



Effect of *Dalk Layyen* with *Roghane Gule Aakh* in Cervical Spondylosis – A Pre and Post analysis Clinical study

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Abstract

Dalk Layyen is a type of gentle massage and it is being in use to treat various musculoskeletal ailments including joints pain. An observational trial pre and post analysis was conducted to evaluate the effect of *Dalk layyen* (Gentle Massage) with *Roghane Gule Aakh* a pharmacopoeial Unani poly herbal formulations oil. Intervention was carried out in 15 patients over a period of 21 days. Primary outcome measure was VAS and NPQ. Secondary end points consisted of all other subjective parameter i.e Axial neck pain / radiating neck pain, tenderness of the neck, difficulty in neck movement and paraesthesia in upper extremities. Paired 't' test and fisher exact test were used for statistical analysis. Significant improvements in objective parameters were observed after 21 days of treatment. The mean of pain was reduced and shows highly significant result ($P < 0.001$) reduction in tender level was observed in 40 % of patients ($P < 0.005$) no significant change in paraesthesia and no change in Spurling and the Neck Distraction Test. Highly significant change ($p < 0.001$) was observed in NPQ.

Keywords: Cervical Spondylosis, *Dalk layyen*, *Roghane Gule Aakh*, Unani Medicine.

Introduction

Cervical Spondylosis (CS) stands for the degenerative arthritis, osteoarthritis of the cervical vertebrae and related tissues¹. It is characterised by degeneration of the intervertebral discs and osteophytes formation². It is often asymptomatic but may cause radiating neck pain into the back of the head, shoulder, arm, or may be the source of headache in the posterior occipital region^{1,3} as per the estimations more than 50% of adults experience neck pain every year, and 60–80% of older adults experience it due to degenerative changes⁴.

Cervical spondylosis should be managed through physical or non pharmacological, pharmacological and/or surgery, the non pharmacological treatment includes lifestyle modification, exercise of neck, application of heat /cold, use of cervical collar, mechanical cervical traction, massage, acupuncture, electrotherapy, therapeutic ultra sound, laser and Non-steroidal anti-inflammatory drugs (NSAID's), opioid analgesics, muscle relaxants, antidepressants, anticonvulsants, corticosteroid drugs^{4,7}.

In Unani medicine arthritis of various parts of the body including Unuq (neck) was treated with the principle of *Ilaj bil zid*, with certain regimens like *Dalk* (massage), *Hijamat* (cupping), *Takmeed* (fomentation), *Tila* (liniment), *Zimad* (Paste), *Fasad* (venesection) etc⁸. Pharmacologically it will be treated with single and compound drugs prescribed for *waja ul mafasil* such as *Suranjan* (*Cholichicum luteum*), *Gule Aakh* (*Calotropis gigantea*), *Muqil* (*Cammiphora mukul*), *Zanjabeel* (*Zingiber officinalis*), *Rogane Shibit*, *Roghane Gul*, *Roghane Baboon*, *Roghane Chanbeli*, etc⁹.

Dalk is literally known to as massage, and it is defined as manipulation, methodical pressure, friction, and kneading of the body¹⁰. A treatment through gentle massage that involve rubbing and kneading the muscle either for medical or therapeutic purpose or simply as an aid to relax¹¹.

Dalk is also defined as a form of *riyazat* under taken by means of hands as manipulative technique over the muscles^{12,13}. *Dalk layyen* is a type of local massage carried out manually. It is also defined as a form of qualitative type of massage, is being under taken very gently. This massage will helps in opening of the skin pores, diversion and expulsion of acrid matters, make organ soft and relaxes the muscle^{14,15}.

Roghane Gule Aakh is pharmacopoeial poly herbal medicated oil is indicated in several types of *waja ul mafasil*, as it possess anti inflammatory and analgesic property¹⁶. It is being advocated and practiced in Unani system of medicine for several ailments of musculo-skeletal system. Whilst, its effects was never been evaluated on scientific parameter, therefore, to evaluate the safety and effect of *Roghane Gule Aakh* with *Dalk layyen* a clinical trial was contemplated

Methodology

This study was a single-centered, open pre and post analysis clinical trial conducted on 15 patients for a period of 21 days with 3 follow ups of each week. This study protocol was approved by the IEC of NIUM, after obtaining written informed consent by strictly adhering to the GCP guidelines this study was conducted.

A total of 80 patients of Cervical Spondylosis were screened, out of them 25 patients fulfilled inclusion criteria, but 16 cases participated in the study as patients of Cervical Spondylosis with or without radicular symptoms, either sex, between 20-60 years of age. Patients having other than osteoarthritis of neck, neck trauma, local wound and infection over neck, all chronic diseases and unwilling to participate in the study were excluded from study.

Test drug: The ingredients of *Roghane Gule Aakh*¹⁶ e.g., *Zanjabeel* (*Zingiber officinalis*), *Suranjan Talkh* (*Cholchicum luteum*), *Roghane Kunjad* (oil of *Sesamum indicum*) were procured from the licensed drug dealers of Bangalore city, and fresh *Gule Aakh* (*Calotropis gegentia*), were collected from the herbal garden of NIUM, oil was prepared under the supervision of chief pharmacist as per the methods described in the texts and GMP.

Dalk Layyen (gentle massage) was performed bilaterally over the cervical region with 10-15 ml with *Roghane Gule Aakh* daily for 15 minutes up to 21 days.

The data was analyzed statistically to measure the study outcome based on the pre and post trial subjective and objective observation. The results on continuous measurement were presented on Mean ± SD and the results on categorical measurement presented in number percentage. Significance was assessed on 5% of level. Pair Student 't' test was used to find the significant the study parameter on continuous scale within group. Fisher exact test was used to find the significance of the study parameter on categorical scale.

The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word have been used to generate tables.

Results and Discussion

Out of 16 patients 15 completed the study as per protocol and 1 lost the follow up. This study evidences 11 (73.3%) of the participants were females, with mean age of 41.70 (SD=10.84) yrs. Socioeconomically 1(6.7%) patients belongs to upper, 5 (33.3%) to upper middle, 5 (33.3%) to lower middle and 4 (26.7%) to upper lower class as assessed by the kuppuswamy socioeconomic scale. Out of 15 patient 14 (93.3%) were married, and the *Mizaj* (temperament) of 12 (80%) patients were *Balghami* (phlegmatic) and 3 (20%) had *Damvi* (sanguineous) temperament. The BMI was observed <25 in 6 (40%) and >25 in 9 (60%) of patients (table-1). 10 (66.7%) patients found with radiating pain and 5 (33.3%) axial pain. (table-2).

The VAS score on pain before treatment was observed as 6.3±0.90 (Mean ±SD) and after treatment it came down up to 2.53±1.51 (P<0.001). The Northwick Park Neck Pain Questionnaire (NPQ) was observed before treatment as

47.80±9.58 and after treatment value as 25.60±9.19 with (P<0.001) (table-3). Similarly, neck movement score was observed before treatment as 2.04±0.74, and after treatment as 1.13±0.35 (P<0.001) (table-4). Tenderness decreased by 40% (P<0.005) and paraesthesia by 13.3% (P<0,024) (table-5). No change was observed in Spurling Test (ST) and Neck Distraction Test (NDT) (table-6).

Over the course (i.e. 21 day) of the study, the improvement in pain, NPQ, tenderness, and difficulty in neck movement was statistically significant on 1st follow up (i.e 7th day) which shows amelioration of symptoms in subsequent follow-ups. Throughout the study no adverse effect of *Dalk* with *Rogan Gule Aakh* was observed.

Table-1
Demography of patients

Demographic parameters	Statistical units	No. of patients with percentage (n=15)
Age	21-40 year	6(40%)
	41-60 year	9 (60%)
Gender	Male	4(26.7%)
	Female	11(73.3%)
Marital status	Married	14(93.3%)
	Unmarried	1(6.7%)
Dietary Habit	Mix	8(53.3%)
	Veg.	7(46.7%)
Socioeconomic status	Upper	1 (6.7%)
	Upper Middle	5 (33.3%)
	Lower Middle	5 (33.3%)
	Upper Lower	4 (26.7%)
Occupation	Business	3(20%)
	Skilled worker	3(20%)
	House wife	7(46.7%)
	Others	2(13.3)
Mizaj	Balghami	12(80%)
	Damvi	3(20%)
BMI (kg/m ²)	<25	6(40%)
	25-30	9(60%)

Table-2
Chronicity and nature of pain

Duration of illness	1-5 month	1(6.7%)
	6-10 month	3(20%)
	>10 month	11(73.3%)
Nature Of Pain	Radiating	10(66.7%)
	Axial	5(33.3%)

Discussion: Since the cervical spondylosis needed long term therapy, as such conventional medicine have limited option in treatment and also carries substantial risk for serious adverse effects. Hence, new therapeutic approaches should be explored. *Dalk* with *roghaniyat* (oil massage) is one of the choice of

therapy is being used for treating pain and functional disability associated with cervical spondylosis.

Table-3

Effect of intervention on pain with Visual Analogue Scale and Northwick Park Neck Pain Questionnaire

Objective Parameters	Mean ± SD		Mean difference	t Value	P Value
	Before treatment	After treatment			
VAS	6.33±0.90	2.53±1.51	3.80	12.838	<0.001
NPQ	47.80 ± 9.58	25.6 ± 9.19	22.20	9.348	<0.001

Table-4

Effect of intervention on Difficulty in neck movements

Difficulty in neck movement	Mean ± SD		Mean difference	t Value	p Value
	Before treatment	After treatment			
	2.47±0.64	1.13±0.35	1.27	6.97	<0.001

Table-5

Effect of intervention on tenderness and paraesthesia

Subjective Parameters	Grade	Before treatment	After treatment	Percentage change
Tenderness	0	3(20%)	9(60%)	40%
	1	10(66.7%)	6(40%)	-26.7%
	2	2(13.3%)	0(0%)	-13.3%
Paraesthesia	Absent	7(46.7%)	9(60%)	13.3%
	Present	8(53.3%)	6(40%)	-13.3%

Table-6

Effect of intervention on Neck Distraction Test and Spurling Test

Objective parameters	Absent / present	Before treatment	After treatment	Percentage changes
Neck Distraction Test	Absent	11(73.3%)	11(73.3%)	0.0%
	Present	4(26.7%)	4(26.7%)	0.0%
Spurling Test	Absent	3(20%)	3(20%)	0.0%
	Present	12(80%)	12(80%)	0.0%

The mean age of study population was 41.07 years which is in accordance with McPhee SJ et al¹⁷ and Reddy RS et al¹⁸. 73.3% of the study population belongs to females which indicates that the prevalence of disease is higher among females that correlates with the findings of Cote et al¹⁹ and Gram et al⁵. On the assessment of the *mizaj* by using *Ajnase ashra*, it was observed that 80% patients having *balghmi mizaj*, this indicates that *balghami* temperament is directly associated with CS, which coincides with the description of Unani physician like *Razi*, *Ibn Sina*, *Ibn Hubal Baghdadi*, *Akbar Arzani*, *Samar Kandi*, and *Aazam Khan*^{8,20-24}.

As *Ilaj bil Zid* is the basic principal of treatment in Unani system of medicine, the ingredients of *Roghane Gule Aakh* are hot in temperament and the temperament of disease is *Balghami* (cold).

It can be stated that *Roghane Gule Aakh* has potential to restore the temperament through *Ta`deele mizaj*. The effects of the study on neck pain showed highly significant in decreasing pain (P<0.001), similarly difficulty in neck movement and NPQ also suggest highly significant. Whereas, the tenderness shown moderate significant improvement (P=0.005) and paraesthesia has no significant change (P=0.241) and no change had been observed in Spurling and Neck Distraction Tests. The observation on neck pain, neck movement and NPQ showed progressive effects in every follow up. This progressive improvement indicates that treatment for longer duration is needed to control the symptoms of Cervical Spondylosis.

The effect of *Dalk Layyen* with *Roghane Gule Aakh* supports the observations of Triala LA et al (2013), Sherman KJ et al (2010), Avery RM et al (2012) studies on the effects of massage alone in alleviating pain, difficulty in movements and tenderness associated with Cervical Spondylosis^{4,25,26}.

The scientific reports on the ingredients of *Roghane Gule Aakh* reveals that *Suranjan Talkh* (*Colchicum luteum*) posses anti inflammatory and analgesic activity. In a study it was found that hydroalcoholic extract of *colchicum luteum* reduced significantly the level of serum TNF- α ^{27,28}. A study on *Zanjabeel* (*Zingiber officinalis*) by Gill Pramdeep reported that it has analgesic and anti inflammatory property²⁹ in another study it was reported as ginger supplement significantly reduced the level of inflammatory mediator (TNF- α , IL-6 and hs-CRP). A study carried out on isolation of preliminary phytoconstituents and anti inflammatory, antipyretic activity of *Calotropis gigantea* extract reported that it has anti inflammatory and antipyretic effects^{30,31}.

According to Unani medicine *Dalk layyen* helps in opening of the skin pores, diversion and expulsion of acrid matters, make organ soft and relaxes the muscles^{15, 14} the possible mechanism of action of massage may conceptualized that it increases blood flow in the muscle, decrease in neuromuscular excitability.

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Conclusion

It can be concluded that *Dalk* with *Roghane Gule Aakh* has potential to ameliorate the symptoms and functional disability associated with Cervical Spondylosis. The inherent limitation of the study was smaller sample size, shorter duration of the study and study design. It is recommended that study with largest sample size and for longer duration with modified methodology is needed.

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