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Case Report

Case Series to evaluate role of Nutool Therapy on Headache frequency, MIDAS (Migraine Disability Assessment Score) headache intensity by VAS in diagnosed cases of Shaqqa (Migraine) in Delhi

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Abstract

Almost all Unani physicians have advocated Nutool therapy in the management of migraine (Shaqqa), particularly with or without medicated oil or liquid, but unfortunately these have not evaluated on scientific parameters. Despite the fact that, this therapy is in the practice of Unani physician and a large number of patients have been treated successfully; this regimen still requires scientific validation to generalize their popularity and acceptability. Present paper is the case series of diagnosed migraine patients to assess the effect of Nutool therapy on headache intensity, MIDAS scale and Pain intensity. The present study entitled "Case Series to evaluate role of Nutool Therapy on Headache frequency (from the daily headache diary), MIDAS (migraine disability assessment score) headache intensity by VAS in diagnosed cases of Shaqqa (Migraine) in patients attending HAHU and SUMER, Jamia Hamdard Delhi was conducted in the Department of Tahaffuzi-wa-samaji Tib, SUMER, Jamia Hamdard, New Delhi during the period of September 2020 to Nov 2020 in Psychiatric OPD of HAHC Hospital, Jamia Hamdard, New Delhi on diagnosed Patients of Migraine as per ICHD^{3rd} (International classification of headache disorders) Criteria. Nutool with Rogan Gul was done for 30 minutes for 12 sittings. The analysis of Nutool therapy on intensity of pain was done and it was found that Nutool therapy reduced the intensity of pain, and it was found statistically significant $P < .005$ (ANOVA of repeated measures) Friedman statistic $F_r = 17.76$. Nutool therapy also reduced the MIDAS (migraine disability assessment score) and was statistically significant ($P < .0047$) and was effective on intensity of headache and found statistically significantly $P < .0001$. Further studies need to be carried out so that it can be advocated on large scale in management of migraine effectively.

Keywords: Migraine, Nutool, Rogan-e-Gul, MIDAS, VAS, Pain.

Introduction

Shaqqa (migraine) is a complex disorder characterized by recurrent attacks or episodes of headache, most often unilateral, accompanied by other neurologic and gastrointestinal symptoms.¹ It is the most common headache that leads to medical attentions.² Migraine is one of the oldest medical condition afflicting mankind. It is a form of primary headache derived from term "hemicrania".^{34,35} Its historical background dates back to Mesopotamian era but first written documentation was done by Buqrat (Hippocrates), also further description about its location and cause was given by Jalinoos (Galen).^{34,35,36} Migraine presentation is multifaceted with symptoms emanating from multiple systems, including vascular, neurologic, gastrointestinal, endocrine and visual.¹ Ancient people held the myth that headache was a sign of evil spirits, and its evidence along with ancient remedies to relieve what was thought to be head pain can be traced 7000 years back.³⁷

The core features of migraine include recurrent headache that is often unilateral, gastrointestinal symptoms such as nausea, or vomiting, and hyperesthesia manifested by photophobia and phonophobia. The headache generally has a pulsatile and throbbing quality, and the pain is exacerbated by routine physical activity involving movements of the head.¹ This disorder is typified as much by nausea and photophobia as it is by pain because of the severity of pain associated with migraine.²

In Unani literature, shaqqa (migraine) has been described under the heading of suda (headache) in most of the classical Unani text as a disease entity.^{21,22,24} The term shaqqa has been derived from an Arabic word 'shaq' which means a part or a side, hence it has been named as shaqqa.²⁴ It is called hemicrania in Greek.^{30,31,33} The English counterpart of shaqqa is migraine.³² Hippocrates (460-377BC), was the first to described a collection of symptoms which comprises aura, pain and vomiting as part of a singular disorder.^{28,29,30,31}

Hippocrates, released shaqqa (migraine) from the realm of the supernatural by attributing it to vapors rising from stomach to the head. He proposed that headache can be triggered by exercise or intercourse, and vomiting could partially relieve the pain of headache.²⁷

Ilaj bit Tadbeer (regimental therapy) is one among the four modes of treatment in Unani system of medicine. *Nutool* (Irrigation) is one among various regimenal therapies. It is useful for various types of chronic ailments and various lifestyle disorders.^{1,2}

Unani system of medicine claims to possess possible treatment for migraine without aura and offers a number of drugs and therapy including (including *Nutool*) for this purpose. Almost all Unani physicians have advocated *Nutool* therapy in the management of migraine (Shaqqa), particularly with or without medicated oil or liquid, but unfortunately these have not evaluated on scientific parameters. Despite the fact that, this therapy is in the practice of Unani physician and a large number of patients have been treated successfully; this regimen still requires scientific validation to generalize their popularity and acceptability.

Present paper is the case series of diagnosed migraine patients to assess the effect of *Nutool* therapy on headache intensity, MIDAS scale and Pain intensity.

Materials and Method

The present study entitled "Case Series to evaluate role of *Nutool* Therapy on Headache frequency (from the daily headache diary), MIDAS (migraine disability assessment score) headache intensity by VAS in diagnosed cases of Shaqqa (Migraine) in patients attending HAHU and SUMER, Jamia Hamdard Delhi was conducted in the Department of Tahaffuzi-wa-samaji Tib, SUMER, Jamia Hamdard, New Delhi during the period of September 2020 to Nov 2020 in Psychiatric OPD of HAHC Hospital, Jamia Hamdard, New Delhi on diagnosed Patients of Migraine as per ICHD^{3rd} (International classification of headache disorders) Criteria.

Inclusion criteria

- Diagnosed patients according to ICHD=3rd criteria
- Patients between 18-60 years of age
- Patients under MIDAS Grade(I-III)
- Patients under VAS score (0 to 4-6)
- Males, Females and Trans-genders.
- Willing to complete daily headache diary
- Willing to take *Nutool* therapy with Roghan-e- Gul

ICHD Criteria

- A. At least 5 attacks per year
- B. Each attack, lasts 4-72 hours (Untreated or Unsuccessfully treated)
- C. The attack has at least 2 of the following characteristics;
 - Unilateral location
 - Pulsating quality
 - Moderate or severe intensity (Inhibiting or prohibits daily activities)
 - Pain aggravated by routine physical activity
- D. During an attack at least 1 of the following should be present.

a. Nausea or Vomiting

b. Photophobia, or Phonophobia

E. Not attributed to any other disorder

Exclusion criteria

- Patients below 18 and above 60 years of age
- Patients under MIDAS Grade (IV)
- Patients under VAS score (7-8 to 9-10)
- Pregnancy and lactation
- Patients with known skin disorder
- Known Drug users of Glucocorticoids
- Major medical illness under treatment
- Patients with known psychiatric and mental disorders
- Participation in another study or previous participation in similar study.

Informed consent

The subjects fulfilling the inclusion criteria were informed in detail regarding the nature of study, method of *Nutool* (Irrigation) and the procedure involving the subjects. A printed sheet containing the information was used for this purpose (see annexure). Subjects who could read or their family members who could read were provided this sheet or its vernacular translation. They were given the opportunity to ask any question and if they agreed to participate in the study, they were asked to sign the informed consent sheet.

Duration of protocol therapy: 30 Minutes

Total sittings: 12

Follow ups on alternate days for first two weeks followed by twice weekly next two weeks.

Clinical examination to assess

- Frequency of headache (Headache diary)
- MIDAS Scoring
- Headache intensity by VAS

Study protocol

On the basis of above criteria patients were selected from psychiatry opd, HAHC hospital, Jama Hamdard New Delhi and subjected for further evaluation, enrolled after explaining the study in detail and receiving the informed consent form.

Study Procedure

Patients fulfilling the inclusion criteria were enrolled in the present study. The patients were assessed clinically by the relevant history taking, general physical examination, systemic examination of nervous system and other acquired parameters. Socioeconomic status was assessed by Kuppuswamy's socioeconomic status scale modified for 2017. All the information was recorded in the case record form designed for the study. After through evaluation of patients by history and clinical examination. Patients were enrolled in the study after obtaining written voluntary informed consent.

Roghan-e-gul manufactured by Hamdard laboratories (India)

Each 100ml of this preparation contains:

Gul-e-surkh (rosa domestica) (petals) 15.0gm

Roghan kunjad (sesamum indicum) 100.0gm

Efficacy Assessment

The assessment of the efficacy of Nutool with Roghan-e-Gul was based on subjective and objective parameter.

Subjective parameters

Headache location (unilateral or bilateral & pulsating or non-pulsating quality) nausea, vomiting, photophobia and phonophobia.

Objective parameter:

- Headache frequency (from the daily headache diary)
- MIDAS (migraine disability assessment score)
- Headache intensity by VAS (Visual analogue scale)

These were assessed before and after treatment. But subjective parameter was assessed on every 0-day, 15th day, 30th day and 45 day by simple asking patients either presence or absence of subjective parameter.

Scales used for subjective parameters

Scale for nausea and vomiting, photophobia and phonophobia

Present	p
Absent	A

Scales used for objective parameters

Arbitrary grading scales for headache frequency

Grades		No. of headache per 15 days
Grade 0		No headache
Grade 1		1-2 times/15days
Grade 2		3-4 times/15days
Grade 3		5-6 times/15days
Grade 4		>= 7 times/15 days
MIDAS Grade	Definition	MIDAS Score
Grade I	Little or No Disability	0-5
Grade II	Mild Disability	6-10
Grade III	Moderate Disability	11-20
Grade IV	Severe Disability	>21

Visual analogue scale for intensity of pain (VAS)

Grade 0 (None), Grade 1 (Mild 1-3), Grade 2 (Moderate 4-6), Grade 3 (Severe 7-10)

Procedure of Nutool therapy

Nutool Therapy with *Roghan-e-gul* manufactured by 'Hamdard Laboratories' will be done on forehead for 30 minutes on alternate days for 2 weeks followed by twice a week for 2 weeks.

Before starting the therapy, eyes were protected by keeping a cotton swab soaked in plain water over the closed eye lids. Medicated oil continuously poured by *Nutool* apparatus in rhythmic stream from a distance of approx. 65cm over forehead of patient lying in supine position.

RESULTS

The mean age of the patients was 28 ± 6.85 and all the participants were females (100%). Majority of the patients were Hindus (66%) and 33% were Muslims and. More than half of the patients were 66% were married and from middle class. All the patients had unilateral headache. Almost all had chronic migraine with duration ranging from four years to nineteen years. Only one patient had migraine form 2-3 years. Headache was pulsating in all the cases and five out of six had moderate intensity headache while only one had mild intensity pain. Four patients had aggravated headache with sunlight exposure. In majority of the patients Vomiting (50%), Nausea (75%), Photophobia (75%), Phonophobia (50%) was associated with migraine. Most of the patients were vegetarian and had strong family history of migraine (4). No addiction and comorbidity was found. The analysis of Nutool therapy on intensity of pain was done and it was found that Nutool therapy reduced the intensity of pain and it was found statistically significant $P < .005$ (ANOVA of repeated measures) Freidman statistic $Fr = 17.76$. (Table 1, Figure 1). Analysis of Nutool therapy on MIDAS (migraine disability assessment score) was analysed and it was found that Nutool therapy reduced the MIDAS (migraine disability assessment score) and was statistically significant ($P < .0047$). (Table-2, Figure-2). The analysis of Nutool therapy was assessed on intensity of headache and was found that Nutool therapy reduced the intensity of pain and it was found statistically significantly $P < .0001$, $q > 4.076$. The analysis of effect of Nutool therapy on vomiting was seen and was found statistically significant $p < 0.0211$. There was decrease in other symptoms as well as photophobia, phonophobia, nausea and vomiting.

Table 1: Analysis of Nutool therapy on intensity of pain N=6

HEADACHE FREQUENCY				
Day 0		DAY 15	DAY 30	DAY 45
	3	2	1	0
	5	3	1	0
	10	8	5	2
	4	3	1	0
	9	6	6	3
	6	4	2	0

Inference: The analysis of Nutool therapy on intensity of pain was done and it was found statistically significant $P < .005$ (ANOVA of repeated measures) Freidman statistic $Fr = 17.76$.

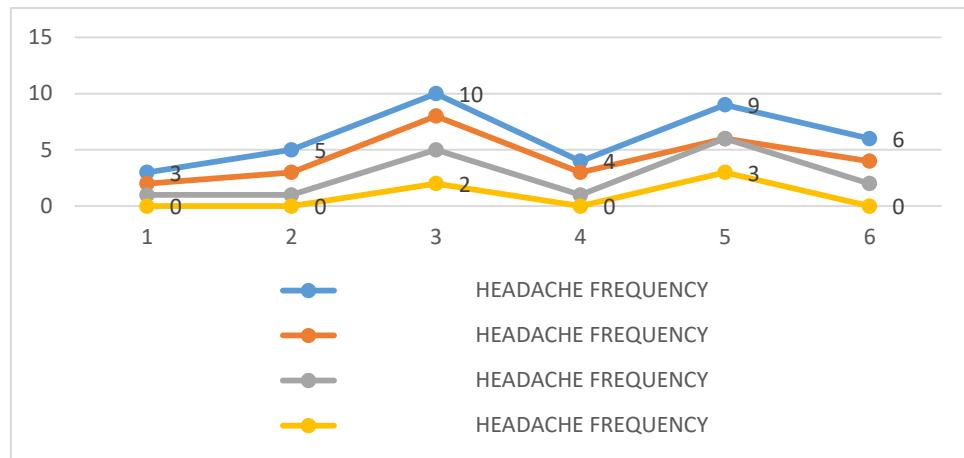


Figure 1: Analysis of Nutool therapy on intensity of pain

Table 2: Analysis of Nutool therapy on MIDAS

MIDAS				
DAY 0	DAY 15	DAY 30	DAY 45	
6	3	1	1	
11	11	6	2	
16	12	5	2	
5	2	1	1	
12	11	11	5	
12	6	3	1	

Inference: Analysis of Nutool therapy on MIDAS was analysed and it was found statistically significant $P < .0047$.

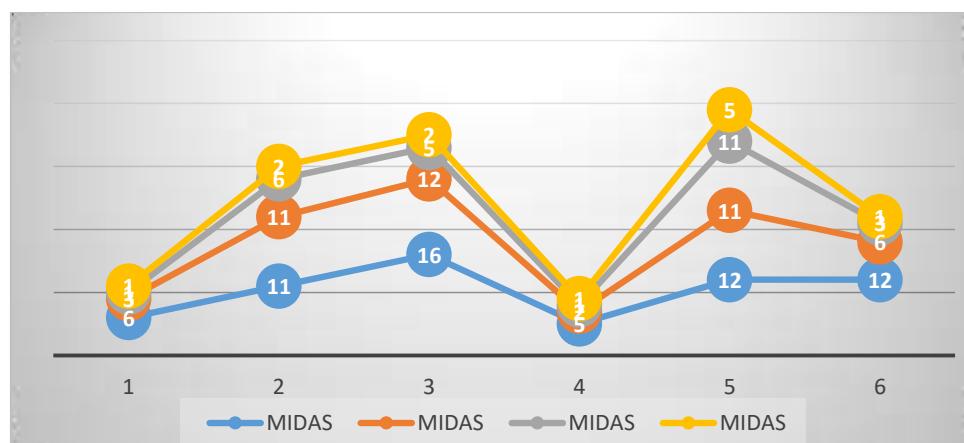


Figure 2: Analysis of Nutool therapy on MIDAS

Table 3: Analysis of Nutool therapy on headache intensity

HEADACHE INTENSITY				
DAY 0	DAY 15	DAY 30	DAY 45	
4	1	0	0	0
6	3	1	0	0
6	5	4	1	1
3	0	0	0	0
6	3	4	0	1
5	2	0	0	0

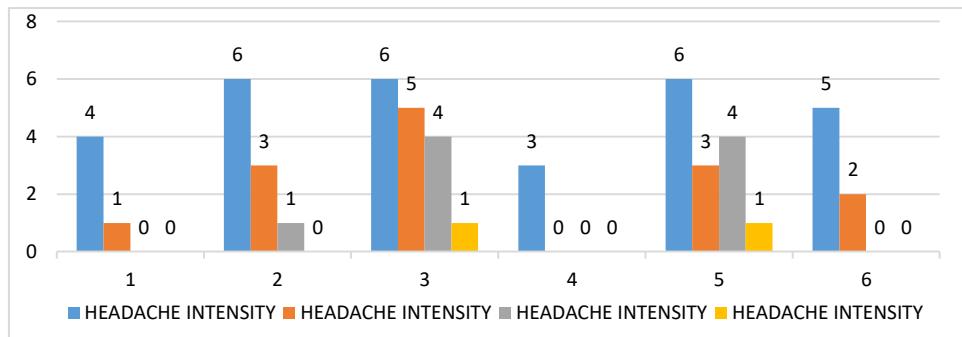


Figure 3: Analysis of Nutool therapy on headache intensity

DISCUSSION

Nutool is very effective mode of regimental therapy for various types of chronic ailments and various lifestyle disorders including migraine. *Nutool* therapy (Irrigation therapy) works on the principle of Tahālīl (resolution), Taskīn (sedation), Tartīb (moistness) and Tadīl-i-Mizaj (temperamental rejuvenation).^{3,4,5,6}

Rogan e gul is a, nervine tonic, analgesic, aperient¹⁸, murattib¹⁷, Mufatteh, musakkin e dard¹⁷, musakkin e hararat e safra¹⁷, radeh, muhallil, muhallil e auram.^{17,20} For Tabreed, Talaiyun e amma¹⁹, Mudammi e quru, musakkin e qumar, qateh bah.¹⁷

A 2006 study in the journal of ethnopharmacology elucidated its antispasmodic effect. In this study, researchers found a potent relaxant effect of R. Damascene oil on the tracheal chains of laboratory animals.¹⁶

In 2007 university of central Lancashire in UK demonstrated anti-anxiety effect of rose oil in laboratory animals exposed to the scent of rose oil.¹⁶

Nutool therapy is effective in Migraine as it induces relaxation similar to that in medication which is reflected by decreased heart rate, bradycardia, lowered sympathetic tone, slowing of alpha waves on EEG, decreased tidal volume and CO₂ excretion. *The effect of Nutool therapy on migraine is due to its functions as Musakkin e alam* (analgesic), *Mukhaddir* (sedative), *Murattib* (emollient), *Mubarrid* (cold), *Munavvim*(hypnotic) &*Muqawi e dimagh*(brain tonic properties)⁷⁻¹⁰

Uebeba et.al declared that the neuro-physiological mechanism of the consequences of irrigation on the psycho-physiological changes is also associated with the tactile stimulation of the skin or hair follicles innervated by the primary branch of the trigeminal nerve nerves.¹¹ *Nutool*, if done on forehead has been proved to own psycho-neuroimmunology effects that additionally ends up in anxiolysis. organic chemistry changes embrace suppression of nor vasoconstrictive, decrease of PMN/lymphocyte magnitude relation and alpha receptors that recommend a sympathetic suppression instead of parasympathetic activation.¹² The impulses from the forehead cause a stimulation of the trigeminus and additionally a somato-autonomic reflexes and changes in levels of varied neurotransmitters as well as monoamine neurotransmitter and hormone, leading to sympathetic suppression and physio immunologic changes of peripheral circulation and natural killer T cell activity.^{11,12}

The perennial stimuli area unit required for consolidation of this data that desires 5-10 minutes and concerning one hour for stronger consolidation. this can be logic and rationalization of completing *Nutool* for concerning 30-45 minutes. Regular or continuous pressure input generates continuous impulse to the central system thereby endlessly stimulating central nervous system. active this procedure frequently for 15days

might cause long lasting stimulation of central nervous system.^{2,11,13}

The *Nutool* therapy has been proved to induce a sense of relaxation. The oils and decoctions in *Nutool* medical care, absorbed through skin, have curative edges and therapeutic effects area unit achieved by the utilization of specific medicine. several studies are disbursed to grasp the efficaciousness of varied oils utilized in *Nutool* medical care.^{2,14}

Nutool, if done on forehead has been proven to have psycho-neuroimmunology effects which also leads to anxiolysis. Biochemical changes include suppression of nor adrenaline, decrease of PMN/lymphocyte ratio and alpha receptors which suggest a sympathetic suppression rather than parasympathetic activation.¹² The impulses from the forehead cause a stimulation of the trigeminal nerve and also a somato-autonomic reflexes and changes in levels of various neurotransmitters including serotonin and catecholamine, resulting in sympathetic suppression and physio immunologic changes of peripheral circulation and natural killer cell activity.^{2,11}

A similar study conducted by Umar Fazal et.al 2021 in NIUM Bangalore has yielded similar results. This was a open, single-arm, exploratory clinical study was conducted in 30 patients of chronic migraine selected by convenient sampling method. One litre decoction prepared with 12 g each of *Astragalus hamosus* L. (*Iklilul malik*), *Matricaria chamomilla* L. (*Babuna*), *Artemisia absinthium* L. (*Afsanteen*), *Origanum vulgare* L. (*Marznjosh*) and *Trigonella foenum graecum* L. (*Hulba*) was poured over painful side of head for 45 minutes on every alternate day for a period of 30 days (15 sittings). The patients, thereafter, were followed until 90th day of the study for various outcome measures comprising headache intensity, headache frequency, Migraine Disability Assessment Scale (MIDAS), and rescue medication. The reduction in headache frequency, MIDAS score and use of rescue medication was significant ($p < 0.001$) after the treatment. Reduction in headache intensity at 30th day, 60th day and 90th day was significant as compared with baseline values ($p < 0.001$) but not statistically significant at 90th day with respect to 60th day ($p > 0.05$). Statistical analysis was done using parametric (paired t-test) and non-parametric tests (Wilcoxon sign ranked test, Friedman with Dunn's multiple comparison tests). Hot irrigation with medicated decoction was found effective in the treatment of chronic migraine which is in accordance with present study.

CONCLUSION

It can be concluded that the *Nutool* therapy has been proven to induce a feeling of relaxation and has effectively reduced the intensity of Pain, MDAS in shaqqa (Migraine). The oils and decoctions in *Nutool* therapy, absorbed through skin, have curative benefits and therapeutic effects are achieved by the use of specific drugs. Further studies need to be carried out to

establish the role of Nutool in Migraine and this regimental therapy can be advocated with conventional medicines too which will help to decrease the drug dependency in migraine patients.

Conflict of Interest: None

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