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Review Article

Clinical studies and safety evidence for human consumption of Shilajit: a herbo-mineral compound with multifaceted health benefits

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ABSTRACT

Shilajit is one of the ancient and traditional herbo-mineral compounds that has been used for multiple health benefits for centuries. It is associated with potent antioxidant and anti-inflammatory effects via modulation of signaling pathways such as NF-kB and Nrf2/HO-1. One of the main components of Shilajit, fulvic acid, is primarily responsible for its diverse health benefits. However, apart from fulvic acid, it also contains humic acid, trace elements, minerals and vitamins, making it a potent health supplement. Recently, there has been a notable increase in Shilajit consumption, resulting in a growing body of scientific evidence from in vitro, in vivo and clinical trials. However, most of the published literature on Shilajit has been limited, mainly emphasizing its history, origin, chemistry or summaries of preclinical research, without thoroughly exploring the mechanisms of action or discussing existing clinical evidence. Hence, this manuscript aims to specifically address this gap by focusing on the mechanisms of action of Shilajit identified in preclinical research and offering a comprehensive overview of various clinical studies and trials.

Keywords: Antioxidants, Anti-inflammatory, Efficacy and clinical trials, Natural product, Safety

INTRODUCTION

The World Health Organization (WHO) estimates that nearly 80% of the global population relies on traditional healthcare practices to address their wellness needs.[1] Despite this widespread reliance, modern scientific investigations disproportionately emphasize treatments derived from plants, often sidelining therapies sourced from minerals or animal products.[2] Traditional healing systems have utilized Shilajit, a naturally occurring herbal-mineral product formed from an organic blend of plants and minerals, for centuries. Mumie and moomiyo are local names that refer to this natural material, which miners primarily extract from mountain rock formations in South and Central Asia. The main extraction areas of Shilajit are found in the Himalayan regions of India, Nepal and Tibet, as well as in mountaintops extending into Russia, Kazakhstan and Uzbekistan, along with geographical areas that include China, Afghanistan and Pakistan.[3] Shilajit is primarily sourced from the Himalayan region, which extends from Arunachal Pradesh in the east to Kashmir in the west. It is also found in several other parts of the world, including Afghanistan's Hindu Kush mountains, the CIS regions such as the Tien Shan and the Urals and Tsao-Shing.[4] Scientists reported discoveries of Shilajit in Australia, Mongolia and the Zarafshan area of Tajikistan.[5] A significant source of Shilajit is found in the Tibet-Himalayan range.[6] The substance Shilajit exists in the territories of Japan and Algeria, according to Garedew et al, as well as Saudi Arabia, where it is referred to as momia and primarily originates from Yemen or India, according to Al-Himidi and Mohammed, 2003.[7,8]

Historical records indicate that ancient Egyptians utilized Shilajit in the mummification process, a technique later embraced by Greek physicians to treat arthritis and address

toxic substances and inflammatory conditions.[3] Avicenna's Canon of Medicine highlights Shilajit's ability to dissolve skin and tumor formations.[3] The Russian Federation imposes export restrictions on Shilajit due to its cultural significance.[3] The therapeutic benefits of Shilajit arise from its bioactive components, including fulvic and humic acids, which are recorded in historical pharmacopeia like Wujinsan from the 15th century, illustrating their anti-inflammatory and coagulation-modifying effects.[3]

ORIGIN AND DISTRIBUTION OF SHILAJIT

Considering the origin and distribution of Shilajit, it is well established that its origins goes back to thousands of years and are formed from the remains of plants and minerals.[2] According to modern biology, using advanced analytical techniques, it has been found that Shilajit is a secondary metabolite that forms beneath the earth and accumulates over time.[2] According to the literature of "Sushruta Samhita" and "Rasarangini," Shilajit is a byproduct of the plant's sap.[9] When Shilajit or its humic substance was analyzed, it was found in the area where other plants, such as Euphorbia royleana and other latex-producing plants, grow.[3] Furthermore, advancements in analytical techniques have revealed that Barbula and Marchantia (bryophytes) play a crucial role in the elemental enrichment of Shilajit.[9]

Despite these developments, the exact origin of Shilajit remains unknown. Three theories strongly support its origin. The biological theory posits that Shilajit forms through the breakdown of microbes, plants or animals under specific environmental conditions. The geological hypothesis suggests that natural mineral processes in the mountain are the primary mechanism for Shilajit formation. Lastly, the bio-mineralogical hypothesis states that mineral fluids infiltrate organic matter, resulting in the formation of Shilajit under specific environmental conditions.[9] Also, it has been documented that Shilajit originates from fossilized marine invertebrates such as mollusks. Its chemical properties, prevalence in high-altitude sedimentary rocks and absence of animal habitats indicate a geological origin. Thus, these diverse theories highlight the complex process behind Shilajit's formation, illustrating the distinct interaction of organic and inorganic components over millennia.

Shilajit can be classified into two primary types: physical composition and sensory attributes. The first type, called gomuthira Shilajit, is a dense, resinous substance with a glossy texture that varies in color from deep brown to jet black. This particular substance emanates a potent pine aroma accompanied by a distinct bitterness. The second type, known as karpura Shilajit, presents as a white or light-colored variant characterized by a unique camphor-like scent fragrance.[9,10] The gomuthira Shilajit category contains four distinct subtypes, each associated with specific metallic ore deposits in geological formations. Ayurvedic practitioners use the red variety linked to gold to address ailments caused by wind and heat, including haemorrhoids and to help manage health issues tied to excessive heat and phlegm. A blue variety associated with copper helps medical professionals relieve symptoms of asthma and disorders related to phlegm. The commonly available iron subtype of Shilajit is used in traditional Indian medicine to treat conditions stemming from a combination of wind, heat and phlegm.[11,12] The gomuthira Shilajit variant, recognized for its iron base, is readily available in the market and is among the most commonly used forms. Historical Ayurvedic texts by Sushruta and Vagbhatta reference several types of Shilajit derived from tin and lead ores, although these types are seldom utilized today.[13]

CHEMICAL COMPOSITION OF SHILAJIT

Shilajit's chemical composition varies due to several environmental and geographical factors, as well as the extent of processing and purification it undergoes.[14] Fulvic acid is a polyhydroxy polycarboxylic acid that forms when organic matter, and it exhibits strong chelating and complexing abilities. According to quality standards, a high-grade Shilajit supplement should contain at least 50% fulvic acids, along with related polymeric compounds. It should also include dibenzo-α-pyrones (DBPs) and their chromoproteins at levels generally exceeding 10% (Figure 1).[15,16] For dietary supplements to be considered high-quality, they should have a water-soluble extraction value greater than 80%. Shilajit contains over 40 minerals as part of its polyphenolic complex, many of which are present in trace amounts.[16,17] Processed Shilajit generally has over 90% of its mineral composition comprising Kindly replace the deleted sentence with 'of Potassium, Calcium, Magnesium, Sulpher, Sodium etc.[18] The color differences in Shilajit is usually related to varying amounts of minerals such as Fe^{2+}, Cu^{2+} and Ag^{2+}.[9]

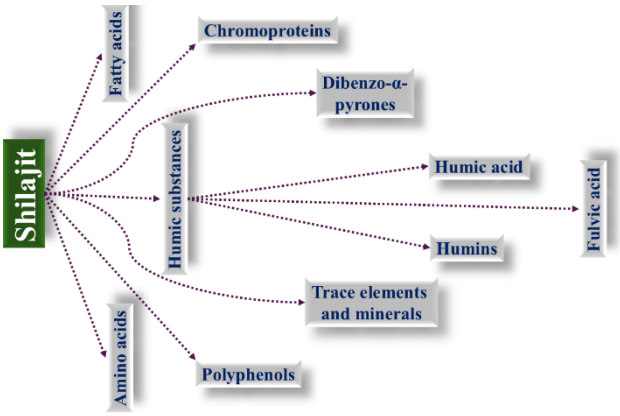

Figure 1: Chemical composition of Shilajit.

PHARMACOLOGICAL ACTION OF SHILAJIT

Antioxidant and anti-inflammatory effect of Shilajit

Shilajit demonstrates a broad spectrum of pharmacological effects that substantiate its traditional and modern

therapeutic applications. Research has established that Shilajit provides significant antioxidant, anti-inflammatory, neuroprotective, hepatoprotective, adaptogenic, immunomodulatory, antidiabetic, cardioprotective and reproductive health benefits.[18] These varied activities mainly result from its abundant presence of fulvic acid, humic substances, dibenzo-α-pyrones and key minerals. Together, these component reduces oxidative stress, balance immune responses, enhance mitochondrial function and ensure hormonal equilibrium.[18]

The antioxidant and anti-inflammatory effects of Shiljit are related to the presence of fulvic acid, humic acid and trace elements or minerals. Various in vitro studies also showed the potent antioxidant activities.[18] Shilajit has been reported to reduce the level of reactive oxygen species (ROS), malonaldehyde, increases the antioxidant activity of catalase, superoxide dismutase (SOD), glutathione (GSH).[19] In the in vivo study, Shilajit has been reported to CAT increase the expression of nuclear factor erythroid 2-related factor 2 (Nrf2) or heme-oxygenase 1 (HO-1), leading to increased antioxidant activity and reduced oxidative stress. The potent antioxidant activity is considered one of the primary attributes leading to protective effects against various disease conditions leading to effect, such as hepatoprotective, cardioprotective, gonadal protective, neuroprotective, etc.

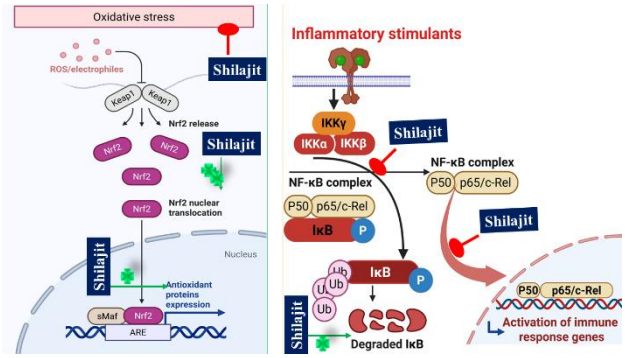

Figure 2: Shilajit's mechanism of action through its antioxidant and anti-inflammatory properties.

Apart from the antioxidant effect, Shilajit also exhibits a potent anti-inflammatory effect. Anti-inflammatory effects are attributed directly to Shialjit and also related to its intrinsic antioxidant effect. For viz., increased antioxidant or increased expression of Nrf2 is directly related to reduced inflammation via modulation of nuclear Factor kappa-light-chain-enhancer of activated B cells (NF-κB), nucleotide-binding domain, leucine-rich repeat containing protein 3 (NLRP3) or other inflammatory pathways. Also, Shilajit has an intrinsic anti-inflammatory effect, where it inhibits the nuclear translocation of NF-κB, leading to inhibition of transcription of proinflammatory cytokines such as tumor necrosis factor alpha (TNF-alpha), IL-6 or IL-1beta, along with the level of myeloperoxidase (MPO). Amid its anti-inflammatory effect, efficacy in inflammatory bowel disease, arthritis, padel edema, infertility and various other conditions has been reported.[20]

The mechanistic representation of the antioxidant and anti-inflammatory effects of Shilajit is shown in Figure 2.

PRECLINICAL EVIDENCE OF SHILAJIT

This manuscript is primarily intended to highlight the clinical studies of Shilajit, which would add value to its use as a health supplement and clarify many doubts regarding its efficacy and safety. Because preclinical studies lay the groundwork for clinical research, we include a summary of key preclinical findings as well. Shilajit has been reported to exhibit potent neuroprotective effects in various neurological conditions, including traumatic brain injury, Alzheimer's disease and other neurological disorders.[2,14,21] Shilajit has also been reported to have an effect on preserving blood-brain barrier integrity and reducing intracranial pressure.[22] The hepatoprotective effect of Shilajit is well supported by various preclinical studies indicating its efficacy against drug-induced hepatotoxicity and nonalcoholic fatty liver disease.[19] In multiple studies, Shilajit reduced the levels of Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), triglycerides, total cholesterol and low-density lipoprotein (LDL), while increasing the level of high-density lipoprotein (HDL) due to its potent antioxidant and anti-inflammatory effects.[23,24] One of the primary uses of Shilajit since ancient times was to improve sexual well-being. In line with this, preliminary studies have shown substantial benefits. Shilajit has demonstrated its efficacy against heavy metals and also against cyclophosphamide-induced testicular dysfunction, compromised spermiogenesis, hormone levels and reduced sperm quality via modulation of antioxidant levels and Nrf2-Keap-1 pathways.[25] In another study, the use of Shilajit significantly improved the reproductive function of male and female Wistar rats.[26]

In recent times, there has been a substantial increase in metabolic disorders such as hypertension, hyperlipidemia and diabetes. In one study of the published, Shilajit has shown significant outcomes in diabetes-related testicular dysfunction, improving testicular function, sperm quality and preserving the blood-testicular barrier.[27] Notably, Shilajit has shown significant outcomes in metabolic disorders.[28-31] The adaptogenic and immunomodulatory effects of Shilajit have been well-established since ancient times. Shilajit has demonstrated efficacy in combating fatigue, enhancing strength and boosting stamina, as well as acting as an immunomodulatory compound.[32] In addition to the studies mentioned above, Shilajit is also reported to function as a potent anticancer agent. Fulvic acid is one of the major active constituents responsible for its anticancer effects. In one in vitro study, the use of Shilajit was associated with reduced proliferation and migration of cancerous cells in oral cancer.[33] Shilajit has also been reported to initiate or stimulate the apoptotic process through the modulation of p53 and bcl-2, specifically involving the Bax and caspase-3 axis.[33] In addition to this particular study, many other studies have also demonstrated the anticancer effect of Shilajit.[34] The

overview of various preclinical studies conducted on Shilajit is illustrated in Figure 3.

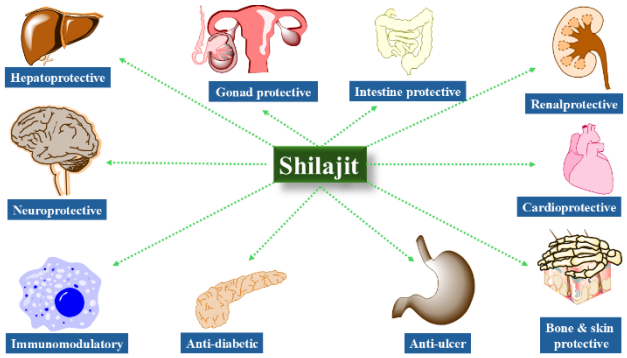

Figure 3: The documented or published pharmacological effect of Shilajit at the preclinical level.

CLINICAL EVIDENCE OF SHILAJIT

Shilajit is currently the focus of scientific research and is accordingly being explored for multiple health benefits, with recent studies confirming its traditional uses in various health areas.[2] In the traditional system of medicine, Shilajit is used for its rejuvenating effects and adaptogenic qualities; however, systematic human studies focusing on its therapeutic use have only recently begun to emerge. This section critically reviews clinical studies involving Shilajit, including randomized controlled trials and observational reports that explore its impact on physical performance, reproductive health, metabolic function, cardiovascular health, and other physiological processes.[2] The evaluation of current human data aims to connect ancient empirical wisdom with contemporary clinical research standards, assessing the safety and translational clinical significance of Shilajit, as shown in Figure 4.

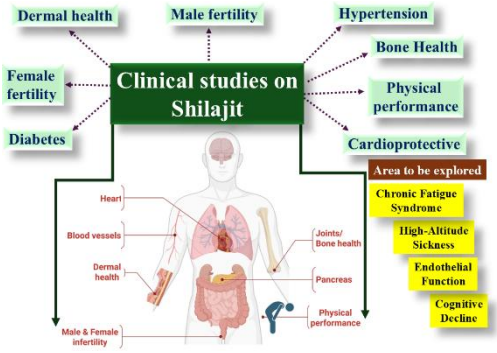

Figure 4: The documented or published pharmacological effect of Shilajit at the clinical level and area for further exploration.

Clinical evidence of Shilajit on physical performance and fatigue

Shilajit supplementation has shown promising benefits for physical performance, fatigue reduction and musculoskeletal adaptation, supported by both clinical and preclinical studies. In a clinical trial (NCT 02026414) conducted by Das et al, 2016, the effects of the PrimaVie ® Shilajit (PVS) standardized extract on skeletal muscle adaptation were investigated in adults overweight or with class I obesity (BMI 25–35).[35] The study involved 16 participants who received PVS at a dosage of 250 mg twice daily for 8 weeks, followed by a 4-week regimen that included 3 days of treadmill exercise at 70-75% of their maximum heart rate. Throughout the study, no safety issues were reported and the evaluated blood markers showed stable levels of glucose, lipid profiles, creatine kinase and serum myoglobin, indicating good tolerance among the participants. Transcriptomic analysis revealed a significant increase in the expression of 17 genes related to the extracellular matrix (ECM) (e.g., COL1A1 A 1, COL3A1, TNXB, DCN, FBN1, FN1), all of which are crucial for muscle structure and repair.[35] Enhanced effects were observed through gene expression analysis via RT-PCR, particularly when exercise was included in the treatment protocol. This research suggests that PVS induces skeletal muscle adaptations by altering extracellular matrix structures in a manner akin to physical exercise, thereby confirming its traditional Ayurvedic applications for musculoskeletal health.[35] Another study by Keller et al., 2019 reported almost similar findings; daily intake of 500 mg of Shilajit helped maintaining muscle strength following exercise-induced fatigue while promoting beneficial changes in muscle structure.[36] This study also showed a notably smaller decline in maximal voluntary isometric contraction (MVIC) strength after fatigue-inducing exercise, with a reduction of only 8.9% compared to 16–17% in the placebo and lower-dose groups. Furthermore, this high-dose group showed reduced baseline levels of hydroxyproline, a marker linked to collagen degradation, which implies that Shilajit may help preserve connective tissue and facilitate muscle recovery after physical exertion.[36]

Shilajit appears to function by upregulating genes associated with collagen synthesis and the remodeling of the extracellular matrix (ECM), enhancing mitochondrial performance, and normalizing stress hormone levels by regulating the hypothalamic-pituitary-adrenal (HPA) axis. Clinical trials suggest that a daily intake of 500 mg of Shilajit is the optimal dosage without significantly affecting muscle structure. Research indicates that traditional Ayurvedic practices have employed Shilajit to boost physical performance and serve as an adaptogen, aiding in fatigue reduction and supporting muscle recovery.[37] The scientific community urges further investigations, particularly long-term studies across diverse populations, to establish Shilajit's efficacy and safety. Neltner et al conducted a randomized, double-blind, placebo-controlled trial to evaluate the effects of Shilajit supplementation on collagen synthesis, which is crucial for tissue integrity and physical resilience. In this study, men received either 500 mg/day or 1000 mg/day of PrimaVie® Shilajit, or a placebo, for eight weeks. Participants who took Shilajit showed increased levels of pro-c1α1 protein

in their blood, indicating enhanced type 1 collagen synthesis.[37] Those on the higher dosage of Shilajit showed the significant increase in pro-c1α1 levels. Eighty-four percent of the high-dose participants and seventy-nine percent of those on the low dose demonstrated clinically significant growth rates, compared to only a thirty percent increase among the placebo group.[37] Given the critical role of type 1 collagen in maintaining muscular and skeletal integrity, Shilajit emerges as a promising substance for enhancing muscle tissue repair and reducing exercise-related tissue damage. The study found no link between dietary habits or exercise frequency, indicating that Shilajit could effectively function as a natural supplement for recovery and improved physical performance.[37]

Clinical evidence of Shilajit on female sexual function

In a 60-day triple-blind, placebo-controlled clinical trial, Mosavi et al, 2023 administered 200 mg of Shilajit orally twice daily to 43 women of reproductive age.[38] The treatment with Shilajit resulted in an increase in the overall Female Sexual Function Index (FSFI) score, rising from a baseline of 23.02±4.03 to 28.92±2.69 by day 90. In contrast, those receiving the placebo showed less favorable changes, with scores decreasing from 22.90±4.84 to 22.09±6.10.[38] Notably, several key areas of the FSFI showed significant improvement with Shilajit. However, the measurements for orgasm and pain remained stable. The study found that Shilajit was well-tolerated among the participants, with no changes in safety biomarkers and no recorded adverse events. Additionally, the Shilajit group experienced a modest improvement in sexual quality of life scores, which increased from 81.32±19.62 to 87.64±16.42.[38] Nevertheless, these improvements did not result in significant benefits when compared to the placebo group, whose scores changed from 74.05±20.86 to 75.38±23.10.[38]

Clinical evidence of Shilajit on diabetes

In a three-month open-label trial, Sheikh et al, 2023 enrolled 212 adults (108 men, 104 women, ages 30–70) with mild to moderate high blood sugar. Participants were randomly assigned to receive either metformin (500 mg twice daily) or Dolabi® a four-ingredient Unani formula that includes Shilajit taking two tablets twice daily.[39] The results showed that both treatments led to 20% reductions in fasting blood sugar, improved long-term glucose control (HbA1c) and slight decreases in insulin levels.[39] Administering Dolabi® at two tablets twice daily was deemed safe for patients, positioning this herbal option as a viable alternative to metformin in managing primary diabetes hyperglycemia.[39] In a three-month clinical trial by Gupta et al, Shilajatu and Asanadi Ghana Vati were compared in patients with type 2 diabetes. Both treatments resulted in significant reductions in blood sugar and HbA1c levels, with no reported side effects. However, Shilajatu showed greater overall symptom relief, particularly in areas like polyuria and loss of libido, underscoring its efficacy and safety as a targeted therapy for managing type 2 diabetes.[40]

A clinical study conducted by Dhiman et al, found that daily intake of Shilajeet Vati for 30 days among 30 pre-diabetic patients resulted in significant improvements in symptoms such as excessive urination, thirst and hunger (improvements ranging from 71.43% to 100%), as well as reductions in blood sugar levels (decreases of 68.89% to 81.11%).[41] Notably, no side effects were reported, highlighting its efficacy and safety for managing diabetes and pre-diabetes. Raju et al, conducted a randomized trial to evaluate the impact of Shilajit Yoga combined with Panchakarma therapy on patients with type 2 diabetes.[42] Those treated with Shilajit showed significantly improved outcomes, with over half achieving controlled blood glucose levels and notable enhancements in fasting and postprandial glucose levels, HbA1c, lipid profiles, along with relief from symptoms like polyuria and neuropathy.[42] The study concluded that Shilajit Yoga, especially when paired with traditional cleansing therapies, can boost pancreatic function, decrease insulin resistance and serve as a powerful natural method for managing diabetes.[42]

Research on Shilajit's ability to regulate blood glucose is still limited, mainly due to significant gaps in existing studies. The available studies show modest success; however, they are often small, short-term designed study. These limitations restrict the broad applicability of research findings to diverse patient groups and raise concerns about long-term safety and efficacy. Shilajit's composition varies significantly based on the source and processing method, which complicates comparative analysis. Additionally, scientists have not yet proven how Shilajit lowers blood sugar levels in humans, as there has been insufficient investigation at the molecular level regarding its components. Current research does not sufficiently evaluate the long-term safety of Shilajit, particularly when used in combination with standard antidiabetic medications or among various population segments, including those with multiple health issues. Most clinical trials concentrate on blood glucose and HbA1c metrics while neglecting crucial data on recurring diabetic complications and mortality. To better understand Shilajit's potential for diabetes treatment, studies should prioritize standardized extraction processes and well-structured clinical trials.

Clinical evidence of Shilajit on reproductive health

Pandit et al conducted a double-blind, randomized, placebo-controlled clinical trial to assess the effects of PS on testosterone levels in healthy individuals aged 45 to 55.[43] The results showed that testosterone levels, including free testosterone and dehydroepiandrosterone (DHEAS), significantly increased in participants taking 250 mg of Shilajit twice daily for ninety days compared to those receiving a placebo ($p<0.05$).[43] Additionally, the treatment helped in stablizing LH and FSH hormone levels, which are responsible for regulating testosterone. These findings

suggest that participants who received Shilajit treatment had elevated DHEAS levels, peaking significantly on day 90 compared to their baseline and placebo results.[43] The study demonstrates that purified Shilajit enhances testosterone production and synthesis in healthy volunteers aged 45 to 55.[43]

In 2010, Biswas et al, conducted a randomized controlled trial involving 28 oligospermic men with a sperm count of less than 20 million/mls.[44] Participants received 100 mg of processed Shilajit twice daily for 90 days. This intervention led to a 61.4% increase in total sperm count, rising from 14.3±2.1 to 23.1±3.2 million/ml.[44] Additionally, sperm motility improved by 17.4%, increasing from 25.1%±4.2% to 42.5%±5.1% ($p<0.001$) and the percentage of normally formed sperm increased by 18.9%, from 35.2%±3.8% to 54.1%±4.6% ($p<0.001$) when compared to baseline.[44] Furthermore, semen oxidative stress, as indicated by malondialdehyde (MDA), decreased by 18.7%, while antioxidant levels of glutathione (GSH) increased. Research in rodents indicates that Shilajit can lead to an impressive 378% rise in spermatogonia-to-spermatid progression, consistent with the current findings; however, clinical data in non-oligospermic subjects remain limited.[44]

Clinical evidence of Shilajit on the cardiovascular system

Sharma et al, 2003 performed a double-blind, placebo-controlled clinical trial examining the effects of purified Shilajit on blood chemistry over 45 days with healthy human volunteers.[45] Participants were administered 2 g of Shilajit each day and the findings showed no significant alterations in vital signs or hematological measures, which validates its safety.[45] However, the supplementation led to a notable decrease in serum triglycerides, total cholesterol, LDL and VLDL cholesterol, while also causing a significant rise in HDL cholesterol, highlighting its hypolipidemic and cardioprotective properties.[45] Furthermore, Shilajit enhanced antioxidant levels, as indicated by increased superoxide dismutase (SOD), vitamin C and vitamin E. These clinical results endorse Shilajit's robust antioxidant and lipid-lowering capabilities in healthy individuals.[45]

Clinical evidence of Shilajit on hypertension

Patil et al, 2023 conducted a randomized controlled trial to evaluate the effectiveness of purified Shilajit (500 mg taken twice daily for 30 days) as a supplementary treatment for older adults with hypertension. The study included two groups of sixty participants aged 60 to 80 years, where one group received standard antihypertensive medication along with Shilajit, while the other group received only the standard treatment. Clinical assessments indicated that Shilajit supplementation led to a significant reduction in oxidative stress by lowering MDA and oxidized LDL levels, while simultaneously increasing three antioxidant markers: TAOC, SOD and GSH. These results imply that Shilajit enhances the natural antioxidant defenses in elderly patients with hypertension. Nevertheless, the measures of arterial stiffness and endothelial function (including baPWV, cfPWV, NOx, eNOS, ADMA and ET-1) remained stable throughout the trial. The study found no safety concerns, confirming that Shilajit is safe for this population. Overall, this research indicates that Shilajit serves as an effective antioxidant that alleviates oxidative stress issues in older individuals with hypertension.[46] In the research conducted by Sharma et al, 2003, which focused on metabolic and cardiovascular parameters, the supplementation of Shilajit did not result in any noteworthy alterations in systolic or diastolic blood pressure.[45]

Clinical evidence of Shilajit on skin health

Das et al, conducted a 14-week double-blind, placebo-controlled trial (NCT02762032) to assess the impact of oral Shilajit on skin health in middle-aged women.[47] The study had two phases, where participants took doses of 125 mg and 250 mg of Shilajit twice daily. The higher dosage of Shilajit (250 mg bid) showed greater benefits in skin microperfusion by enhancing dermoscopic skin redness.[47] The effects of Shilajit on gene expression in skin tissue revealed increased activity in genes linked to extracellular matrix (ECM) remodeling, particularly in crucial collagen genes (Col1A1, Col5A2, Col14A1), which were verified via RT-PCR.[47] Administration of Shilajit stimulated angiogenesis-related genes, vascular endothelial growth factor A (VEGFA) and transforming growth factor beta 1 (TGFβ1), as well as genes involved in the migration of vascular endothelial cells, such as Integrin alpha-5 (ITGA5), junctional adhesion molecule3 (JAM3), matrix metalloproteinase -2 (MMP2), and platelet-derived growth factor receptor beta (PDGFRB). This molecular analysis indicates that Shilajit contributes to blood vessel formation, aiding skin repair processes.[47] As a supplement, Shilajit was well-tolerated, with users reporting no side effects and maintaining normal skin barrier function, including hydration and elasticity.[47] The research results demonstrate that Shilajit offers safe advantages for both skin vascular development and structural protein synthesis, thereby promoting skin health amidst age-related microcirculatory and matrix deterioration.[47]

Moghadari et al, conducted a double-blind clinical trial with intensive care patients suffering from pressure ulcers to assess the effectiveness of topical "mummy" (Shilajit).[48] The study included 75 male ICU patients, who were randomly assigned to receive either routine care with a daily 20% aqueous Shilajit dressing applied to the ulcer or standard care alone.[48] Ulcer healing was monitored over a 28-day period and evaluated using PUSH criteria that focused on ulcer area, exudate volume and tissue characteristics. Both groups showed improvement, but the Shilajit group experienced significant enhancements: the mean ulcer area in this group decreased from 3.26 cm^2 to 0.53 cm^2, while the control group's area reduced from 5.10 cm^2 to 3.46 cm^2.[48] Additionally, the Shilajit group exhibited greater improvements in exudate and tissue assessments.[48] The Shilajit treatment led to considerably more pronounced overall wound closure ($p<0.05$). The

topical application of the Shilajit dressing significantly enhanced the closure and granulation of pressure ulcers compared to saline dressing.[48] Notably, the study by Neltner et al, 2024 observed a marked increase in type I collagen production with Shilajit supplementation, indicating its possible supportive function in preserving skin structure integrity.[37]

Clinical evidence of Shilajit on bone

A randomized clinical trial by Pingali et al, investigated the effects of Shilajit extract on postmenopausal women with osteopenia over a 48 weeks period, specifically examining their bone mineral density (BMD), oxidative stress markers, inflammatory response and bone turnover rates.[49] The study comprised sixty women aged 45 to 65, who were randomly assigned to receive either a placebo or one of two daily doses of standardized aqueous Shilajit extract (250 mg and 500 mg). The goal was to determine if Shilajit could help reduce bone loss due to estrogen deficiency in postmenopausal women.[49] Clinical findings showed that both Shilajit groups experienced dose-dependent increases in BMD at the lumbar spine and femoral neck. While the placebo group continued to lose bone throughout the study, those receiving Shilajit demonstrated a more substantial increase in BMD from baseline at both 24 and 48 weeks, especially in the 500 mg group.[49]

The supplemented groups also displayed favorable changes in bone turnover markers, indicating positive effects on bone health, with significant reductions in CTX-1, BALP and RANKL and elevated levels of OPG. These changes in bone remodelling suggested improved bone preservation.[49] Furthermore, markers for systemic inflammation and oxidative stress decreased with Shilajit supplementation. MDA (malondialdehyde) levels dropped significantly, while GSH (glutathione) concentrations began to rise after week 12.[49] The intake of Shilajit resulted in sustained reductions in inflammatory status, assessed through high-sensitivity C-reactive protein (hsCRP), throughout the study in both intervention groups, underscoring its protective influence on overall health.[49]

Sadeghi et al, 2020 conducted a randomized, double-blind, placebo-controlled clinical trial involving 160 patients aged 18 to 60 with acute tibial shaft fractures who were undergoing surgical repair.[50] Participants were randomized to receive either oral "Momiai" (purified Shilajit) at a dose of 1000 mg per day (two 500 mg capsules) or a matching placebo for a period of 28 days, starting immediately after surgery. The primary outcome measured was the time to radiographic bone union.[50] The group receiving Shilajit showed a notably quicker recovery: the average time for tibial union was 129 days in the Shilajit group, while it was 153 days in the placebo group (p=0.049).[50] No significant differences in adverse events were noted between the two groups (p=0.839). The authors concluded that oral Shilajit substantially enhanced fracture healing compared to the placebo, indicating its potential as an adjunct for bone healing.[50] The detail of various clinical studies conducted on Shilajit is shown in Table 1.

SAFETY STUDIES OF SHILAJIT FROM A CLINICAL PERSPECTIVE

Shilajit offers numerous health benefits and is widely used as a health supplement globally. Therefore, understanding its safety profile is crucial. Various preclinical and clinical studies indicate that Shilajit is safe when taken at the recommended doses, leading to its classification as GRAS. In one preclinical study, the LD50 of Shilajit in rats was determined to be 1000 mg/kg when given intraperitoneally, while it was found to be 2000 mg/kg for oral administration.[51] Another preclinical experiment administering Shilajit at doses of 100 mg/kg and 500 mg/kg over a month revealed no histopathological damage in mice and rabbits.[52] Conversely, a different study, which administered Shilajit at doses of 200 and 1000 mg/kg for 90 days (considered a subacute toxicity study), indicated toxicity.[53] Regarding its embryogenic effects, research involving pregnant rats and mice found no teratogenic or embryotoxic effects from Shilajit consumption.[53,54] Nonetheless, it is our position that the use of Shilajit by pregnant women remains unsafe and is not advisable.

However, for normal and healthy women, two clinical studies have reported its safe use.[38,47] In essence, the relevance of this research for human consumption is limited. Thus, it is recommended that pregnant or lactating women avoid it. Considering the clinical evidence of Shilajit from a safety perspective, a placebo-controlled trial found that taking 2000 mg of Shilajit capsules daily for 45 days resulted in no changes in body weight, liver function biochemical markers, kidney function or cardiovascular system performance.[45] In addition to this specific study, numerous clinical studies, as discussed in table 2, substantially validated the safety profile of Shilajit. In conclusion, numerous studies on Shilajit (mumie) involving both animals and humans demonstrate its robust safety profile.

Table 1: The clinical studies conducted on Shilajit.

Study	Participants	Intervention	Disease targeted	Key findings	References
Das et al	16 adults with overweight/obesity (BMI 25–35)	PrimaVie® Shilajit (250 mg twice daily for 8 weeks + exercise)	Obesity/Physical Fatigue	Upregulated 17 ECM-related genes (e.g., COL1A1, COL3A1) enhance muscle repair.	35
Neltner et al	Recreationally trained men	Shilajit (500 mg/day or 1000	Musculoskeletal Health	Enhanced type 1 collagen synthesis demonstrated an	37

Continued.

Study	Participants	Intervention	Disease targeted	Key findings	References
		mg/day for 8 weeks)		84% improvement in the high-dose group.	
Mosavi et al	43 reproductive-aged women	Shilajit (200 mg twice daily for 60 days)	Female Sexual Dysfunction	Improved Female Sexual Function Index (FSFI) scores rose from 23.02 to 28.92.	38
Sheikh et al	212 adults with hyperglycemia	Dolabi® (Unani formula with Shilajit) vs. metformin for 3 months	Type 2 Diabetes	Fasting blood sugar and HbA1c decreased by 20%, comparable to metformin's effect.	39
Gupta et al	Type 2 diabetes patients	Shilajatu vs. Asanadi Ghana Vati for 3 months	Type 2 Diabetes	Reduced blood glucose and HbA1c; symptoms have improved (polyuria, libido).	40
Dhiman et al	30 pre-diabetic patients	Shilajeet Vati (30 days)	Pre-Diabetes	Blood sugar levels decreased by 68–81% and symptoms, including thirst and hunger, improved.	41
Raju et al	Type 2 diabetes patients	Shilajit Yoga + Panchakarma therapy	Type 2 Diabetes/Neuropathy	Improved glucose regulation, lipid levels and neuropathy symptoms.	42
Pandit et al	Healthy men (45–55 years)	Purified Shilajit (250 mg twice daily for 90 days)	Age-Related Hormonal Decline	Increased testosterone and DHEAS; LH and FSH stabilized levels.	43
Sharma et al	Healthy volunteers	Shilajit (2 g/day for 45 days)	Cardiovascular Health	Lowered triglycerides and LDL; increased HDL and antioxidants (SOD, vitamins C and E).	45
Patil et al	60 elderly hypertensive patients	Shilajit (500 mg twice daily + antihypertensive meds for 30 days)	Hypertension/Oxidative Stress	Reduced oxidative stress (↓MDA, ↑GSH/SOD); no safety concerns.	46
Das et al	Middle-aged women	Shilajit (125 mg or 250 mg twice daily for 14 weeks)	Age-Related Skin Deterioration	Enhanced skin microperfusion and remodeling of the extracellular matrix (elevated COL1A1, VEGFA).	47
Pingali et al	60 postmenopausal women with osteopenia	Aqueous Shilajit extract (250 mg or 500 mg/day for 48 weeks)	Osteoporosis	Increased bone mineral density (BMD) and reduced levels of bone turnover markers (CTX-1).	49

DISCUSSION

Recently, numerous studies have documented the pharmacological properties of Shilajit in both preclinical and clinical contexts. These investigations have thoroughly examined the potential mechanisms through which Shilajit may influence various diseases. The evidence published thus far confirms that Shilajit possesses a strong safety profile, showing no adverse effects when taken at the recommended dosage. Most studies highlight Shilajit's androgenic properties and its effects on fatigue and energy metabolism. Additionally, animal research indicates that DBPs may protect mitochondria, which could further clarify Shilajit's advantages for physical performance and fatigue reduction.

Between 1960 and 1990, extensive research in the USSR explored the revitalizing benefits of Shilajit for both physical and mental health; however, these results have not been published. It was observed that Soviet Olympic athletes and military special forces commonly utilized Shilajit for its energy-boosting and adaptogenic properties.[55] Additionally, animal studies have explored the possible effects of Shilajit on different neurotransmitters, demonstrating significant cholinergic and parasympathomimetic effects. These results could highlight potential advantages for cognitive performance and enhanced fertility.

Moreover, Shilajit showcases specific neuroprotective mechanisms by activating the GABAergic system and blocking interactions with the dopaminergic system. Shilajit has also shown significant effects on bone and skin health in preclinical (not discussed in the previous section) and clinical studies.[49]

Its strong antioxidants and anti-inflammatory properties play a crucial role in neuroprotection by regulating Bax, Bcl-3, p53 and caspase-3 expression levels. There is a significant gap between the traditional use and scientific evidence of Shilajit; therefore, well-designed preclinical and clinical studies must be conducted to bridge this gap.

CONCLUSION

Undoubtedly, Shilajit is a powerful herbal-mineral compound with numerous health benefits. Recently, there has been a significant shift toward the use of natural products globally, resulting in increased consumption of Shilajit. However, there is a notable lack of comprehensive cellular and molecular studies examining the precise mechanisms through which Shilajit provides multiple health benefits. Therefore, conducting well-structured preclinical and clinical studies is crucial. Given that Shilajit is widely used as a health supplement, it is essential for consumers to be aware of product quality, especially due to the high risk of adulteration or counterfeiting.

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REFERENCES

1. Soliman WS, Salaheldin S, Amer HM. Chemical composition evaluation of Egyptian lemongrass, Cymbopogon citratus, essential oil. Int J Sci Eng Res. 2017;8:630–4.
2. Wilson E, Rajamanickam GV, Dubey GP, Klose P, Musial F, Saha FJ, et al. Review on Shilajit used in traditional Indian medicine. J Ethnopharmacol. 2011;136:1–9. https://doi.org/10.1016/J.JEP.2011.04.033.
3. Schepetkin I, Khlebnikov A, Kwon BS. Medical drugs from humus matter: Focus on mumie. Drug Dev Res. 2002;57:140–59.
4. Ghosal S. Chemistry of Shilajit, an immunomodulatory Ayurvedic rasayan. Pure Applied Chemistry. 1990;62:1285–8.
5. Khalikov SK, Alieva S V. Isolation of vitamin D3 from natural mumiyo. Chem Nat Compd 2003;39:410.
6. Kwon BS, Khlebnikov AI, Schepetkin IA, Woo SB. Fulvic acid fractions from mumie. 8th Korea-Russia International Symposium on Science and Technology –Proceedings. KORUS. 2005;3:352–5.
7. Garedew A, Feist M, Schmolz E, Lamprecht I. Thermal analysis of mumiyo, the legendary folk remedy from the Himalaya region. Thermochim Acta. 2004;417:301–9.
8. ARA-H, MU. Safe Use of Salajeet During the Pregnancy of Female Mice. J Biol Sci. 2003;3:681–4.
9. Agarwal SP, Khanna R, Karmarkar R, Anwer MK, Khar RK. Shilajit: a review. Phytoth Res. 2007;21:401–5.
10. Saleem AM, Gopal V, Rafiullah MRM, Bharathidasan P. Chemical and pharmacological evaluation of Karpura Shilajit bhasma, an ayurvedic diuretic formulation. African J Trad, Complem Alt Med. 2006;3:27–36.
11. Ghosal S. Shilajit in perspective. Oxford: Alpha Science International Limited; 2006.
12. Nadkarni K. Indian Materia Medica. 3rd edition. Vol 2. Popular Prakashan Private Ltd Bombay, India. 1954:2.
13. Bhishagratna KK, Bhishagratna K, Dwivedi L. Susruta Samhita: Text with English Translation, a Full and Comprehensive Introduction, Additional Text, Different Readings, Notes, Comparative Views, Index, Glossary and Plates. Chowkhamba Sanskrit Series Office. 1998.
14. Stohs SJ. Safety and efficacy of Shilajit (Mumie, Moomiyo). Phytotherapy Res. 2014;28:475–9.
15. Kamgar E, Kaykhaii M, Zembrzuska J. A Comprehensive Review on Shilajit: What We Know about Its Chemical Composition. Crit Rev Anal Chem. 2023;3:698.
16. Frolova LN, Kiseleva TL. Chemical composition of mumijo and methods for determining its authenticity and quality (a review). Pharm Chem J. 1996;30:543–7.
17. Kamgar E, Zembrzuska J, Zembrzuski W, Kaykhaii M. Quantifying of thallium in Shilajit and its supplements to unveil the potential risk of consumption of this popular traditional medicine. BMC Chem. 2025;19:1–8.
18. Qadir A, Ali A, Singh T. Phyto-Therapeutic Potential and Pharmaceutical Impact of Shilajit (Asphaltum punjabianam): Current Research and Future Prospect. 2024.
19. Ghezelbash B, Shahrokhi N, Khaksari M, Ghaderi-Pakdel F, Asadikaram G. Hepatoprotective effects of Shilajit on high fat-diet induced non-alcoholic fatty liver disease (NAFLD) in rats. Horm Mol Biol Clin Investig. 2020;41:87.
20. Joshi A, Das SK, Bisht L, Sakat S, Sharma V, Sharma N, Joshi K, Verma S, Sharma VK, Balkrishna A, Joshi CS. LC/MS-QToF Profiling, Anti-Diabetic and Anti-Adipogenic potential of Divya MadhuKalp: A Novel Herbo-mineral Formulation. bioRxiv. 2020.
21. Kim S, Seo C, Park H, Kwon JG, Kim JK, Moon HJ, et al. Shilajit, a Natural Phytocomplex Acts as a Neuroprotective Agent Against Amyloid Beta-induced Cytotoxicity and Inflammation. Persp Integ Med. 2024;3:114–22.
22. Khaksari M, Mahmmodi R, Shahrokhi N, Shabani M, Joukar S, Aqapour M. The Effects of Shilajit on Brain Edema, Intracranial Pressure and Neurologic Outcomes following the Traumatic Brain Injury in Rat. Iran J Basic Med Sci. 2013;16:858.
23. Saqib M, Malik R, Kausar S. Effect of Shilajit on Obesity in Hyperlipidemic Albino Rats.10.
24. Yadav S. valuation of Shilajit with Special Reference to Antioxidant and Hepatoprotective Activity. 2013.
25. Mishra RK, Jain A, Singh SK. Profertility effects of Shilajit on cadmium-induced infertility in male mice. Andrologia. 2018;50:13064.
26. Park JS, Kim GY, Han K. The spermatogenic and ovogenic effects of chronically administered Shilajit to rats. J Ethnopharmacol. 2006;107:349–53.
27. Rajpoot A, Pandey AK, Roy VK, Mishra RK. Shilajit Mitigates Diabetes-Induced Testicular Dysfunction in

Mice: A Modulation in Insulin Sensitivity, Germ Cell-Junctional Dynamics and Oxido-Apoptotic Status. Andrologia. 2025;2025:5517176.
28. Kanikkannan N, Ramarao P, Ghosal S. Shilajit-induced potentiation of the hypoglycaemic action of insulin and inhibition of streptozotocin induced diabetes in rat. Phytoth Res. 1995;9:478–81.
29. Aparna A, Rege A, Chowdhary AS. Evaluation of Alpha-Amylase and Alpha-Glucosidase Inhibitory Activities of Shilajit. Int J Adv Res. 2014;2:735–40.
30. Trivedi NA, Mazumdar B, Bhatt JD, Hemavathi KG. Research Paper - Effect of Shilajit on blood glucose and lipid profile in alloxaninduced diabetic rats 2004.
31. Bhattacharya SK. Shilajit attenuates streptozotocin induced diabetes mellitus and decrease in pancreatic islet superoxide dismutase activity in rats. Phyto Res. 1995;9:41–4.
32. Bhattacharyya S, Pal D, Gupta AK, Ganguly P, Majumder UK, Ghosal S. Beneficial effect of processed Shilajit on swimming exercise induced impaired energy status of mice. Pharmacology. 2009;1:817–25.
33. Alqarni A, Hosmani J, Mohammed R, Alqahtani A, Alasiri S, Alhamid N, et al. Shilajit (Mumio) Elicits Apoptosis and Suppresses Cell Migration in Oral Cancer Cells through Targeting Urokinase-type Plasminogen Activator and Its Receptor and Chemokine Signaling Pathways. Pharmacogn Mag. 2025;21:491–506.
34. Pant K, Singh B, Thakur N. Shilajit: A humic matter panacea for cancer. International J Toxicol Pharmacol Res. 2012;4:17–25.
35. Das A, Datta S, Rhea B, Sinha M, Veeraragavan M, Gordillo G, et al. The Human Skeletal Muscle Transcriptome in Response to Oral Shilajit Supplementation. J Med Food. 2016;19:701–9.
36. Keller JL, Housh TJ, Hill EC, Smith CM, Schmidt RJ, Johnson GO. The effects of Shilajit supplementation on fatigue-induced decreases in muscular strength and serum hydroxyproline levels. J Int Soc Sports Nutr. 2019;16:3.
37. Neltner TJ, Sahoo PK, Smith RW, Anders JP, Arnett JE, Schmidt RJ, et al. Effects of 8 Weeks of Shilajit Supplementation on Serum Pro-c1α1, a Biomarker of Type 1 Collagen Synthesis: A Randomized Control Trial. J Diet Suppl. 2024;21:1–12.
38. Mosavi S, Tabarrai M, Tansaz M, Salehinia H, Grylka S, Rahmani A, et al. Effects of oral Shilajit tablets on sexual function and sexual quality of life among reproductive-aged women: a triple-blind randomized clinical trial. Trad Med Res. 2023;8:66.
39. Sheikh H, Alam MdK, Samad MdA. Comprehensive Evaluation of the Clinical Efficacy of an Anti-Diabetic Polyherbal Formulation. Turkish J Agricul-Food Sci Technol 2023;11:1905–16.
40. Gupta V, Keshari B, Tiwari S, Narasimha Murthy KHHVSS. A comparative study of Shilajatu and Asanadi Ghana Vati in the management of Madhumeha w.s.r. to type-2 diabetes mellitus. Ayu 2016;37:120.
41. Dhiman E, Jha N, Kumar Panda P. A clinical study of shilajeet vati in prameha purvarupa (pre-diabetic state). 2021;266-2670.
42. Raju KN, Sharma RS. A Comparative Clinical Study of Vamana & Virechana with and without Shilajit Yoga in the Management of Madhumeha wsr to Type-2 Diabetes Mellitus. MJF Ayurved College & Hospital Chomu, Jaipur. 2016.
43. Pandit S, Biswas S, Jana U, De RK, Mukhopadhyay SC, Biswas TK. Clinical evaluation of purified Shilajit on testosterone levels in healthy volunteers. Andrologia 2016;48:570–5.
44. Biswas TK, Pandit S, Mondal S, Biswas SK, Jana U, Ghosh T, et al. Clinical evaluation of spermatogenic activity of processed Shilajit in oligospermia. Andrologia 2010;42:48–56.
45. Sharma P, Jha J, Shrinivas V, Dwivedi LK, Suresh P, Sinha M. Shilajit: evalution of its effects on blood chemistry of normal human subjects. Anc Sci Life. 2003;23:114–9.
46. Patil SG, Patil KA, Sarashetti R, Hadimur K, Patil SG, Patil KA, et al. Effect of purified Shilajit (Asphaltum punjabianum) on oxidative stress, arterial stiffness and endothelial function in elderly with hypertension: A randomised controlled study. Indian J Physiol Pharmacol. 2023;67:197–204.
47. Das A, S. El Masry M, Gnyawali SC, Ghatak S, Singh K, Stewart R, et al. Skin Transcriptome of Middle-Aged Women Supplemented With Natural Herbo-mineral Shilajit Shows Induction of Microvascular and Extracellular Matrix Mechanisms. J Am Coll Nutr. 2019;38:526–36.
48. Moghadari M, Rezvanipour M, Mehrabani M, Ahmadinejad M, Tajadini H, Hashempur MH. Efficacy of mummy on healing of pressure ulcers: A randomized controlled clinical trial on hospitalized patients in intensive care unit. Electron Physician. 2018;10:6140–7.
49. Pingali U, Nutalapati C. Shilajit extract reduces oxidative stress, inflammation and bone loss to dose-dependently preserve bone mineral density in postmenopausal women with osteopenia: A randomized, double-blind, placebo-controlled trial. Phytomed 2022;105:154334.
50. Sadeghi SMH, Hosseini Khameneh SM, Khodadoost M, Hosseini Kasnavieh SM, Kamalinejad M, Gachkar L, et al. Efficacy of Momiai in Tibia Fracture Repair: A Randomized Double-Blinded Placebo-Controlled Clinical Trial. J Alternative and Complem Med 2020;26:521–8.
51. Acharya SB, Frotan MH, Goel RK, Tripathi SK, Das PK. Pharmacological actions of Shilajit. Indian J Exp Biol. 1988;26:775–7.
52. Kel'ginbaev NS, Sorokina VA, Stefanidu AG, Ismailova VN. Treatment of long tubular bone fractures with Mumie Assil preparations in experiments and clinical conditions. Eksp Khir Anesteziol. 1973;18:31–5.

53. Anisimov VE, Shakirzyanova RM. Application of Mumie in therapeutic practice. Kazan Med Zh. 1982;63:65–8.
54. Al-Himaidi AR, Mohammed U. Safe use of salajeet during the pregnancy of Female mice. Online J Biol Sci. 2003;3:681–4.
55. Bucci LR. Selected herbals and human exercise performance123. Am J Clin Nutr. 2000;72:624-36.

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