<0.0150
Weakness	0.6±0.51	0.1±0.31	<0.0150
Tingling	0.5±0.52	0.1±0.31	<0.0368

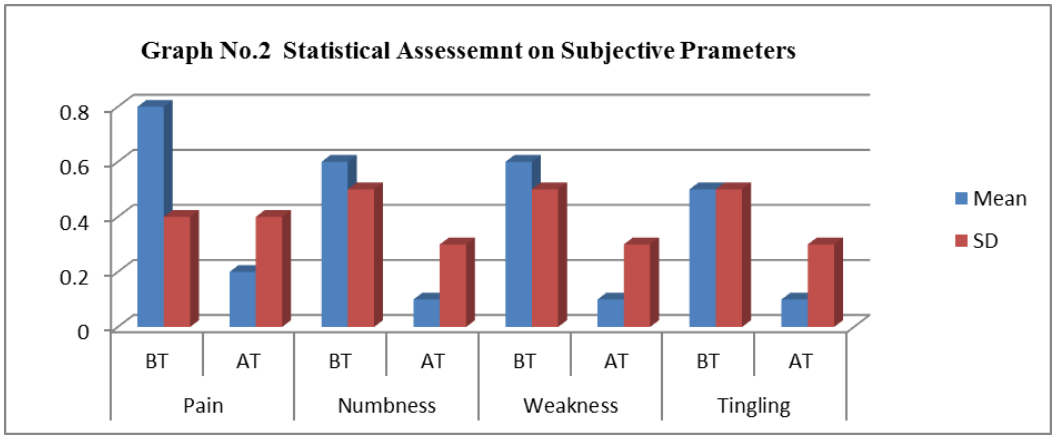
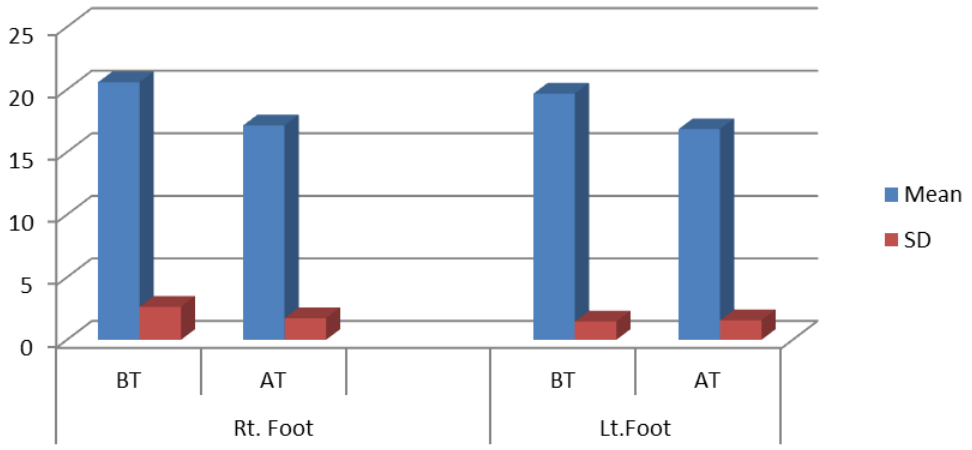


Table 4: Assessment on VPT.				
S.No	Rt. Foot (Mean of 6 points)		Lt. Foot (Mean of 6 points)	
	BT (in Volts)	AT (in Volts)	BT (in Volts)	AT (in Volts)
1	16.05	14.14	17.95	15.01
2	19.12	16.13	18.23	15.23
3	22.62	18.15	19.16	17.11
4	24.53	20.12	21.51	20.05
5	21.11	17.23	19.51	15.03
6	23.12	19.01	22.03	17.29
7	19.26	17.22	18.11	16.15
8	22.62	17.51	20.99	18.02
9	18.15	16.22	19.03	17.11
10	19.22	15.53	20.22	17.29

Table No.5 Assessment on VPT				
	Right Foot		Left Foot	
	BT(Mean±SD)	AT(Mean±SD)	BT(Mean±SD)	AT(Mean±SD)
VPT	20.58±2.642	17.13±1.731	19.67±1.459	16.83±1.561
P value	<0.0001		<0.0001	



Graph No.4: Assessment on VPT.

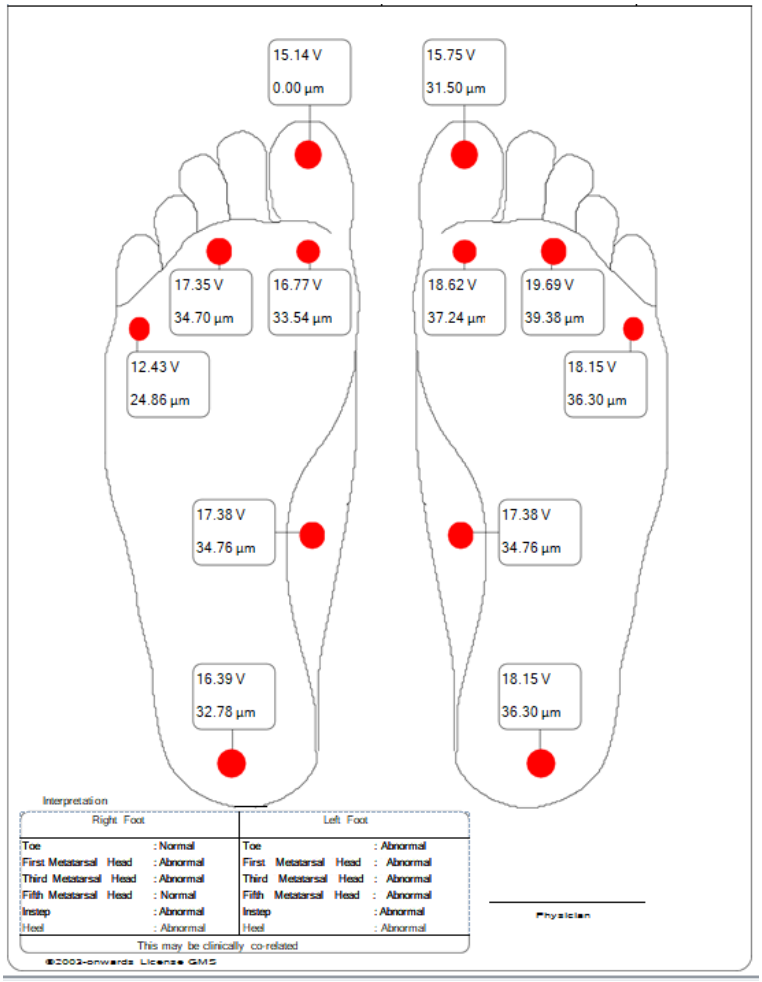
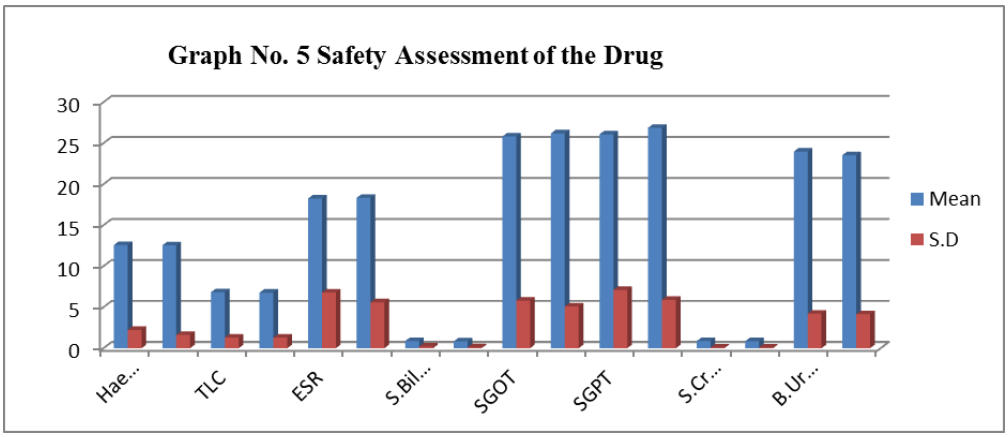


Fig.1: Showing Image of VPT of both foot of a Patient before the intervention.

Table No. 6 Safety Assessment of the Drug			
	BT(Mean ± SD)	**AT(Mean ± SD)**	**P value**
Haemoglobin	12.58 ± 2.2	12.55 ± 1.6	0.84
TLC	6.83 ± 1.3	6.782 ± 1.3	0.2
ESR	18.26 ± 6.8	18.34 ± 5.6	0.88
S.Bilirubin	0.88 ± 0.2	0.84 ± 0.1	0.31
SGOT	25.82 ± 5.8	26.20 ± 5.1	0.33
SGPT	26.08 ± 7.1	26.88 ± 5.9	0.27
S.Creatinine	0.87 ± 0.09	0.86 ± 0.09	0.12
Blood Urea	23.98 ± 4.22	23.54 ± 4.14	0.24



Data Analysis

Recorded data was compiled and entered in a spreadsheet and then exported to the data editor of SPSS version 20.0 and Graph pad prism software. Continuous and categorical data were presented as mean ± standard error and percentage respectively. Student Paired t test was employed for intergroup comparison of categorical variables The graphical representation of data was presented by means of bar. A p value of less than 0.05 was considered statistically significant.

RESULTS

Out of 10 patients, 6 were male, and 4 were female. Among them, 5 patients were in the age group of 45-50 years, 3 were in the age group of 40-45 years, and only 2 were in the age group of 35-40. Eight patients had a history of DM for more than 5 years, while only 2 had a history of DM for less than 5 years. According tom Mizaj maximum number of patients was of *Balghami Mizaj* i.e,40%.According to symptoms, 8 patients (80%) complained of pain, of which 6 patients experienced complete relief. The mean and SD of pain were 0.8 ± 0.42 before starting the intervention, and it was 0.2 ± 0.42 at the end of 45 days, showing significant improvement. The p-value was < 0.01, which is highly significant. Six patients presented with weakness and numbness, and among them, 5 patients experienced complete relief. The mean and SD were 0.6 ± 0.51 before starting the intervention, and it was 0.1 ± 0.31 at the end of 45 days, with a p-value < 0.01. Five patients presented with tingling, of which 4 patients experienced complete relief with a p-value < 0.05.

In the objective parameter, i.e., VPT, there was a significant improvement with a p-value< 0.0001.

DISCUSSION

There is a huge burden of diabetes-related complications, both microvascular and macrovascular, in India. With the rising prevalence of Diabetes Mellitus the number of people with complications of DM also increases. Diabetic peripheral neuropathy (DPN) is the most common complication among DM patients, with a prevalence ranging from 18.8% to 61.9% in India. Early diagnosis of DPN can reduce associated complications.In our case series study, the preponderance of the disease was found in patients aged 45-50 years with a history of >5 years of diabetes. These findings support the epidemiological study done by Hicks, Caitlin W, and Elizabeth Selvin, which suggests that the disease is more prevalent in advanced age and with long-standing diabetes.[8]Unani Medicine plays a significant role in the management of neuropathic pain, mainly with drugs having *Muqawwi-e- Asab wa Muharrik-e- Asab* properties. *Qurs-e-Asbi* possesses *Muqawwi-e-Asab and Musakkin-e-Asab* properties. Its therapeutic uses includes *Waj-ul-Mafasil*, *Waram-e-Asab*, *Zof-e-Asab*. Its ingredients consist of the following properties.[9,10,11,12]

Ood Saleeb (*Paeonia emodi*)

Muqawwi-e-Asab (Nervine Tonic)[9] *Muhallil* (Resolvent), *Musakkin* (Sedative), *Mulattif* (Demulcent)[10,11]

Jadwar Shireen *(Delphineum denudatum)*

Muhallil, (Resolvent), *Musakkin* (Sedative), *Muqawwi-e-Asab*,[9,10,11,12] *Daf-e- Amraz-e-Barida*

Malkangni *(Celastrus paniculata)*,

Daf-e-Amraz-e-Balghamiya, *Muqawwi-e-Asab (*Nervine Tonic)' *Muharrik-e-Asab*, (Nervine Stimulant) *Muhallil* (Resolvent).

The effect on the subjective parameters, i.e, Pain, Numbness, Weakness, and Tingling, is attributed to the various properties mentioned above in the ingredients of the compound formulation. The inflammatory process holds great significance in the development of Neuropathy.[13] All the ingredients in the test drug exhibit resolvent or anti-inflammatory properties. Nerve ischemia and nerve hypoxia due to thrombus formation also play a role in the pathogenesis of DPN. As thrombus formation occurs mainly due to excess of *Balgham* (phlegm), this also supports the effect of our drug in managing DPN, as the constituents are effective in phlegmatic disorders and neuralgia in the Unani system of medicine is itself considered a phlegmatic disorder. Additionally, neurons are known to have limited ability to regenerate.[14] Thus, the neuroprotective properties of the drug help in preserving nerve function and providing strength. Relief in pain and tingling is mainly due to the *Musakkin-e-Asab* property of the ingredients.[9,10,11,12,13] The effect of *Qurs-e-Asbi* on DPN is also supported by various studies on *Ood Saleeb*, *Jadwar*, and *Malkangni*.[15,16,17]

Assessment of Safety

The safety outcomes were assessed through laboratory investigations (Haemoglobin, TLC, ESR, SGOT, SGPT, B. Urea, S. Creatinine) conducted before and after the study. There was no significant change in these parameters, with a p-value > 0.01.

CONCLUSION

This case series study suggests that the Unani Formulation has the potential to reduce subjective and objective parameters of Diabetic Peripheral Neuropathy. However, a long-duration study with a larger sample size and a standard control group is needed to further confirm the efficacy.

ACKNOWLEDGEMENT

Work is duly acknowledged to patients who are participated in this case series study.

Funding and Competing Interest: Nil.

REFERENCES

1. Gogas Yavuz, Dilek. Classification, risk factors, and clinical presentation diabetic neuropathy in Diabetic neuropathy edited by Mitra Tavakoli, 2022.
2. Ray, Jasaswi & Sahoo, Chinmaya & Mohanty, Rajashree & Sahoo, Rakesh & Dalai, Rajashree. A Review on Diabetic Peripheral Neuropathy, 2021.
3. Jameson, Fauci, Kasper, Hauser, Longo, Lascalzo. Harrison's principles of internal medicine. Mc graw hill education. 21st edition, 2022; 3124.
4. Richard I.G. Holt, Clive S. Cockram, Allan Flyvbjerg, BARRY J. Goldstein Textbook of Diabetes, Wiley –Blackwell A John Wiley & Sons, Ltd., Publication.4th edition, 2010; 615.
5. Ralsto H S, Penman D I, Strachan J W M, Hobson P R. Davidson's principles andpractice of medicine. Elsevier. 24thedition, 2022; 758-759.
6. Thesis Nusrat Fathima "Study of Diabetic Peripheral Neuropathy and Therapeutic Evaluation of Unani Formulation in its Management" National Institute of Unani Medicine Banglore, 2011.
7. National formulary of unani medicine. Part II. Vol.VI. Ministry of health and family welfare, Govt. of India, New Delhi, 2007; 26.
8. Hicks, Caitlin W, and Elizabeth Selvin. "Epidemiology of Peripheral Neuropathy and Lower Extremity Disease in Diabetes." *Current diabetes reports*, 19,10 86.
9. Khazainul advia Ghani Hakim N. *Khazainatul Advia*.Vol.II Idara Kitabul Shifa Daryaganj, New Delhi,YNM, 552,955,1211
10. Makhzanul mufridat Kabeeruddin Hkm. *Makhzanul Mufradat*. Ejaz Publishing House, New Delhi. YNM, 174,297,376.
11. Bayanul advia Hk. Ram Lubhaya. *Goswami Bayanul advia*, part I, Goswami pharmacy, Gali Qasimjaan, Delhi, 1977; 159-160,353-354,444-445.
12. Bustanul Haleem AM. *Bustanul Mufradat Jadeed*. Idara Kitabul Shifa, New Delhi, 2002; 30,214,533.
13. Schomberg, D., Ahmed, M., Miranpuri, G., Olson, J., & Resnick, D. K. Neuropathic pain: role of inflammation, immune response, and ion channel activity in central injury mechanisms. *Annals of neurosciences*, 2012; *19*(3): 125–132.
14. Schreiber, A. K., Nones, C. F., Reis, R. C., Chichorro, J. G., & Cunha, J. M. Diabetic neuropathic pain: Physiopathology and treatment. *World journal of diabetes*, 2015; *6*(3): 432–444.
15. Hussain, Zaffar. "Assessment of therapeutic efficacy and safety of delphinium denudatum wall (jadwar) and local application of Iris florentina (roghan sosan) in painful diabetic neuropathy: A randomised single blind standard controlled study." *Global journal for research analysis*, 2018.
16. Kulkarni, Yogesh A et al. "Effect of Jyotishmati (Celastrus paniculatus) seeds in animal models of pain and inflammation." *Journal of Ayurveda and integrative medicine*, 2015; 6(2): 82-8.
17. Zahra, N., Iqbal, J., Arif, M. *et al*. A comprehensive review on traditional uses, phytochemistry and pharmacological properties of *Paeonia emodi* Wall. ex Royle: current landscape and future perspectives. *Chin Med*, 2023; 18: 23.