

**AAY CENTRE, JAIPUR INDIA AND KRASS
FOUNDATION**

**HERBAL FORMULATION BASED ON
WHO STANDARDS USEFUL FOR
TREATMENT OF SCIATICA /
LUMBER DISC PROLAPSE**

Proposal

Dr. Sunil Gupta

6/13/2015

HERBAL NUTRITIONAL SUPPLEMENT FOR TREATMENT OF SCIATICA / LUMBER DISC PROLAPSE

Lumber disc prolapse/ sciatica is a painful condition for which no specific medical treatment is available. The medical advice is usually based on bed rest for long time and pain killers.

Lumbar disc herniation occurs 15 times more often than cervical (neck) disc herniation, and it is one of the most common causes of lower back pain. Americans spend at least \$50 billion each year on low back pain, the most common cause of job-related disability and a leading contributor to missed work. About 250,000 Americans have disk surgery for sciatica each year, while another quarter-million instead choose physical therapy, painkillers or rest until they feel better. In India no definite figures are available. Some studies reported the prevalence of disease about 3-8%.

Most of the cases do not relieved by this medical advice and if relieved, the recurrence is one of the major problems, and normally the patient is advised for surgery. Review of literature indicates that the result of surgery varies from 10-30%, and once there is failure of surgery, the treatment is very difficult. Hence it is needed to have some sort of medical treatment, which can give curative effects to these patients and bring out them from this malady.

So far specifically, neither allopathic nor herbal medicine/ supplement is claiming to have a cure for this disease. Here are the details of the herbal nutritional supplement as developed by KRASS and which have been found to be useful in the treatment of this disorder.

There are many choices of treatment available (Annexure 1) But any of such treatment do not provide full relief from the symptoms or disease (Annexure 2), good amount of financial involvement (Annexure 3) fair amount of recurrence (Annexure 2), low success rate, surgical complications (Annexure 1) etc.

Where as the treatment with this herbal nutritional supplement (Annexure 4) have the following advantages over the ongoing treatment

1. Complete cure after due course of treatment
2. Rest only for 3 weeks – You can do day to day activity
3. No recurrence after 15 years follow up study
4. No side effects
5. More then 90% cure rate
6. Financial implications are affordable to lower medium class community
7. Avoiding all complications of surgery
8. No repeated surgery

The improvement with this supplement starts in 3 weeks of starting the treatment (Annexure 5). The details of product are given in annexure 6.

Choice of available treatments and prognosis

Physical therapy : About 46 % CASES RESPOND TO bed rest for 4-6 months followed by physiotherapy. Out of these cases most on the cases shows recurrence

Medication : There are several different types of medicines that you may be prescribed to help ease the symptoms of a slipped disc. These are described in more detail below.

- Analgesics (painkillers), such as paracetamol
- Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, diclofenac and naproxen
- Codeine (a stronger type of painkiller), often taken in combination with paracetamol
- Corticosteroid (steroid) injections
- Muscle relaxants, such as diazepam

Surgery

The aim of surgery is to cut away the piece of the disc that bulges out. This is known as a discectomy and can be done in several ways. Some of these procedures are explained in more detail below.

Open discectomy : An open discectomy is a procedure to remove part or all of the slipped disc.

Prosthetic intervertebral disc replacement : Prosthetic intervertebral disc replacement involves having a prosthetic (artificial) disc inserted into your back to replace the slipped disc. One study found that 87% of people felt that their quality of life had improved three months after having this procedure.

Endoscopic laser discectomy : Endoscopic laser surgery involves making a small incision (cut) to access the spine and using an endoscope to view the disc. One study found that 67% of people could move around more easily six months after having endoscopic laser surgery, and around 30% of people needed less pain

relieving medication. Around 2-4% of people needed another operation. Another study reported that, on average, people returned to work after seven weeks.

For most people, this type of back surgery helps to ease symptoms. You can usually return to work after two to six weeks. However, the surgery does not work for everyone, and you may require further operations and treatment if the initial surgery does not work.

Surgical Complications

Possible complications resulting from surgery may include:

- an infection
- nerve injury
- haemorrhage (severe bleeding)
- temporary dysaesthesia (impaired sense, for example not being able to sense touch)

Before having surgery, ask your surgeon what complications you may be at risk of developing and how long it will take to recover. You may be given a rehabilitation programme to follow.

One review of a number of studies found that exercise programmes which started four to six weeks after surgery on the lumbar spine (lower back) helped to:

- decrease pain
- improve people's ability to function

Dewing et al reported that after Microdiscectomy for symptomatic lumbar disc herniations the mean decrease in VAS leg pain score was 4.7 points (from mean preoperative 7.2 to mean postoperative 2.5). The mean Oswestry index improved from 53.6 before surgery to 21.2 at final follow-up. A recurrence rate 6 % have also been reported.

Atlas et al reported that over the 4 years there was little evidence of harm from either treatment. The 4-year rate of re-operation was 10%, which is lower than the 19.4% reported by MLSS at five years.

It appears, despite the improvement in symptoms, that except for the first 6 weeks after surgery, work status is not related to treatment. Work status showed a non-significant benefit for surgery at 4 years.

James N. Weinstein,¹ Jon D. Lurie,¹ Tor D. Tosteson et al. Surgical versus Non-Operative Treatment for Lumbar Disc Herniation: Four-Year Results for the Spine Patient Outcomes Research Trial (SPORT). *Spine (Phila Pa 1976)*. 2008 December 1; 33(25): 2789–2800.

Dewing CB, Provencher MT, Riffenburgh RH, Kerr S, Manos RE. The outcomes of lumbar microdiscectomy in a young, active population: correlation by herniation type and level. *Spine (Phila Pa 1976)*. 2008 Jan 1;33(1):33-8.

Atlas SJ, Keller RB, Chang Y, et al. Surgical and nonsurgical management of sciatica secondary to a lumbar disc herniation: five-year outcomes from the Maine Lumbar Spine Study. *Spine*. 2001;26:1179–87

Cost of surgeryEconomics of Surgery: PLDD vs. Traditional Back Surgery

PLDD is an outpatient procedure approved by the FDA, with no general anesthesia, no operating room cost, no recovery room cost, and no hospitalization cost. Office workers usually return to work in five days.

Item	PLDD Costs	Traditional Back Surgery Costs
Doctor's Fee	---	\$45,000
Operating Room & Recovery Room	N/A	\$4,475 (3 hrs.)
Anesthesiologist	N/A	\$4,000
Hospital Stay	N/A	\$25,000 (3 days)
Total	---	\$78,475
Each Additional Disc:		\$10,000
Lumbar	\$5,500	
Thoracic	\$6,000	

The above numbers speak for themselves. It's easy to see which procedure is more cost effective.

Details of Herbal Nutritional supplement

Disease Name	SCIATICA // PIVD // SLIP DISC // LUMBER DIS PROLAPSE
Work Started	1990
Total Patients in India	
Total Patients in World	
Patients Handled	ABOUT 150
Patients Cured	145
Success Rate of other diagnosis	30%
Success Rate of AAY	More then 90 %
No. of Records Available	More then 100
Treatment Methodology	AAY
Duration of AAY Treatment	4-6 Months
Total Cost of other treatments	In India - 60-100 thousand ; In other western countries \$ 12 - 45 thousand (Approx. INR 80000 – 200000)
Total Cost of AAY treatment	About INR 12000-15000
AAY Internal Expenses	About INR 2000

There are about 400 patients who received the treatment and about 100 patients are ongoing

Finance

Disc related disorders of spine are estimated to compromise high percentage of low back pain Indian population with incidence of 23.09% with lifetime prevalence of 60-85%. 5% of the general population is affected by serious disc problems.

Spinal diseases are the most common cause of disability in persons under the age of 45. Indian population is about more than 1.271 billion people (2015), (under 15yrs - 0.372 ; 15-64 yrs – 0.819 and 65+ yrs - 0.065 billion)

If we roughly consider 40% of 0.819 billion (15-64 yrs) as a population between 30-45 years (Most prevalent age for PIVD) it comes to 0.32 billion (3200 million = 1000000X3200), which is the vulnerable population.

If we consider 18000 Rs for treatment per patient then the market is of Rs. 57600000/- Million. Even 5% coverage will give Rs. 160 Million.

Annexure 5

Symptom	Duration of relief
Radiation of pain to areas beyond known dermatomal patterns	90 - 120 days
Pain in buttocks (referred)	90 - 120 days
Sitting uncomfortable	60 - 90 days
Backpain	Variable improvement (depending on physiotherapy) in 120-360 days
Sciatica	60 - 90 days
Neurogenic claudication	90 - 120 days
Sensory dysfunction	60 - 90 days
Cold feet	60 - 90 days
Burning	60 - 90 days
Tingling, hyperaesthesia Saddle pain – genital hypaesthesia	60 - 90 days
Stance- tilted to one side	60 - 90 days
Movements restricted	Improvement in SLR start by 21 days Improvement continues and SLR comes to normal by 90 days
Lordosis obliterated	90 - 120 days
Leg: sensations – Hypoaesthesia	60 - 90 days
Weakness of muscles	90 - 120 days
Wasting in muscles	120-360 days
Reflexes	90 - 120 days

PRODUCT DETAILS

Product

- This is a herbal nutritional supplement.
- It does not contain any "Bhasma"
- This supplement is being successfully used by KRASS for more than 11 years.
- This herbal nutritional supplement has shown the significant clinical improvement / cure for treatment of sciatica/lumber disc prolapse.
- A new formulation not marketed anywhere in the world as yet.

Product characteristics

- Fine granule form – powder.
- Mildly bitter in taste
- Shelf life for the product is 2 years

Usage

- Dispensed in capsule form.
- Generally, duration of treatment is about 120 days.

Claim to fame

- Effective in improving/cure Sciatica
- Cure rate varies from 90-95% in a case study of about 150 cases.
- Effective in improvement/cure of lumber disc prolapse
- Effective in improvement/cure of chronic Sciatica / lumber disc prolapse cases not responding to any treatment.

Genesis of the product

- Developed as long-term research on cases of Sciatica / lumber disc prolapse.
- Scientific paper have not been published because of the conditions of patent.

Substantiation of safety and claims

- Product has been tested as per WHO standards
- Data to substantiate the claim is available for review.
- Safety data for the product is also available for review.
- In vitro data is also available to support the product.
- Heavy metal testing data is available as quality assurance documents.

Differentiation from existing products (USP)

- No formulation or even drug, marketed in India or abroad is making such claims.

Market Potential

- Lumber disc prolapse/ sciatica being considered as difficult to cure disorder. Once subsided it has recurrence in most of the cases. Surgical treatment is also not satisfactory.
- A ray of hope in this field may be a break through in the medical treatment of these disorders.

This product is envisaged to hit the international market very strongly and also attack all other areas effectively due to its broad-spectrum characteristics.

CASE STUDIES

Case 1.

TREATMENT SLIP - Followup "KRISHNA RAM AYURVIGYAN SHODH SANSTHAN"

Name Hanahy Ram Age 50 Sex M Reg. No.

Diagnosis Ang PVD L.S

Date	Treatment Plan		Treatment	Duration
	Physiotherapy	Treatment		
9/8/10		<u>Scrub</u> 2x2 <u>Med. RA</u> 2x2	- Tab. Omniazithil 5mg 1 - Tab. Mononin 1 - Tab. Ganak 5mg 1 - Tab. Zekicam 100	
9/9		<u>RA</u> 2x2 (Leab = 10)	(A) - Tab. Omniazithil 5mg 1 - Tab. Mononin 2 - Tab. Zekicam 100 - Tab. Ganak 5mg 1 - Tab. Macosex 5mg 1 (B)	

TREATMENT SLIP - I

"KRISHNA RAM AYURVIGYAN SHODH SANSTHAN"

Name Hanuman Rao Age 50 Sex ♂ Reg. No. _____

Diagnosis SVS / Lumbar spondylitis

Salient features _____

Reports of patient
Photograph
POWP

Originals with parents / Originals in file
Due / Submitted
Due / Submitted

Details of previous ongoing treatment

Date	Treatment Plan		Treatment	Duration
	Physiotherapy	Treatment		
<u>11/3/10</u>		<u>Sresth</u> <u>2x2</u>	<u>Tab. Zolixam</u> <u>100</u> <u>- Tab. Serrax plus</u> <u>x 1 month</u>	
<u>11/5/10</u>		<u>Sresth</u> <u>2x2</u>	<u>Tab. Serrax plus</u> <u>x 15</u>	
<u>10/6/10</u>		<u>Sresth</u> <u>2x2</u>	<u>Tab. Zolixam</u> <u>100</u> <u>- Tab. Acadolon</u> <u>100</u> <u>- inj. At m...</u>	

[Handwritten signature]

10/7/10

gine
Viv aty
2 month

- Sresth
2x2
- Physiotherapy
- Hot fomentation
- Tab. Zolixam
100
- Tab. Serrax plus
x 1 month

SCIATICA (LUMBER DISC PROLAPSE) INVENTORY

AAY CENTRE (Allopathy-Ayurveda-Yoga Centre)

File No. _____ Date/Time 11/11/10
Name Nanaku Ram Age 20 Sex [M/F] M
Address Ratha Swami Religion Bahy Occupation (Gadawadi Ki Shiksha)
Shomu Ward no 19
Phone No(s) 9314654244
Diagnosis :

Complaints :

1. Radiating pain lower limb Rt. / Lt ✓ 1 yr days.
2. Low backache 3 yr days.
3. Burning toes Bl.
4. _____

Past/Present illnesses/injuries/operations:

CVS :

Hypertension:

Respiratory Problem NIL

Diabetes Bl. Sugar (2) 81

Chronic GI Disorder NIL

CNS NAD

Any other specify ds _____

Medication _____

SCIATICA (LUMBER DISC PROLAPSE) INVENTORY

Physical Examination

Wt. (Kg.) 65 kg

Respiration (/mt)

B.P. 130/80

Pulse rate (/mt)

Examination

Movement Range

	11/4/10	11/5/10	9/8/10	9/9/10
Touch to toe	(N)	(N)	N	N
SLR - Rt	90°	90°	N	(N)
SLR - Lt	90°	90°	N	(N)
Sitting in squatting position	± 5 Mts		(N)	(N)

Burning
Loc.

Walking

100 Mts with aids

1 km.
NO burning
Loc.

Cycling

Up Stairing

unable

Better

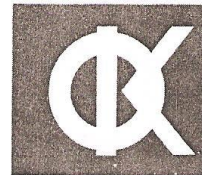
Down Stair

painful

Better.

KAY DIAGNOSTIC RESEARCH CENTRE PVT. LTD.

4, VIVEKANAND MARG, C-SCHEME, OPP. S.M.S. HOSPITAL, JAIPUR
PHONE : 2366494, 2367099, 9929597880



NAME NANCHU RAM AGE 43Yrs.
DATE April 15, 2009 ID.NO. 2979
REF. BY DR. A.S. CHAUHAN

SEX M

MAGNETIC RESONANCE IMAGING (M.R.I) REPORT (1.5 TESLA MRI SYSTEM)

M.R.I SCAN OF LUMBO-SACRAL SPINE:

MR imaging of lumbar spine was performed using spin echo and fast spin echo techniques. Serial sections were obtained in sagittal and axial planes using dedicated quadrature lumbar spine coil.

The vertebral bodies are normal in size, shape, height and signal intensity. Mild end plate degenerative changes are seen in L4 to S1 vertebral bodies.

L5-S1 disc height is reduced.

L4-5 and L5-S1 discs are hypointense on T2 weighted images suggesting them to be degenerated and dehydrated.

Spinal canal dimension are as follows:

LEVELS	A.P.	T.D.	CROSS SECTIONAL AREA
T12-L1	1.40cm	2.10cm	2.94sq.cm
L1-2	1.30cm	2.30cm	2.99sq.cm
L2-3	1.10cm	2.10cm	2.31sq.cm
L3	1.20cm	2.10cm	2.52sq.cm
L3-4	1.20cm	2.00cm	2.40sq.cm
L4	1.20cm	2.30cm	2.76sq.cm
L4-5	1.00cm	2.00cm	2.00sq.cm
L5	1.20cm	2.10cm	2.52sq.cm
L5-S1	0.70cm	1.50cm	1.05sq.cm

(Lumbar canal stenosis is characterized by narrowing of central canal area <1.5sq.cm or A.P. diameter <11.5mm.)

At L5-S1 diffuse circumferential bulging and posterocentral protrusion of disc with caudal extension causes mild compression on thecal sac and moderate narrowing of bilateral neural foramina.

Conus medullaris is normal. No intra-spinal mass is seen.

No pre or para vertebral collection seen. Facet joints are normal.

OPINION:

- MODERATE NARROWING OF BILATERAL NEURAL FORAMINA AT L5-S1.

DR. TRIPTI SHAH
MD (RADIOLOGIST)

DR. VIVEK BHARGAVA
MD (MEDICINE)
MD (RADIOLOGIST)

Case 2.

TREATMENT SLIP - I

"KRISHNA RAM AYURVIGYAN SHODH SANSTHAN"

Name Rachin S Age 39 Sex M Reg. No.

Diagnosis P.V.D

Salient features

Reports of patient Originals with parents / Originals in file
 Photograph Due / Submitted
 POWP Due / Submitted

Details of previous ongoing treatment

Date	Treatment Plan		Treatment	Duration
	Physiotherapy	Treatment		
<u>20/12</u>		<u>A. 2100 - 202</u>	<u>Jab. Senak plus</u> <u>Jab. Senak 2.500</u>	
<u>2/12/11</u>		<u>Rot. Sen</u>		

SCIATICA (LUMBER DISC PROLAPSE) INVENTORY

AAY CENTRE (Allopathy-Ayurveda-Yoga Centre)

File No.

Date/Time

Name रचना शर्मा Age 39 Sex [M/F]

Address गिण्टी बंगला रास्ता वीलीवत
मदन Religion Occupation

Phone No(s) 9828803088

Diagnosis :

Complaints :

1. Radiating pain lower limb Rt. / Lt 5-7 days days.
2. Low backache 20 yrs days.
- 3.
- 4.

Past/Present illnesses/injuries/operations:

CVS :

Hypertension: ~~+~~

Respiratory Problem ~~NA~~

Diabetes ~~NA~~

Chronic GI Disorder ~~NA~~

CNS ~~NA~~

Any other specify ds -

Medication -

OKAY DIAGNOSTIC RESEARCH CENTRE PVT. LTD.

4, VIVEKANAND MARG, C-SCHEME, OPP. S.M.S. HOSPITAL, JAIPUR
PHONE : 2366494, 2367099, 9929597880



NAME RACHANA AGE 35YRS SEX F
DATE October 29, 2010 ID.NO. 43014
REF. BY DR. SUNIL GUPTA

MAGNETIC RESONANCE IMAGING (M.R.I) REPORT (1.5 TESLA MRI SYSTEM)

M.R.I SCAN OF LUMBO-SACRAL SPINE:

MR imaging of lumbar spine was performed using spin echo and fast spin echo techniques. Serial sections were obtained in sagittal and axial planes using dedicated quadrature lumbar spine coil.

Mild degenerative changes are seen in lumbar spine showing marginal osteophytes.

The vertebral bodies are normal in height and signal intensity.

L3-4, L4-5 and L5-S1 discs are hypointense on T2 weighted images suggesting them to be degenerated and dehydrated. Posterior annular tears are present in L4-5 and L5-S1.

Spinal canal dimension are as follows:

LEVELS AREA	A.P.	T.D.	CROSS SECTIONAL AREA
T12-L1	1.20 cm	1.90 cm	2.28 sq.cm
L1-2	1.20 cm	1.90 cm	2.28 sq.cm
L2-3	1.10 cm	1.70 cm	1.87 sq.cm
L3	1.20 cm	1.70 cm	2.04 sq.cm
L3-4	0.90 cm	1.40 cm	1.26 sq.cm
L4	1.10 cm	1.70 cm	1.87 sq.cm
L4-5	0.90 cm	1.40 cm	1.26 sq.cm
L5	1.10 cm	1.50 cm	1.65 sq.cm
L5-S1	0.90 cm	1.30 cm	1.17 sq.cm

(Lumbar canal stenosis is characterized by narrowing of central canal area <1.5sq.cm or A.P. diameter < 11.5mm.)


Diffuse disc bulge with mild central disc protrusion seen at L4-5 and L5-S1 causing mild narrowing of bilateral neural foramina. Thecal sac is relatively normal.

Mild ligamentum flavum hypertrophy is seen at L4-5.

Conus medullaris is normal. No intra-spinal mass is seen.
No pre or para vertebral collection seen. Facet joints are normal.

OPINION:

- DIFFUSE DISC BULGE WITH MILD CENTRAL DISC PROTRUSION SEEN AT L4-5 AND L5-S1 CAUSING MILD NARROWING OF BILATERAL NEURAL FORAMINA.
- POSTERIOR ANNULAR TEARS IN AT L4-5 AND L5-S1 DISCS.


DR. PRADEEP KUMAR GOYAL
MD (RADIOLOGYSIS)
(AIIMS)

DR. VIVEK BHARGAVA
MD (MEDICINE)
MD (RADIOLOGYSIS)

This is radiological / Pathological Impression & not the final Diagnosis. It should be Correlated with relevant clinical data & Investigation
Not valid for Medico-Legal Purpose • Subject to Jaipur Jurisdiction only