IMMEDIATE NORMOTENSIVE EFFECTS OF LEECH THERAPY: A PILOT STUDY


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ABSTRACT

Background: A disease means when somebody is not at ease, in case of what is called hypertension or hypotension majority of patients are usually without symptom. We usually label someone with hypertension, hypotension or normotension by using blood pressure apparatus. While following different criteria’s which are being changed time to time. Clinically hypertension is more important and is usually treated with almost 9 groups of medicine, out of them no one is reducing any body’s blood pressure but are reducing blood volume, reducing pumping rate of heart, dilating blood vessels etc. As we are living in a “scientific era” yes, we have been able to invent diseases but still we don’t have any drug or modality to keep hypertension or hypotension with-in the statically average scale called normal. Now need of time is to find a solution for both hypertension or hypotension and this pilot study may open a new chapter not only useful in management of hypertension/ hypotension but also will be point of interest for discussion & research in front of researchers.

Aims and Objective: To find out a natural solution for maintaining “normal” blood pressure and evaluation in the management of hypertension / hypotension by leech therapy (hirudotherapy).

Materials and Methods: The present study carried out at Unani and Panchakarma hospital, Sekidafar Chowk, Eid Gah, Srinagar. This research is single open clinical pilot study, having a sample size of seven patients of either sex. 6-8 leeches (H. medicinalis) were applied on interscapular region for fifteen minutes.

Results: Results were measured by measuring the blood pressure before and after 15 minutes of leech therapy.

Conclusion: Leech acts as anti-hypotensive in hypertension and normotensive in hypotension. Thus, leech is only a wonder therapy which is effective to stabilize blood pressure immediately in hypertension as well as in hypotension.

Keywords: Hypertension, Hypotension, Normotension, Leech therapy, Unani Medicine.
INTRODUCTION

According to Merry curry science is measurement and measurement is science. So, anything which is not measurable is not science. Blood pressure also became the science after the invention of blood pressure meter or blood pressure gauge (now called Sphygmomanometer) was invented in year 1881 by Samuel Siegfried Karl Ritter Von Basch. Now in the advanced scientific era we know ninety to ninety five percent causes for hypertension are idiopathic and only five to ten percent are known causes. Idiopathic is a Greek word, idio means of “once own” and pathic mean “suffering”. The idiopathic hypertension is some time synonyms to essential hypertension. If a man / woman called physician or a doctor is not knowing the cause of essential hypertension the question arise how he does or she is knowing the treatment of essential hypertension. On the other end if we analyzing the word idio means own then again question arise whose own blood pressure and why we need to interfere in idiopathic hypertension. Does it mean after invention of blood pressure machine after approx. 141 years ago we are not able to name a relevant term for idiopathic or essential hypertension. Hypotension is not considered a disease unless until we the physician suspect it may cause hypoxia and again there is no criteria for “when physician will suspect”. So individually different physician considered hypotension independently.

Before discussing further about the hypertension/ hypotension we should know the normal blood pressure.

No one knows that what is normal blood pressure? We only have statistical average which are being considered as normal levels. If one understands basic statistics, one quickly realizes that converting averages into normal, brings in significant false positives and false negative results. The false positives might let many normal people into the hypertensive category. Normal blood pressure keeps going up and down continuously and varies from time to time and with changes in moods and emotions. It also depends to a large extent on the surroundings- weather, time of the day, the most important, who checks the BP? There could be 17 errors in BP checking by inexperienced people. Please also be informed that two readings at any time checked by the same individual cannot be identical.¹

The definition of normality in medical science is also not scientific. It is the mean plus/minus two standard deviations of the normal Gaussian distribution of blood pressures in society. This becomes very vague when you realize that blood pressures of normal people are not static. There is a dynamic marked variation in the pressure from second to second called as healthy chaos. In a dynamic system like the human body the healthy chaos results in 5-15% of absolutely normal people being labelled hypertensives on routine checkup, this applies to all other parameters of the body like blood sugar, cholesterol etc. making routine checkup of apparently healthy people in society the most dangerous activity.²

In contrast, what the doctor measures with his BP box is probably the volume of blood in that segment of the vessel at that point in time. If that were so it has no relevance to the blood flow in the whole system. Pressure does not produce lateral pressure in laminar flows but volume does. Two examples will suffice. In areas with severe winter when the ground temperatures become ice inside the vessel increasing its burst because water becomes ice inside the vessels increasing its volume. Same way when someone bleeds profusely and reduces the blood volume, the BP record is very low. Similarly, when the heart become too weak to contract just before death BP cannot be recorded,
so what we record is not blood pressure. What matters between health, life and death is the mean capillary pressure, which cannot be measured on the bed side.\(^3\)

It is now estimated that, as of today, 7.4 millions of Americans are on drug therapy for wrong reasons, with the potential dangers of deadly drug side effects. The committee also suggested that beta-blockers, ACE inhibitors and ARBs are not the ideal drugs for hypertension because of their side effects. Diuretics should be the main line drugs with, may be, calcium channel blockers as a second-choice drugs. But the mainstay of treatment should be diet, exercise and mental tranquility modalities. Statins and aspirin have no role to play in this disease unless there are other complications.

One example is enough. Seventeen studies of drug therapy of hypertension when computed together give the following picture. Relative risk reduction was 21\% (This measure alone is flaunted on doctors and lay press readers and TV viewers.) However, the absolute risk reduction was only -0.8\%. The expected life expectancy without treatment was 96\% but the same with drugs was only 96.8\%.\(^7\) 420 Better than all these is the NNT (number needed to treat measure). Look at the WOSCOPS, “200 men without any prior heart disease have to swallow 357,700 tablets over five years to save one of them from dying from coronary heart disease.”\(^4\) The MRC mild- moderate hypertension study published in the BMJ in 1985 showed “to save one life from probable stroke in the next five-year, 850 people will have to be drugged” means (1,551,250 tablets are to be consumed to save one person from stroke). “This is due to fact that no exact knowledge exists as to who of these 200 and 850 will benefit from the treatment”.\(^5\) If we present these data to our intelligent people in simple language, they would opt out of drug therapy on their own and could be saved from the unnecessary ADR deaths which take a very heavy toll of other- wise useful human lives.\(^6\)

Controlling hypertension with chemical drugs does not seem to be as good as having normal blood pressure to being with or controlling elevated blood pressure by diet exercise, and change of mode of living. The largest MRFIT study, after 25- year follow-up, showed that there are no risk factors and controlling the so-called risk factors with chemicals does not prevent the final risk of premature death and disability.

**History of Blood Pressure**

The modern history of hypertension begins with the understanding of the cardiovascular system based on the work of physician William Harvey (1578–1657), who described the circulation of blood in his book De motu cordis. The English clergyman Stephen Hales made the first published measurement of blood pressure in 1733.\(^7,8\) Descriptions of what would come to be called hypertension came from, among others, Thomas Young in 1808 and especially Richard Bright in 1836.\(^7\)Bright noted a link between cardiac hypertrophy and kidney disease, and subsequently kidney disease was often termed Bright's disease in this period. In 1850 George Johnson suggested that the thickened blood vessels seen in the kidney in Bright's disease might be an adaptation to elevated blood pressure.\(^9\) William Senhouse Kirkes in 1855 and Ludwig Traube in 1856 also proposed, based on pathological observations, that elevated pressure could account for the association between left ventricular hypertrophy to kidney damage in Bright's disease.\(^10\) Samuel Wilks observed that left ventricular hypertrophy and diseased arteries were not necessarily associated with diseased kidneys,\(^11\) implying that high blood pressure might occur in people with healthy kidneys; however the first report of elevated blood pressure in a person without evidence of kidney disease was made by...
Frederick Akbar Mahomed in 1874 using a sphygmograph. The concept of hypertensive disease as a generalized circulatory disease was taken up by Sir Clifford Allbutt, who termed the condition "hyperpiesia". However hypertension as a medical entity really came into being in 1896 with the invention of the cuff-based sphygmomanometer by Scipione Riva-Rocci in 1896, which allowed blood pressure to be measured in the clinic. In 1905, Nikolai Korotkoff improved the technique by describing the Korotkoff sounds that are heard when the artery is auscultated with a stethoscope while the sphygmomanometer cuff is deflated. Tracking serial blood pressure measurements was further enhanced when Donal Nunn invented an accurate fully automated oscillometric sphygmomanometer device in 1981.

The term essential hypertension ('Essentielle Hypertonie') was coined by Eberhard Frank in 1911 to describe elevated blood pressure for which no cause could be found. In 1928, the term malignant hypertension was coined by physicians from the Mayo Clinic to describe a syndrome of very high blood pressure, severe retinopathy and inadequate kidney function which usually resulted in death within a year from strokes, heart failure or kidney failure. A prominent individual with severe hypertension was Franklin D. Roosevelt. However, while the menace of severe or malignant hypertension was well recognized, the risks of more moderate elevations of blood pressure were uncertain and the benefits of treatment doubtful. Consequently, hypertension was often classified into "malignant" and "benign". In 1931, John Hay, Professor of Medicine at Liverpool University, wrote that "there is some truth in the saying that the greatest danger to a man with a high blood pressure lies in its discovery, because then some fool is certain to try and reduce it". This view was echoed in 1937 by US cardiologist Paul Dudley White, who suggested that "hypertension may be an important compensatory mechanism which should not be tampered with, even if we were certain that we could control it". Charles Friedberg's 1949 classic textbook "Diseases of the Heart" stated that "people with 'mild benign' hypertension ... [defined as blood pressures up to levels of 210/100 mm Hg] ... need not be treated". However the tide of medical opinion was turning: it was increasingly recognised in the 1950s that "benign" hypertension was not harmless. Over the next decade increasing evidence accumulated from actuarial reports and longitudinal studies, such as the Framingham Heart Study, that "benign" hypertension increased death and cardiovascular disease, and that these risks increased in a graded manner with increasing blood pressure across the whole spectrum of population blood pressures. Subsequently, the National Institutes of Health also sponsored other population studies, which additionally showed that African Americans had a higher burden of hypertension and its complications.

CHEMICAL COMPOSITION OF LEECH SALIVA

The near painlessness of leech’s bite is due to the contents of leech saliva, which contains a number of different chemical compounds. The saliva of leech contains anaesthetic, which makes the bite of the leech painless to its host; an histamine like vasodilator which increases the blood flow to the feeding areas by increasing the diameter of the blood vessels; and a chemical enzyme called hyaluronidase, which facilitates the degradation of the connective tissues around the bite site allowing the vasodilator substance, wider access to the area. There is also an anticoagulant Hirudin, which is responsible for inhibiting blood coagulation and is employed as an anticoagulant in surgical operations and has been recommended for the prevention of phlebitis and post-operative pulmonary inflammation. Leech saliva also contains several other bioactive substances as mentioned in Table-01.
Table-01-Important composition of leech saliva

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Bioactive Substance</th>
<th>Mode of action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Acetylcholine</td>
<td>Acetylcholine vasodilator</td>
</tr>
<tr>
<td>2.</td>
<td>Bdellins</td>
<td>Anti-inflammatory, Inhibits trypsin, plasmin, and acrosin.</td>
</tr>
<tr>
<td>3.</td>
<td>Calin</td>
<td>Inhibits blood coagulation by blocking the binding of von willebrand factor to collagen-mediated platelet aggregation.</td>
</tr>
<tr>
<td>4.</td>
<td>Carboxypeptidase</td>
<td>A increase the inflow of blood at the bite site of inhibitors</td>
</tr>
<tr>
<td>5.</td>
<td>Complement inhibitors</td>
<td>May possibly replace natural complement inhibitors, if they are deficient.</td>
</tr>
<tr>
<td>8.</td>
<td>Factor Xa- inhibitor</td>
<td>Inhibits the activity of coagulation factor Xa by forming equimolar complexes.</td>
</tr>
<tr>
<td>9.</td>
<td>Hirudin</td>
<td>Inhibits blood coagulation by binding to thrombin</td>
</tr>
<tr>
<td>10.</td>
<td>Hirustasin</td>
<td>Inhibits kallikerin, trypsin, chymotrypsin, neutrophilic cathepsin G</td>
</tr>
<tr>
<td>11.</td>
<td>Histamine like</td>
<td>A vasodilator increases the inflow of blood at the bite site.</td>
</tr>
<tr>
<td>12.</td>
<td>Hyaluronidase</td>
<td>It reduces the viscosity and renders the tissues more readily permeable to injected fluids, increasing the speed of absorption. This promotes re-absorption of excess fluids and extravagated.</td>
</tr>
<tr>
<td>13.</td>
<td>Tryptase</td>
<td>Inhibitor Inhibits proteolytic enzymes of host mast cells.</td>
</tr>
</tbody>
</table>

**Indication of Leech therapy:** Varicose vein, Ringworm, Alopecia, Lymphadenitis, Malignant ulcer, Psoriasis, Eczema, Elephantiasis, CVS disorder, Gangrenous wound, Osteoarthritis, Phlebitis and thrombotic conditions, Preventing post-surgical, blood clotting, Odontalgia, periodontitis and alveolar abscess, Hypertension, Post-operative skin grafting lesions, Revascularization of amputated fingers & toes after replantation procedure.

**Recent Scientific research of leech therapy in different diseases**

**Use of leeches in phlebology and cardiovascular disorders**

Leech therapy has been proven effective in treating disorders of venous origin such as acute, subacute, chronic thrombophlebitis and post-phlebitis syndrome. \(^{30}\) Forty patients suffering from postphlebitis syndrome underwent leech therapy by having 7-12 leeches placed on their legs every 3-4 weeks. After the treatment, 70% of the patients claimed they could walk further, 52% stated they had less pain, 40% had better leg skin colour and 12% had reduced leg swelling. No infections or significant blood loss were reported post leech therapy. \(^{31}\) As for leech therapy in cardiovascular disorders, a study by Kuznezeva et al. revealed that more than 50% of patients suffering from coronary heart failure showed a reduction in dyspnoea and peripheral oedema and an increase in physical stress
tolerance.\textsuperscript{32} Besides that, significant reductions in blood pressure were also observed in patients suffering from hypertension.\textsuperscript{30,32}

**Cardiovascular diseases:**

CVDs are a group of chronic abnormalities affecting the cardiovascular system including heart, veins and arteries.\textsuperscript{33} Among the incurable diseases, CVDs were considered the principal culprit of mortality, causing up to 30\% of global deaths by the year 2008.\textsuperscript{34} The on-going incidence rate of morbidity and mortality caused by CVDs were the main reason behind intensive researches looking for potent medications with fewer side-effects.\textsuperscript{35} Leech therapy has established itself as an alternative remedy for the treatment of vascular disorders, since leech saliva can temporarily improve blood flow and ameliorate connective tissue hyperalgesia.\textsuperscript{36} By the year 1997, a novel antithrombotic and anticoagulant pharmaceutical preparation was released to the Russian markets under the trade name “Piyavit”, which consisted of the medicinal leech saliva extract. The product was prescribed as thrombolytic and antiplatelet. Clinical studies revealed that it can reduce blood hypercoagulability with an anti-inflammatory effect in patients with thrombophlebitis.\textsuperscript{37} Likewise, patients with phlebitis who received topical leeching exhibited better walking ability, less pain and minor leg swelling, along with near-normal leg skin colour.\textsuperscript{38} In such cases, medics usually apply 4-6 leeches directly to the affected area. Many therapists used leeches for the healing of hypertension, varicose veins, hemorrhoids, gonarthrosis, and secondary ischemia-related dermatosis.\textsuperscript{36,39} The effectiveness of leech saliva in CVDs is the results of specific thrombin inhibitors, hirudin, which was first isolated from H. medicinalis \textsuperscript{40,41} and was shown to possess a potent inhibitory effect on both free and clot-bound thrombin.\textsuperscript{42,43} Furthermore, other thrombin inhibitors were identified from different leech species. For instance, bufrudin was isolated from H. manillensis with a chemical structure closely similar to hirudin.\textsuperscript{44} A tight-binding thrombin inhibitor named haemadin was identified from the whole-body extract of the leech species Haemadipsa sylvestris.\textsuperscript{45} Another antithrombin named granulin-like was isolated from the leech species H. nipponia.\textsuperscript{46} Finally, a human granulocyte and monocyte protein inhibitor known as theromin was characterized from the head extract of Theromyzon tessulatum leech species with an antithrombin activity.\textsuperscript{47} Noteworthy, hirudin is the only hematophagous animal-derived anticoagulant has been approved by FDA for clinical purposes.\textsuperscript{35} Many studies revealed that hirudin is more effective than heparin in preventing deep venous thrombosis (DVT) and ischemic events in patients with unstable angina.\textsuperscript{35} In contrast to the indirect thrombin inhibitors, heparin and low molecular weight heparins, hirudin has the advantage of exerting a direct inhibitory effect on thrombin without the need for endogenous cofactors (antithrombin III). Thus, hirudin became the drug of choice for patients with a disseminated intravascular coagulation syndrome (antithrombin III deficiency). Hirudin can be used safely in patients with platelet abnormalities or heparin-induced thrombocytopenia because it has no immune effects on erythrocytes.\textsuperscript{43} Furthermore, and unlike heparins, hirudin has a promising prophylactic activity in patients who are at a high-risk of developing cardiovascular events because it can hinder thrombus growth due to its ability to block thrombin-fibrin binding. Consequently, it was reported that hirudin can reduce DVT, pulmonary embolism and the spread of venous thrombosis.\textsuperscript{35,43} Hirudin discovery was the motive for developing many new promising anticoagulants using recombinant technology methods. For example, two analogs, lepirudin, and desirudin have been approved by FDA and are currently in use under the trade names, Refludan® and
Iprivask®, respectively. Precisely, desirudin is meanwhile in use for the prevention of DVT following hip or knee replacement surgery. On the other hand, leeches have developed other active compounds targeting different coagulation factors, such as antiplatelet, factor Xa (FXa) inhibitors, and fibrinolytic enzymes. First, a potent antiplatelet named decorsin was identified from Macrobdella decora with a high affinity to glycoprotein IIb-IIIa receptors. Second, a platelet adhesion and activation inhibitor named calin was isolated from the salivary secretion of the European leech H. medicinalis and it was believed to act by inhibiting collagen and von Willebrand factor. In addition, saratin from the leech Haementeria ghilianii has been described as a platelet aggregation inhibitor via blocking the binding of collagen to integrin α2 β1 and von Willebrand factor. From a pharmacological point of view, the activated platelet glycoprotein IIb-IIIa functions as a receptor for fibrinogen, vitronectin, von Willebrand factor and fibronectin. Therefore, the inhibitors of these surface receptors could be used as medications for the treatment of acute coronary syndrome disease. Furthermore, several inhibitors of factor Xa were identified from leech saliva extract such as ghilanten, lefaxin and therostatin from H. ghilianii, H. depressa and T. tessulatum, respectively. It has been evidenced that FXa plays a key role in the human body hemostasis. Both extrinsic and intrinsic pathways of the coagulation process result in the activation of FXa, which mediates the conversion of prothrombin (FII) into thrombin (FIIa). Moreover, hementin and hementerin were characterized from H. ghilianii and H. depressa and reported as fibrinogenolytic enzymes. Interestingly, the cleavage of fibrinogen leads to early blockade of the coagulation cascade, which also makes fibrinogenolytic compounds very promising therapeutic tools.

Mode of action of Leechtherapy

Bioactive compounds like hyaluronidase and collagenase secreted through the leech saliva help open the host tissue upon biting. Following this, leeches have an evolved mechanism to control their host coagulation processes. This is mainly achieved by blocking peripheral nociception effect during the bite to reduce local inflammation as well as producing anti-coagulants, anti-aggregating agents and vasodilating substances to maintain the blood in a fluid state during intake and subsequent digestion. This is necessary as any stress due to the bite will induce a host inflammatory response leading to the migration of large number of leucocytes to the site of injury. Migrations of these leucocytes are undesired because they release protein blood-degrading enzymes. So, by employing the strategy mentioned, leeches can prevent leucocyte migration and in return obtain a long window period necessary for blood meal digestion. This concept led to a search for a variety of coagulation inhibitors from blood sucking animals such as bats, ticks, leeches and hookworms. Among these inhibitors, hirudin, from a leech species, was the first thrombin inhibitor isolated and studied. Due to the useful bioactive compounds in the leech saliva and the efficient mode of action, leeches have been extensively used for therapeutic purposes. Some of the successful medical treatments performed using hirudotherapy have been described in the following section.
Mechanism and adverse effects of Antihypertensive drugs

1- **Diuretics**- It inhibit Na\(^+\)- Cl\(^-\) symport in early DCT
   - \(\downarrow\)
   - Promote Na and Water excretion
   - \(\downarrow\)
   - \(\downarrow\)Na\(^+\) Concentration in vessels
   - \(\downarrow\)
   - \(\downarrow\)PVR
   - \(\downarrow\)
   - \(\downarrow\)BP

**Adverse effects**- Hypokalemia, Hyperglycemia, Hyperuricemia, Hypercalcemia

2- **ACE- inhibitor** (Angiotensin converting enzyme inhibitor)
   - This group of drugs inhibit the enzyme kininase II or ACE. So, these drugs decrease the activity of RAAS and also potentiate the vasodilatory action of bradykinin.

**Adverse effects**- Cough, Hypokalemia, Hypotension, Acute renal failure, Angioedema, Rashes, Urticaria, Dysgeusia, Foetopathic and neutropenia.

3- **ARBs** (Angiotensin receptor blockers)
   - These drugs act by antagonizing the action of angiotensin II at AT I receptors.

**Adverse effects**- Headache, Hypotension, Rashes, Nausea, vomiting and teratogenic effects.

4- **Renin inhibitors**- These groups of Antihypertensive drugs are inhibit the enzyme renin and decrease the activity of RAAS causing fall in BP.

**Adverse effects**- Aliskerin can cause diarrhea at higher doses and they also causes cough and angioedema.

5- **Beta-adrenergic blockers**- Inhibition of beta I receptors leading to decreased cardiac output.
   - Decrease in renin release due to inhibition of beta I receptors in JG cells of kidney, along with this inhibit AT-II and aldosterone production and lower peripheral resistance.
   - Inhibit of central and peripheral sympathetic outflow due to inhibition of presynaptic stimulatory beta receptors on adrenergic neurons.

**Adverse effects**- Fatigue, lethargy, loss of libido, cognitive defects, difficult to stop suddenly withdrawal symptom and bronchospasm.
6- **Alpha-adrenergic blockers**

These drugs produce a comparative block of alpha I adrenoceptors. They decrease PVR and lowers arterial BP by causing relaxation of both arterial and venous smooth muscle. Therefore, long term tachycardia does not occur but salt and water retention does.

**Adverse effects**: Fluid retention in monotherapy, headache, dry mouth, weakness, blurred vision, drowsiness and failure of ejaculation in male.

7- **Calcium Channel Blocker**- CCBs block the inward movement of calcium by binding to L type calcium channels in the heart and in the smooth muscles of the coronary and peripheral vasculature.

This cause vascular smooth muscles to relax, dilating mainly arterioles,

**Adverse effects**: Constipation occur in 10% of patients treated with vera pamil, and dizziness, headache, falling of fatigue caused by decrease in BP are most frequent with dihydropyridines.

8- **Vasodilators**

Arteriolar vasodilators: - Hydralazine muscles combined with receptors in the endothelium of arterioles.

No release relaxation of vascular smooth muscles fall in BP.

Subsequent fall in BP- stimulation of adrenergic system lading to cardiac stimulation producing palpitation and rise in IHD and patients – anginal attack.

Tachycardia and increased Renin secretion -Na⁺ retention.

These effects are countered by adminstration of beta blockers and diuretics.

**Adverse effects**: Headache, tachycardia, nausea, sweeting, arrhythmic preceipitation of angina. A lupus like syndrome can discontinuation of the drug. Water retention leading to volume overload, edema and CHF.

**Mechanism of Leeching in Comparison of Anti-hypertensive drug**

The blood thinning effect, vasodilator effect, thrombolytic effect can be co related with enzymatic actions of Hirudu medicinalis Such actions can be understood once leeches are employed in hypertension, but when same number of leeches are applied in patients with hypotension their blood pressure goes upwards to the normal range means vasodialation thrombolytic and blood thinning effect is not sufficient to justify the role of leech therapy in hypertension. That means there are certain substances as well which may be acting on arteries, capillaries walls, kidneys, on baroreflexes & blood pressure regulating center in brain, hence helpfull in normalizing the blood pressure. As on date there is no known drug or modelty which can directly act as antihypertensive and at the same time as hypotensive that means leech therapy is giving us a strong clue to understand the unknown factors in the treatment of hypertension & hypotension. But further studies are to be needed to understood their actual mechanism of action as normotensive if human race will be able to understand this mechanism it will open a new chapter in medical sciences. Hence further detailed scientific study is required.
Materials and Methods:

The present research is an open clinical pilot study. Seven patients were selected from OPD of Unani and Panchakarma Hospital, Sekidafer, Srinagar and were properly screened undergoing the clinical study.

Objective:

To evaluate the efficacy of Leech therapy as immediate normotensive effect.

Place of Study:

Unani and Panchakarma Hospital, Sekidafar Chowk, Srinagar.

Duration of Study:

One month

Sample Size:

Seven patients

Inclusion criteria:

Age between 40 to 60 years
Either sex male or female
Patients not on antihypertensive drug
Voluntarily participants who have signed ICF.

Exclusive criteria:

Patients age below 40 years and above 60 years.
Patients with Metabolic disorder.
Hemophilia and other blood related disorders.

Subject of selection:

Patients selected from OPD were told to sit at ease for fifteen to twenty minutes then only, examined and blood pressure were measured in right as well as in left arm by Mercury sphygmomanometer. In this study only those patients were selected who were having unremarkable fluctuation in the three readings. The difference of blood pressure between the two arms were also observed before and after leech therapy. Apart from symptomatic relief in hypertension / hypotension patients our main focus was to observe the measurable difference in hypertension / hypotension which has shown significant results.

Procedure:

The medicinal leeches were applied on interscapular region after proper hematological investigation. The area (intrascapular) was exposed and cleaned with distilled water. Patients were asked to be in prone position on the bed and fresh leeches were applied six to eight in number. The leeches were allowed to suck the blood without disturbance for fifteen minutes, leech therapy was followed by proper dressing with antiseptic measures. After the completion of leech therapy patients were asked to wait for fifteen minute and then blood pressure was measured again in both the arms. Blood pressure was recorded before and after the therapy on a designed format for this study.

Now we are also observing the long-term effects of leech therapy in hypertension as well as in hypotension.
Investigation before leech therapy:
Blood Sugar random
Hemogram
Bleeding time
Clotting time

Route of Administration:
Locally on interscapular region

Study design:
An open clinical pilot study

Assessment of Efficacy:
Assessment of efficacy based on measuring the blood pressure by Mercury sphygmomanometer after fifteen minutes of leech therapy.

Result and Observation:

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Right Arm</th>
<th>Left Arm</th>
<th>Right Arm</th>
<th>Left arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>180/110 mmHg</td>
<td>170/110 mmHg</td>
<td>140/85 mmHg</td>
<td>120/85 mmHg</td>
</tr>
<tr>
<td>2</td>
<td>100/70 mmHg</td>
<td>90/60 mmHg</td>
<td>120/80 mmHg</td>
<td>110/70 mmHg</td>
</tr>
<tr>
<td>3</td>
<td>210/90 mmHg</td>
<td>200/100 mmHg</td>
<td>180/80 mmHg</td>
<td>160/80 mmHg</td>
</tr>
<tr>
<td>4</td>
<td>180/120 mmHg</td>
<td>180/130 mmHg</td>
<td>130/85 mmHg</td>
<td>130/90 mmHg</td>
</tr>
<tr>
<td>5</td>
<td>150/90 mmHg</td>
<td>160/100 mmHg</td>
<td>120/80 mmHg</td>
<td>120/80 mmHg</td>
</tr>
<tr>
<td>6</td>
<td>160/100 mmHg</td>
<td>150/100 mmHg</td>
<td>120/80 mmHg</td>
<td>120/80 mmHg</td>
</tr>
<tr>
<td>7</td>
<td>95/60 mmHg</td>
<td>90/60 mmHg</td>
<td>100/70 mmHg</td>
<td>100/80 mmHg</td>
</tr>
</tbody>
</table>

Table-02-Showing Blood pressure before and after the therapy.

Discussion:
Till date medical fraternity is not scientifically able to understand while monitoring blood pressure whether measurement shall be taken from right or left arm. A general perspective is if an individual is lefty, right arm should be examined and vice versa. But our study has shown variable readings while examining left arm & right arm. Irrespective of using more left or right arm So, we called it as an error in the measurement. As there is no scientific explanation to select a particular arm to taking reading that is why we have taken readings from both the arms which shows significant variation.

All the patients with or without symptomology labelled as hypertension or Hypotension were observed before and after the leech therapy. Apart from symptomatic improvement significant changes were observed in the blood pressure readings.
Considering and correlating the vasodilatation effect of leech therapy. Theoretically hirudotherapy should be contraindicated in hypotension rather “syncopal attack” shall be the consequence. Instead of that we are observing significant positive changes immediately after the leech therapy. Means the healing abilities is known to wonder doctor (leech) more than a doctor.

We know there are different enzymes in the leech more than hundred biologically substance many of them are lytic and involve blood flow in the vessels and the tissue. Most probably a mechanism working inside the body responsible to mention every function of the body in a balanced manner perhaps called wisdom is receiving something which compel wisdom to normalize the different functions including blood pressure.

Most probably certain enzyme may have the normotensive effect or the enzyme in synergy may have such effects that in HTN it will reduce BP and in hypotension it will increase BP so leech has established as normotensive effects.

Leech enzymes may have role in blood pressure regulating center (medulla oblongata) which is responsible to maintain the blood pressure of an individual. We have been successful to observe immediate result of leech therapy for maintaining the BP but in future we need to study the long-term effects so that we can established the normotensive effects of leech therapy at large sample size. We may also able to understand the second dose and third dose/ booster dose required in long term treatment.

Even we feel that blood pressure is a respond of wisdom once a tissue or a organ needs more blood, wisdom increases extra pressure. Leech is helping in obstructions in blood vessels hence wisdom decreases extra pressure, but role of body wisdom in case of hypotension need to be understood.

More important is leech is understood blood flow, blood regulation and blood pressure more efficiently than existing scientific knowledge.

**CONCLUSION**

For the management of HTN and hypotension till date we have been able to prescribe one two or three drugs but MRFIT study shows that by reducing the coat and uncoat risk factors we cannot prevent disabilities and premature deaths.

We are trying to understand the creators of nature and how beneficial they are for another creators (Human race). It is our collective responsibility to conduct extensive research. So, that a unique or permanent solution can be identified or designate for this circulatory disorder.
References:


