Clinical Study of Wajah-Uz-Zahr (LUMBAGO) and its Management with Hijama-Bil-Shurth (Wet Cupping)

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Abstract: <u>Background and Introduction</u>: Waja uz zahr(Alam fi safiluz zahr, Waja ul Khasirah) or Low back pain (LBP), also known as lumbago, is a common condition affecting the muscles, nerves, and bones of the back, located between the lower edge of the ribcage and the lower fold of the buttocks. Pain can range from a faint aching to a strong stabbing sensation. Low back pain can be classified as acute (lasting less than 6 weeks), sub-chronic (6 to 12 weeks), or chronic (lasting more than 12 weeks). Depending on the underlying cause, the condition can be characterised as mechanical, non-mechanical, or referred pain. Though lumbago is not a specific disease in modern medicine rather, it is a symptom that might develop as a result of pathology caused by a range of conditions. Discomfort in the lumbosacral area is a common symptom of low back pain. It affects between 60-85 percent of the population, putting a significant strain on society. But in UNANI MEDICINE many physicians and scholars considered it as disease and at the same time symptom for many diseases. In the Unani school of medicine have specified numerous medications and regimens for the treatment of Waja'uz zahr (LOWBACK PAIN) in their classical books. So, with this in mind, the Hijama -Bil-Shurt regimen was chosen. The purpose of this study was to determine the effectiveness of Hijama- bil- shurt in the treatment of Waja'u zahr (LUMBAGO). Materials and Methods: From September 2020 to July 2022, the study was done as an openlabelled single Arm clinical trial with a total of 20 individuals suffering from low back pain. Patients were administered for Hijama -bil- shurt(wet cupping), In total, four (4) sittings were completed in 28 days. Base line day (0 Day) and before the treatment and after the treatment $(21^{st} day)$ the patients were examined using the Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI). Outcomes were compared and statistically examined. <u>Results</u>: After intervention, highly significant (p<0.001) reduction was observed in VAS scale (8.2±1.794 to 1.65±1.34) as well as ODI score (25.0±6.223 to 6.0±1.7199). Interpretation & Conclusion: This study reveals that Hijama bil shurt found significant in the treatment of Lumbago, Hijama- bil- shurt (Wet Cupping)appears to be effective in reducing pain and increasing function and quality of life in patients with Waja-uz- zahr.(Lumbago)

Keywords: Low back pain, Waja-uz- zahr, Hijama-bil- shurt, wet cupping, lumbo-sacral

	N N N N N N N N N N N N N N N N N N N		
%	Percentage	ESR	Erythrocyte Sedimentation Rate
<	Lesser than	et al.	et alli or et alia (and others)
>	Greater than	etc.	et cetra (other similar things)
AD	Anno Domini	Govt.	Government
AIDS	Acquired Immune Deficiency Syndrome	Н	Hindu
AT	After Treatment	Hb%	Hemoglobin
В	Basophils	BT	Bleeding Time
B.C CT	Before Christ Clotting time	HIV	Human Immune- Deficiency Virus
B/L	Bilateral	HTN	Hypertension
BT	Before Treatment	i.e.	idest (that is)
С	Christian	ICMR	Indian Council of Medical Research
CR	Central Registration	IEC	Institutional Ethics Committee
CRF	Case Report Form	IPD	Inpatient department
DALYs	Disability Adjusted Life Years	L	Lymphocytes
DLC	Differential Leukocyte Count	LC	Lower Class
DM	Diabetes Mellitus	Μ	Married
DOP	Duration of Pain	Μ	Muslim
E	Eosinophils	Mix	Mixed
ECG	Electrocardiograph	MS	Marital Status
e.g.	exempli gratia (for example)	CTRI	Clinical Trail RegistryIndia
GNTC	Govt.Nizamia Tibbi College and GeneralHospital	no.	Number
NSAIDs	Non steroidal Anti Inflammatory Drugs	ODI	Oswestry Disability Index
OLBPS	Oswestry Lower Back Pain Scale	Р	Polymorphs
RA	Rheumatoid Factor	RBS	Random Blood Sugar
REL	Religion	S.E.S	Socioeconomic Status
Sl.	Serial	TLC	Total Leukocyte Count
ULC	Upper lower Class	UM	Unmarried
UMC	Upper Middle Class	VAS	Visual Analogue Scale
OLBP	Oswestry low back pain scale		

List of Abbreviations and Symbols Used

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1. Introduction

Aim

To treat the patients of Waja uz zahr(Lumbago) with hijama bil Shurth(Wet Cupping)

Objective

- To evaluate the effect of Hijama bil shurt in the management of Waja'uz zahr.
- To evaluate the patient's perceived improvement and change in quality life of in Waja-uz- zahr patients.

2. Review Literature

- 1) Buqrat (460- 377 BC), the father of medicine first described back pain with its cause as preponderance of balgham (phlegm) in the body, also if the patient feels numbess and burudat in calf muscles and back it indicates chronic condition.
- 2) Aurelianus (5 AD) clearly described the symptoms of sciatica. He noted that sciatica arose from either hidden causes or observable causes, such as a fall, a violent blow, pulling, or straining.
- Zakaria Razi (865- 925 AD), described low back pain as Waja'uz zahr, Dard- e- pusht, with its etiology mainly being trauma, disc prolapse and spinal abscesses.
- 4) Ibn Sina's (980- 1037 AD), view on low back pain is as Dard-e-pusht, which mainly happens in the muscle and ligament of the back internally as well as externally, which can be distinguished by palpating the external surface of the back, which evidences presence of tenderness.
- 5) Akbar Arzani (1721 AD) described Waja'uz zahr as Dard-e-pusht with its classification based on the etiology of disease.
- 6) Hakim Ghulam Jilani described different causative factors of Waja-uz- Zahr such as Thakan, Laghri and excessive labour etc.
- 7) Virchow (1857 AD) and Kocher (1896 AD) described acute traumatic ruptures of the intervertebral disc that resulted in death. The correlation between the disc rupture and sciatica was not appreciated by these examiners.
- 8) Oppenheim and Krause (1909 AD), performed the first successful surgical excision of a herniated intervertebral disc. Unfortunately, they did not recognize the excised tissue as disc material and interpreted it as an enchondroma.
- 9) In early 1900's displacement and distraction of the sacroiliac joint was felt to be a common etiology for pain.
- 10) Goldthwait (1911 AD) ascribed back pain to posterior displacement of the disc and postulated that the oddness of the facet joints were responsible for low back pain and instability.
- 11) Dandy and Alajouanine (1929 AD) reported removal of a disc tumor, or chondroma, from patients with sciatica. The commonly held opinion of that time was that the disc hernia was a neoplasm.
- 12) Mixter and Barr (1934 AD) attributed low back pain and sciatica to lumbar disc herniation. This report also included a series of four patients with thoracic disc

herniations, and four patients with cervical herniations.

- 13) Semmes and Love (1939 AD) presented a new procedure to remove the ruptured intervertebral disc that included subtotal laminectomy and retraction of the dural sac toexpose and remove the ruptured disc with the patient under local anesthesia. This procedure, now the
- 14) Classic approach for the removal of an intervertebral disc, has been improved with the use of microscopic and video imaging. As more people were treated for herniated lumbar discs, it became obvious that surgery was not universally Successful. Over the past several decades, studies of patients with back or leg pain have led to improved treatment of those in whom a specific diagnosis was possible. Unfortunately, this group remains the minority of patients who are evaluated for low back or leg pain. Complex psychosocial issues, depression, and secondary gain are a few of the non anatomical problems that must considered when evaluating these patients. In addition, the number of anatomical causes for these symptoms increased as our understanding and diagnostic capabilities have increased. In an attempt to identify other causes of back pain Mooney and Robertson popularized facet injections, thus resurrecting an idea proposed originally in 1911 by Goldthwait.
- 15) Smith et al. (1963 AD) approached the problem by suggesting a radical departure in treatment enzymatic dissolution of the disc by injection of chymopapain. Although this technique is still used in Europe, it rarely is used in the United States because of medico legal concerns
- 16) The anatomical dissections and clinical observations of Kirkaldy-Willis and associates identified pathological processes associated with or complicating the process of spinal aging as primary causes of disc disease. Additional information about this process and its treatment continues to be collected. Back pain, though an ancient curse, is now an international health issue of major significance.

Pain (Waja')

The word pain is derived from Latin word "poena" which means penalty or punishment. Pain defined as an unpleasant and emotional experience associated with actual or potential tissuedamage or described in terms of such damage.

Classification

The International Association for the Study of Pain recommends using specific features to describe a patient's pain:

- 1) region of the body involved (e.g. abdomen, lower limbs etc.,),
- 2) system whose dysfunction may be causing the pain (e.g., nervous, gastrointestinal),
- 3) duration and pattern of occurrence,
- 4) intensity, and
- 5) cause

Before the relatively recent discovery of neurons and their role in pain, various different body functions were proposed to account for pain. There were several competing early theories of pain among the ancient Greeks: Hippocrates believed that it was due to an imbalance in vital fluids. In the

11th century, Avicenna theorized that there were a number of feeling senses including touch, pain and titillation. In 1644, René Descartes theorized that pain was a disturbance passed along nerve fibers until the disturbance that reached the brain. Descartes's work, along with Avicenna's, prefigured the 19th-century development of specificity theory. Specificity theory saw pain as "a specific sensation, with its own sensory apparatus independent of touch and other senses". Another theory that came to prominence in the 18th and 19th centuries was intensive theory, which conceived of pain not as a unique sensory modality, but an emotional state produced by stronger than normal stimuli such as intense light, pressure or temperature. By the mid-1890s, specificity was backed mostly by physiologists and physicians, and the intensive theory was mostly backed by psychologists. However, after a series of clinical observations by Henry Head and experiments by Max von Frey, the psychologists migrated to specificity almost en masse, and by century's end, most textbooks on physiology and psychology were presenting pain specificity as fact.

Waja (PAIN) is a perception of incongruity in the body, which is caused due to sudden changes of temperament, or variable ill temperament (Sue mizaj mukhtalif) and loss of continuity (Tafarruq -e-ittisaul). The newly developed abnormal temperament becomes garm (Hot) or sard (Cold) contrary to the original temperament. The perception of such a contrarytemperament is pain. Ibn Sina uses the word Waja' as a general name for pain. However, he also uses Alam (Pain) interchangeably with Waja' to describe how the patient feels. He defined Waja' as 'one of unnatural (abnormal) conditions that affects the body' and it is a 'feeling of incongruity'. He offers further clarity in thestatement 'Waja' is the sudden sensation of a different stimulus such as a sudden feeling of cold which leads to cooling of an otherwise hot organ'.

According to Galen, loss of continuity is the only real cause of pain, and thus, if cold producespain, it is through a breach of continuity by shrinking and retracting the tissue particles and thus dislocating these from their original positions. Waja-uz- zahr (Low back pain)

Waja[•]uz zahr (Low back pain) is a pain arising from the spinal or paraspinal structures in the lumbosacral region, extends approximately from the iliac crests to the coccyx.

Radicular leg pain or sciatica may accompany low back pain but should be regarded as a separate entity with a distinct pathophysiology.

In Unani system of medicine, Waja-uz- zahr is described as a disease in which pain arises from internal and external muscles, ligaments surrounding the lumbar and lumbosacral region.

Ibn Sina (980- 1037 AD) described Low back pain as Darde-pusht, which mainly happens in the muscle and ligament of the back internally as well as externally, which can be distinguished by palpating the external surface of the back, which evidences presence of tenderness.

Akbar Arzani described Waja'uz zahr as Dard-e-pusht and

said that main cause behind it is Su-i-mizaj barid sada of pusht.

Ibn Hubl Baghdadi defined Waja'uz Zahr as Dard-e-pahlu, caused by Su-i- mizaj Har, Kasarat-i-Jima' and involvement of Kidney. Low back pain can be defined as pain and discomfort below the costal margin and above the inferior gluteal folds, with or without referred leg pain. It may be experienced as aching, burning, stabbing, sharp or dull, welldefined or vague with intensity from mild to moderate.

Mahiyatul Maraz (Pathogenesis)

Eminent unani physicians like Ibn Sina and Zakaria Razi attributes Kham balgham (ghair tabyee balgham), as the most common causative matter of *Waja'uz zahr*, which is formed due to defective metabolism of second and third stages of digestion, i.e. hazme kabidi and hazme urooqi. As the mizaj of Balgham is barid, so when this abnormal balgham gets accumulated in the joint structures of lumbar region, it leadsto Sue mizaj barid. The Mizaj (temperament) of joint structure i.e., muscles, tendons, ligaments, bones and nerves is *barid* and *yabis*, so a little addition of *burudat* can lead to deviation of temperament in these joint structures, which results in pain. Riyah, the second most causative matter, causes pain only if there is loss of continuity in the sensitive organs by penetrating between muscle fibers and diffusing under the membranes such as periosteum. So we can say that the basic pathology of *Waja'uz zahr* lies in the nags hazam particularly in hazme kabidi and hazme urooqi.

Pain in any structure requires the release of inflammatory agents that stimulate pain receptors and generate a nociceptive response in the tissues. The spine is unique in that, it has multiple structures that are innervated by spine fibers, usually present within the spinal ligaments, in the apophyseal joint capsules, in the periosteum at the facial and tendon attachments and in the blood vessels; but only in the outer layers of the intervertebral discs. Thus low back pain can arise from

- Anterior structures i.e. disc, vertebral bodies, ligaments, muscles.
- Posterior structures i.e. facets, ligaments, sacroiliac joints.
- Midline structures i.e. spinal cord, neural compress, muscles.
- Pain is produced by pressure on these structures from disc protrusions, osteophytes or trauma.Calliet has proposed a construct for understanding low back pain analyzing function. Pathophysiological static and kinetic components are structural abnormalities of the static spine including postural changes such as kyphosis or scoliosis, functional abnormalities include accentuation of normal lumbar lordosis because of an increased lumbosacral angle, secondary to muscle weakness, responsible for 75% of low back pain. Further information concerning the mechanism of LBP is obtained by examination of the kinetic spine. Analysis shows forward flexion is anatomically more difficult than extension, but crucial for most daily activity. Normal range of motion is dependent on the extensibility of the longitudinal ligaments and elasticity of the articular capsule, intervertebral disc, and muscle groups. This activity is quantified as a flexion range of 167° with hip flexion input of 122° for isolated spinal flexion and 45° in

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extension. Thus, the anatomic basis for low back pain is the mobility of the lower lumbar segments, L5-S1 and L4-L5 responsible for 60% to 75% and 20%- 25% of this motion, respectively.

Individual radiographic features of the spine, commonly studied and referred to as the "Three joint complexes", are the structures of vertebral osteophytes, facet joints osteoarthritis and disc space narrowing from intervertebral disc degeneration.³⁹ Due tothe various risk factors, the disc may age prematurely and dries due to loss of water content of nucleus, leading to narrowing of the disc spaces. This allow abnormal movements between vertebrae and stresses the adjacent vertebral bodies and facet joints, which leads to progressive degeneration to facet joints characterized by capsular fibrosis and thickening. Degenerated disc and articulating cartilage cannot be regenerated and arecompensated by bony projection at the margin of the joints, known as 'Osteophytes'. These degenerative changes can occur at one level or in different levels of the lumbar spine. Narrowing of intervertebral foramen presses over the nerve root passing through it, giving rise to radiating pain.^{24, 38}

Asbab (Etiology)

Most of the renowned *Unani* physicians described the causes of *Waja-uz- zahr* under the broad heading of *Waja'ul mafasil*.

- *Buqrat* first described its cause as predominance of *Balgham* (Phlegm) in the body.
- Zakaria Razi, an eminent Unani physician described the disease in his book Al- Hawi, though his description is not systematically arranged, but covers all possible causes related to disease. According to him, the first and foremost cause of Waja'ul mafasil lies in the abnormal formation of rutubat e mukhatia (chyme) due to naqs (defect) in Hazm e kabidi and Hazm e urooqi, due to which the abnormal chyme produces abnormal humours, particularly ghair tabyee balgham (abnormal phlegm), which then gets accumulated and adheres in the joints of the body, thus causing swelling, tenderness and pain. Thus we can say that the root cause of Waja-uzzahr is the naqs in hazm e kabidi and urooqi, in which abnormal balgham gets accumulated in the joint structures of lumbosacral region. Razi also says that sometimes weakness or extensiveness of joint structures either congenitally or due to some other disease, gives the seat to accumulate the ghair tabai akhlat (abnormal humours) in general, or ghair tabai balgham (vitiated phlegm) in particular.18
- According to *Ibn Sina*, *Waja-uz-zahr* arises from internal and external muscles, ligaments surrounding the lumbar and lumbosacral region due to *fasaad* in *mizaj* (*sue mizaj*). This *fasaad* in *mizaj* is due to surplus *burudat* and accumulation of *kham balgham* (raw phlegm). He
- Further stated that pain may also arise due to accumulation of *ghaleez riyah* in the lumbar and lumbosacral region.

In addition to the above mentioned causes, Jurjani in Zakheera Khawarzam Shahi and Akbar Arzani in Tibbe Akbar have described low back pain as Dard-e-pusht with

different causes as:

- a) Kasrate jima.
- b) Mumtali rag.
- c) Zoaf wa laghari gurda.
- d) Musharikate reham.
- e) Excessive physical work.

A variety of condition either related or unrelated to spine causes backache. The most common causes described in conventional medicine are:

- Back muscle strain.
- Prolapsed lumbar intervertebral disc.Obesity
- Poor posture. Facet joint arthritis.
- Unaccustomed activities.

<u>Congenital causes</u>: Kyphoscoliosis, lordosis, spina bifida, spondylolisthesis, spondylolysis, spinal stenosis.

<u>Infective causes</u>: Tuberculosis (pott's spine), Acute and chronic lumbosacral osteomyelitis, Brucellosisetc.

<u>Traumatic causes:</u>Vertebral fractures or compression fracture, ligamentous injury, Lumbosacral or sacroiliac strain & sprain, damage to spinal cord or nerve roots and post laminectomy. Inflammatory & <u>Immunological:</u> Rheumatological disorders, Ankylosing spondylitis, lumbar spondylitis, psoriaticarthropathy etc.

Degenerative causes: Osteoarthritis, lumbar Spondylosis etc.

<u>Metabolic causes:</u>Osteoporosis, osteomalacia, osteosclerosis (Paget's disease).

<u>Neoplastic causes:</u>Benign osteoid osteoma, Malignant secondaries, multiple myeloma.

<u>Neurological and psychogenic causes:</u>Anxiety, depression, chronic pain syndrome, malingering, psychosis.

Other causes: Referred pain from gynecological diseases, genitourinary diseases, gastrointestinal conditions etc.

Risk factors for Low back pain:

In the past decade, various additional etiologic factors for disc degeneration have been sporadically reported in the literature; however, many investigators also continue to place tremendous emphasis on the following factors: ^{13, 43}

- a) Ageing
- b) Obesity
- c) Sedentary lifestyle
- d) Occupational- prolong sitting or standing, heavy weight lifting andtwisting.
- e) Previous injury to low back.
- f) Poor posture- Posture inappropriate for the activity being performed.
- g) Congenital abnormalities.
- h) Smoking
- i) Pregnancy
- j) Poor sleeping position

Classification

Classification of LBP based on cause of pain

Akbar Arzani in *Tibbe Akbar* has described seven types of *Waja-uz- zahr*, which are:

- Waja-uz- zahr due to sue mizaj sada: It is characterized by gradual onset; painwithout heaviness or tension; feeling of coldness and lasts for long time.
- 2) Waja-uz- zahr due to kham balgham: It is

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characterized by pain with heaviness, which increases day by day.

- 3) *Waja-uz- zahr* due to *riyah*: It is characterized by fleeting type of pain withtension.
- 4) *Waja-uz-zahr* due to *azeem rag*: In this type, pain (throbbing) is felt vertically, from first cervical vertebrae up to last lumbar vertebrae and gets aggravated with movements.
- 5) *Waja-uz- zahr* due to *zoafe gurda*: It is associated with kidney affliction and pain is felt diagonally.
- 6) *Waja-uz- zahr* due to *kasrate jima*: In this type, history of excessive indulge in sexual activities is found.
- Waja'uz zahr due to awarizate reham: This type of Waja'uz zahr

Occurs in females during pre menstrual period.¹⁹

On the basis of cause, LBP is broadly classified into two types as:

- 1) **Mechanical pain:** It is related to activity and is generally relieved by rest; its onset is often acute, associated with lifting or bending. Mainly confined to the lumbosacral region, buttock or thigh, is asymmetrical, and does not radiate beyond the knee. This pain accounts for more than 90% of back pain episodes, usually affecting patients aged 20-55 years.³
- 2) Non-mechanical pain: Non mechanical pain is constant and has little variation in intensity or with activity. Causes of non mechanical LBP include neoplasia, infection and inflammatory arthritis. Typically, patients with a non mechanical cause of LBP report pain that occurs at rest and is less affected by motion.

Classification of LBP based on specificity and duration of pain

- Specific low Back pain: Pain which is attributable to a recognizable, known specific pathology for eg, infection, tumour, <u>osteoporosis</u>, lumbar <u>spine</u>, <u>fracture</u>, <u>structural deformity</u>
- 2) Non specific low back pain: It is defined as low back pain not attributable to arecognizable, known specific pathology i.e pain is not due to any specific.Nonspecific low back pain is further categorized in 3 subtypes. This subdivision is based on the duration of the back pain.
 - a) **Acute LBP:** Pain which lasts less than 6 weeks duration.
 - b) **Sub acute LBP:** Back pain which lasts more than 6 weeks, butless than 3 months of duration.
 - c) **Chronic LBP:** Chronic LBP is generally defined as pain that has persisted beyond normal tissue healing time (or about 3 months); it is not merely acute pain that has lasted longer than would be expected for an acute episode.

Classification of LBP based on nature of pain

- a) **Musculoskeletal pain:** It may be related to spasm of paraspinal muscles as a result of injury or structural abnormality of the spine. The spasms are accompanied by abnormal posture, taut paraspinal muscles, and dull pain.
- b) **Radicular back pain:** It is usually sharp in character. Coughing, sneezing and straining typically exacerbate the pain by increasing intraspinal pressure.

- c) **Pain referred to back:** Pain may arise from abdominal or pelvic viscera. The pain is usually described as primarily abdominal or pelvic but is accompanied by back pain and usually unaffected by posture. The patient may occasionally complain of back pain only.
- d) **Pain of spinal origin:** Compression of the long tracts, may lead to an unpleasant sensation in the extremities that also is enhanced by increased intraspinal pressure or movements that stretch the cord. Pain may be located in the back or referred in the buttocks or legs. Diseases affecting the upper lumbarspinal tear refer pain to the lumbar region, groin, or anterior thighs.

Local pain and tenderness: It may occur from irritation of sensory nerve endings at the site of pathology, such as in the vertebral periosteum. Similarly degeneration or protrusion of intravertebral discs causes pain by compression of nerve endings in the annulus posterior ligaments. Pain of muscle or ligamentous origin or related to a herniated disc is usually alleviated by recumbency.

Alamaat (Clinical features)

Description of clinical features of *Waja-uz- zahr* present in the classical text books of *Unani* medicines are based on causative factors as:

In case of *Sue mizaj barid sada*, the clinical features of *Waja'uz zahr* are:

Feeling of coldness. Pain without heaviness.,Pain relieved by temperamentally hot regimens.

In case of Kham madda (balgham kham)

Pain with heaviness. Pain relieved by exercise andmassage

In case of *Riyah*(*Air*) *Waja* '*mumaddida* (pain with tension).Pain aggravates by taking those foods which produce flatulence.

In case of *Azeem rag: Waja' zarbani* felt along the course of *rag* (vertically).

In case of *Zoafe gurda wa laghari: Zoafe bah. Darde qutn.* Bladder symptoms.

Symptoms of Low back pain: Symptoms are most severe in the morning and again at he end of the day and tend to improve with rest.

- The pain may be dull or sharp and it may be in one small area or overbroad area.
- Difficulty in moving that can be severe enough to prevent walking or standing.
- Pain that tends to be achy and dull.
- Muscles spasm
- Local soreness upon touch
- Weakness or numbness in both legs and loss of bladder or bowel control.

Tashkhees fariqah (Differential diagnosis)

The differential diagnosis of low back pain is extremely lengthy and complex. It includes diseases intrinsic to the spine and those involving adjacent organs but causing pain referred to the back or leg. For simplicity, lesions can be

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categorized as being extrinsic or intrinsic to the spine. Extrinsic lesions include diseases of the urogenital system, gastrointestinal system, vascular system, endocrine system, nervous system not localized to the spine, and the extrinsic musculoskeletal system. These lesions include infections, tumors, metabolic disturbances, congenital abnormalities, and the associated diseases of aging. Intrinsic lesions involve those diseases that arise primarily in the spine. They include diseases of the spinal musculoskeletal system, the local haemopoietic system, and the local neurological system. These conditions include trauma, tumors, infections, diseases of aging, and immune diseases affecting the spine or spinal nerves. Although the predominant cause of low back pain in healthypeople usually is lumbosacral strain and lumbar disc disease, one must be extremely cautious to avoid a misdiagnosis. Common diseases that can mimic disc disease include Ankylosing spondylitis, multiple myeloma, vascular insufficiency, and arthritis of the hip, osteoporosis with stress fractures, extradural tumors, peripheral neuropathy, and herpes zoster

Lumbosacral strain: The word 'strain, which denotes an injurious tension, does not cover the mechanical faults that are present, however, lumbosacral strain is quiet common among the young adults due to faulty adoption of the back. The nature of pain is spasmodic which increases with activity, tenderness on palpation and limited range of motion. There are essentially two problems:

- 1) Compression on bony structures, present especially in standing or sitting.
- 2) Tension on muscles and ligaments in standing or sitting and during movements.

Acute disc herniation or disc prolapsed: Disc prolapse occurs most commonly in middle age about 30-50 years but can also occur in adolescence and elderly. It commonly lasts for 2-6 weeks but may continue for longer. It is often associated with neurological symptoms like altered sensation, weakness in the muscles, asymmetric reflexes. The quality of pain is sharp, shooting or burning pain, paraesthesia in leg, decreased with standing, increased with bending or sitting.

Spinal osteoarthritis: This is osteoarthritis of the joints in the spinal column, involving the intervertebral joints, the facet joints or both. It is one of the most common findings on plain spine radiographs of patients with (and without!!) low back pain and is almost universal after the age of 55-60, although to varying degrees. The radiograph may show osteophytes, which are sometimes large, with a reduction in the articular space and subchondral sclerosis. The osteophytes of the facet joints may narrow the intervertebral foramina leading to nerve root compression. The same is true for intervertebral osteophytes in a posterolateral location. The most obvious osteophytes in a standard film, however (marginal anterior and lateral), cannot cause nerve compression and are important mainly as indicators of general alterations in the morphology and function of the spine and not as individual sources of symptoms.

Ankylosing spondylitis: It is an inflammatory disease affecting various joints mainlyof the axial spine associated with calcification and ossification of ligaments and capsules

of joints, resulting in complete bony ankylosis. This is relatively uncommonbut can present with painful stiffness of the spine. It is more common in males, ageabout 15-40 years. Human leucocytes antigen (HLA) B 27 positive in 88-96 % of cases, negative RA Factor. It is particularly felt in the early hours of the morning, waking the patient from the bed. Gradually the disease progresses upwards and involves different joints which are in order of frequency sacroiliac, spinal, hip, and shoulder joints.

Spinal stenosis: Progressive narrowing of the neural foramina can result in the development of spinal stenosis. This may be caused by a combination of bony overgrowth (e.g. Osteophyte formation, Paget's disease), disc protrusion or herniation or congenital anomalies, such as shortened vertebral pedicles. Neural impingement is worsened by activities such as walking, and claudication like symptoms usually require the patient to slowdown or to stop and rest. Forward flexion of the spine may also relieve the pressure, and patients often acquire a forward flexed posture and learn to lean on objects (e.g. shopping carts) for symptom relief.

Spondylolisthesis: This is caused by a defect in the vertebral isthmuses allowing the vertebral body to lose the fixation represented by the facet joints and slide over the underlying vertebra. It is often congenital, but may be caused by trauma. The relationship with clinical manifestations is highly variable. The patient may mention lumbar pain that is generally worse in extension. The greater the degree of dislocation, greater is the probability of its causing On occasions symptoms. rare it may cause nervecompression.

Neoplastic disease: Malignant neoplasm accounts for less than 1% of episodes of low back pain. However, metastatic cancer should be considered as a potential etiology in any patients with a previous history of cancer, until proved otherwise. The most common primary sites are the breasts, lungs, or prostate. Primary neoplasms such as multiple myeloma are less commonly the cause. A key historical finding is that back pain due to cancer is unrelieved by bed rest and typically worsen at night. Onset is usually slow and progressive.

Infection: Infectious etiology of acute low back pain include Osteomyelitis, septic discitis, and paraspinal or epidural abscess, whereas infectious etiologies of chronic lowback pain include fungal or tuberculosis infections. Patients typically first report fever and sharp focal pain in the lumbar spine. Physical examination reveals tenderness to percussion.

Visceral disease: Common diseases causing referred back pain included renal disease (e.g. Nephrolithiasis. pyelonephritis), vascular diseases (e.g. abdominal aortic aneurism, epidural hematoma), disease of pelvic viscera (e.g. endometriosis, PID, salpingitis) and gastrointestinal disease (e.g. pancreatitis, Cholecystitis). Patients with back pain caused by visceral diseases often have pain unrelated to activity and pain that is worse when they are lying down. The pain associated with Nephrolithiasis can be severe, colicky and radiates to the groin. Pyelonephritis is another urologic cause of back pain; costovertebral angle tenderness can be elicited by per cussing the paraspinal areas of affected

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patients.

Tashkhees (Diagnosis)

Traditional medical diagnosis aims to attribute a pathological cause to the symptoms through a process based on the history, physical examination and investigations. These three diagnostic processes are equally important in elucidating the cause of low back pain; but there is no agreed pathological cause for the symptoms in 85% of cases. The patients with low back pain suffer from the idiopathic form (i.e. a presumed strain or sprain that will likely improve with time). These patients complain of low back discomfort that does not radiate. A smaller percentage of patients have radicular symptoms with pain down either or both legs, sometimes with and sometimes without accompanying low back pain.

History: It is crucial that the history should focus on ruling out worrisome symptoms that may suggest these diagnoses. Factors that may increase the risk of neoplasm and infections include the patient's age (>50 years), a history of cancer, unexplained weight loss, fever, injection-drug use, chronic infection, unremitting pain, night time pain and a lack of response to prior therapy. Key elements of the history should also include the characterization of the pain and determining whether there are symptoms suggesting neurologic involvement. These symptoms include leg pain with walking (pseudoclaudication), numbness, or paraesthesia. Sciatica due to disc herniation typically worsens with coughing, sneezing, or with the valsalva manoeuvre, bowel or bladder dysfunction (e.g. retention with overflow incontinence), perianal anesthesia, leg weakness, and sciatica may be features of caudaequina compression. Patients suspected of having this syndrome require urgent surgical evaluation.³¹

Physical Examination: Most patients will describe pain in the lower back; buttocks, or legs, palpation of these areas is generally not helpful in establishing the diagnosis. For example, vertebral tenderness has sensitivity for infection (discitis) but lacks specificity for other diagnoses. Similarly, the presence of limited spinal mobility is a nonspecific finding and can be observed in a wide array of conditions that cause back pain. Neurological examination identifies nerve root irritation. Straight-leg rising is performed with the patient supine. The sciatic nerve is stretched by raising the straight leg until this becomes painful; a restriction to 45° or less is often misinterpreted. Root irritation is present if pain is produced in the anterior thigh on flexing the knee, with the patient in prone position.

Diagnostic tests: Most cases of low back pain are mechanical, with no alarm signals, and do not require any tests, as the clinical examination provides enough information to diagnose and treat it. If we request spine radiographs for all these patients, we will find some kind of structural abnormality in many of them, especially varying degrees of spinal osteoarthritis. These findings should not, however, change our choice of treatment, as we do not have specific measures for each condition and the relationship between radiology and clinical examination is very weak. An investigation that does not change treatment is unnecessary. In addition, unnecessary x-rays are far from harmless. The dose of radiation in repeated x-rays is by no means negligible, but the most important thing is the impact that

these investigations and their findings have on the patients' approach to their condition.³⁴ when faced with a structural diagnosis that they find hard to interpret, patients naturally focus on the disease and not on their mobility. This may reinforce their tendency to avoid exercise, which is the opposite of what is required, and also to justify their "role as a patient" or secondary gains. If we want the patient to remain active in spite of the pain, it is better to play down irrelevant x- ray results than to lend them too much importance. Computed tomography and MRI should be reserved for patients in whom underlying infection or cancer is suspected, or for patients with significant or progressive neurologic deficits. MRI is the preferred modality for the detection of spinal infection, neoplasm, herniated discs and spinal stenosis. Bone scanning is used primarily to detect bony metastases, occult fractures and infection.

<u>Usool – E- Illaj (Principle of treatment)</u>

The principle underlying the management is to remove the *Maddi asbab* (causative matter) and correction of *sue mizaj* (ill temperament) which usually manifests in two ways; i.e. *sue mizaj maddi* and *sue mizaj sada* and restoration of these is called *tadeel* (normalization), which can be achieved by two main procedures *tanqiya mawad* and *tadeel mizaj*.

Waja[•] (pain) can be alleviated by removing its cause or can be relieved by substances producing cold and analgesia, as all the narcotics do; but the first is the real alleviating factor.

As the root cause of *Waja'uz zahr* is *naqse hazam* (defective digestion) which leads to the production of *ghair tabyee balgham* (*kham balgham*) in the lumbosacral region; so the management should be with suitable modification (*tasaruf*) in the *asbab-e-sitte zarooriya* viz.

- 1) Hawa (Atmospheric air).
- 2) Maqool-o-Mashroob (Food and drink).
- 3) Harkat-o-Sukoon e Badani (Rest and physical activity).
- 4) Harkat-o-Sukoon e Nafsani (Psychological activity).
- 5) Naum-o-Yaqza (Sleep and wakefulness).
- 6) Istifragh-o-Ihtibas (Evacuation and retention).

In case of *sue mizaj maddi*, the first line of treatment, to remove the morbid matter from the body is *nuzij wa istifraghe akhlat-e-ghair tabayiah* (concoction and expulsion of abnormal humour) specially *balgham* (*phlegm*) with:

- 1) *Munzij*: This procedure matures the *kham balgham* from the structuresof lumbar region; so that they can be easily expelled out.
- 2) *Mus'hil*: This expels the matured matter via intestines.
- 3) *Qai* (emesis).

In case of *sue mizaj sada* and after *istifragh* (in case of *sue mizaj maddi*), the line of treatment, to restore and normalize the deranged temperament (*mizaj*) - which is the main cause of pain, is achieved by the intervention of *tadabeer* (regiminal therapies) like:

- Zimad (liniment).
- *Natool* (irrigation).
- *Takmeed* (hot fomentation).
- *Fasd*: Usually done in case of *imtilai rag* on *rage Basleeq* or *Mabaz. Hammam*: Used in case of deep seated *madda* (morbid matter). It disperses the matter towards periphery and thus helps in relaxing the

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lumbosacral muscles.

- Riyazat (exerscise).
- *Dalk* (massage): Done with *har mizaji* (hot temperamental) medicinal oils like *raughan shibitt*, *raughan baboona* etc.

Hijama (CUPPING) etc.

Ilaj (Treatment)

According to Zakaria Razi, *Waja 'uz zahr* is a type of *Waja 'ul mafasil*; its treatment is same as that of *Waja 'ul mafasil barid*. So the treatment of *Waja 'uz zahr* should be done with *habbe munten, habbe sheetraj* as *mushil balgham*. *Raughan arandi*, as *muqi* (emetic), *raughan biskhapra* as massage, *musakhin zimad, itrifal kabeer* and *garm murabah*. He has mentioned in Al-Hawi that, two drugs namely *dafli* and *haliyoon* have a unique property to benefit in chronic *Waja 'uz zahr* and in *Waja 'uz zahr barid* respectively.

Jurjani in Zakhira Khawarzam Shahi has recommended almost the same treatment as above with more emphasis on the use of habbe sikbeej and tiryaq arbah as mushil. raughan firfiyoon, raughan qust, raughan sosan and raughan sudab as massage. Jograj gogul, ashq, jowsheer, sikbeej, jundbeedastar and farfiyoon as zimad.

For tanqiya badan, the following drugs are best to use:

As mushil balgham: like habbe munten, habbe sikhbeej, iyarij feeqra, tiryaq arbah. As muqi (emetic): raughan arand.

Intervention and Treatment Options: There are four primary categories of interventionin modern medicine:

Physical Therapy (associated modalities and behavioural techniques)Pharmacotherapy

Injection Therapy Surgical Intervention

Physical Therapy (associated modalities and behavioural techniques):Exercise Therapy (Aerobic exercise, Muscle strengthening and Stretchingexercise)

Transcutaneous Electrical Nerve Stimulation Therapy (TENS) Back school (first introduced in Sweden-exercise, joint manipulation,myofascial therapy, educational therapy) Lumbar supports (Massage, Heat)

Lumbar Traction Spine Manipulation Massage therapy *Pharmacotherapy:*

Non-Steroidal Anti-inflammatory Drugs (COX2 inhibitors) Opioid medications Anti-depressants

Muscle Relaxants (e.g. Benzodiazepine

Injection Therapy:

Epidural steroid injection (through Interlaminar, Transforaminal orCaudalapproaches) Facet injection Sacroiliac joint injections **Surgical options:** Decompression surgery

HIJAMA

Hijama is an *Arabic* word derived from "*Hajm*" which stands for "Sucking". The term

Hajjam denotes the person who performs the cupping while *Mihjam* or *Mihjamah* is the instrument of the *Hajjam*. It is a procedure used for local evacuation or diversion of morbid *Humours* and thereby releases the toxins from the body tissue and organs. In classical *Hijama* a *Singhi* (horn) is used and suction is made by mouth to create a vacuum, now it is replaced by glass cups and vacuum is created by vacuum pump, hence the procedure is called as cupping. Types

Hijama has been classified in to two main types:

Hijama bila Shurt (Dry cupping or cupping without scarification)

Hijama bil Shurt (Wet cupping or cupping with scarification)

On the basis of method *Hijama bila Shart* is further divided in to two types:

- 1) *Hijamae Nariyah* (Cupping with fire)
- 2) Hijamae Ghair Nariyah (Cupping without fire)

In case of *Hijamae Nariyah*, fire is used to create a negative pressure; the whole process is called as *Mahjamae Nari*. While in case of *Hijamae Ghair Nariyh* (Dry cupping) now a day vacuum pump is used to create negative pressure.

According to need *Hijama bish Shart* is further classified into two types:

- 1) Hijamae Iztirariyah (Mandatory or essential)
- 2) Hijamae Ikhtiyariah (Optional or voluntary)

Mechanism of Action in the light of *Unani* and Modern view

The mechanisms of action of cupping therapy need to be elucidated. In the light of modern medicine many theories exist to explain benefits of cupping therapy. First of all we will discuss here the mechanism of action of cupping therapy according to the *Unani* system of medicine which elaborates that cupping therapy works by two ways:

1) Tanqiyae Mawad (Evacuation of morbid matter)

2) *Imalae Mawad* (Diversion of morbid matter)

As it is discussed earlier, the root cause of any disease is the imbalance of *Humours* which accumulates in particular sites. By the application of *Hijama bish Shart*, we just evacuate these morbid matters from the affected site. In case of *Hijama bila Shart* (Dry cupping) which works on the principle of *Imalae Mawad* causes the diversion of morbid matter from one site to another. In both cases when these morbid matters are get away from the diseased part the *Tabiyat Mudabbarae Badan* takes in the part and helps the body to restores the normal condition.

According to the modern concept so many theories are given to describe the mechanism of action of cupping, among them some are given here:

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According to Hong et al. cupping therapy works via creating specific changes in local tissue structures as a result of local negative pressure in the cups stretches the nerve and muscle causing an increase in blood circulation and causing auto-hemolysis.

Gao et al. suggested that putting cups on selected part on the skin produces hyperemia or hemostasis which results in a therapeutic effect. However, it is not enough to explain therapeutic benefits of cupping therapy as regard effect of cupping therapy in treating RA, cellulitis and others.

Taibah theory states that when negative pressure (suction force) is applied to the skin using cups creates uplifting of skin, due to elastic nature of skin there is gradual increase in size, it results decrease in pressure (Boyle's law) around capillaries. This causes increased capillary filtration, local collection of filtered fluids, lymph and interstitial fluids and their retention inside skin up lift part. This dilutes chemical substances, inflammatory mediators, and nociceptive substances, bathes nerve endings in collected fluids and breaks tissue adhesions causing decreased pain.

Indication and their sites of *Hijama*

S. No	Site	Indication
1	Yafookh (Middle of thehead)	Ikhtilate Aql, Disease of the eye
2	Qamhadwa (Occiput)	Kuduratul Hawas
3	Nuqrah (Nape of neck)	Ramad, Kalaf, Wajaʻul Uzn
4	Akhdain	Disease of the eye, face, tooth andneck
5	Kahil (Inter scapularregion)	Amraze Sadar
6	Tahatus Sadayin	Menorrhgia
7	Warkain (Buttocks)	Bawaseer, Warame Rahem, Warame Miqad,
8	Qatn (Lumbar region)	Niqris, Reyahul Masana and Reham

9	Rakaba (Knee)	Waja 'ur Rakaba
10	Miq'ad	Intestinal disorder, Piles, Disorder ofanus
11	Fakhzain (Thighs)	Warame Khusaiyah,Warame Rahem
12	Ka'bain	Ihtebase Tams, Irqunnasa, Niqris

Contraindication:

Children below 2 years and elders above 60 years.⁶⁴

Pregnant and lactating women. During menstrual cycle.

Patients having history of cardiac complications. Patients on anticoagulant medicine

Patients of contagious disease. Should be avoided

It should be avoided after sexual intercourse, excessive heavy work (Due to

Kasrate Tahleel).*Hijama* should be avoided in the beginning and the end of lunar month.

3. Methodology

The present study entitled as "Clinical Study Waja uz zahar and its Management With Hijama bil Shurth (Wet Cupping) has been carried out in the department of Moalijat (General Medicine) at Govt.Nizamia Tibbi College and General Hospital (GNTC) Hyderabad. Before going to start the project, a comprehensive protocol was chalked out and put forth for ethical clearance (GNTC/IEC/2019-20/MOJ/101) from the Institutional Ethical Committee of GNTC, Hyderabad. After ethical clearance, CTRI Registration done (CTRI/2022/04/041840) clinical study was started by enrolling eligible patients. This study stretched from September 2019 to JULY 2022. The blue print of the study was conceptualized in materials and methods which can be described under few headings for convenient comprehension.

Criteria for selection of Patients				
Inclusion Criteria	Exclusive Criteria:			
• Age group 18-50 years.	• Major Trauma and Systemic disorders (CVA, CAD, D.M etc.)			
• Either sex.	Pregnant and lactating women.			
 Diagnosed cases of Waja uz zahr 	• Low back pain secondary to a malignant or autoimmune disease.			
No radiation of low back pain to other region. Congenital deformities of the spine.				
No radiation of low back pain to other region. Congenital deformities of the spine.				

Note: Willing to participate in the study and follows the instruction.

Recruitment of Patients

The patients were recruited from OPD/IPD of Govt.Nizamia Tibbi College and General Hospital, PG OPD Dept.of Moalijat (Gen.Medicine) from September 2021 to July 2022. During the enrolment procedure of the patients, we strictly followed the Inclusion and Exclusion criteria. Complete history taking including general physical and systemic examination was carried out and recorded on a predesigned format; Case Record Form (CRF) which was prepared according to the objective of the study. During examination main emphasis was given on lower back examination. All diagnostic (i.e. X-ray L.S. Spine AP/Lat) and safety parameters were carried out in each patient before starting the study to confirm the diagnosis or to exclude the patients with pathological conditions mentioned under exclusion criteria. Local examination was done to emphasize on spinal deformity, Para spinal muscles spasm/ tenderness, gait and SLR (straight leg raise)Test, cross leg Rise test and ROM (range of motion) test.

Informed Consent

Patients fulfilling the inclusion criteria mentioned above were given the information sheet having details regarding the nature of the study, intervention to be used, side effects if any and duration of the trial. Patients were given enough time to go through the contents of informed consent sheet. They were free to ask any question and, if they agreed to participate in the study; they were asked to sign the informed consent form.

Investigations

Certain investigations were carried out with an aim to

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Licensed Under Creative Commons Attribution CC BY DOI: https://dx.doi.org/10.21275/SR231103131128 exclude the patients with pathological conditions mentioned under exclusion criteria also for safety of intervention used. Followinginvestigation were performed

- X- Ray Lumbosacral Spine- AP & Lateral
- Hb%, TLC, DLC, ESR
- CT, BT
- RBS (>200mg/dl)
- Viral Screening (HbsAg, HCV, Tridot I &II)

Study Design: Open Labeled Single Arm clinical trial **Sample Size:** 20 patients

Allocation

Total of 200 patients were screened, out of which 45 patients fulfilling the study criteria, were subjected to clinical and laboratory investigation, finally 40 patients were enrolled after taking written informed consent. 15 patients lost to follow up, a total of 20 patients completed the study protocol.

Intervention

Hijama bil shurt: WET CUPPING

Size of Cups: Medium (5.5cm)

No of Cups: 06 (02 on Cervical Region 02 on each side of Lumbar Region)

Location: cervical and Lumbosacral region on each side of vertebral column Duration of intervention: 20 min, WITH 7 days interval (WEEKLY ONE SITTING) Duration of therapy: 30 days

Follow up: 0, 7th, 14th, 21st Day

Materials for Procedure

Cupping Chair, Normal Saline, Betadine, Spirit, Surgical Gloves, Surgical Blade (15no), Cotton, Kidney Tray, Hijama Cups, Vaccumegun, Antiseptic Powder, and Disposable Covers.

Procedure of Hijama bil shurt

Before starting the procedure the patients were helped to be in correct posture, Hijama bil shurt (Wet Cupping) in sitting position while some feel relaxed in prone position. The area to be cupped was exposed properly and then the hair if present was removed to enable the cups to fix firmly on the body. Site of cupping was cleaned with N.S, spirit and betadine solution, vacuum pump is used to create negative pressure inside the cup, medium sized cups (total 06 cups) of diameter 5.5 cm is applied on Cervical and lumbosacral region on each side of vertebral column, 4-5 suction was made to create enough negative pressure, the cup was adhered to skin for 5 minutes and the site was observed carefully for any adverse reaction like formation of blister. After 5 minutes cups were removed by pulling up the valves of the cups easily.

And then with the help of Sterile surgical blade no: 15, incision (15-21) of 5mm to 10mm was taken and the cups placed again with the help of the vacuum gun on the site of

incision, site and the collection will be carefully observed for any reaction and to note the morbid matter, after 15 minutes the cups was removed and the antiseptic powder applied to protect from infections.

Outcome Assessment: The assessment of outcome was carried out by the following

Parameters

Primary outcome/ Primary end point: The primary end point was the mean pain score obtained from the Visual Analogue Scale (VAS).

Visual Analogue Scale: At Zero D a y and 21st day, pain was assessed by VAS. Patients after initial training in reading VAS scale were verbally asked to mark on the scale. VAS is a subjective measure of pain. It consists of a 10 cm line with two end points representing 'no pain' and 'worst pain' imaginable; a photocopy of the same line is done on an A4 sheet which is numbered from 0 to 10 which exactly corresponds to the no pain, Mild Pain, Moderate Pain, severe pain and worst pain respectively, before the patients were asked to rate their pain by placing a mark on the line corresponding to their current level of pain, the A4 Sheet is folded at the dotted line and numerical scale is not shown to the patient. Further this scale allows arbitrary categorical consideration of pain intensity in terms of grades such as Grade 0 (none), Grade I (mild 1-3), Grade II (moderate 4-6), and Grade III (severe 7-10).

Secondary outcome/ Secondary end point: The Secondary end point was the patient's functional disability obtained from the Oswestry Disability Index

The Oswestry Disability Index (ODI):

The Oswestry Disability Index (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the 'gold standard' of low back functional outcome tools. It contains ten topics concerning about intensity of pain, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling. In this questionnaire each section contains 6 statement describing different potential scenarios in the patient's life. Each question is scored on a scale of 0-5 with the first statement being 0 and indicating the least amount of disability and the last statement is scored 5, indicating most severe disability. The patients were asked to answer every question that described their condition and finally these scores are added to get a whole score. Similarly, again scoring was done at 0th and 21st day. Scores of all questionsanswered are summed at each assessment point to obtain a back pain score with a maximum value of 50 points. Further this scale allows arbitrary categorical consideration of disability in terms of grades such as: Grade 0 (None), Grade I (Minimal 1-15), Grade II (Moderate 16-35), and Grade III (Severe 36-50).

4. Observations and Results

 Table 1: Distribution of Patients according to Age

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S. No	Age in years	No. of Patients	Percentage %
1	21-30	5	25
2	31-40	7	35
3.	41-50	8	40
	Total	20	100



Observations

Out of 20 (100%) patients, the highest number of patients i.e. 8 (40%) were from the age group of 41-50 years, 7 (35%) were from the age group of 31- 40 years, 5 (25%) were from the age group of 21-30 years.

Table 2: Distribution of Patients acc	ording to	Gender
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S. No	Gender	No. of Patients	Percentage %
1.	Male	12	60
2.	Female	8	40
	Total	20	100



Observations

Out of 20 (100%) selected patients of LUMBAGO, 12 (60%) are male and 8(20%) are female.

Fable 3: Distribu	tion of F	Patients a	ccording t	o Religion
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S. No	Religion	No. of Patients	Percentage %
1.	Hindu	2	10
2.	Muslim	18	90
	Total	20	100

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Observations:

Out of 20 Patients (100%) selected patients of LUMBAGO, 18 (90%) areMuslims and 2(10%) are Hindus.

Tab	Table 5: Distribution of Patients according to Marital Status						
	S. No	Marital Status	No. of Patients	Percentage%			
	1.	Married	15	75			
	2.	Unmarried	5	25			



Observations:

Out of 20 (100%) selected patients of LUMBAGO, 15 (75%) were married, 5(25%) were unmarried.

		U	
S. No	Socioeconomic Status	No. of Patients	Percentage%
1.	Upper Class	5	25
2.	Middle Class	10	50
3.	Lower Class	5	25
	Total	20	100

Table 6: Distribution of Patients according to Socio Economic Status



Observations:

Out of 20 (100%) patients, 5 (25%) belongs to upper class, 10 (50%) belongs to middle class, 5 (25%) belongs to lower class.



Table 7: Distribution of Patients according to Occupation

Observations

Out of 20 (100%) patients, 5 (15%) are skilled workers, 1 (5%) are Unskilled worker, 9 (45%) are professionals, 2 (10%) are businessmen and 5(25%) are House wives.

Table 8: Distribution of Patients according to	Diet
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Iun	Distribution of Tutients decording to Diet					
S. No	Diet	No. of Patients	Percentage%			
1.	Vegetarian	2	10			
2.	Non- Vegetarian	18	90			
	Total	20	100			



Observations

Out of 20 (100%) selected patients of lumbago, 18 (90%) are Non-Vegetarians, 2 (10%) are Vegetarians.

		U	- / 1
S. No	MIJAZ	No. of Patients	Percentage%
1	DAMVI	6	30
2	BALGAMI	11	55
3	SAFRAVI	3	15
4	SAUDAVI	0	0
	TOTAL	20	100

Table 9: Distribution of Patients according to Mizaj Temperament



Observations

Out of 20 (100%) patients, 6 (30%) are Damavi, 11 (55%) are Balghami, 3 (15%) are Safrawi, and 0 (0%) are Saudavi.

S. No	Pain (OLBP)	0 Day	21 ST Day	Percentage %
1	0-4	0	11	55
2	5-14	5	9	45
3	15-24	10	0	0
4	25-34	5	0	0
5.	35-50	0	0	0

Table 10: Distribution of Patients according to OLBS



Observations

Out of 20 (100%) patients, 11 (55%) are Relived, 9 (45%) are Partially Relived.

Table 11. Distribution of Fatients according to VAS					
S. No	Pain (VAS)	0 Day	21 ST Day	Percentage %	
1	0	0	11	55	
2	1-3	0	9	45	
3	4-6	9	0	0	
4	7-9	8	0	0	
5.	10	3	0	0	



	Distribution Of Patients (VAS) Before and After Treatment							
	60							
	50							
INTS	40							
ATIE	30							
OF I	20							
ž	10					_		
	0	0	1-3	4-6	7-9	10		
	ODAY	0	0	9	8	3		
	21ST DAY	11	9	0	0	0		
	PERCENTAGE	55	45	0	0	0		

Observations

Out of 20 (100%) patients, 11 (55%) are Relived, 9 (45%) are Partially Relived.

Table 12: Distribution of Patients ac	ccording to T	Fenderness
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S. No	Tenderness	0 Day	21 ST Day	Percentage %
1	0	1	9	45
2	1-3	19	11	55
3	4-6	0	0	0
4	7-9	0	0	0
5.	10	0	0	0



Observations

Out of 20 (100%) patients, 9 (45%) are Relived, 11 (55%) are Partially Relived.

Table: Showing changes in OLBP Scale after Treatment in patients

S. No Parameter Total No. of Patients Base Line (Mean ± SD) After Treatment (Mean ± SD) P ValueTwo Tail 1 OLBP 20 25.0±6.223 6.0±1.719981 0.0001						
1 OLBP 20 25.0±6.223 6.0±1.719981 0.0001	S. No	Parameter	Total No. of Patients	Base Line (Mean ± SD)	After Treatment (Mean ± SD)	P ValueTwo Tail
	1	OLBP	20	25.0±6.223	6.0±1.719981	0.0001

		Table: Sho	wing changes in VAS af	ter Treatment in patients	
S. No	Parameter	Total No. of Patients	Base Line (Mean ± SD)	After Treatment (Mean \pm SD)	P ValueTwo Tail
1	VAS	20	8 2 +1 794	1 65+1 348	0.0001

5. Discussion

Waja uz zahr *or* Low back pain (LUMBAGO) can be defined as pain and discomfort below the costal margin and above the inferior gluteal folds, with or without referred leg pain. It may be experienced as aching, burning, stabbing, sharp or dull, well defined or vague with intensity from mild to moderate. The LBA can be managed in lot of ways such as pharmacotherapy, physical therapies like massage and surgical intervention. Mainly its management depends upon the cause.

Management by pharmacotherapy mainly suggests use of NSAID's which may have several adverse effects on the body. These adverse effects lead many patients to go for alternative health care options which are more or less equally effective but having fewer side effects than the conventional medicine. There are various Regimenal modalities in Unani system of medicine which are effective in the management of Waja uz zahr. Such as *Dalk, Hijama, Riyazat* etc. the validation of these claimed to be effective Regimenal modalities should be done on modern scientific parameters. Hence, a Randomized controlled clinical trial was designed to evaluate and compare the effect of *Hijama* in the Management of *Waja uz zahr*.

The present study entitled as "**Clinical Study of Waja UZ Zahr (LUMBAGO) And Its Management with Hijama Bil Shurt (WET CUPPING)**" has been carried out in the PG department of Moalijat (Gen.Medicine) at Govt. Nizamia Tibbi College and General Hospital (GNTC&GH) Hyderabad. Before embarking upon the project, a comprehensive protocol was chalked out and put forth for ethical clearance from the Institutional Ethical Committee of GNTC, Hyderabad. After ethical clearance, clinical study was started by enrolling eligible patients. The patients were recruited from OPD/IPD of Govt. Nizamia Tibbi College and General Hospital (GNTC&GH). A total of 200 patients were screened, out of which 40 patients fulfilling the study criteria, were subjected to clinical and laboratory investigation, finally 40 patients were enrolled after taking written informed consent

Randomization was done according to a lottery method. 15 were lost to follow up, a total of 40 patients completed the study protocol, 20 Patients were treated with *Hijama bil Shurt*, With interval of 7 days 4 sittings for 4 weeks. The pre and post change in objective parameters were assessed by VAS and Oswestry Disability Index.

Demographic data

Age: In present study, the maximum no of subjects 8 (40 %) were in the age group of 41-50 years, followed by 7 (35 %) in the age group of 31-40 years, and 5(25%) in the age group of 21-30 years respectively, Mean age of the patient enrolled was 41.15 ± 8.93 .(Table no 1). This data shows a higher incidence in patients below the age group of 41-50 years, which coincides with the studies conducted by D. Hoy et al. which found the incidence of LBP highest in the third decade of life, these results are further supported by *Zakaria Razi*, who have quoted the same in his book Al Hawi, that the prevalence of *Wajaulmafasil* is more in the age of *Sin- e- Shabab* (age of maturity) which last from 25 to 45 years. Gender: Our study population comprised predominantly of males 12(60 %) while remaining8 (40%) was females (Figure no. 2). In several studies higher

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prevalence of LBA has been documented in Women. Which does not coincide with our observation, the reason may be the negligence on the part of the women.(Table no 2)

Religion: Out of total patients, 18 (90%) patients were Muslim followed by 02 (10%) patients as Hindu (Table no. 3). No convincing data is available that demonstrates the distribution of LBP among different religious communities in the society. This study, however, reflects a preponderance of Muslims among the patients of low back pain. The probable reason may be the majority of Muslim patients visiting GNTC&GH, as Unani Medicine is more popular among Muslim community.

Marital status: As far as the marital status of the patients is concerned, 15 (75%) were married and 5 (25%) unmarried (Table no.5). This indicates that LBP is more common among married patients; which strongly coincides with the studies conducted by A Charlotteet al. (2002) and Sanchez SJ et.al (2012). Our observation is also in conformity with the etiology mentioned by *Akbar Arzani* in *Tibb e Akbar* and Jurjani in Zakhira Khawarzam Shahi, that indulge in excessive sexual life is one of the cause of *Waja'uz zahr*.

Socioeconomic status: The association of LBA with low socioeconomic status was reported by Hestback L *et al* and G J Macforlane *et al*. The highest incidence of 10(50%) was observed in lower class , and 5(25%) in lower class followed by 5(25%) in UPPER class (Table No.5). The maximum patients belonged to the lower class, and upper lower class. Current study results are further supported by the findings of Bindra *et al.*, which strongly suggest that there is a significant association between a low socioeconomic status and the risk of LBA in Indian population. However, they suggested that well designed studies embedded with long term prospective cohorts are required for confirming the results.

Personal History

Duration of pain: In relation to the duration of pain, 13 (32.5%) subjects were having pain since 4 months, followed by 9 (22.5%) subjects who complained history of pain since 5 months, 7(17.5%), 5 (12.5%) and 4 (10%) subjects were having history of pain since 6, 8 and 3 months respectively. 1 (2.5%) each have duration of pain since 1 and 2 months respectively. (Table no 6) Our study somehow coincides with Ganesan S *et al*, which showed that duration of pain is more in low back pain patients (Figure no 7)

Diet Distribution: All patients in our study had mixed diet. (Table no 8) This study corresponds to **Ganesan S** *et al*, whose result specified that the low back pain is found more in non-vegetarians than vegetarian.²⁸ *Jurjani*, quoted in *Zakhīra*, excess use of $k\bar{a}s\bar{i}f$ ghidā (meat of aged animals) forms the $R\bar{a}ddi$ Akhlāt which accumulates in the body and causes back pain.

Assessment parameters:

VAS (Visual Analogue Scale): highly significant reduction was observed in VAS Scale from baseline 8.2 ± 1.794 to 1.65 ± 1.348 after 14 days of intervention and mean difference

was 2.9 (p<0.001). it was found that test group (*Hijama*) lead to greater reduction after 21 days, and this difference was highly significant (p<0.001). (Fig no 11)

OLBP: highly significant reduction was observed in OLBP Score from baseline 25.0 ± 6.2223 to 6.0 ± 1.7199 after 21 day of intervention and mean difference was 6.55, (p<0.001). it was found that *Hijama* Bil Shurth lead to greater reduction After 21 days, and this difference was highly significant (p<0.001).(Fig no 10)

Tenderness in low back: Tenderness was assessed on a 4 point arbitrary scale of 0, 1, 2, 3 i.e. nill, mild, moderate and severe respectively. at baseline 1 patients (5%) had no tenderness, 19 patients (95%) had mild tenderness. At the end of 28 days of treatment 9 patients (45%) had no tenderness, 11 patients (30%) had mild tenderness, and 0 patients (0%) had moderate and severe tenderness. Paired proportion test was applied. There was an improvement with respect to baseline (p<0.001**). (Table no 12).

Difficulty in walking: Difficulty in walking was assessed on a 4 point arbitrary scale of 0, 1, 2, 3 i.e. nill, mild, moderate and severe respectively. at baseline 5 patients (25%) had mild difficulty in walking, 10 patients (50%) had moderate difficulty in walking and 5 patients (25%) had severe difficulty in walking. At the end of 21 days of treatment 11 patients (55%) had no difficulty in walking, 9 patients (45%) had mild difficulty in walking, 0 patients (0%) had moderate difficulty in walking. Paired proportion test was applied. There was an improvement with respect to baseline (p <0.001)

6. Conclusion

There is converging evidence that *Hijama bil shurt* can induce comfort and relaxation on a systemic level and the resulting increase in endogenous opioid production in the brain leads to improved pain control.⁷⁵ Many theories have been suggested to explain numerous effects of *Hijama* therapy and its mechanisms of action.⁷⁶ Several researchers proposed biological and mechanical processes associated with the Hijama session. For instance, reduction of pain may result from changes in biomechanical properties of the skin as explained by the "Pain-Gate Theory" (PGT),⁷⁷ "Diffuse Noxious Inhibitory Controls" (DNICs),⁷⁸ and "Reflex Zone Theory" (ZRT).⁷⁹

- 1) **Pain-Gate Theory (PGT)**: "Pain Gate Theory" is one of the most influential theories of pain reduction.⁸⁰ proposed by Melzack and Wall (1965). This theory comprehensively explains how the pain is transmitted from the point of its inception to the brain, and how it is processed in the brain which sends back the efferent, protective signal to the stimulated or injured area.⁸¹ It is reported that local damage of the skin and capillary vessels acts as nociceptive stimulus.⁸² This is explanation based on a neuronal hypothesis whereby *Hijama* influences chronic pain by altering the signal processing at the level of the nociceptors both of the spinal cord and brain.⁸³
- 2) **Diffuse Noxious Inhibitory Controls (DNICs):** Another theory related to pain reduction as a mechanism

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of action of *Hijama* therapy is Diffuse Noxious Inhibitory Controls. DNIC signifies inhibition of activity in convergent or wide dynamic range-type nociceptive spinal neurons triggered by a second, spatially remote, noxious stimulus. This phenomenon is thought to underlie the principle of counter- irritation to reduce pain. Herein "one pain masks another", or pain inhibits pain.

3) **Reflex Zone Theory:** *Hijama* therapy of defined zones or areas of the shoulder triangle segmentally related to the median nerve to treat carpal tunnel syndrome has been practiced in European folk medicine and is supported by various studies.⁸⁴ Only a suction stimulation is done on the disturbed point and thereafter the red blood cells from the vascular system are brought out to the surrounding tissue areas without injuring capillary vessels. This is known as dry diapedesis.

These extravasations are digested or removed by the connective tissue. This happens when the disturbed area is better supplied with blood causing an activation of biological processes on the treated area, i.e., disturbed reflex zone.⁸⁵Many other theories are also given to describe the mechanism of action of *Hijama* (cupping), Hong et al.⁶¹ described that Hijama (Cupping) acts by creating specific changes in local tissue structures as a result of local negative pressure in the cups used which stretches the nerve and muscle causing an increase in blood circulation and causing autohemolysis, while Gao et al.⁶² suggested that putting cups on selected part on the skin produces hyperemia or hemostasis which results in a therapeutic effect. Another theory *Taibah theory* suggested that when negative pressure (suction force) is applied to the skin, it causes decrease in pressure (Boyle's law) around capillaries. This results in increased capillary filtration, local collection of filtered fluids, lymph and interstitial fluids and their retention inside skin up lift part. This dilutes chemical substances, inflammatory mediators, and nociceptive substances, bathes nerve endings in collected fluids and breaks tissue adhesions causing decreased pain.⁶⁴

Some of the potential limitations inherent in this study include small sample size, short duration of the study and limited parameters of assessment. Thus, it is recommended that clinical trial of this type should be done on larger sample size, for longer duration with other assessment scales. Further studies are recommended with improved methodology to limit these inadequacies for better reliability and acceptability of such clinical trials.

7. Summary

Waja 'uz Zahr (low back pain) manifests as most expensive disease in the productive years. Any part of the back may ache; but the commonest site is the lower back that is, lumbar and lumbosacral region. It is the leading cause of activity limitation and work absence throughout much of the world and it causes an enormous economic burden on individuals, families, communities, industry and governments. Until 15 years ago, it was largely thought of as a problem confined to Western countries, however, since that time an increasing amount of research has demonstrated that low back pain is also a major problem in low and

middle-income countries.

Keeping all this in view, an Open Labelled Single Arm clinical study was conducted at the GNTC to evaluate the effect of *Hijama bil Shurth* in *Waja'uz Zahr*. Patients having low back pain as main complaint were selected for the study. The patients were allocated afterconsent a total of 20 patients completed the study protocol .patients were treated with *Hijama bil Shurth and*, on weekly interval days for 30 days. So, a total of 4 sittings of *Hijama bil Shurth* (wet Cupping) therapy was done to the assigned patients. The pre and post change in objective parameters were assessed by VAS and Oswestry Disability Index.

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