Indian Journal of Traditional Knowledge
Vol 22(3), July 2023, pp 543-546
DOI: 10.56042/ijtk.v22i3.5732

A comparative parallel design clinical study of *Qurse Asabi* in cases of post herpetic neuralgia

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Received 05 August 2020; revised 25 October 2021; accepted 06 May 2022

In the case of established post herpetic neuralgia (PHN), the medication is simple analgesics, opioid derivatives (Tramadol), antidepressant (Amitriptyline), anticonvulsant (Carbamazepine), GABA agonist (Gabapentin & Pregabaline), etc., but the benefit of treatment does not outweigh its cost and hazards. Therefore, there is always an area of thrust that arises to find out a cost-effective and hazardless medication before expert of Physical medicine, Regimenist, Dermatologist, and general Physicians. As far as Unani Pharmacopeia is concerned there are several single and compound drugs indicated in ailment like wajaula'asab (neuralgia) but their efficacy in terms of documentation and validation is not established yet. A very important formulation prepared from Dawakhana Tibbiya College, Aligarh Muslim University Aligarh is usually indicated for neuralgic pain in routine practice. As far as PHN is concerned there is no medication indicated in classical literature. Therefore, this study was designed to find out the therapeutic efficacy of *Qurse Asabi* in comparison to most commonly prescribed allopathic medicines *i.e.*, Neurokind-G containing Methyl Cobalamin 1500 mcg and Gabapentin 100 mg as a controlled drug while the *Qurse Asabi* is given as a test drug. The methodology was followed as per the Good Clinical Practice (GCP) guideline. Results were much interesting and encouraging which was also found statistically significant (t=10, p<0.0001).

Keyword: Herpes zoster, Post herpetic neuralgia (PHN), *Wajaula'asab*

IPC Code: Int Cl.[23]: A61K 9/00, A61K 36/00, A61K 45/00

Herpes zoster itself is a painful condition that occurs as a residue of chickenpox infection at any stage of life. After the infection limits, a painful condition arises which may last long and hamper the routine activity of life and known as Post Herpetic Neuralgia (PHN). PHN is defined as pain persisting beyond 4 weeks, affects 16% of patients younger than 60 years but in 47% of those older than 60 years[1]. Patients may report a variety of painful sensations with different components including spontaneous and continuous deep aching and throbbing pain, burning, lancinating pain sometimes provoked by clothing, and temperature change[2].

There is degeneration of small fibers of afferent dermatomes in pain associated with peripheral damage in dorsal root ganglion, spinal cord, and afferent neuron, ectopic impulse generation may occur at the site of damage and these impulses can be evoked by mechanical or thermal stimuli in the local environment. For this type of disorder membrane-stabilizing drugs are likely to work best. There is some evidence that nociceptors in the painful skin of PHN patients have enhanced adrenergic sensitivity. It is a well-accepted reality that several pain mechanisms may be operating in any one individual and it is unrealistic to expect any one drug to completely alleviate the pain in all neuropathic pain disorders or neuropathic pain conditions in all patients. Here, a drug formulation consisting of nociceptors membrane-stabilizing and adrenergic sensitivity enhancers like activity is subjected to the study in the cases of PHN with the following aims and objectives[3-4].

- To evaluate the efficacy of said drugs formulation *Qurse Asabi* and Neurokind-G in case of PHN.
- To compare the efficacy of both drugs by a parallel design study.
- To evaluate observable adverse effects, if any, in both groups
- If the test drug is found effective may be proposed for PHN with confidence and evidence.

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Methodology

This study was carried out in the Ajmal Khan Tibbiya College Hospital, Aligarh Muslim University Aligarh India, from the period 2016 to 2018. The study was carried out by obtaining clearance from board of research committee as well as department ethical committee and informed written consent was obtained from the patient. The enrolment of the patient was assessed for eligibility of inclusion and exclusion criteria mentioned elsewhere. The sample size was calculated as per the eligibility and error of the study and it was n=40. The allocation for intervention was random and based on lottery *i.e.,* in test group (A) n=20 and control group (B) n=20. The follow-up was carried out fortnightly for up to 3 months and analysis was on objective, subjective as well as statistical parameters.

Inclusion criteria

1. Patients with a history of exposure to Herpes zoster with a complaint of varied characteristics of pain like throbbing pain, burning, and lancinating pain.

Exclusion criteria

1. Patients in immunocompromised state and concomitant therapy.
2. Pregnant and lactating mothers
3. Diabetes mellitus

Composition of drug

The test drug was procured from Dawakhana Tibbiya College Muslim University, Aligarh, (Manufacturing unit). The formulation is a classical one and based upon the personal experiences that is of 40 years late Hakim (Prof.) Mohammad Tayyab. The same formulation is being prepared by the Dawakhana Tibbiya College and marketed since long time for neurological ailments. The group-B drug Neurokind-G was procured from Mankind Pharmaceutical Private Ltd. and it was given as a positive control.

Test drug (Group-A): *Qurse Asabi*

Oodsaleeb (*Paeonia officinalis* Linn.)[5-8]	2 Parts
Jadvar (*Delphinium denudatum*)[5,7-9]	2 Parts
Malkangani (*Celastrus paniculatus*)[5,6,8,10]	1 Part
SamagheArbi (*Acacia arabica*)[5,8,10]	Q.S.

Test drug and its dosage

Each tablet contain 750 mg drugs

Group-A

Qurse Asabi: 2 tablets twice a day for 90 days

Control drug (*Group-B*) *Neurokind-G*

Methyl cobalamin[11,12]	500 mcg
Gabapentin[11,12]	100 mg

Group-B

Control drug and its dosage

Neurokind-G: 1 tablet twice a day for 90 days

Statistical analysis

Paired-t test was applied, the effect of test drug Qurse Asabi was compared with control group and It was found statistically significant t=10, p<.0001
T=53 at dof 18, p<.0001 (Test drug)
T= 20 at dof 18 (Control drug)
(dof= degree of freedom)

Results and Discussion

In this study post herpetic neuralgia patients were not only assessed for clinical improvement but were also analysed for the incidence of herpes and its associated nerve involvement according to the temperament of the patients and sites of infection. Though there was the highest number of suffering associated with bilious temperament which is more likely an incidence rather draws any inference, and in this study it was observed that other humoral temperaments are also suffered from this ailment which do not correspond with the description in classical Unani literature, but as per the ideology and philosophy of the Unani system of Medicine there is always an area of thrust and unsung condition that required to be explored on modern scientific parameters. The common site of involvement was intercostals and the male was outnumbered. As far as the site is concerned it is more likely with the findings of other studies already carried out. (Table 1, 2 & 3)

The evaluation of efficacy was carried out fortnightly and the clinical parameters were mainly focused these were pain, burning sensation, uneasiness, and spasm-like conditions. There was remarkable improvement noticed after 45 days of treatment and most of the patients of all sites showed

Table 1 — Showing age and sex distribution (n=40)

Age groups (years)	Males		Females	
	No. of cases	% age	No. of cases	% age
20-30	4	10.0	1	2.5
31-40	10	25.0	2	5.0
41-50	6	15.0	3	7.5
51-60	6	15.0	4	10.0
61-70	4	10.0	1	2.5
Total	30	75.00	10	25.0

Table 2 — Showing distributions of patients according to temperament (n=40)

Type of Temperament	Total no. of cases (% age)	No. of males (% age)	No. of females (% age)
Bilious (Safravi)	30 (75.0)	24 (60.0)	6 (15.0)
Sanguinous (Damvi)	3 (7.5)	1 (2.5)	2 (5.0)
Phlegmatic (Balghami)	1 (2.5)	0 (0)	1 (2.5)
Melancholic (Saudawi)	6 (15)	5 (12.5)	1 (2.5)
Total	40 (100.0)	30 (75.0)	10 (25.0)

Table 3 — C Distributions according to Site of infections (n=40)

Site of involvement	Total no. of cases (% age)	No. of males (% age)	No. of females (% age)
Intercostal	20 (50.0)	15 (37.5)	5 (12.5)
Thoracolumbar	10 (25.0)	7 (17.5)	3 (7.5)
Inguinofemoral	6 (15.0)	4 (10)	2 (5.0)
Ophthalmic	4 (10.0)	2 (5.0)	2 (5.0)
Total	40 (100.0)	28 (70.0)	12 (30.0)

improvement in 75th and 90th days (t=10, <.0001) without any apparent side effect reported and the best improvement was noticed in thoracolumbar and inguinofemoral patients and almost all the patients were free from pain and abnormal sensation. While in the Control group patients were having improvement since 15th days but it remained with symptoms in all patients even after termination of the therapy except in ophthalmic condition where it was noticed that the Control drug is more effective the reason behind need exploration. The overall wellbeing of the patients was better in the Test group than in the control group. (T=53 at dof 18, p<.0001 test group and T= 20 at dof 18 control group), (Table 4, 5 & 6)

The most probable effect of the drug present in Test group formulation *i.e., Qurse Asabi* is a neurogenic, neurotropic and effective myelin sheath activator that is why the overall cumulative effect of the drug plays a pivotal role in the dermatome regeneration process. The overall soothing and sedative effect is also to be at par with the analgesic opiod derivatives. The description in authentic material medica is also coherent with the findings as evident from the observation[5-10]. Hence its efficacy may be assessed on more sophisticated neuro-physiological parameters along with clinical parameters to be proposed as a safe and effective choice for the said ailment. It is pertinently observed that there were no apparent adverse effects reported by any individuals.

Conclusion

The pain of PHN directly influences the quality of life[13] it is therefore Qurse Asabi may be a safe and effective management free from any adverse effects. From the observation and discussion, it is obvious that the Test drug is far effective than the Control drug both in terms of efficacy and tolerance. The test drug has many neurotropic drugs *viz., Oodsaleeb, Jadwar, Malkangani* having its proved efficacy for Neuritis and Neuralgia (*warmea'asab & wajaula'asab*) like condition and they are used both in the single formulation and compound formulation but in compound formulation with present composition has an additive effect to relieve the most painful and agonising condition of Herpes zoster *i.e.,* Post Herpetic Neuralgia, not only its efficacy is proved worthy but its cost is also friendly with the common people. Hence it can be recommended with confidence and evidence for the patients of post herpetic neuralgia and definitely, it will be one of the best options for them.

Table 4 — Effect of Test Drug (*Qurse Asabi*) (n=20)

Site of involvement	0 day	15 day	30 day	45 day	60 day	75 day	90 day
Intercostal	4+	4+	3+	2+	1+	1+	-
Thoracolumbar	4+	4+	3+	2+	1+	-	-
Inguinofemoral	4+	4+	3+	2+	-	-	-
Ophthalmic	4+	4+	4+	4+	3+	3+	2+

T=53 at d of 18, p<.0001

Table 5 — Effect of Control Drug (Neurokind-G) (n=20)

Site of involvement	0 day	15 day	30 day	45 day	60 day	75 day	90 day
Intercostal	4+	3+	2+	2+	2+	2+	2+
Thoracolumbar	4+	3+	2+	2+	2+	2+	2+
Inguinofemoral	4+	2+	2+	2+	2+	2+	1+
Ophthalmic	4+	2+	2+	1+	1+	-	-

T= 20 at d of 18

Table 6 — Comparative effect of Test and Control drugs

Site of involvement	90 days Test	90 days control
Intercostal	0	2
Thoracolumbar	0	2
Inguinofemoral	0	1
Ophthalmic	2	0

Paired-t test was applied, and the effect of *Qurse Asabi* was compared in test and control group. It was found statistically significant t=10, p<.0001

Acknowledgement

Authors acknowledge Prof. Hakim Mohammad Tayyab, the person behind this formulation (*Qurse Asabi*).

Conflict of Interest

Authors declare that there is no conflict of interest.

Author's Contributions

MM contributed mainly for diagnosis of the cases, MS contributed particularly to rule out neuralgia of any other reasons and also played role in the preparation of the manuscript, MA documented the cases and played key role in the preparation of the manuscript.

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