

Diagnosis and treatment of chronic low back pain by differential intervention of disc, nerve root, facet joint: an open level prospective study : NRS protocol

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Abstract

To develop a diagnostic and treatment protocol for chronic low back pain due to involvement of nerve root, disc and facet joint by differential intervention and to find out the efficacy of the protocol (NRS protocol) in treating chronic low back pain.

This is an open level prospective study, involving patients with chronic low back pain of more than 6 weeks. We at NRS developed a protocol which included clinical assessment with imaging and intervention. On concurrence of diagnosis made by imaging and clinics we went for intervention to treat the condition with components of NRS Cocktail. Pre-intervention assessments were done and followed up at specific intervals after treatment. Results were analysed to see if the NRS Protocol and cocktail in disease diagnosis and treatment of the selected cohort.

A total of 32 patients, data were analysed over a period of 6 months. Assessment was made pre-intervention (0), at 3 weeks (1), at 3 months (2), at 6 months (3). Pain was assessed by visual analogue scale or VAS. Paired t test was employed to analyse results. Paired {VAS0-VAS1 (p value=0.000), VAS1-VAS2 (p value=0.557), VAS2-VAS3 (p value=0.536)} data showed a very significant reduction in pain in the first visit after intervention (3 weeks) and maintenance of this reduction up to end of study (6 months). Disability was assessed by Oswestry Disability Index (ODI) and paired t test, when employed, showed similar trends [ODI0-ODI1 (p value=0.000), ODI1-ODI2 (p value=0.355), ODI2-ODI3 (p value=0.212)].

This protocol was able to diagnose and treat chronic low back pain due to facet, nerve root and disc in a very significant manner

Key words : Chronic low back pain, facet, nerve root, disc, differential intervention, open NRS protocol.

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Two-thirds of adults suffer from low back pain (LBP) at some time of their life or other. Low back pain is the second commonest cause of visit to a physician^{1,2}. There are no standardised approach for its diagnosis and treatment. There have been evidences of excessive imaging and surgery for LBP. Many experts believe that the problem has been “over medicalised” for commercial ends^{3,4}.

Experimental studies suggest that low back pain may originate from many spinal structures, like the discs, facet joints, the spinal nerve roots and others. Commonest affection is age-related degenerative processes in the intervertebral discs and facet joints. Other common problems include spinal stenosis and disk pathology. Eighty- five percent of patients with isolated LBP cannot be given a precise patho-anatomical diagnosis because no physical examination has sufficient reliability or enough validity^{5,6}. Moreover the association between symptoms and imaging is also weak^{1,2,3,8}.

Based on the above facts along with the easy and safe accessibility of spine by various interventional techniques we have tried to develop a different approach for diagnosis and treatment of LBP semi-conservatively. This has been the core philosophy behind this study in response to increasing usage of spinal interventions⁷⁻⁹.

Methodology :

- A prospective open label, longitudinal, monocentric study.
- Total number of patients screened : 203
- Total number of patient enrolled : 47
- Follow-up rate : 68 percent
- Sample size: 32
- Study centre : Dept involved Physical Medicine & Rehabilitation (PM&R) & Dept of Orthopaedics of NRS Medical College, Kolkata, West Bengal, India.
- The project was approved duly by the institutional ethics committee.

Duration of study : Duration 1,2/12 year

Commencing date: November 2009

End date: December 2010

Inclusion criteria:

- (1) Low back pain > 6 weeks
- (2) Radiculopathy \geq 6 weeks
- (3) Neural claudication \geq 6 weeks
- (4) Failure of oral drug and other physiotherapeutic modalities

Exclusion criteria :

- (1) Red Flag Cases as established in our protocol. ⁷
- (2) Waddel's signs \geq 3 ¹⁰
- (3) Vascular claudication.
- (4) Those that have fear avoidance established as the cause of pain¹¹.
- (5) Those with other systemic, psychiatric or neurological diseases except depression due to pain.
- (6) Myofascial bands
- (7) Ligamentum flavum hypertrophy on MRI
- (8) Vertebral compression fracture of body with signal enhancement in MRI
- (9) Fibromyalgia
- (10) Interspinous ligament band
- (11) Sympathetic mediated pain
- (12) From other coexisting articular and periarticular conditions.

NRS (NILRATAN SIRCAR MEDICAL COLLEGE) PROTOCOL

- Part I: Screening
- Part II: Clinical diagnosis
- Part III: Image based diagnosis
- Part IV: Interventional diagnosis
- Part V: Treatment based on diagnosis by NRS cocktail.

Part I : All selected patients were screened for positive red flag, fear avoidance believe scale and waddle's signs and other exclusion criteria. Patients fulfilling inclusion criteria were assessed for pain by VAS (visual analogue scale), for disability by Oswestry disability index (ODI) ¹²⁻¹⁴.

Part II: Clinical diagnosis: In addition to general, systemic neurological and musculoskeletal examination, following specific examinations were done.

- (a) Quadrant loading test. spinal range of motion¹⁵
- (b) Straight leg raising test (passive)
- (c) Femoral stretch test.
- (d) Dural stretch test

Part III : Imaging diagnosis (x-ray and magnetic resonance imaging).

Part IV: Interventional diagnosis : Clinical and radiological diagnosis were matched to ascertain the source of pain i.e. discogenic pain, facet or root. In these selected cases, spinal intervention was done to confirm the diagnosis⁷⁻⁹.

Facet: facet block with intra-articular local anaesthetic were noted for disappearance of pain and nature of dye spread

Disc: Provocative discometry and disco gram with 4 cc non-ionic dye OMNAPAUQE done and noted for concordance of pain and internal disc morphology on disco gram.

Nerve root: Nerve root block with local anaesthetic done and noted for pain response and epidural morphology near the nerve root noted on epidurogram.

PART V: Interventional treatment: Which primarily consisted of injecting steroid, local anaesthetic and hyaluronidase mixture for facet and nerve roots and ozone for nucleolysis in cases of discogenic pain, disc prolapse or canal stenosis due to disc.

Therapeutic interventions were done at the same sitting as per the suspected diagnosis in accordance to the NRS protocol. This algorithmic approach is enumerated in the

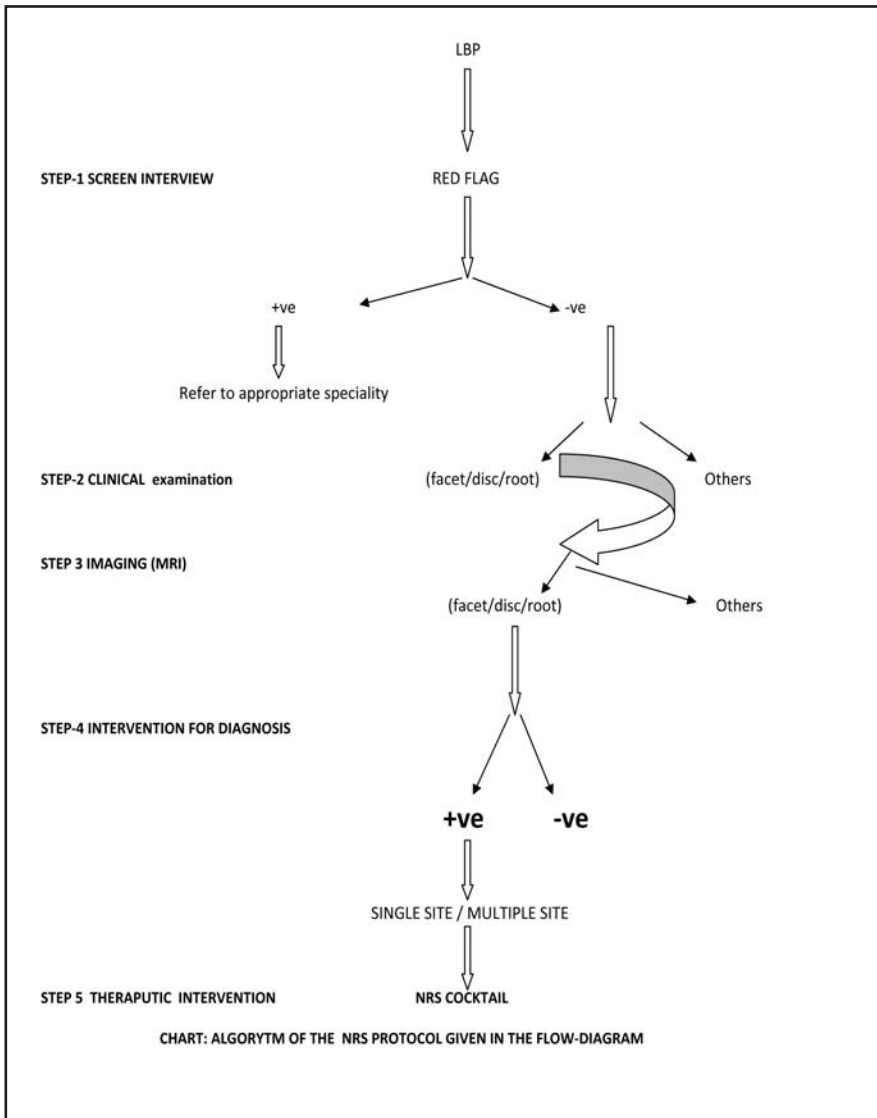


Chart : Algorithm of the NRS Protocol Given in the Flow - Diagram

flow diagram of the chart.

Data were recorded on relevant scales. Our primary scale was VAS or visual analogue scale and secondary scale was a disability scale i.e. Oswestry disability index (ODI). Following codes were used. Pre-intervention scales were coded as VAS0 & ODI0, similarly at first visit it was VAS1 & ODI1 so on. We consider the protocol a success when VAS score is down to 50% of pretreatment level at the end of 6 months.

The NRS Cocktail :

We considered various drugs that can be injected under fluoroscopic guidance in a day care set up. An extensive literature search was done for possible pharmacological interventions possible in spine¹⁶⁻²⁴. Finally we decided on a connotation of the following after a multispecialty consensus was achieved among the treating physiatrists, orthopaedic surgeons, anaesthesiologists and pharmacology faculties. Due consideration was given to the safety aspects of such interventions. Procedures were carried out in a well manned operation theatre with emergency set up. Consent of the patient was taken after full explanation of the procedure and intent of such intervention. We decided to call it NRS COCKTAIL after the institution.

FACET JOINT & ROOT BLOCK: Combination of

- Deposteroid 5 mg (Depomedrol, Pfizer Products India Pvt Ltd)
- Bupivacaine 0.25% (Anawin 0.25%, Neon Laboratories Limited, India)
- Lignocaine 2% (NI Pharmaceutical Works Pvt Ltd, India)
- Hyaluridase (Hynidase 1500 Iu, Sheraa Pharmaceutical, India).

DISCS

- 3-7 ml of oxygen-ozone mixture concentration 29-32 mc/ml

(Generated from ozone generators of D M Enterprise,

Kolkata)

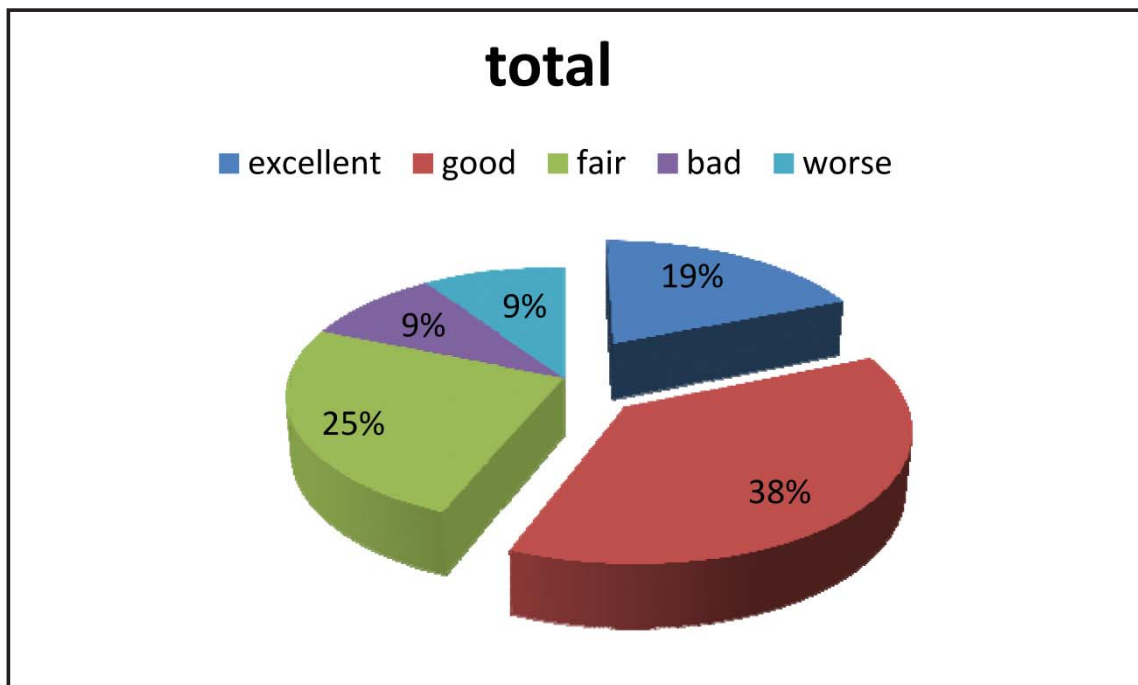
A non-ionic dye iohexol was used for delineating the nerve roots, discs and facet joint. (OMNIPAQUE 300MGI/ML, GE HEALTH CARE IRELAND)

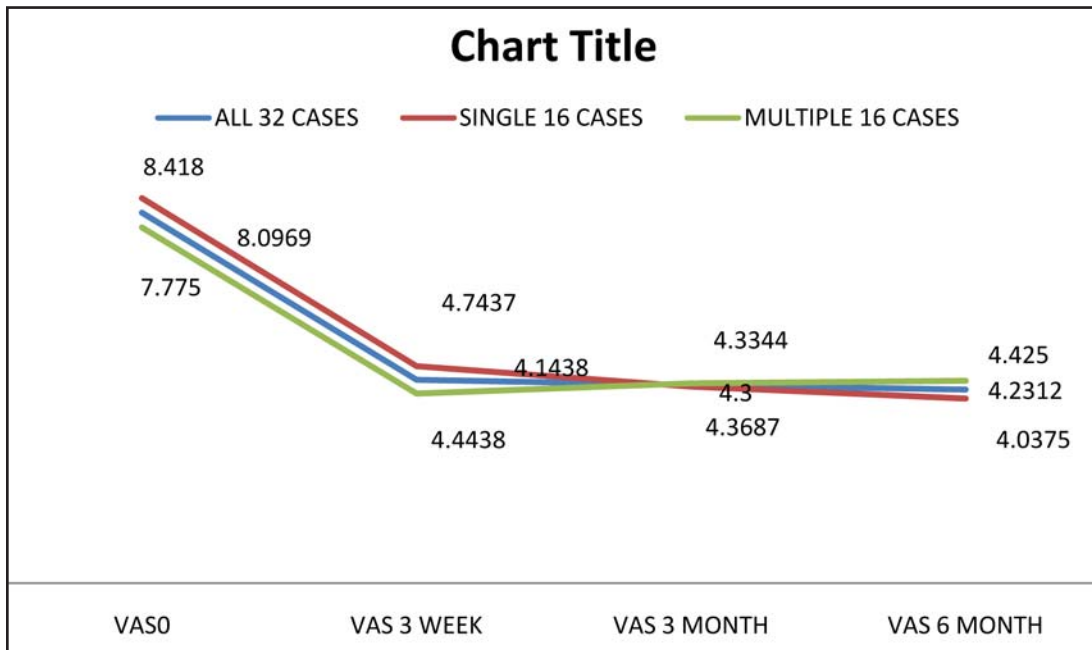
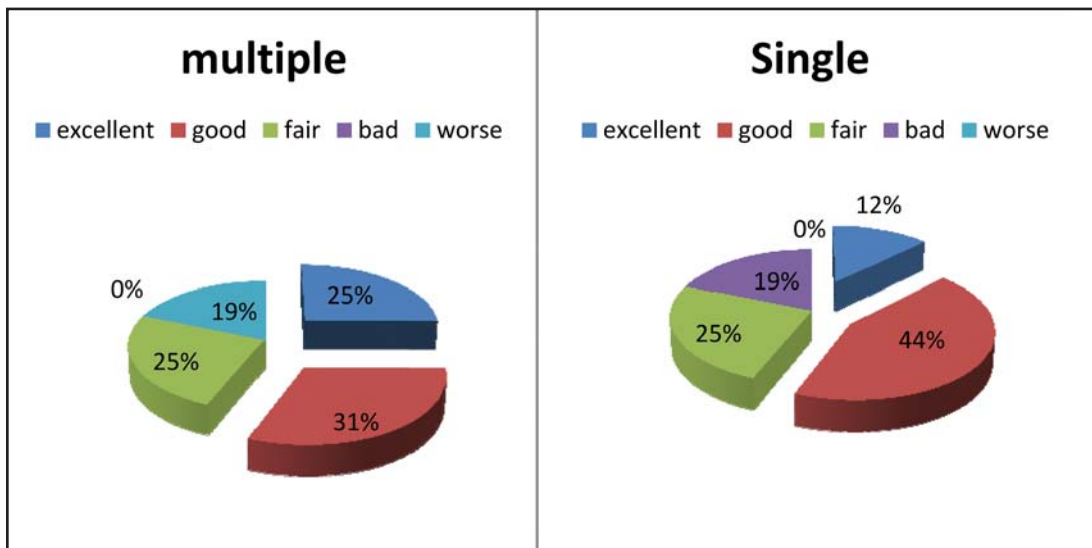
Procedural Methodology of Intervention :

Informed consent was obtained from all the patients. Intravenous cannulation was secured for emergency drugs administration in cases required. The patient was monitored by a non-invasive cardiac monitor and vital parameters were noted constantly. A stand by anaesthetic team was kept available during the whole procedure. Ceftriaxone (Xone, 1g, Alkem Laboratories Ltd) was injected intravenously after proper skin test . We did not use conscious sedation with intravenous midazolam. The patients were explained in detail about the whole procedure and were briefed about how to conduct throughout the intervention.

Patients were asked to lie down in prone position with a pillow under lower chest and upper abdomen. The needle puncture site was identified and marked on skin. After proper antiseptic dressing and draping, proposed site of needle entry was infiltrated with local anaesthetic (2% lignocaine).The procedure was performed under C-arm guidance. Anteroposterior, oblique cephalocaudal, and lateral views were used to guide appropriate needle

introduction and placement at the exact site of suspected pain. A 22 gauge 12 cm long needle (spinal needle Quincke type, Vygon Laboratoires Pharmaceutical, France) was introduced in the targeted disc facet and epidural space of nerve root sleeve. The procedures are elucidated in details in the picture plate (A,B,C,D,E,F,G,H,I). In case of suspected disc diagnosis 3-7 ml of oxygen –ozone mixture at a concentration of mc/ml? was injected into the disc by ozone resistant syringe (Dispovan, Hindusthan Syringe 7 Medical Devices Ltd, India) over a period of 15-20 seconds and the patient was asked to notice concordance pain for confirming clinical and radiological diagnosis .For infiltration of facet and for root block we used cocktail of deposteroid 5mg ,bupivacaine 0.25%, lignocaine 2%, hyaluronidase 1000 IU. Volume for facet was 1.5 to 2 cc and for selective root block or transforaminal epidural volume was determined by disappearance of non-ionic contrast dye used for delineating the radicles (as shown in picture plate in figure F &G). At the end of procedure patients were advised to rest in supine decubitus position for at least 1-2 hours . After which all patients were discharged on the same day or evening. They were advised to gradually resume normal activities. All patients underwent follow-up examination at three weeks, three months and 6 months after the procedure.





RESULTS

GENERAL DESCRIPTIVE STATISTICS:

A total of 32 patients (16 male and 16 female) were included for the study with a mean age of 40 years (40 years - 71years) and mean duration of disease for about 13 month (2 months - 51 months).

Sixteen patients (9 male and 7 female) had single site pathology as suggested by a clinical or combination of

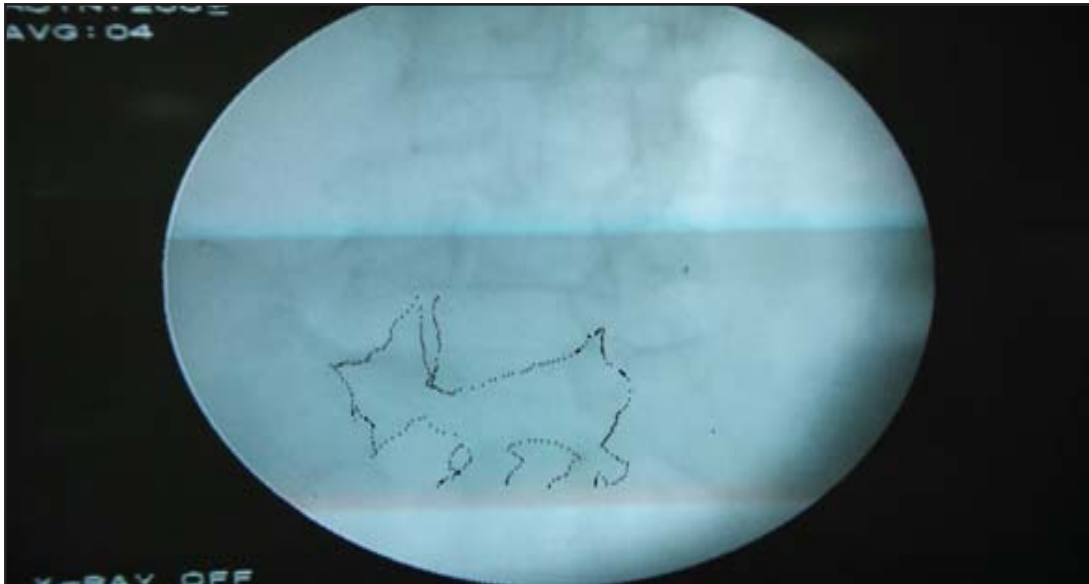
clinical and MRI findings. The mean age of this group with single site diagnosis was 38 years (21 years - 54 years) with a mean duration of disease for about 9 months (3 months - 32 months). These patients received single site intervention (ie, either disc nucleolysis by ozone and root / facet block by NRS cocktail).

Again, 16 patients (7 male and 9 female) had multiple site involvement. The mean age of this group was 42 years (24 years - 71 years) with a mean duration of disease for about 17 months (2 months - 51 months).

These patients received multiple site intervention (i.e. combination of either disc nucleolysis by ozone and root block / facet blocks by cocktail mix) (Table 1)

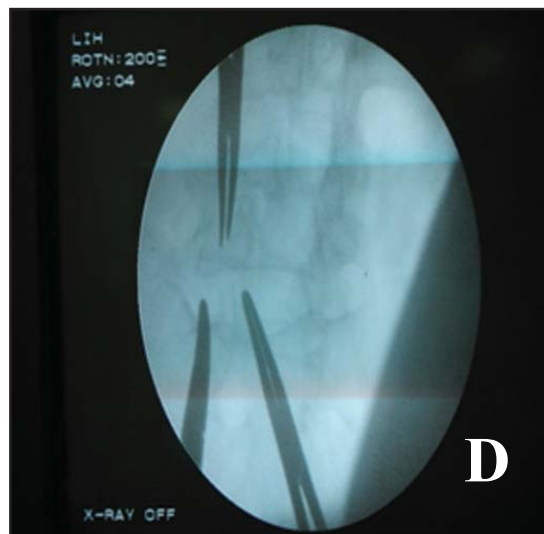
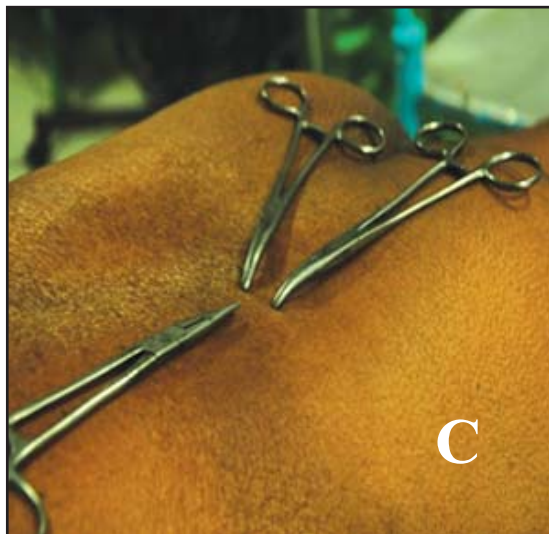
VAS: We subdivided the final % reduction from

pretreatment VAS score (Table 4) as excellent those achieving 100-75% reduction, good those with 74% to 50 %, fair those with 49-25 % reduction of pain, bad those with 24% pain score reduction and those in whom pain increased we scored them worse.

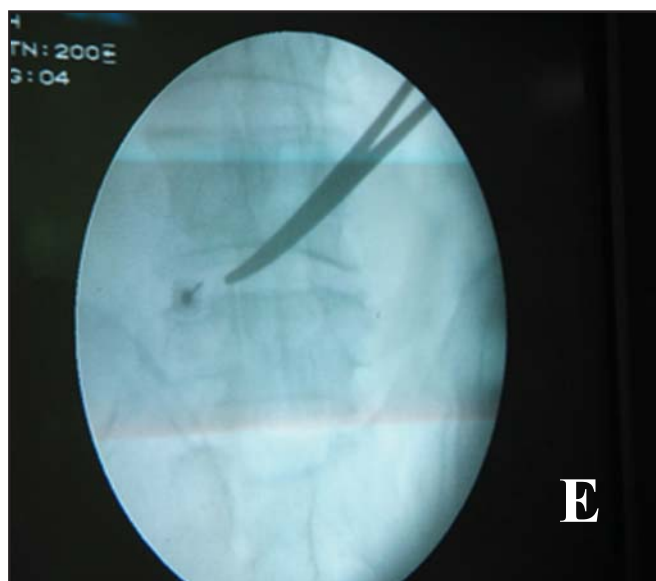


We first ascertain the exact spinal level by doing a count from cephalic to caudal and caudal to cephalic with 12th rib at cephalic level and L4/5 Lumber junction at caudal level as two pivotal land mark, first physically then under anterior-posterior fluoroscopic view.

A & B: We then hunt down the **Scotty Dog** (here L5 spine) by an oblique view of fluoroscope and adding to it cephalic or caudal tilt, till we are satisfied with the picture as per our interventional aim with target areas maximally opened for access.



After target areas to the disc, facet or root are opened up satisfactorily we put radio opaque marker like artery forceps to guide our spinal needle into the exact site under fluoroscopic guidance. As shown in **C & D**



E Depicts gun barrel positioning or end on view of our access needle's hub.

The disc space is maximally opened up with the Scotty dog's ear in the middle of the frame and end plates of upper and lower vertebrae are squared up to give maximum area of disc.

The needle was inserted into the disc, lateral to the doggy's ear in a gun-barrel position. This ensures that the needle is targeted for the disc.

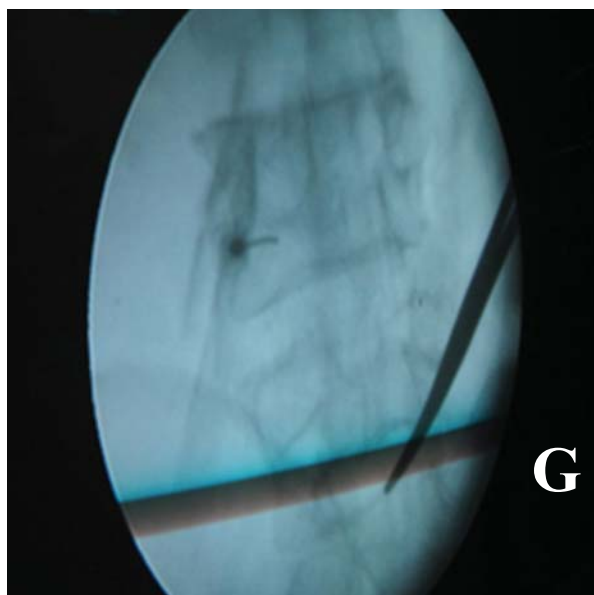
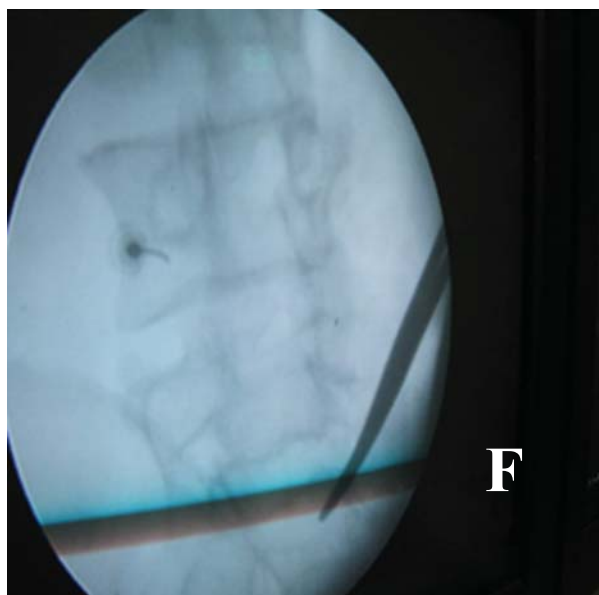
For the whole study group mean pre intervention VAS0 was 8.0969 which subsequently reduced to 4.4438 at 3 weeks and to 4.334 at 3 month and finally to 4.2312 at the 6 month period with an overall decrease of 46.8144% when we compared pre-intervention vas 0 with vas 3 at the end of the study.

In the single intervention cases mean pre intervention vas0 was 8.4188 and at three weeks it came down to 4.7437, at three months the dip marginal continued (4.3000) and this trend continued up to 6 months period with final vas3 (4.0375) with an overall decrease of 47.2075 % when we compared pre-intervention vas0 with vas3 at the end of the study.

For multiple intervention groups VAS came down from 7.7750 to 4.1438 at 3 weeks to a slight increase at 3 months to 4.3687 finally to 4.4250 at 6 months at the end of study with an overall decrease of 46.4213 % when we compared pre-intervention VAS0 with VAS3 at the end of the study (Table 2) .

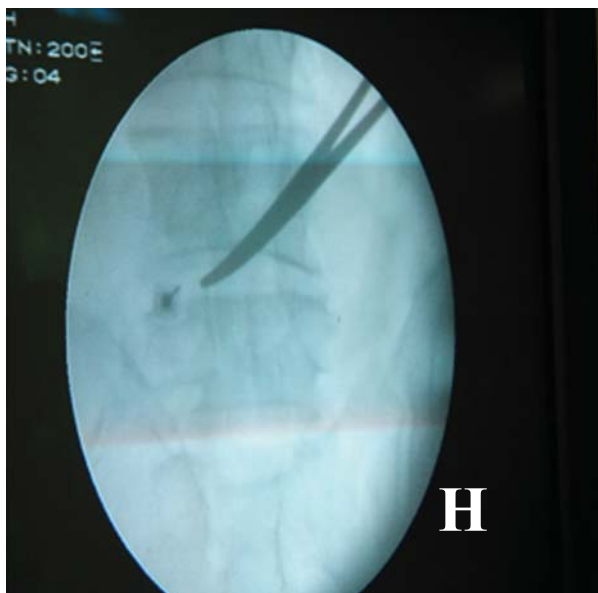
ODI: For the whole study group mean pre intervention ODI 0 of 57.6741 which subsequently reduced to 32.8578 at 3 weeks, to 31.3728 at 3 months and to 32.5603 at the 6 months period with an overall decrease of 43.6619 % when we compared pre-intervention ODI 0 with ODI 3 at the end of the study at 6 months.

For the single intervention cases mean pre intervention ODI 0 was 56.1125, at three weeks it came down to 28.5144, at three month the dip continued though marginal to 28.044 and this remained at 28.044 up to 6 months period with an overall decrease of 48.2169 % when we compared pre-intervention vas0 with vas3 at the end of the study.



F gun-barreling of the needle hub at 6 o'clock position just below the eye of Scotty dog. The eye represents the pedicle of the vertebrae. Once bone contact is made non ionic dye omnapaque mixed with distilled water is injected to delineate the nerve root which shows up in

G as an descending radio opaque tram line shadow. Now after the shadow of root is achieved we inject our cocktail till the shadow disappears on fluoro image. This represents selective nerve root block.



H represents opened up facet obtained with an oblique view along with cranio-caudal positioning of fluoroscope. The facet is then accessed through the opened up space by gun barreling our needle.

For multiple interventions group ODI came down from 59.2356 to 37.2013 at 3 weeks to a decline at 34.7013 at 3 months and again up to 37.0763 at 6 months end period with an overall decrease of 39.1069 % when we compared pre intervention ODI0 with ODI3 at the end of the study at 6 month (Table 3).

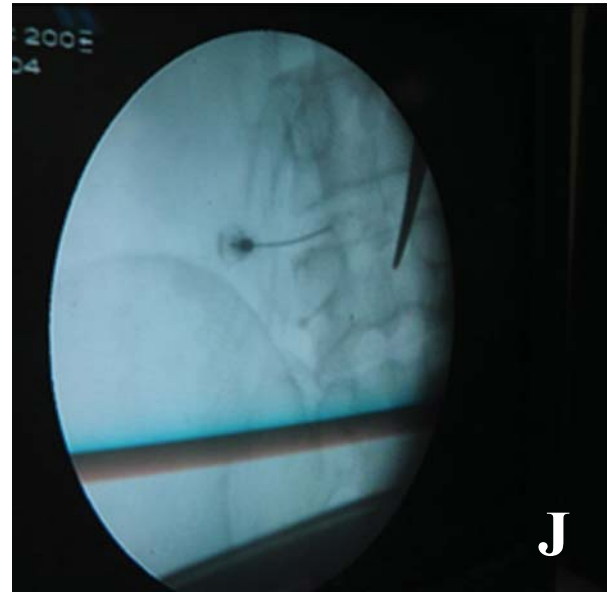
Paired 't' test :

VAS: We paired VAS 0-VAS1, VAS1-VAS2 and VAS2-VAS3 to find any significant changes in score following intervention at various time points. A paired sample 't' test was done. Results showed VAS0-VAS1 (p value=0.000), VAS1-VAS2 (p-value =0.557) and VAS2-VAS3 (p-value=0.536)

ODI: We paired ODI0-ODI1, ODI1-ODI2 and ODI2-ODI3. Results showed ODI0-ODI1 (p value=0.000.) ODI1-ODI2 (p-value =0.355) and ODI2-ODI3 (p-value=0.212)

We then pared VAS0-VAS3 and ODI0-ODI3. In both the cases p-value =0.000, Thus the treatment used brought about very significant reduction of pain and disability at 6 month end period.

Independent Sample T-test : We made two independent group one with single site diagnosis and the other with multiple site diagnosis. We compared the percent decrease



After preliminary needle position is achieved as explained above by oblique view with cephalo caudal correction we then go for check fluoro –images to ascertain the correct depth as well as correct position by lateral and anterior posterior view. Lateral view in **I** shows the upper needle in the anterior 2/3rd of a disc and the lower needle at a shallower depth into the facet joint.

Antero-posterior view for confirming correct direction of needle placement has to be done. A medial disposition of the needle indicates its position in the disc as shown in **J**.

On satisfactory needle position at oblique, antero-posterior and lateral views we go for our interventions with NRS cocktail every time checking the vital parameters by a non invasive cardiac monitoring within a full resuscitation set kept ready for back up.

in VAS for the two cohorts (at treatment completion) by independent sample t-test to see if the outcome varied. We found that the result of the two groups did not vary in a statistically significant manner (p value = 0.944) and the percent decrease in ODI score for this two group at 6 months also did not vary significantly (p value = 0.441).

Discussion

The whole exercise of the study was to develop a uniform protocol for the institution in treating patients with low back pain due to facet root and discs more efficiently and economically. We considered the above mentioned three structures as a continuum under the current functional diagnostic classification system of Kirkaldy-Willis²³ which is intuitively sound and clinically correlatable. We tried to diagnose and treat each of these three components and see if the protocol is helpful in the above respect.

It should be noted that the initial presentation of symptoms can occur anywhere along this continuum, implying that sub-pain threshold degenerative changes occur throughout

life. Also, degenerative changes in one motion segment may predispose to a similar process in adjacent segments. Interestingly it has been found that the aging process does not always correlate with the clinical phase of degeneration²⁴ hence various patient of different age group suffering from the common condition of chronic LBP from facet, root and disc can be considered as a single cohort which is what the study has exactly done by taking various age group with such pathology as a single cohort.

The lack of clinically reliable signs as demonstrated by Revel *et al*²⁵ and others^{5,26} has been overcome by directly intervening in the suspected structure. There by this study is unique in the sense that the above continuum of Kirkaldy-Willis model is inbuilt into the diagnostic approach as well as treatment protocol. Hence the name of the protocol NRS protocol and NRS cocktail can be considered unique to the institution where we attempted to clinically explore and extend the current Kirkaldy-Willis model in light of spinal interventions.

A significant number of chronic LBP cases due to facet, nerve root and disc were diagnosed by NRS protocol.

Table 1 — Showing age and sex distribution, single and multiple intervention

	AGE	SEX	DISEASE DURATION
ALL PATIENTS=32	MEAN=40 MAX =71 MIN =21	M=16 F=16	MEAN=13 months MAX=51 months MIN=2 months
SINGLE INTERVENTION GROUP=16	MEAN=38 MAX =54 MIN =21	M=9 F=7	MEAN=9 month MAX=32 month MIN=3 month
MULTIPLE INTERVENTION GROUP=16	MEAN=42 MAX =71 MIN =24	M=7 F=9	MEAN=17 month MAX= 51 month MIN=2 month

Table 2 — Changes of VAS with time

	VAS0 preintervention	VAS 1 3week	VAS2 3 months	VAS3 6months	% decrease VAS at 6 month
ALL PATIENTS =32	Mean=8.0969 Maximum=10 Minimum=5	Mean=4.4438 Max=9.70 Min=0.3	Mean=4.3344 Max=9 Min=0.2	Mean=4.2312 Max=9 Min=0.2	46.8144%
SINGLEINTERVENTION CASES=16	Mean=8.4188 Max=10 Min=6	Mean=4.7437 Max=9.7 Min=1.50	Mean=4.3000 Max=7.20 Min=0.3	Mean=4.0375 Max=7.20 Min=0.3	47.2075%
MULTIPLE INTERVENTION CASES=16	Mean=7.7750 Max=9.80 Min=5	Mean=4.1438 Max=8.70 Min=0.3	Mean=4.3687 Max=9 Min=0.2	Mean=4.4250 Max=9.5 Min=0.2	46.4213%

This conclusion was based on the following logic. First we applied the protocol to make a diagnosis. We considered it true or false on retrospective analysis in the end of treatment at 6 months.

The justification for comparing at 6 months is based on recent systemic reviews by Saladdhi *et al*²⁷. Other studies by Dilke *et al*²⁸, Pirbudak *et al*²⁹ and Carette *et al*³⁰ on long term effect of various combination of depot steroid and other drugs have also shown greatest improvements at 3 months of intervention.

Also the fact that depot-steroid does have ion channel blocking function was given consideration³¹. Since such effects should not be discernable after 3 months time, we could thus eliminating chances of false positive

diagnosis from more central or peripheral cause.

If there is more than 50% pain relief (excellent to good) and the pain relief persisted up to 6 months we considered the case diagnosed and treated. Subsequently a very significant number of cases showed reduction of pain at the end of study. More than 57% of the patients treated had 50 % or more reduction of pain. Thus we were able to make a correct diagnosis in 57% of cases. This is very significant.

On the basis of such reasoning we wanted to compare the multiple interventions with single intervention cohort at 6 months. We found that these two cohorts responded to the protocol similarly. Since the pain reduction in these two groups were statistically very significant till the end

Table 3 — Changes of ODI with time					
	ODI0 preintervention	ODI 1 3week	ODI 2 3 months	ODI3 6months at 6 month	% % decrease ODI
ALL=32	Mean=57.6741 Max=92 Min=17.70	Mean=32.8578 Max=84 Min=1	Mean=31.3728 Max=84 Min=.08	Mean=32.5603 Max=84 Min=0.8	43.6619%
SINGLE INTERVENTION=16	Mean=56.1125 Max=92 Min=17.70	Mean=28.5144 Max=78 Min=0.8	Mean=28.0444 Max=78 Min=0.8	Mean=28.0444 Max=84 Min=0.8	48.2169%
MULTIPLE INTERVENTION=16	Mean=59.2356 Max=90 Min=26	Mean=37.2013 Max=84 Min=1	Mean=34.7013 Max=84 Min=1	Mean=37.0763 Max=84 Min=1	39.1069%

Table 4			
	All patients	Single	Multiple
EXCELLENT	6 (19%)	2(12%)	4(25%)
GOOD	12(38%)	7(44%)	5(31%)
FAIR	8(25%)	4(25%)	4(25%)
BAD	3(9%)	3(19%)	0
WORSE	3(9%)	0	3(19%)

of study, we were able to diagnose the exact site of pain in both these groups. Fifty-six percent of the multiple site pain were diagnosed where as fifty-eight per cent of single site pain were diagnosed by using this protocol.

Such significant number of exact site specific diagnosis had been impossible to establish previously with conventional approaches. The main reason being poor association of imaging and clinics as stated in the introduction^{32,33}. Previously we also lacked the concept of applying intervention for diagnosis of pain. In the 1990's, new precision diagnostic tests have been developed, evaluated and implemented. Thus, if appropriate tests are used, a diagnosis of chronic spinal pain can be made in at least 50% of the cases, and perhaps in as many as 70% of the cases⁷⁻⁹. So in this study we were successful in showing the role of intervention as the third arm of diagnosis and the results are in agreement with published data sated before.

Having established the satisfactory diagnostic capability of intervention in the selected cohort, we wanted to find

the therapeutic potentials of NRS cocktail. It was found to be effective in treatment of chronic LBP. Though sufficient reports are there for use of its each component separately like local anaesthetics (lignocaine 2% and bupivacaine 0.25 %), deposteroids, hylalurindase and ozone however literature about this connotation is not available. This has been the unique aspect of our study. We tried this entire component as per requirement of the established diagnosis.

First and foremost this cocktail was found to be safe with no immediate side-effects and no such were observed at end of study. Only few reported hypotension and bradycardia during the procedures which were transient and within the physiologic limit as recorded on a non-invasive cardiac monitor. All such cases reversed after few seconds to minutes. None had to be resuscitated or admitted post procedure. None of the component showed untoward drug-drug interaction or incompatibility. Neither did it precipitate any untoward anaesthetic toxicity. However significant improvement recorded might indicate potentiation of various components used. This can be studied in the future.

Three patients complained of postspinal headache and all recovered normally. In one patient we had to go for an epidural blood patch to control the headache. One interesting observation was a failure case that was ultimately diagnosed as neuritic Hansen disease, which our protocol was unable to diagnose. Thus it appears that an electro diagnostic arm should be thought of in future protocol design. There is also an interesting aspect of

diagnosing pathology with post discography CT which is being reported to be more sensitive for diagnosing internal disc disruption than MRI^{34,35}. We certainly have planned to add this approach in the next edition of NRS protocol.

Maximum reduction of pain occurred immediately after intervention and was maintained up to final visit at 6 months. More than half achieved excellent to good results in this study.

However other studies of ozone nucleolysis, transforaminal epidural blocks and facet injections had shown even better results²⁰⁻²². This might be due to the following facts. First these are the reports of initial 6 months of starting our physiatric intervention clinic at NRS. Second almost all of the interventionist had to be trained for the procedure which might have brought the success rates down. With skills of the faculty developing with time a better success rate can be hoped for. Thirdly in cases of facet we didn't apply the dual block strategy which is recommended by some to secure diagnosis³⁸. This might have diluted the result. The most encouraging thing has been the fact that even if we start from scratch, good enough results can be achieved.

Regarding disability there were significant reduction of disability observable within 3 weeks postintervention and was maintained till the end of study without any significant deterioration. However those with multiple diagnosis a marginal increase in disability at 6 months was observed when compared to ODI values at 3 months. This occurred mostly among the low socio-economic group who were compelled to do heavy work immediately after treatment. Thus not getting adequate time to heal. Most of them got back to their job despite some residual disability with significant pain reduction.

This experience is a pointer to the fact that these interventions apart from being cost effective and safe can be mastered in a very short span of time. However mastering the interpretation of fluro-image needs an exponential learning curve. We were at the flat part of the curve when the study started hence there were unavoidable biases in the Part iii of the protocol where we made our interventional diagnosis. Did it affect the results? Only future study from the same team can tell.

All positive attributes from the study makes such treatment strategy a very pertinent weapon for disability management in chronic LBP. We observed that the protocol had a universal acceptance among the poor as well as the rich patients. Hence no doubt ozone a

component of our NRS cocktail has been jokingly referred to as a socialist molecule by some learned counterpart in the west.

Conclusion

The protocol was successful in making a diagnosis and was also useful in treatment of chronic LBP due to structural facet, root and disc pathology. The study population was small and there were some biases that crept in the study as this has been done on the soaring wings of a learning curve. Many interesting facet of LBP care came forward and need to be contemplated upon in the next version of NRS protocol. More data on the above approach is imperative to make it a standard physiatric practice in the coming years.

To remain competitive in business of medicine more such intervention protocol and molecules should be encouraged those that does not cut the skin or purse.

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