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# HIV Associated Arthritis

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## Abstract

**Objectives:** To find out pattern of joints involved and effectiveness of a treatment program in HIV associated arthritis

**Methods:** A cohort of 26 Human Immunodeficiency Virus (HIV) associated arthritis patients (21 males and 5 females) who attended Department of Physical Medicine and Rehabilitation of the Regional Institute of Medical Sciences, Imphal was studied during 2002 and 2005. CD4 count and joint fluid examination including culture and sensitivity were performed before initiation of the treatment. A management program consisting of NSAIDs, intra-articular (I/A) methyl prednisolone injection upto a maximum of 3 times, range of mobilization exercises, strengthening of muscles around the joint, local restriction of activities to protect joints was instituted. Low dose oral corticosteroids was considered when there was persistence of joint effusion after I/A methyl prednisolone injection(s). Joint score, pain score and activities of daily living score were assessed at baseline, 3 and 6 months.

**Results:** Mean age of the patients was 33.2 (SD, 6.6) years. Knee joint was involved in 22 cases followed by

ankle joint in 5 cases. More than two joints were involved in 7 cases. Median CD4 count was 484 (range 231-897). The synovial fluid showed features of inflammation and was sterile. Nineteen cases (73%) remained symptom free for at least 3 months after I/A injection of methylprednisolone. Of the 7 refractory cases, all in knee joints, two had associated hyperuricemia. Synovial biopsy showed tuberculosis in one and the case responded to the addition of antitubercular drugs. And other case responded to hypouricaemic drug. Four cases responded to low dose oral corticosteroids and another case responded only after initiation of antiretroviral treatment.

**Conclusions:** Knee was the most commonly involved joint. Intraarticular methylprednisolone seem to be effective in the management of these cases in addition to the rehabilitation program. Low dose oral prednisolone was found to be a good adjunct in refractory cases.

**Key words:** Human Immunodeficiency Virus (HIV), Acquired Immunodeficiency Disease Syndrome (AIDS), Arthritis, Intra articular Methylprednisolone.

## Introduction

Following the global epidemic of HIV infection, India already has the second highest number of people estimated to be living with HIV/AIDS in the world<sup>1</sup>. In Manipur, a north eastern state of India bordering Myanmar, HIV infection is among the highly prevalent states in the country. Till February 2007<sup>2</sup>, number of sero-positive cases was 25,602 with sero-positivity rate per 1000 samples screened was 136.15. Prevalence of Intravenous Drug Users (IDUs) among HIV infected persons in Manipur was as high as 72.78% in 1998 and it has come down to 19.8% in the year 2006. Whereas, the prevalence of Sexually Transmitted Diseases (STD) had shown an increasing trend from 3.9% in 1995 to 12.2% in 2005. Among antenatal women, seropositivity rate has been consistently above 1% since 1997. Presently, due to increasing life expectancy among HIV infected persons, musculo-skeletal manifestations are frequently seen<sup>1</sup>. HIV associated arthritis<sup>3</sup> is a separate entity which resembles subacute form of the painful articular syndrome, but joint effusion is present. It is further differentiated from reactive arthritis and Reiter's syndrome by absence of HLA-B27 and extraarticular manifestations like conjunctivitis and urethritis respectively. It is emerging as one of the important causes of arthritis in this state

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and there has been no report on HIV associated arthritis from this regional population. Therefore, this study was conducted to find out the pattern of joints involved and effectiveness of a treatment program in HIV associated arthritis.

## Material and Methods

This study was conducted on 26 arthritis patients (21 males and 5 females) associated with HIV infection who attended the Department of Physical Medicine and Rehabilitation, Regional Institute of Medical Sciences, Imphal for treatment from the year 2002 through 2005. Written informed consent was taken from all patients for the study and interventions before taking up as a study subject. Institutional ethical committee clearance was also taken for the study. Out of 26 HIV infected patients, twenty two were referred cases from various out patient departments and clinics in Manipur and the remaining 4 patients were found HIV infected on further investigations for arthritis. Diagnosis of HIV infection was done as per National Guidelines based on three ERS (Elisa/Rapid/Simple) with different antigens or different principles<sup>4</sup>. Necessary pre-test counselling and informed consent were taken from the patients before doing the testing in the Voluntary, Confidential, Counselling and Testing Centre (VCCTC), Department of Microbiology, Regional Institute of Medical Sciences. Patients who had already undergone treatment with intra-articular hydrocortisone injection, having acute systemic diseases, history of conjunctivitis and urethritis, and refusal to sign informed consent were excluded from the study. Variables like age, sex, duration of HIV infection, probable mode of transmission were recorded. CD4 count and joint fluid examination for biochemical, cytological, culture and sensitivity were also carried out wherever feasible before initiation of the treatment.

A management program consisting of non steroidal anti inflammatory drugs (indomethacin was used as preferred drug), range of mobilization exercise, strengthening of muscles around the joint, local restriction of activities/life style modifications to protect joints was instituted for all patients. Intra-articular methyl prednisolone (80 mg) injection up to a maximum of three times were given to all patients who were not relieved by the initial therapy and whose CD4 count is  $\geq 200$  cells/mm<sup>3</sup>. Low dose oral corticosteroid was considered when there was persistence of joint effusion after intra-articular methyl prednisolone injection (s). Initiation of antiretroviral therapy (ART) was considered to those patients whose CD4 count was less than 250 cells/mm<sup>3</sup> before intra-articular injection or oral steroid therapy. Antibiotics, hypouricaemic drugs were considered whenever applicable. Synovial biopsy was considered in refractory cases.

Joint score (number of swollen joint), pain score using visual analog scale (VAS) and activities of daily living (ADL) score using Modified Health Assessment Questioner were recorded before initiation of the treatment programme and reviewed at 3 and 6 months for every patient.

Descriptive statistics were employed analysis of the various findings.

## Results

The age of patient ranged from 21 to 48 with a mean of  $33.2 \pm 6.6$  years. The group included 9 transsexuals, 16 intravenous drug users and 1 with unknown risk factor. Duration of HIV infection ranged from 18 months to 8 years in 22 patients (mean  $5 \pm 1.9$  years). The HIV positive on remaining 4 patients were found during investigations for arthritis. Knee joint was involved in 22 cases followed by ankle joint in 5 patients. More than 2 joints were involved in 7 cases. Median CD4 count was 484 (range 239-897).

The synovial fluid studied in 19 cases showed features of inflammation and were sterile. Seventy three percent of cases (n=19) remained symptom free for at least 3 months after intra articular injection of methylprednisolone. Intra-articular injection was repeated more than twice in 7 cases. Of the 7 refractory cases, all in knee joints, two had associated hyperuricaemia. One patient responded following addition of hypouricaemia drugs and the other to anti tubercular treatment as the case was diagnosed through synovial biopsy. Another 3 cases responded to supplementation of low dose oral corticosteroids (5-10 mg) for about 3 weeks and in one patient, oral prednisolone was continued for about 10 weeks. One case responded only after initiation of antiretroviral treatment.

Mean pain scores (VAS) before the initiation of the treatment programme, at 3 months and 6 months were  $6.6 \pm 0.8$ ,  $2.3 \pm 1.2$  and  $1.0 \pm 0.9$  respectively. Again, swollen joint score before the initiation of the treatment programme, at 3 months and 6 months were  $1.9 \pm 1.0$ ,  $0.2 \pm 0.5$  and  $0.08 \pm 0.2$  respectively. ADL score measured by using Modified Health Assessment Questionnaire at the time of admission was  $13.8 \pm 2.7$  followed by  $4.9 \pm 2.5$  and  $2.1 \pm 1.4$  respectively at 3 and 6 month follow up.

## Discussion

As many as 75% of HIV infected individuals will experience musculoskeletal complications which includes aseptic inflammatory or rheumatoid processes, infection, neoplasia and therapy related side effects during the course of the disease<sup>5</sup>. The majority of musculoskeletal manifestations of HIV disease are reactive in nature,

whether secondary to HIV infection itself or reactive to opportunistic infections elsewhere<sup>6</sup>. Infective causes are unusual until CD4 count drops below about 200 cells/cu mm<sup>7</sup>. Clinically some form of rheumatoid symptoms was seen in up to 30% of patients, with some frank inflammatory arthritis in up to 15%<sup>8</sup>. Unlike infective and neoplastic pathologies occurring in HIV infection, the inflammatory/rheumatic processes are seen earlier in the natural history and at higher CD4 counts, although there is a further increase in incidence associated with the development of definite AIDS or AIDS related complexes<sup>9</sup>. This association is a reflection of HIV immunopathy. There is renewed interest in the role of retroviruses in immune-mediated inflammatory disease. In HIV infected individuals with arthropathy, HIV antigens and DNA have been isolated from the synovium<sup>10,11</sup>.

HIV associated arthritis<sup>12,13</sup> occurs at least as frequently, and sometimes more commonly, than HIV indirectly associated spondyloarthropathy. It is usually presented as an oligoarthritis, predominantly affecting lower extremities, which tend to be self limiting, lasting for less than 6 weeks. Although early reports in western communities reported asymmetrical oligoarthritis as the usual pattern, polyarticular involvement is now seen frequently<sup>14</sup>. The synovial fluid leucocyte count is lower than that seen in HIV-associated reactive arthritis (500 - 2,000/l). Synovial fluid cultures are typically sterile. Isolation of HIV from one synovial fluid sample showed particles resembling retrovirus in electron microscopy. No mucocutaneous involvement is observed, and enthesopathy is also absent. The treatment, by and large, includes NSAIDs, and in more severe cases, low dose corticosteroids. Patients may respond equally well to hydroxychloroquine and sulphasalazine. Most of the patients with HIV associated arthritis are in the late stage of infection. The aetiology is still unclear, however recently both HTLV-I and -II have been suggested to induce inflammatory or autoimmune reactions which can increase significantly the incidence of arthritis.

Casado and Coworkers<sup>15</sup> studied 74 HIV patients with osteoarticular manifestations. The study group comprised 61 men (82.4%) and 13 women (17.5%) with a mean age of 34.2 years (range 17-62). Marquez J and Coinvestigators<sup>16</sup> also evaluated seventy-five individuals with HIV infection and musculoskeletal manifestations 65 (86%) men and 10 (14%) women. Mean age was 32 ± 4.5 years (range 21-58). Mean age is comparable with the present study (33.2 years).

The group in Marquez's study<sup>16</sup> included 40 (53%) heterosexuals, 30 (40%) intravenous drugs users, 9 (12%) homosexuals, 3 (4%) who had received blood transfusion,

and 2 (2.6%) with unknown risk factors. Present study included 9 (34.4%) transsexuals, 16 (61.5%) intravenous drug users and 1 (3.8%) with unknown risk factor. However, Casado<sup>15</sup> reported IV drug users as high as 70.3% (n=52). High rate of IV drug users in the present study signifies common route of transmission of HIV infection in the state Manipur.

Casado<sup>15</sup> reported the mean CD4 of 164.7 cells/mm<sup>3</sup> in septic arthritis, 127.1 cells/mm<sup>3</sup> in soft tissue involvement, 245.8 cells/mm<sup>3</sup> in spondyloarthropathies, 132.8 cells/mm<sup>3</sup> in lymphoma, and 233.6 cells/mm<sup>3</sup> in osteomyelitis. He suggested that CD4 counts may be useful predictors to determine the type of musculoskeletal manifestation in HIV infected persons. Median CD4 count among HIV associated arthritis in the present study was 484 cells/mm<sup>3</sup> (range 239-897) which showed existence of the HIV associated arthritis in higher CD4 counts among HIV patients in Manipur.

A review of patients presenting at the rheumatology clinic of the Parirenyatwa Hospital, University of Zimbabwe School of Medicine by Davis P and Stein M<sup>17</sup> revealed 14 arthritis cases with HIV infection. These 14 patients, mostly males, all had acute onset arthropathy, 5 with polyarthritis and 9 with oligoarticular diseases, usually affecting knee and ankle joints.

Stein CM and Davis P<sup>18</sup> reported oligo/polyarticular arthritis associated with HIV infection in 26 patients (22 men, 4 women) where joints commonly involved were ankles (65%) and knees (54%), often with associated enthesitis (31%) and dactylitis (23%). They concluded that arthritis associated with HIV is most commonly characterized by oligoarticular, asymmetrical, large joint arthritis, with or without features of Reiter's syndrome, and is not associated with HLA-B27. Present study showed knee joint being involved commonly (n=22) followed by ankle joint in 5 patients. More than 2 joints were involved in 7 cases. However, a similar features like oligoarticular, asymmetric and large joint involvement was noticed in the study.

Joint fluid showed features suggestive of inflammation and cultures were sterile in the present study. Similar findings were also reported by Berman A et al<sup>20</sup> and Ntsiba H and Coworkers<sup>19</sup>. Ntsiba<sup>19</sup> also reported microcrystals in the synovial fluids and X-ray features showing non destructive arthritis or otherwise normal study. Edward JP<sup>4</sup> however expressed that the joint fluid is typically not inflammatory (<10<sup>3</sup> cells per milliliter), though patient may respond dramatically to intraarticular steroids.

Asymptomatic hyperuricaemia is associated with ritonavir therapy, but gout has rarely been reported. Creighton S

and Co-worker<sup>21</sup> recorded 18 cases of gout among 1825 HIV-positive patients, of whom 15 were receiving antiretroviral (ritonavir) therapy. Gout was seen in patients with known risk factors for gout or who were receiving ritonavir as boosted protease inhibitor and also who had lipodystrophy. Present study also featured 2 cases of hyperuricaemia but none had been treated earlier with antiretroviral therapy.

Belzunegui J and Co-investigators<sup>22</sup>, studied the characteristics of patients with the human immunodeficiency virus (HIV) and concomitant mycobacterial skeletal infection. Infections involved the knee (4 cases), spine (3 cases), hip (2 cases), elbow (1 case) and tibia (1 case). *M. tuberculosis* was the responsible organism in 9 cases, *Mycobacterium tuberculosis* plus *Staphylococcus aureus* in one case and *M. Kansasii* in one case. Patients who received specific treatments showed good results. Surgery was necessary in 4 cases. In the present study, synovectomy specimen from one patient showed tuberculosis and responded in antitubercular treatment. The spectrum of HIV-associated rheumatic disease remains a diagnostic and therapeutic challenge for the clinician<sup>22</sup>.

Human Immunodeficiency Virus has been identified in synovial fluid dendritic cells and in the synovium; immunohistochemical analysis revealed the nature of the lymphocyte infiltrate in the synovium of affected individuals. Postmortem studies suggest that there may be histologic evidence of premature aging in clinically unaffected joints from patients with acquired immunodeficiency syndrome<sup>23</sup>.

Keat A and Rowe I<sup>24</sup> reported that conventional treatments of rheumatic lesions, including intraarticular steroids, appear to be safe and reasonably effective. Anecdotal evidence suggests that treatment with methotrexate and azathioprine leads to exacerbation of HIV disease and should be avoided.

Stein CM and Davis P<sup>18</sup> treated all HIV patients with arthritis with a nonsteroidal anti-inflammatory drug (NSAID), most commonly indomethacin, with the addition of low-dose prednisolone (5-10 mg for 4 patients) and/or chloroquine (150 mg base daily for 11 patients) if clinically indicated. In patients in whom arthritis improved, the effect was gradual over 3-6 months.

In the present study, methylprednisolone intra-articular injection to a maximum of three times was given to all patients since all these patients remained nonresponsive to the usual conservative treatment including NSAIDs and physical modalities before attending the arthritis clinic and as initial treatment protocol for the present study. Nineteen patients (73%) got significant relief at 3 months

and 92.3% (n=24) remained symptom free at 6 months follow up. Two patients remained symptomatic even after 6 month. Our findings contradict the usual belief that HIV associated arthritis usually resolved with NSAIDs within 2-4 weeks. And intra-articular corticosteroid injection remained mainstay over and above the rehabilitation programme in the treatment of HIV associated arthritis.

## Conclusion

Knee is the most commonly involved joint in HIV associated arthritis. Intra-articular methylprednisolone seems to be the mainstay in their management in the present study over and above the rehabilitation programme. Low dose oral prednisolone, hyperuricaemia drugs and antibiotics have a role in refractory cases.

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# Effect of Alprazolam in Spasticity: A Pilot Study

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## Abstract

**Background:** Alprazolam, given in 0.5 mg dose for some other reason (like anxiety), showed reduction in spasticity and spasm lasting for a few hours. On searching the literature we did not come across any study to authenticate this effect of alprazolam. Hence, this study was planned.

**Methodology:** This was a prospective pilot study. 38 cases suffering from spasticity of any origin were included. 0.5 mg (for 15 days) followed by 1mg (for another 15 days) of Alprazolam once daily ½ hour before bed time was given to every patient and repeat evaluations were done at day 15 (0.5mg) and 1 month (1mg). Spasticity were assessed by MAS, PSFS, Peak torque at 30°, 60°, and 90°/sec, time taken for ADL (drinking, dressing, hand activity), and FIM motor score.

**Results:** 34 completed the 1 month period of study. Significant improvement was observed in MAS score, PSFS at each time, peak torque at 30° /sec velocity (only with 1mg), peak torque at 60° and 90° /sec, FIM score, drinking activity (only with 1mg), dressing activity and hand activity.

**Conclusion:** Alprazolam is a safe and effective drug for the treatment of spasticity as well as spasms, that is, both the phasic and tonic part of stretch reflexes responds to alprazolam when used up to 1 mg for 1 month. Performance of ADL improved favorably with 0.5 and 1 mg alprazolam. Further studies are required in this area regarding the long term safety and efficacy and effective dose for spasticity.

**Key words:** Spasticity, Alprazolam, FIM, MAS, PSFS

## Introduction

Spasticity is a motor disorder characterized by a velocity dependent increase in tonic stretch reflexes with exaggerated tendon jerks, resulting from hyper-excitability of the stretch reflex, as one component of the upper motor neuron syndrome<sup>1</sup>. Spasticity is associated with some very common neurological disorders like multiple sclerosis, stroke, cerebral palsy, spinal cord injury, brain injuries, and neurodegenerative diseases. Although the exact incidence of spasticity is unknown, it is likely that it affects more than half a million people in the United States alone, and more than 12 million people worldwide<sup>2</sup>. Following stroke, approximately 65% of individuals develop spasticity<sup>3</sup>. Roughly, 70% of persons with spinal cord lesion are spastic one year after injury and around half of these receive antispastic medication<sup>4</sup>.

Spasticity can cause discomfort, stiffness, pain, pressure sore and difficulty in performing physical activities such as walking, transferring, picking up objects, washing, dressing and sexual activity can all be affected with increase muscle tone. Poorly managed spasticity can also be responsible for muscle shortening and the development of tendon and soft tissue contractures, which together with spasms can lead to compromised safety in lying and sitting<sup>5</sup>. Contractures are responsible for major functional implications, including difficulties with personal hygiene or dressing, positioning, and at times the inability to sit, which may lead to restricted community mobility and social isolation.

While managing some patients having spasticity, alprazolam was given to these patients in the dose of 0.5mg at bed time for some other reason, like insomnia or anxiety. It was noticed that these patients showed reduction in spasticity and spasm lasting for a few hours. On searching the literature we did not come across any study to authenticate this effect of alprazolam. Hence

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working on this finding that alprazolam may have a role in the reduction of spasticity, we planned this study.

## Methodology

It was a prospective pilot study. Aims and objectives of the study were to find out whether alprazolam given in the dose of 0.5 mg or 1 mg once daily at bed time, has any effect on muscle tone in patients suffering from spasticity of any origin. 38 Consecutive cases, satisfying our inclusion criteria, attending PMR out-patients at AIIMS, New Delhi, (between December 2006 and July 2008), suffering from spasticity of any cause, in whom spasticity was interfering in activities of daily living or causing any discomfort where treatment of spasticity was warranted were included in this study. The patients were not treated simultaneously with any other drug for spasticity at the time of recruitment into the study, except for baclofen. If baclofen alone was being given earlier, alprazolam was started only in case the effect of baclofen in reducing spasticity was inadequate and if there was a need to enhance the dose of the baclofen or add another drug for treating spasticity. In such a case the dose of baclofen was maintained as per the previous level and alprazolam was added.

**Inclusion criteria:** Age above 12 years of both sexes, all old and new diagnosed cases of spasticity from any underlying cause requiring treatment of spasticity and patient not taking any other drugs that affect muscle tone except baclofen.

**Exclusion criteria:** Unwillingness to participate, any kind of deformity and/ or contracture, any other acute medical condition and significant cognitive dysfunction which might interfere in assessment of spasticity or ADL assessment. Major psychiatric disorder and patient on anti psychotic medicine and any acuteness of the condition that may interfere with the patient's level of spasticity, like acute urinary tract infection, in-growing toe nail, pressure ulcer etc. Patient suffering from Myasthenia gravis or acute narrow angle glaucoma and pregnant females and infants were also excluded.

All patients were explained about the procedure to dispel and correct misconception. They were explained about harms and benefits of the alprazolam. Informed written consent was taken from all patients and from parents in case of minors in this drug trial. Following investigations were done for every patient at base line and follow-up: Complete haemogram (Hb, DLC, TLC and ESR), Liver function test (SGOT, SGPT, and ALP), Kidney function test (serum urea and creatinine) and urine routine and microscopy. Other investigations were done depending upon the clinical condition.

**Intervention:** A dose 0.5 mg of alprazolam once daily ½ hour before bed time was given to every patient, included in the study. The repeat evaluation was done at day 15. At the end of 15 days, if no significant improvement was seen in ADL till the level where further treatment was not warranted, so the dose was increase to 1 mg and repeat evaluation was done after another 15 days. If no response was seen and or any untoward effect was noted at the end of one month study, the drug was stopped. All the patients were subjected to regular passive range of motion (150 repetitions) of all joints of upper and lower limb affected with spasticity and one week was taken to optimize the effect of physiotherapy on the patient before starting drug evaluation.

**Spasticity assessment:** In each assessment session, the spasticity was assessed by the following tools:

**(1) Clinical assessment:** was done by using Modified Ashworth Scale and Penn Spasm Frequency Scale.

Spasticity was scored with MAS by setting grade 1 to 1, grade 1+ to 2, grade 2 to 3, grade 3 to 4 and grade 4 to 5 as Skold et al<sup>6</sup> had done, for all the affected muscle groups in extremities (hip, knee, ankle, shoulder, elbow, and wrist). All patients were evaluated for MAS<sup>7</sup> under same circumstances, (time of the day, ambient temperature, testing position-lying down position). If any patient was affected with some general health (such as urinary tract infection, constipation, pain, fatigue) during follow-up then such patient was excluded from study.

The PSFS<sup>8</sup> is based on self-reporting by using a scale from 0 to 4, with the following rankings: 0, no spasm; 1, mild spasms induced by stimulation; 2, infrequent full spasms occurring less than once per hour; 3, spasms occurring more than once per hour; and 4, spasms occurring more than 10 times per hour. A complete history about spasm frequency was taken, patients were advised to note the frequency of spasm / fall, whether it was decreasing or not during treatment period.

**(2) Biomechanical method (by Isokinetic dynamometer):** Peak torque responses were assessed at 30°, 60° and 90°/sec of angular velocity at knee joint (flexion and extension) on continuous passive motion mode (with computerized isokinetic dynamometer-Biodex system-2)<sup>9,10,11,12</sup>, at each assessment session. Assessment was done in the sitting position with 15° seatback tilt and in the morning hours (10:00 am) before patients had undergone any therapeutic activity. Alignment of knee axis of rotation with power-head shaft was done with a line drawn in the sagittal plane through the femoral condyles to mechanical axis of dynamometer. Calf pads were placed 4 cm proximal to the lateral malleolus. Patient was stabilized with thigh strap, pelvic strap and shoulder



straps across the chest. The test program was selected and data were entered. Each trial was conducted through 90° range of motion of knee joint at each angular velocity and same ROM was used at each follow-up. Ten consecutive passive joint motions were performed at three pre-selected angular velocities (30, 60, and 90°/sec) for affected knee joint. Gravity correction option was in built in the Biodex machine, was undertaken. Resistance to passive motion was determined for both knee flexor and extensor muscle groups by the maximum peak torque values among ten repetitions. Average of maximum peak torque for each patient was calculated by summing the two or four maximum peak torques and then divided by 2 or 4 according to affected extremities, for all three velocities at base line, 1<sup>st</sup> follow-up and 2<sup>nd</sup> follow-up.

**(3) ADL Assessment:** Patients were assessed for three ADL and time taken in these activities was noted with stop watch in seconds. Time taken in picking a glass of water from table to putting it on lips with each hand separately, time taken in lower extremity dressing with or without assistive devices and time taken in picking a book from one corner of table to putting it on another corner with each hand separately were measured initially and at follow-up. Same glass, clothes and book were used.

**(4) Functional Independence Measure (FIM):** FIM motor score was used to assess improvement in one’s ability to function with independence at base line and at follow-up as used by sipiski ML et al<sup>13</sup> and P. Azouvi et al<sup>14</sup>. The best and worst possible FIM motor sub-score is 91 and 13 respectively. Total FIM motor score was compared at base line, at 15 day and 1 month.

**Statistical Analysis** Descriptive statistics like mean, median, minimum, maximum and standard error were calculated for each of the quantitative variables. Repeated measure ANOVA/Friedman test for testing the significance of change in various variables was used. In case of significant result, multiple comparison tests was done by Post hoc by using Bonferroni /adjusted Wilcoxon signed ranks test. For categorical data like Penn Spasm Frequency scale, Mc-Nemar test was used. A result was considered significant at 5% level of significance, that is, p<0.05.

**Results**

38 subjects were enrolled, only 37 and 34 completed 15 day and 1 month follow-up period respectively. The patients were contacted through telephone for follow-up. The reasons for drop-out were side effect of alprazolam (1), difficulty in transport (1) and loss of health due to other causes (1). One case was lost to follow-up and could not be contacted.

**Demographic distribution:**

**Age and Sex:** The age distribution of the 38 subjects (29 males, 9 females) included in this study varied from 16 -65 years, with the mean of 33.92 ± 15 years.

**Case profile:-**Based on the site of lesion patients were divided into three neurological groups namely cerebral, cervical and dorso-lumbar. 22 had lesion in dorso-lumbar region, 8 had lesion in cervical region and 8 were those where spasticity was of cerebral origin. In spinal origin of spasticity, most cases were spastic due to traumatic spinal cord injury (table 1).

Cause of spasticity	No. of patients
1. Cerebral palsy	3 (7.89%)
2. Traumatic brain injury	3 (7.89%)
3. Space occupying lesion in brain	1 (2.63%)
4. Traumatic Spinal cord injury	16 (42.11%)
5. Compressive myelopathy	9 (23.68%)
6. Pott’s paraplegia	4 (10.53%)
7. Non-compressive myelopathy	1 (2.63%)

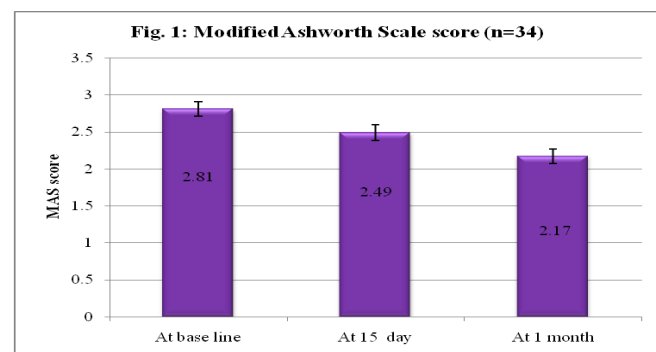
Table 1: Causes of spasticity (n=38)

**Duration of spasticity:-** Mean duration of spasticity was 48.80 ± 76.55 months, with a range 15 days to 288 months. Most (n=16) of patients had spasticity for duration of less than 6 months.

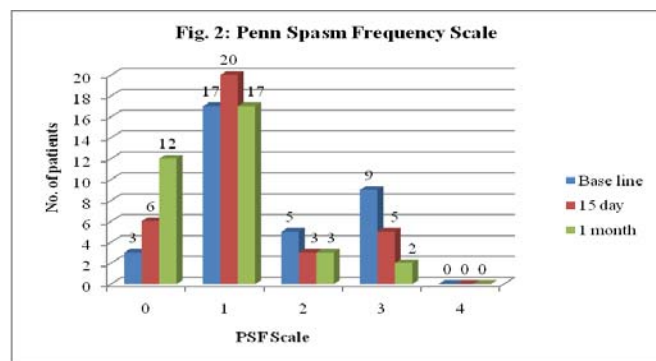
**Treatment received:** Out of 34 cases that completed the study, in 29 cases alprazolam was given alone. Rest 5 cases, were those where baclofen being given earlier, in such case the dose of baclofen was maintained as per the previous level and alprazolam was added.

**Modified Ashworth Scale (MAS):** Mean MAS scores at base line, 1<sup>st</sup> and 2<sup>nd</sup> follow up were 2.81 ± 0.098, 2.49 ± 0.11, and 2.17 ± 0.099 respectively. There was significant improvement in MAS (p=0.0001). Significant improvement in spasticity as measured by MAS was also seen, when comparison was done between base line and 1<sup>st</sup> follow-up, base line and 2<sup>nd</sup> follow-up and 1<sup>st</sup> follow-up and 2<sup>nd</sup> follow-up (fig 1).

**Penn Spasm Frequency Scale (PSFS) score:** Significant improvement in PSFS score was seen, when



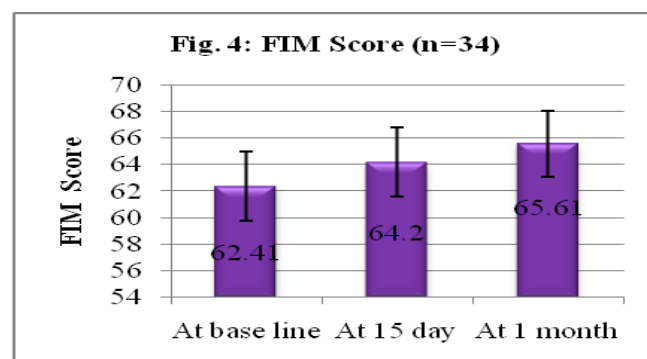
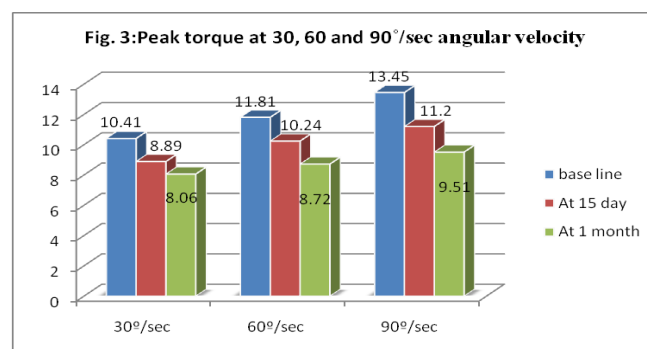
comparison was done between base line and 1<sup>st</sup> follow-up (p=.0234), 1<sup>st</sup> follow-up and 2<sup>nd</sup> follow-up (p=.0148) and between base line and 2<sup>nd</sup> follow-up (p=.0019). At base line out of 34 cases, 20 cases belonged to 0 and 1 PSFS, which increased to 26 at 1<sup>st</sup> follow-up and further increased to 29 at 2<sup>nd</sup> follow-up (fig 2).



**Biomechanical assessment of spasticity using Isokinetic dynamometer: Peak torque at 30°/sec angular velocity:** Mean peak torque during base line, 1<sup>st</sup> and 2<sup>nd</sup> follow up are shown in table 2 and figure 3 at 30°/sec, 60°/sec, 90°/sec angular velocity. Significant (p=0.018) decreased in mean peak torque at 30° /sec angular velocity was seen only when comparison was done between base line and 2<sup>nd</sup> follow-up. **Peak torque at 60°/sec angular velocity:** There was significant (p=.001) decrease in mean peak torque at 60°/sec angular velocity. Significant decrease in mean peak torque at 60°/sec angular velocity was also seen, when comparison was done between, base line and 2<sup>nd</sup> follow-up (p=.006) and 1<sup>st</sup> and 2<sup>nd</sup> follow-up (P = .014). When comparison was done between base line and 1<sup>st</sup> follow-up, it was borderline non-significant (p=.053) improvement. **Peak torque at 90°/sec angular velocity:** significant decrease in mean peak torque at 90°/sec angular velocity (p=.0001). Significant decrease in mean peak torque at 90°/sec angular velocity was seen, when comparison was done between base line and 1<sup>st</sup> follow-up (p=.009), base line and 2<sup>nd</sup> follow-up (p=.001) and 1<sup>st</sup> and 2<sup>nd</sup> follow-up (P = .011)

	Atbase line	At15 days	At1 month	1-2	2-3	1-3	P value
Mean ± S.E at 30°/sec	10.41±1.22	8.89±.663	8.06±.672	NS	NS	*	0.018
Mean ± S.E at 60°/sec	11.81±1.42	10.24±1.06	8.72±.82	NS	*	*	0.001
Mean ± S.E at 90°/sec	13.45±1.50	11.2±1.13	9.51±.89	*	*	*	0.0001

Table 2: Peak torque (n=34). (N=number of cases, S.E-Standard error, 1=Base line, 2=1<sup>st</sup> follow-up, 3=2<sup>nd</sup> follow-up, NS = Non significant, \*=Significant at 5% interval between baseline and the corresponding follow-ups)



**Functional Independence Measure:** Mean FIM motor scores at base line, 1<sup>st</sup> and 2<sup>nd</sup> follow up assessment were 62.41 ± 2.623, 64.2 ± 2.581 and 65.61 ± 2.484 respectively (Fig. 4) Significant increase in mean FIM motor score was seen (p=.0001). Improvement was seen mainly in lower extremity dressing, transfer, and bathing. Significant increase in mean FIM score was observed when comparison was done between base line and 1<sup>st</sup> follow-up (p=.0001), base line and 2<sup>nd</sup> follow-up (p=.0001) and 1<sup>st</sup> and 2<sup>nd</sup> follow-up (p = .0001).

**Time taken in Lower Extremity dressing:** The descriptive statistics of base line and follow-up cases are shown in table 3. Significant decrease in mean time taken in lower extremity dressing (p=.001) was seen. Significant decrease in mean time taken in lower extremity dressing was seen when comparison was done by using post hoc/adjusted wilcoxon signed ranks between base line and 1<sup>st</sup> follow-up, base line and 2<sup>nd</sup> follow-up and 1<sup>st</sup> and 2<sup>nd</sup> follow-up.

**Time taken in hand activity: Time taken in drinking activity:** All cases where lesion was in dorso-lumbar region of spinal cord were excluded for analysis. At base line, only 8 patients were able to perform this activity<sup>1</sup> excluding. At 1<sup>st</sup> follow-up, one case dropped and one patient who was not able to perform initially, started performing this activity. Analysis was done, it showed significant improvement in median time taken in this activity only when comparison was done between base line and 2<sup>nd</sup> follow-up (p=.026) (Table 4).

**Time taken in picking a book** At base line, only 8 patients were able to perform this activity (pareplegic were excluded). Analysis was done for 7 patients,

	Atbase line	At15 days	At1 month	P value=.0001		
				1-2	2-3	1-3
Mean± S.E	159.78±42.15	108.6±23.45	75±14.23	*	*	*
Median	85.00	60.00	40.00			
Min-Max	15-720	13-420	10-240			

Table 3: Time (sec.) taken in Lower Extremity dressing (n=23). (n-number of cases, S.E-Standard error, 1=Base line, 2=1<sup>st</sup> follow-up, 3=2<sup>nd</sup> follow-up, \*=Significant at 5% interval between baseline and the corresponding follow-ups)

	Atbase line	At15 days	At1 month	P value=0.026		
				1-2	2-3	1-3
Mean± S.E	14.14±3.82	11.57±2.61	9.57±2.71	NS	NS	*
Median	12.00	12.00	8.00			
Min-Max	5-35	4-25	3-25			

Table 4: Time (sec.) taken in drinking activity ((n=31). (n-number of cases, S.E-Standard error, 1=Base line, 2=1<sup>st</sup> follow-up, 3=2<sup>nd</sup> follow-up, NS = Non significant, \*=Significant at 5% interval)

	Atbase line	At15 days	At1 month	P value=0.003		
				1-2	2-3	1-3
Mean± S.E	21.14±7.64	17.14±6.82	8.0±1.52	*	*	*
Median	17.00	12.00	8.00			
Min-Max	5-62	4-56	3-16			

Table 5: Time (sec.) taken in hand activity: (n=31). (N-number of cases, S.E-Standard error, 1=Base line, 2=1<sup>st</sup> follow-up, 3=2<sup>nd</sup> follow-up, \*=Significant at 5% interval between baseline and the corresponding follow-ups)

excluding 1 drop-out case and there was significant decrease in median time taken to perform this activity (p=.003). Significant decrease in median time was seen, when comparison was done between base line and 1<sup>st</sup> follow-up, base line and 2<sup>nd</sup> follow-up and 1<sup>st</sup> and 2<sup>nd</sup> follow-up (Table 5).

**Reported Adverse Events:** Out of 38 patients, 19 reported adverse event during treatment, i.e. mild drowsiness in 9 patients, light headache in 4 patients, both light headache and drowsiness in 3 patients, and dry mouth in 3 patients. All these side effects were mild and did not warrant drug discontinuation, except in one case where drowsiness was more marked and patient could not tolerate the increased dose of alprazolam. This patient was excluded from study and drug was withdrawal

gradually. All side effects were generally observed at the beginning of drug treatment, mostly at night and morning hours and disappeared in most of cases with continuation of medication (with range of 3-12 days). In 3 cases these side effect were observed with increment of dose from .5 to 1 mg (for a range of 5-7 days).

### Discussion

To our knowledge this is probably the first study to evaluate the effect of alprazolam on spasticity. Alprazolam, a triazolobenzodiazepine derivative is mainly used as an anxiolytic, in panic attacks and in panic disorder with or without agoraphobia. On searching the literature we did not come across any study to authenticate this effect (antispastic) of alprazolam. Hence working on this finding that alprazolam may have a role in the reduction of spasticity, we planned this study.

The results of our study showed that there was significant reduction in spasticity and spasm with 0.5 and 1 mg alprazolam, given half an hour before bed time as measured by many of the standardized measures of spasticity i.e. MAS, PSFS, passive peak torque at 30°, 60° and 90°/sec angular velocity, FIM motor score, and in ADL activities.

In our study spasticity, as measured on MAS, decreased significantly after treatment with alprazolam (p<.0001) in dose dependent manner. Mean MAS decreased from 2.81 ± .098 (S.E) to 2.49 ± .11 with 0.5 mg of alprazolam given for 15 days, and further reduced down to 2.17± .099 With 1 mg. for another 15 days. Similar improvement in MAS was also reported in previous studies with various anti-spasticity medications. Nance PW<sup>15</sup>, reported that MAS was significantly reduced (p = 0.0001) by tizanidine treatment in spinal cord injury patients. Guillaume D<sup>16</sup> noted that patients with spinal origin spasticity, MAS decreased in lower extremities from 3.68 ± 0.81 to 1.92 ± 0.75 (p < 0.001) and in upper extremities from 1.65 ± 0.78 to 1.34 ± 0.50 (p < 0.001), after intrathecal baclofen treatment with 3, 6, 9 and 12 month follow-up. Mueller et al<sup>17</sup> noted that MAS reduced significantly after treatment with Gabapentin 400 mg, given three time in a day in 15 patient with multiple sclerosis (p = 0.007). Since similar improvement in Modified Ashworth Scale was noticed in our study, Alprazolam may have role in treatment of spasticity like other oral medication (i.e: Tizanidine, intrathecal Baclofen, and Gabapentin).

We observed significant decrease in frequency of spasm score with 0.5 mg of alprazolam for 15 days (p=.0234) and further decrement was reported after increment in dose by 0.5 mg for another 15 days (p=.0019). In our study, most of the improvements in spasm were reported during night time. This could be due to short duration of

action of drug or because of alleviation of anxiety, which may aggravate spasms. Decrement in PSFS after alprazolam, again go in the favor of antispastic effect of alprazolam. PSFS decreased significantly with antispastic medications in various studies, like our study. Neill<sup>18</sup>, reported that 3 of 4 patients had greater improvement of spasms on diazepam given at dose 16 mg/day, increasing after 1 week to 24 mg/day, continued for a further 1 week, in multiple sclerosis patients. Kathleen Hawker<sup>19</sup> reported that PSFS score was reduced from  $2.7 \pm 0.65$  to  $0.9 \pm 0.29$  with levetriacetam treatment in multiple sclerosis.

In our study we found peak torque decreased significantly at 30°, 60° and 90° per sec. of angular velocity with 1 mg of alprazolam. But we did not find any significant improvement at 30°/sec. angular velocity when alprazolam was given in a dose of 0.5 mg. Similar results were also reported by Perell K<sup>20</sup>, he found significant decrease in peak torque at 60° and 90° per sec. of angular velocity in spinal cord injury (spastic patients) as compared to control group, but not at 30° per sec angular velocity. This can be explained by the definition of spasticity itself, that spasticity is a velocity-dependent increase in tonic stretch reflexes that is, at lower angular velocity less stretch reflex will be generated and so why less peak will be obtained, so decrement in peak torque at 30°/sec may not be significant with treatment. In our study we also found that peak torque had a linear relationship with angular velocity. We also found there was significant correlation between peak torque and MAS, like MN Akman<sup>21</sup> who also reported similar finding.

In this study we assessed only motor part of FIM score because we expected that after drug treatment, motor power of affected extremity would increase, which was previously hindered by increased muscle tone. Study result showed significant improvement in functional status of spastic patients with Alprazolam as measured with FIM motor score and time taken to perform some common ADL. We observed most of the improvements in lower extremity dressing, turning in bed, , bathing and transfer, mainly observed in patients where motor power was not completely lost and or spasticity hindered the motor power like; incomplete SCI, compressive or non compressive myelopathy etc, in a dose dependent manner. Though the separate analysis was not done but improvement in FIM motor score was mainly observed in patients who had lesion in dorso-lumbar region of spinal cord. Similar finding was also observed by Dario A<sup>22</sup>. He observed significant improvements in FIM scores in 20 patients with severe spinal spasticity after treatment with chronic intrathecal baclofen infusion. Improvements were mainly in bathing, dressing lower body, and transfer. In our study the mean FIM motor score improvement was less (3-3.5

score), this could be because of short duration of treatment or may be because of inadequate dose of drug. Similar result was also reported by P. Azouvi<sup>42</sup> in sever spastic SCI patients with intrathecal baclofen. We found similar improvement in FIM score, so results of our study showed that alprazolam might have similar effect in improvement of once ability to function with independence compared to intrathecal baclofen.

The current established safety and pharmacokinetics profile of alprazolam suggest that it might be well tolerated in patients with spasticity, who typically required treatment with multitude of drugs, there by placing them at risk for drug interaction and adverse events, including cognitive dysfunction. In this study we observed that alprazolam had effect on spasticity and spasm as well with fewer reported adverse events which were mild and well tolerated and did not require drug discontinuation, with the exception of one patient where drowsiness was marked and patient was excluded from study, as compare Cocchiarella et al<sup>23</sup>, observed while studying 19 spastic subjects, that many of the participants experienced fatigue and drowsiness, which resulted in 5 subjects dropping out of the study while taking diazepam and in another study of 12 spastic subjects, it was observed that ambulation speed was negatively affected<sup>24</sup> with diazepam treatment due to drowsiness and fatigue caused one subject to withdraw from the study. Alprazolam also showed improvement in one's ability to function with independence and many of the activity of daily living with minimum side effects at this dose. So this might be a useful drug in treatment of spasticity compared to other drug used for the treatment for spasticity. Alprazolam is also a cost effective drug compared to other drugs, used for treatment of spasticity. Rather than reducing spasticity it is also helpful in reducing anxiety and insomnia that are commonly associated with stroke and spinal cord injury patients.

## Conclusion

It can be inferred from our study that: Alprazolam was safe and effective drug for the treatment of spasm and spasticity of any origin and had milder and tolerable side effects when used up-to 1 mg of dose, for the treatment of spasticity. Performance of activities of daily living like dressing, transfer, hand activity, hygiene, bathing, turning in bed and one's ability to function with independence, improved favorably with .5 and 1 mg alprazolam. It is easily available and cheaper drug compared to other anti-spasticity drugs.

## Recommendations

In this study Alprazolam was given only for a period of 1 month, further studies are required to establish the long

term efficacy and safety profile and tolerance of alprazolam. In this study the number of patients was small, so before generalization of the results, further studies are required involving large number of patients. Further studies are required in the area regarding the effect of alprazolam on spasticity of specific underlying cause, because in this study we included all the cases of spasticity that satisfied our inclusion criteria's. Cost effective analysis of alprazolam was not done with other available antispastic medications, it could become the scope of future studies. Significant improvement in spasticity and spasms were observed mainly during night time and morning hours. As we measured spasticity during early morning hours, carryover effect of the drug in reducing muscle tone cannot be concluded from this study. To observe the carryover effect of the drug, further studies are required, regarding doses of drug, timing of drug administration, dosing schedule (single or divided doses).

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# Effect of Play and Exposure on Development of Children with Intellectual Disabilities through Community Based Rehabilitation

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## Abstract

This paper studies the effect of play and exposure on the development of children with intellectual disabilities through community Based Rehabilitation in the impoverished, tribal population of Madhya Pradesh state, India. In study, 23 children (male -13 & Female - 10) ranging from mild to profound disability, were selected from seven villages of Thikari block of Barwani district. Parents and community based rehabilitation workers (CBRWs) worked rigorously with these children for one year. Children were exposed to play and participation in household activities under the guidance of a professional therapist. The goal was to mainstream these children at play and in the home. Before starting intervention, both groups (CBRWs and parents) were provided training at Ashagram Trust Center. A Likert scale was applied pre and post intervention to record progress on the development of children. A standard test VSMS also administered on 10 randomly selected children to verify Likert scale progress. Obtained pre and post scores of Likert scale and VSMS test were analyzed in conclusion.

Keywords: Community Based Rehabilitation, Intellectual Disability, Mainstreaming, Play and Exposure.

## Introduction

People with intellectual disabilities (formally known as mental retardation or mentally challenged) are perceived as a challenge to mainstream by Government due to distended characteristics and manifold needs. Recent rehabilitation models available are being tried out at many levels by different agencies to address the maximal needs of such individuals<sup>1-3</sup>. The Institutional Based Rehabilitation (IBR) Model predominantly focuses on the medical and educational needs of such individuals. It's reach has extended no further than the urban communities. Usually IBR brings more quantitative than qualitative results. Other Community Based Rehabilitation (CBR) models are being applied<sup>4-6</sup>. Evaluation of a CBR in rural India) and are of great help in developing countries. Available research proves these are most suitable models to address the needs of children with intellectual disabilities in more humanitarian ways. CBR brings both quantitative and qualitative results. Application of CBR models is found to be cost effective and most acceptable by the communities. A CBR approach needs to be practiced more as more disabled people live in rural areas. In India, 21 million people suffer from some kind of disability. This is equivalent to 2.1% of the population. Among the total disabled in the country, 12.6 million are male and 9.3 million are female. The number of disabled is more concentrated in rural areas. As of the 2001 Census, rural occurrences totaled 76%, while urban disability rates are only 24%. In total males accounted for 59% while Females are at 41% (NSSO). In Madhya Pradesh we have 14,08,528 total disabled people. Out of this total, 115,257 are mentally disabled (Census 2001).

All children follow the same pattern of development whether they are disabled or not. Their growth and learning also occurs in same manner. Irrespective of impairment or disability, all children deserve and require the same kind of environmental stimulation for acquiring lifelong skills and abilities. In well-accepted theory the development in four major developmental areas i.e. motor; language, social and cognitive, progressed much better and healthier when children get adequate opportunities to explore and observe. Children with disabilities are victims of social attitudes. They are deprived from having equal access to developmental opportunities.

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Many children in especially poor rural areas do not get the freedom to enjoy a natural environment. Predetermined attitudes towards children with developmental impairments restrict their participation in family or community based occasions. They face many social obstacles due to a poor awareness level throughout rural communities. Misconceptions towards mentally disabled children are widespread in these communities. Such attitudes restrain them directly and indirectly from participating in various activities. Parents are not an exception to this behavior. They carry a double load in terms of managing presupposed attitudes and opinions that are formed due to a lack of understanding, not to say that these parents dislike their children. Parents want to give them the best platform on which to grow because parents expect best for them. But this does not always happen in the case of disabled children. Parents do not readily compensate for their slow cognitive development and learning abilities. Parent's decreased expectations affect their parenting style, which turns into a negative and discouraging environment for the children.

Since these children are developmentally delayed<sup>6</sup>, they are unable to acquire certain behaviors and skills at right age. They lag behind in communication, motor skill, and concept formation and socialization skills. Very often they pick up undesirable behaviors. Most commonly; thumb sucking, spitting, body rocking, crying, defiance, throwing objects, repeating words and stammering among others. Community members; including parents, misread these characteristics. They don't understand the reason promoting the behavior. This is typically viewed as a physical disease; thus, it is looked at from different angle. A number of people; including some parents, make false judgments about their disabled children. Sadly, some parents in rural communities fear that contact with disabled children will affect their non-disabled children, making them disabled by proximity. Initially parents seek help from medical professionals, who try everything possible to diagnose them. When these attempts don't yield any improvement in their condition they loose hope and patience. As time passes, parents feel helpless and frustrated. This frustration leads improper and disparate parenting. Children not involved in mainstream interaction are often ignored or overprotected. An unhealthy parenting style creates more barriers for disabled children. They are segregated and restricted from sharing a uniform atmosphere available for healthy children within families as well as in the overall community. As a result disabled children lose natural opportunities to grow and learn.

Play activities are essential to healthy development<sup>7</sup> for children and adolescents. "Play is the work of the child" (Maria Montessori). Research shows that 75% of brain development occurs after birth. The activities engaged in by children both stimulate and influence the patterns

of connections made between the nerve cells. This process influences the development of fine and gross motor skills, language, socialization, personal awareness, emotional well-being, creativity, problem solving and learning ability. The most important role that play can have is to help children to be active, make choices and practice actions to mastery. They should have experience with a wide variety of content because each is important for the development of a complex and integrated brain. Play links sensory-motor, cognitive, and socio-emotional experiences, and provides an ideal setting for natural brain development.

Children learn by observing and participating in activities. Children without disability are usually encouraged to engage in household courses while kids with impairments are discouraged from everything. Due to sub average intellectual capacity, slow reaction and performance these children are unable to follow the pace of non-disabled children. They are very capable of learning many things at their speed if the instructions are provided in a graded manner. Communities at large do not understand this fact so they give little importance to these children. Comparisons between non-disabled and disabled happen all the time. That leads to emotion-based reactions in parents. Most parents end up making uninformed opinions about them. Most often they feel that these children can't learn or perform tasks correctly<sup>7-10</sup>. Resulting in the sidelining of these children from normal course. Parental focus shifts from disabled to non-disabled children. Non-disabled children receive more attention and disabled children; in turn, become isolated. Bonding between disabled children and parents grows weaker.

#### Objectives

- 1 To assess effect of play and exposure on children with Intellectual disabilities in parental views.
- 2 To assess impact of community-based rehabilitation in children with intellectual disabilities in rural poor tribal area.

#### Methods

**Design and settings:** This study was done in year 2005-2006 under a collaborative project "Empowerment of persons with disabilities through capacity building initiatives" (June 2005 to Dec 2007). This project was implemented by two organizations Ashagram Trust, Barwani (MP) and Concerned Action Now, Delhi (CAN) in 36 villages of Thikari block. Department of International Development (DFID) funded this project. DFID is a department comes under UK Ministry. Usually DIFD do not work or support to grassroots organization directly. Organization support and work through government system. But this was under it's a unique scheme Poorest Area Civil Society (PACS) through a New Delhi based

organization called "Development Alternatives" (DA). Researcher was the employee (May 1999 to July 2007) of Ashagram Trust who played crucial role in planning and implementing this project. More important study was not the part of project plan. The idea of such study came in researcher mind first. Then the other important persons at Ashagram Trust also supported it. Researcher was also a Project Director of this project.

All selected children were called in medical camps where researchers and highly trained therapists for mental retardation carried out diagnostic procedures with them. Therapist visited the rest of the children who could not be brought in to the camp by parents for diagnostic purpose. Diagnoses were made using three major diagnostic tests used in Mental Retardation. These are Gassels Developmental Drawing Test (GDT), Developmental Screening Test (DST) and Vineland Social Maturity Scale (VSMS). Their medical history and functional ability were also assessed (NIMH, Secuendrabad model). Orthopedic surgeon, ENT specialist and a Physician also examined these children for any other disability or medical condition.

Once diagnostic exercise was completed for all children therapist conducted home visits to every child in the selected group. Local CBRWs were also taken along. Therapist then carried out a detailed needs assessment. Usually it took on an average two and half hours with per client. Therapists then shared details of the progress of individual projects with parents. How does this empower and build capacity for people with disabilities? Specific steps and intervention envisaged for selected groups were shared elaborately. Attempts were made to address the whole family at a time but in 36% of instances only mothers and grandparents were available. Most of them have not shown enthusiasm to participate in the program but also none of them refused to participate. This whole exercise of need assessment was done in 11 visits by therapist over the period of one month.

Alongside parents, CBRWs received residential training at the Ashagram Trust Institute. This training was done in 5 rounds. Each round took three days, 15 days in total. Training had two basic components. First, a therapeutic component in which they learned different theories, concepts and skills applicable to children with intellectual disabilities and secondly, social components are learned including how to conduct meetings in the village, communicate with parents, school teachers and other stakeholders and also about to create awareness in the community. People and children at all levels are encouraged to create conducive atmosphere for such children to participate that includes important mainstreaming. After each round of theoretical training all trainees were sent on field. They were assigned

agendas to practice under the supervision of experienced supervisors of other CBR project areas. Later on; additional and specific to research, input was provided to select CBRWs who participated in study.

CBRWs contacted each parents and administered the questionnaire using the Likert rating scale. They were asked to rate their responses on 0 to 10 point scale on questions mentioned below. All questions were asked in their local languages (Nimari and Bhilali). The questionnaire comprised the following questions addressing all four major areas of development. (1.) How much you allow your child to participate in house hold activities? (2.) How much you communicate with your child daily? (3.) How much you socialize/ play with your child daily? (4.) How much you think your child shows appropriate behaviors? (5.) How much are you happy with the natural development/ progress occurring in your child. (6.) How much are you worried with his/her future?

**Intervention in Family and Community:** CBRWs were asked to make compulsory visits to each house at least once per week or more if possible. During visits they played with kids. Took them out and encouraged them to play with other children of the community. They also talked very frequently to other children to allow and involve disabled children in their play. Some disability sensitivity activities were done in the village and school level. Parents made it a point that all their children should play together involving their disabled siblings. Most of the families work in agriculture or as a manual laborer where they started taking their kids along in order to provide comprehensive life skill exposure. Grandmothers played a great role by involving these children in all household activities such as cleaning, sweeping, arranging beds, peeling, cutting vegetables, washing dishes, washing cloths, bringing water from hand pump, feeding livestock etc. Parents started taking subject children to the markets. These changes in the parent's behavior have created a very positive and conducive atmosphere in which children can grow and progress.

In initial months of study, parents were brought into the project for implementing organization and exposure. During these visits they were given some form of orientation on mental disability. They were also shown some useful videos demonstrating positive changes in children with mental disability through encouraging play and involvement in family and community activities. This exercise was aimed to educate and motivate parents, mostly. In project agenda it was also ensured that each child should be entitled to a disability certificate and a social security pension. Admitting children to Aaganwadis and primary schools did educational mainstreaming. After completion of one full year of intervention in study, another group of CBRWs was sent to each family to record



parental responses on a similar Likert scale questionnaire. This was done in order to minimize error and rule out subjectivity, which might have come if the same CBRWs were asked to administer it. In broader terms, overall attempts had been made to mainstream these children through exposure to play and by promoting active participation in all household activities following CBR principles.

**Sample:** The Community-based Rehabilitation project “Empowerment of persons with disabilities through capacity building initiatives” implemented in 36 villages (populations 41,629, census-2001). There were total 107 children with intellectual disabilities identified in preliminary survey done by CBRWs. Entire project area was divided into 11 smaller clusters comprising 3-4 villages in each. Out of these 11 clusters two clusters were selected randomly by picking up their names for this research. These two clusters had seven villages (Semalda Dev, Mehgoon Dev, Ranswa, Junapani, Uchawad, Bhmauri & Rangoon Dev) with 9,638 populations. Caste wise distribution is SC – 12.71 %, ST – 40.73% & other – 46.56 (census 2001). There were total 31 children with intellectual disabilities in selected sample. Out of them - 8 (25.80%) children those had borderline mental disabilities were excluded strategically from research because they were already seen in mainstream. And we found it unethical to bring their disability in notice. Rest all 23 (M - 13 & F- 10) had mild to profound disability was taken for study. These children’s age range is 0-5 years – 08 (34. 78 %), 05- 11 years - 09 (39.13 %) & years 10 onwards – 06 (26.08%) and diagnosis Mild – 07 (22.58 %), moderate – 11 (35.48%), Severe – 04 (12.90%) and profound - 01 (03.22%). It can be said that all selected children were known as disabled by community.

**Measures:** Parents together with CBRWs are given orientation and inputs to understand different plays those are crucial role players in development of children. These are **Motor Play**, which provides critical opportunities to develop both individual gross motor and fine muscles and strengthen overall integration of brain function. **Social Play** by which children learn social rules such as give and take, reciprocity, cooperation and sharing, **Constructive Play** that allow children to manipulate their environment to create things and to find out combination that work and don’t work. **Fantasy Play** in which children learn to abstract, to try out new roles and possible situations, and experiment with language and emotions and also through this they develop flexible thinking, stretch the imagination. And Games with rule to grow from an egocentric view of the word to an understanding of the importance of social contracts and rules. **Solitary Play**, that means playing alone by him / her only. **Parallel Play**

children play alongside with other kids without much interaction with each other. **Group Play** when children play in group by which learn social skills such as sharing and turn taking. **Task Analysis** that is most effective technique in training children with mental disability was exposed to whole group so that they can break down steps of all play & house hold activities in which child encouraged to participate. Training also covered various parenting styles such as **Authoritative, Permissive, and Rejecting/ neglecting** and **Democratic**. Focus was given to be **democratic** in parenting and rearing the children.

## Results

Obtained finding on likert scale of all areas are mentioned below in table.

Items	Pre/Post	Mean	SD +	t-value	p-value
Participation	Pre	2.00	1.65	9.64	0.05
	Post	6.91	1.80		
Communication	Pre	2.04	1.42	6.11	0.05
	Post	5.43	2.25		
Socialization	Pre	2.56	1.64	5.03	0.05
	Post	5.43	2.19		
Appropriate Behaviour	Pre	2.26	1.32	5.25	0.05
	Post	5.08	2.21		
Natural Progress	Pre	1.43	1.03	5.53	0.05
	Post	4.17	2.14		
Worry Level	Pre	6.56	1.97	7.30	0.05
	Post	2.79	1.97		

Table 1: Scores on Likert-rating Scale (n= 23, males-13 & females-10). P < 0.05, DF- 44, t-value on one tail- 1.68, two tail – 2.01 & P < 0.005, DF- 44, t-value on one tail – 2.69 & two tail- 2.95, mean difference highly significant.

Verification of Results on Standard Test: In order to validate parent’s responses and verify whether the children really made progress the “Vineland Social Maturity Scale” (VSMS) was administered again on 10 randomly picked up children from the group. Score shows that there is a good progress on children’s development. Actually it was not planned earlier to use this test at the end of this study. Implementing organization was in plan to administer this test on few children of entire project area (36 villages) at the end of project (June 2005 to Dec.2007) to get the some idea of project outcomes.

VSMS has developed by US psychologist Edgar Arnold in 1936. In India its Indian version is being used for the making part diagnosis and measuring functioning level of different areas of persons with mental retardation. This measures eight category of behavior, self help general, self-help eating, self-help dressing, locomotion, occupation, communication, self-direction and socialization. It is also used very effectively in planning

for therapeutic intervention or Individualized instruction for persons with mental retardation. VSMS can be used from birth up to the age of 30 years. It consists of 117-item interview with a parent or other primary caregiver.

Test	Pre/Post	Mean	SD +	t-value	p-value
VSMS	Pre	42.1	11.25	2.13	0.05
	Post	52.2	9.90		

Table 2: VSMS pre & post scores (n= 10, females- 6 & males -4). P < 0.05, DF- 18, t-value on one tail- 1.73, two tails – 2.10. Mean difference is highly significant.

Referring table 1, obtained score on pre and post assessment on likert-rating scale analyzed to see significance of true mean difference by calculating t-value on P<0.05. Participation of children in all activities (Pre-Mean-2.00, SD-1.65, Post- Mean-6.91, SD-1.80) t-value is 9.64 on p<0.05 & p<0.005 (t-value 1.68) indicates that mean difference is very significant. Communication of children improved quantitative and qualitatively, has (pre-Mean-2.04, SD- 1.42, Post- Mean- 5.43, SD-2.25) has t-value 6.11 on both p<0.05 & higher shows mean difference is significant. Similarly Socialization aspects of all these children found better in all settings (pre – Mean – 2.56, SD-1.64, post- mean- 5.43, SD- 2.19) t-value is 5.03 on p<0.05 have high significant mean difference. Parents found that their children have acquired desired behaviors and showing Appropriate behavior in their settings (pre- mean 2.26, SD-1.32, post- mean- 5.08, SD- 2.21) t-value is 5.25 indicates that mean difference is highly significant on p<0.05 & p<0.005. Natural Progress considered overall development of children in parental views which has improved a lot since statistics also (pre-mean-1.43, SD-1.03, post- mean-4.17, SD-2.14) t-value is 5.53 on p<0.05, p<0.005 indicates very high significance of mean difference. Parents Worry level with children' future was very high in the beginning, which came down significantly by this whole exercise. They developed realistic picture and some hopes. On (Pre-mean 6.56, SD-1.97, post- mean- 2.79, SD- 1.97) t-value is 7.30 on p<0.05 & p<0.005 indicates that mean difference is significant. Thus statistics shows high level of improvement in all areas. Analysis on VSMS a standard psychological test the statistical scores (table-2) is (pre- mean 42.1, SD-11.25, post –mean 52.2, SD-09.90) t-value 2.13 on p<0.05 indicates that results are true.

## Discussion

Analysis of result findings on likert scale strengthens the hypothesis that by providing adequate natural play opportunity and systematic inclusion in daily routine brings a great positive change in children with intellectual

disabilities. It also indicates that provided intervention improved child-parent, child-peer, child-community & parent-community relationship. It also increased awareness as well as build up hope and sense of pride among parents for their kids. Same time carried out intervention reduced inappropriate practices. More important dying hopes rejuvenated towards hope and success. Other than statistical findings, research team observed great integration and mainstreaming of these children in their communities by end this study. The outcomes of this study are very positive which proves that children exposed to natural play, household tasks and brought up in democratic parenting styles develop significantly. Post VSMS findings also indicate that there was significant development occurred in all children. Intervention also helped in reducing disability percentage in children and prevented them from acquiring secondary handicaps.

## Limitations

In this kind of intervention community also play very significant role but here perceptions of community have not been assessed at any level from beginning to the end of this study. It would have been better to do this exercise in order to see its impact on other beneficiaries of this program such as community at large.

## Conclusion

Obtained results strengthen the arguments that play and exposure provided under community-based rehabilitation model helps children with intellectual disabilities to enhance their development and reduce parental worries significantly. This study is supporting CBR, as a suitable approach of rehabilitation for persons with intellectual disabilities living in poor rural areas.

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# Cognitive Rehabilitation in Stroke Cases

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## Abstract

In the conducted study, we observed the effect of cognitive rehabilitation in the stroke patients. Stroke patients irrespective of gender, attending physical medicine and rehabilitation OPD and stroke clinic were included in study. Cognitive ability was assessed clinically using relevant assessment scales (MMSE, ACER,) and various tasks. Assessment of patients was done at three monthly intervals (0, 3, 6, 9 months) the results were compared with control group and analysed by appropriate statistical methods.

There was a significant improvement, in cognitive status after 9 month from the from the base line value (paired t test) in both cases and controls. However, statistical analysis failed to show any significant intergroup difference.

Key Words: Cognitive Rehabilitation, Stroke.

## Introduction

With the understanding of neuropsychology and restorative neurology, cognitive rehabilitation has become an integral component of stroke management. Cognitive impairment is a major sequela of stroke, with significant cognitive deficits found in 35% of stroke patients<sup>1, 2</sup> a

3.7-point drop in Mini-Mental State Examination (MMSE) scores<sup>3</sup>. Patients with stroke who have cognitive impairment in addition to physical impairments have less recovery of physical function and more dependence in living after stroke<sup>2,4,5</sup>. These associations are evident despite variation in the instruments used to measure cognition and when the cognitive impairment is not severe enough to meet the criteria for dementia<sup>6</sup>. Although functional recovery can be affected by cognition-related factors such as preexisting dementia and depression. It may be that cognitive impairment also affects outcome through its interaction with the rehabilitation process. Numerous studies have noted a relation between rehabilitation success and degree of cognitive impairment, leading researchers to call for cognitive assessments an integral part of rehabilitation. How cognition interacts with the rehabilitation process is controversial & is largely backed by empirical evidence<sup>7</sup>. Patient characteristics, provider perceptions, practice guidelines & available treatments may all play a role in shaping the impact of cognitive impairment on stroke rehabilitation outcomes. For instance, a cognitive impaired patient may not be provided the same level of rehabilitation because of his her impairment (e.g., the patient is perceived as a poor candidate). Alternatively, rehabilitation program may not be designed to respond effectively to cognitive impairment in patients accepted for treatment<sup>8</sup>. For example, a program may fail to assess such patients for conditions like depression that are commonly associated with cognitive impairment<sup>9</sup>. In addition, cognitive impaired patents may not be able to benefit fully from rehabilitation because of their impairment<sup>10</sup>. Research suggests that this may occur in patients with a sensory deficit (contralateral neglect), attention deficits or impaired comprehension & learning. The purpose of cognitive retraining is the reduction of cognitive problems associated with brain injury, other disabilities or disorders.

The overall purpose of the therapy is to decrease the everyday problems faced by individuals with cognitive difficulties, thereby improving the quality of their lives<sup>11</sup>. Cognitive retraining includes a considerable amount of repetitive practice that targets the skills of interest. In fact, repetitions are essential for the newly retrained skills to become automatic<sup>12</sup>. Regular feedback is another important element of cognitive retraining. Retraining usually begins with simpler skills and proceeds to skills that more complicated. The therapist may address cognitive skills while the person is practicing real-life task,

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in an effort to improve their performance of these tasks. In fact, practicing skills in the ways and setting they will be used in real life is critical to the success of retraining efforts. The length of time for cognitive training varies according to the type and extent of the injury and the type of retraining skills used. For example, retraining memory may take months or years. In comparison, it may take only a few days or weeks to retrain someone to organize his or her home or workplace. The use of computers for cognitive retraining has become an increasingly common practice. In the study, the effect of cognitive rehabilitation in stroke patients was analysed<sup>13,14,15</sup>.

## Materials and Methods

Stroke patients of both genders admitted in IPGMR and SSKM hospital and attending Physical Medicine and Rehabilitation OPD and stroke clinic were included in study. Cognitive ability of patients assessed clinically using relevant assessment scales (MMSE, ACER) and various tasks (Blockdesign, Stick Construction). The study was conducted in the Department of Physical Medicine and Rehabilitation and Stroke Clinic at IPGMR, SSKM Hospital, Kolkata, during May 2006 to September 2007.

**Inclusion criteria** were patient admitted with stroke, out of coma, medically stable, out of crisis, requirement for a skilled level of care and not on maintenance level care, treatment program is supervised by a physician, requiring active nursing care such as administration of medications the services are reasonable and medically necessary and are within accepted standards of good medical practice.

**Exclusion criteria** were stroke cases aged less than 14 yrs of age, pregnancy, uncontrolled hypertension, uncontrolled blood glucose, associated co morbid condition e.g. cancer, AIDS etc.

Total number of patients were 107 (n=107), with 11 drop outs at various stages. Divided into cases (n=51), Group I and controls selected randomly (n=45) group II. Group I was experimental group, while group II was taken as control. Cognitive rehabilitation was given to group I (experimental group) only. Duration of study was 9 months. Numbers of visits: four (0 initial visits 2<sup>nd</sup> after 3 mth, 3<sup>rd</sup> visit after 6mth, 4<sup>th</sup> visit after 9mth).

Informed consent was obtained and the study was carried out in accordance with the Institutional Ethics Committee.

**Intervention:** Only non-pharmacologic interventions were utilized in accordance to patient's cognitive impairment in the form of cognitive retraining. Informed consent was obtained from all the individuals and study was carried out in accordance with the Institutional Ethics Committee guidelines.

Types of cognitive retraining: used were: attention and concentration retraining, memory retraining, organizational

skill retraining, reasoning, problem solving, decision making, executive skill.

**Parameters for assessment:** (alertness/level of consciousness) Alert, or somnolence, obtundation, stupor or semicoma, coma, attention, memory, thinking, perception, psychomotor behaviour higher cognitive functions, insight, judgment.

### Characteristics of the Environment for Assessment

**Physical Environment:** Comfortable ambient temperature, adequate lighting, Free of distraction Position self to maximize individual's sensory abilities.

**Interpersonal Environment:** Pre assessment was done with friendly conversation to establish patient-professional relationship and use of self-paced rate for assessment.

**Timing Considerations:** The timing of the assessment selected was to reflect the actual cognitive abilities of individual and not extraneous factors. Assessment was divided to avoid fatigue and subsequent over exaggeration of deficits. Times of the day generally avoided were: Immediately after or before sleep, meals, and medical diagnostic or therapeutic procedures. The pain or discomfort were avoided.

**Preparation:** Cognitive retraining usually took place in a quiet environment without distractions. The individual was felt relaxed and calm while being retrained in cognitive skills. The cognitive retraining was avoided during emotional distress. The person's level of cognitive skills and extent were evaluated before retraining begins. This to monitor improvement by comparing the patient's skill levels during and after retraining to his or her skill levels before retraining. Patients were given cognitive retraining for 21 hours on an average (twice a week for 3 months). On each day they had a session of one hour (for 20 minutes each of block design training, stick construction and visual cancellation). Letter cancellation could not be done in uneducated patients.

**Block Design:** Blocks of different colours, sizes and shapes were used. The training used to begin with blocks of single colour, to different colours and then to various sizes and shapes. The test consisted of two block models that were presented one at a time. The patient was asked to construct an exact replica, selecting blocks from an assortment of 18 blocks. The time taken to complete each model was recorded in seconds, with a maximum of 5 minutes allowed. The score was obtained by crediting one point for each correctly placed block. If time taken to construct the two models was greater than the stipulated time, two points were subtracted from the score.

**Stick Construction:** Wooden sticks (1/2"x1/2"x3") were used to construct various designs from a given figure of stick construction (14 designs). The designs were assembled before the patient, who was then allowed to view each one for 10 seconds. The design was then swept away

and the patient was asked to reproduce it. One point for each correct item was given.

**Visual Cancellation:** The patient was asked to search the letter 'A' through a large number of letters and was asked to strike out the same. When he could not search any number he was cued by pointing out to them. If the patient neglected letters of one side, he was asked to scan the whole visual field.

For assessment of immediate memory, digit repetition test was used. For short term and long-term memory the patient was asked to remember four words (e.g., Rose, Apple, Chair, Salt) & then test his immediate recall and recall after 5 minutes and 30 minutes. If he was unable to recall any one, he was given cues figures. It was the name of flower; it was something we sit on). To improve attention the training was given in a quiet environment. The patient was verbally called to the task or if needed, his hand was moved to start the activity. To improve memory, initially the block or stick design were to be made with models kept in front. Later on, they were asked to reproduce them from memory. The patient was asked to rehearse any information he needed to remember. His attendants or family members were asked to give him visual or verbal cues to recall the names of things or persons (e.g., by using, photographs or by telling them the first letter of the word). As there were a very small number of educated patients, diaries or notebooks could not be used by of them. Notebooks were used only by 7 patients. In three cases, at the patient's home, we used a form of structured environment by labeling drawers and small boxes of daily utility items. 17 patients used alarm clocks to remember the time of taking medicines and other purposes.

The above mentioned training methods of Block Design and Stick construction, basically being a method of evaluation and treatment of Apraxic disorders were used as tools to improve memory, orientation, attention and concentration. Visual letter cancellation, basically being a method of testing visual neglect was also used to improve attention and concentration. For prosopagnosia pictures of popular movie stars and relatives (where possible), were shown and patients were asked to name them. These were done with each patient for 12 weeks and the patient evaluated at the end. Again each patient was evaluated at the end of 6 months and 9 months. (All the percentage values given in the study have been brought down to the nearest round figures). Aftercare we tried to promote the transfer of skills learned using cognitive retraining techniques to the patient's everyday life settings and demands. Training may be continued until the patient's skills are improved, transferred to, and maintained in real world activities. Cognitive retraining may be considered successful if performance on a behavior related to a particular cognitive skill has improved. It is important for

the patient his friends or family members not to assume that improvement on training exercises and tests automatically lead to transfer of the skills to real-life settings. It is ultimately successful if it helps the injured person improve his or her functioning and meet his or her needs in real-life situations and settings.

## Results and Discussion

**Demographics Age/Sex distribution:** The age of the patients ranged from 29 to 76 years (range 65 years). Mean age of the patients was 51 years (Range 29-78 yrs). No. of males in Group I was 23 (45.10%) while females was 28 (54.90%). In Group II number of males was 26 (57.78%) while females was 19 (42.22%). 62.75% Group I cases were from urban area and 37.25% from rural area, which may be due to easy accessibility for urban population. 51.11% Group II cases were from urban area and 48.89% from rural area.

**Socioeconomic status:** 49.02% of Group I cases belonged to low socioeconomic group and 37.25% were lower medium group 3.92% to medium group 5.88% to upper medium group 3.92% to upper lower group. None of the patients belongs to Upper group. 42.22% Group II cases belonged to the low socioeconomic group and 20.00% were lower medium group 2.22% to medium group 4.44% to upper medium group 28.89% to upper lower group and 2.22% of the patients belongs to Upper group.

**Educational status:** In Group I cases 19.61% received education up to higher secondary level, 45.10% up to primary school, and 13.73% were graduate and 19.61% uneducated. The educational status of Group II cases was 11.11% received education up to higher secondary level, 46.67% up to primary school, 2.22% were graduate, and 33.33% were uneducated, 2.22% were post graduate 4.44% attended secondary school. This difference was non-significant by Chi-square test (2-tailed  $p = 0.091$ ) Handedness was Predominantly Right handed. Stroke Type was Predominantly Ischemic type. Associated medical condition: High Blood Pressure was observed to be more common than Diabetes Mellitus. This difference was non-significant by Fisher's exact test (2-tailed  $p = 0.382$ ). In case of group I the mean value for MMSE score at first visit was found to be 23.725 and 26.411 at four visit (SD- 1.57 and 1.85 respectively), the mean value for ACER at first visit was 83.86 and at 9 month 88.43 (std.deviation - 2.34 and 3.82 respectively), for block design mean at initial value for ACER at first was 83.86 and at 9 month 88.43 (std. deviation- 2.34 and 3.82 respectively), for block design mean at initial visit and final visit was 14.00 and 18.00 respectively (std.deviation- 1.85 and 1.89 respectively) and for stick construction mean at initial visit and final visit was 12.00 and 14.00 respectively (std. deviation -1.39 and 1.51 respectively). In case of group II the mean value for MMSE score at

first visit was found to be 23.622 and 26.2888 at fourth visit (std.deviation – 1.52 and 1.74 respectively), the mean value for ACER at first visit was 84.244 and at 9 month 90.022 (std.deviation – 2.49 and 3.49 respectively), for block design mean at initial visit and final visit was 13.55 and 17.20 respectively (std. deviation – 1.17) and for stick construction mean at initial visit and final visit was 13.55 and 17.20 respectively (std.deviation – 1.17 and 1.35 respectively) and for stick construction mean at initial visit and final visit was 11.60 and 13.20 respectively (std.deviation – 1.07 and 1.14 respectively).

When comparison of numerical variable was done by unpaired t test the p value (0.037), t-value; - 2.11 was found in case of ACER at 9 at month score, (with mean for Group I = 88.43 and for Group II = 90.02). When comparison of numerical variable done by done by unpaired by unpaired t test the p value (0.037), t-value of -2.11 was found in case of ACER at 9 month score, (with mean for Group I = 88.43 and for Group II = 90.02).

For gender distribution (2-tailed p = 0.228) and urban and rural (2-tailed p=0.303) by Fisher's exact test in educational status (2-tailed p = 0.091) by Chi-square test were insignificant.

When comparison within Group I - baseline versus 9 month value – by paired t test was done the p-value (0.0000) was found, for MMSE Score (at t-value- 15.66), ACER Score (at t- value-11.85) block design (at t-value-13.42) and stick construction (at t-value-11.35) was found significant.

When comparison within Group II – baseline versus 9 month value – by paired t test was done the p-value (0.0000) was found, for MMSE Score (at t-value- 14.39), ACER Score (at t- value-11.99) block design (at t-value-18.32) and stick construction (at t-value-10.63) was significant. There was no significant difference in improvement of cognitive status in experimental group against control groups.

Due to poverty, illiteracy and resource constrains It is very difficult to convince that stroke has its associated cognitive problem& such impairment can be improved to improve their quality of life in day to day activity. This was evident by some of the patients who did not turn up after initial evaluation & cognitive retraining. In many other cases, the patients were brought only after some persuasion of the family. Most of cases were in the age group of 36 to 53 years. The cognitive impairment was observed in most of the patients irrespective of type of stroke. The cognitive improvement was observed on all parameter of assessment more or less in both the experimental as well as control group during the course of study similar to other studies.

## Conclusion

In this case control study consisting of a sample of 106

stroke cases we found statistically significant improvement in over all cognitive status in both cases and controls. There was statistically significant positive co-relation with socio economic status which was noted irrespective of intervention.

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# Effect of Task-specific Training on Gait Parameters in Hemiparetic Stroke Patients

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## Abstract

Functional mobility is viewed as essential to enabling an individual to engage in full range of life areas and is central to enabling the individual to participate in live situations. The walking after stroke is characterized by slow gait speed, poor endurance and in the quality and adaptability of walking patterns. The instantaneous adaptation to speed and load changes during over ground locomotion has major implication for mobility after stroke. Task specific training is a therapeutic approach based on System theory given by Bernstein in 1967 to retrain the patients with movement disorders.

It is a one group pre test post test quasi experiment design with the objective of to find out the effectiveness of task specific training on gait parameters in right hemiparetic patients.

10 right hemiparetic patients (n=10) of either sex in the age group of 40-65 yrs (mean age 54.44 yrs) were selected by convenient sampling method and were assigned in one group. Different tasks in a prefixed pattern aiming at functional activities were introduced over a period of 40 min duration per day/session, 3 days a week and for total duration of 4 weeks. i.e. total 12 sessions.

Main outcome measures: Changes were measured in terms of Cadence, Step length, Stride length and Gait Velocity.

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Significant statistical improvement was measured in terms of cadence (P= 0.038) step length and gait velocity (P= 0.033) whereas there is no significant statistical improvement in Step length (P= 0.140) and Stride length (P= 0.162).

Key Words: Hemiparetics, Gait Parameters, Task related Training, Cadence

## Introduction

Stroke is rapidly developing clinical symptoms and / or signs of focal, and at times global (applied to patients in deep coma and to those with subarachnoid hemorrhage) loss of cerebral functions, with symptoms lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin<sup>1</sup>.

Ischemic stroke is the most common form of stroke, which accounts for 61% to 81% of all strokes. Hemorrhagic strokes account for 12% to 24% of strokes. Middle cerebral artery is the largest branch of cerebral artery which is most commonly affected in stroke. Clinical syndromes from middle cerebral artery infarction of either hemisphere results in contra lateral spastic hemiparesis and sensory loss of face, upper extremity and lower extremity, with face and upper extremity more involved than lower extremity<sup>2</sup>.

The primary clinical manifestations following stroke are somatosensory deficits, motor deficits such as (alteration in muscle tone, abnormal synergy patterns, motor programming deficits and disturbances of postural control and balance), visual deficits, behavioral and intellectual deficits, perceptual dysfunction, cognitive dysfunction bowel and bladder dysfunction, impaired balance and coordination which all result in the impairment of locomotion and functional mobility<sup>2</sup>.

The walking after stroke is characterized by slow gait speed, poor endurance and in the quality and adaptability of walking patterns. The instantaneous adaptation to speed and load changes during over ground locomotion have major implication for mobility after stroke<sup>3</sup>.

In persons with hemiparesis, postural tone and co-ordinate reciprocal movements which are required for normal gait are usually impaired. Normal reciprocal movement is often replaced by a fixed pelvic retraction which makes it difficult for the patient to swing the affected lower



extremity forward. This result in a short step length and asymmetric steps often called 'Hemiplegic gait'. This slow gait can be observed in clinical setting as a decrease in gait speed and cadence<sup>4</sup>.

Task specific training is a therapeutic approach to retrain the patients with movement disorders, based on system theory of motor control. This approach utilizes a training program that focuses on specific functional tasks to engage the Neuromuscular and Musculoskeletal systems. Patients are instructed to practice those tasks that present difficulties for them and to practice them<sup>2</sup>.

Berstein, 1967 who gave the system theory recognized that it is impossible to understand the neural control of movement without understanding the characteristics of system that is moving and external and internal forces acting on the body and looked at the whole body as a mechanical system with mass, external forces such as gravity, and internal forces such as joint stiffness and inertia etc. He also suggested that control of integrated movement was probably distributed throughout many interacting systems working co-operatively to achieve movement<sup>5</sup>.

## Materials and Methods

**Study Design:** It is a quasi experimental design where the pre test values are compared with post test values within one group after treatment.

**Study Setting:** Tagore Hospital and Research Center, Jalandhar.

**Population And Sampling:** 10 Patients with right hemiparesis from Tagore hospital, Jalandhar were chosen as population for the study and were assigned in a single group.

### Inclusion Criteria:

Ischemic stroke involving Left Middle Cerebral Artery Territory.

Right Hemiparesis with symptoms less than 6 months in the age group of 45-60 years.

Able to walk 10 meters independently with or without an assistive device.

Intact sensations.

### Exclusion Criteria:

Stroke involving other arterial territories.

Hemorrhagic stroke.

Sensory impairments involving lower limbs.

Severe orthopedic or rheumatologic conditions interfering with gait.

Cognitive disorders.

During pre test, each subject was evaluated for Cadence, Step length, Stride length and Gait velocity. They received

Task-Specific training program as per protocol after obtaining informed consent from the patients.

Task-Specific program consisted of 8 activities. These activities were primarily intended to improve gait performance. 10 patients received task-specific program. The training session was of 40 min duration per day/session (3 days a week) and total duration is 4 weeks (Total 12 sessions).

The post test scores were measured again after completion of 12th session for above selected gait parameters and results were compared for pre test and post test values to identify the amount of changes in the parameters selected.

The specified protocol was administered that included,

- Sitting at a table and reaching in different direction for objects located beyond arm's length.
- Stepping forwards, backward and sideways onto blocks of various heights.
- Sit to stand from various stool heights Heel lift and standing (Figure 1)
- Standing with base of support constrained with feet in parallel and random condition reaching for objects including down to the floor
- Reciprocal leg flexion and extension.
- Standing up from a chair.
- Walking a short distance and returning to a chair.
- Walking over slopes.

Material used: 3 Minute walk test, Stop watch, Finger paint, Paper roll, Calculator, Measuring Tape.

Cadence, Step length, Stride length and Gait velocity were used to measure the gait performance during pre test and post tests. Cadence measured the number of steps per minute. Step length measured linear distance from



Figure 1: Sitting to standing transition position

the point of heel strike of one extremity to the point of heel strike of opposite extremity.

Stride length measured the distance from the point of heel strike of one extremity to the point of heel strike of same extremity and Gait velocity measured the rate of linear forward motion of the body which can be measured in meters per minute.

### Results and Discussion

The aim of the study was to investigate the effect of task-specific training program on gait parameters in patients with right hemiparesis.

10 patients (6 Males and 4 Females) participated in this study with mean age of 54.44 years (SD = 5.69). Paired 't' test was performed between pre test and post test values to analyze the significance of task-specific training program. Table value at degree of freedom 9 and at 0.05 significance level is 2.262.

For Cadence, the mean value before treatment was 59.90 steps/minute whereas the value at post interval, it was 61.60 steps/minutes. Calculated 'T' value (2.429) was greater than Table value and "p" value (0.036) was also too low. This indicates that there is a significant improvement in gait performance (Table 1).

	Cadence (Steps/minute)		Step Length (Meters)	
	Pre Value	Post Value	Pre Value	Post Value
Mean	59.90	61.60	0.26	0.25
SD	4.45	4.81	0.03	0.03
T value	-2.42		1.620	
P value	0.038		0.140	

Table 1: Cadence and Step length, pre and post interval.

	Stride Length (Meters)		Gait Velocity (meters/sec)	
	Pre Value	Post Value	Pre Value	Post Value
Mean	0.52	0.51	20.57	20.85
SD	0.06	0.07	1.21	1.16
T value	1.52		-2.50	
P value	0.162		0.033	

Table 2: Stride Length & Velocity, pre and post interval.

For Step Length, calculated value (1.620) was less than table value and 'P' value is also too high. This indicates that there is no statistical significant improvement in Step length.

For Stride Length, calculated value (1.522) was less than table value 'P' value is also too high. This indicates that there is no significant improvement in gait performance (Table 2).

For Gait Velocity calculated value (2.509) was greater than table value. This indicates that there is significant improvement in gait performance.

Slow walking after stroke may be a behavioral adaptation to poor endurance, poor balance and decreased stability. Improvement in cadence and gait velocity is attributed to more appropriate timing of lower limb muscles, improved balance and coordination as a result of improved ability to use the affected leg for support, increased load taken through the affected foot; coordinated muscle activity is stimulated more. Yang YR et al<sup>6</sup> examined the effectiveness of additional backward walking on gait outcomes including walking speed, cadence, gait cycle and symmetry in 25 stroke subjects and observed significant improvement in selected gait parameters. The results of this study also support improvement in cadence and gait velocity. Salbach NM<sup>7</sup> et al evaluated the efficacy of task-oriented intervention comprising of 10 activities in enhancing walking ability and found significant improvements.

As the cadence increases, gait velocity will also increase and this will result in shorter step length. With improved cadence and gait velocity, the duration of double support decreases, person walks fast resulting in shorter step length<sup>8</sup>.

Appropriate timing of lower limb muscles might be due to increase in the strength of calf and tibialis anterior muscle. This may also be due to decreased in muscle tone in hypertonic muscles. Improved balance and coordination could be because of improved proprioception, repetitions and instructions to walk fast without compromising stability. Other factor could be successful accomplishment of one of the task trained and asked to complete it within the shortest period possible as home-based activity. Monger et al<sup>9</sup>, also demonstrated that a home-based task-specific training program can improve gait performance.

Although many literatures suggested task-specific training program with other treatment techniques for improving gait performance in hemiparetic stroke patients, but task-specific training program alone has significant effect on gait performance.

All the subjects participated in this study showed significant improvement in Cadence and Gait velocity with no improvement in Step length and Stride length.

## **Conclusion**

Based upon this clinical study, it was observed that the task related circuit training is a useful mean for improving cadence and gait velocity parameters whereas its having no significant effect on step length and stride length in right hemiparetic stroke patients.

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# Lornoxicam: a Newer NSAID

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## Abstract

Pain relieving drugs are one of the most commonly used drugs worldwide either through prescription or as over the counter medication. Non-steroidal anti-inflammatory drugs usually abbreviated as NSAIDs, are the drugs with analgesic, antipyretic and, in higher doses, with anti-inflammatory effects. NSAIDs inhibit cyclooxygenase (COX) 1 and 2. So, most of the side effects develop as a result of cyclooxygenase inhibitory activity. Certain NSAIDs, for example, rofecoxib and nimesulide have been banned because of their adverse effects. Lornoxicam (chlortenoxicam) is a strong analgesic and anti-inflammatory NSAID of the oxicam class with better tolerability profile when compared to other NSAIDs. Its analgesic activity is comparable to that of opioids. It has been shown to be effective in the treatment of post operative pain and rheumatoid arthritis (RA). The present review provides an overview of lornoxicam.

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Key words: Lornoxicam, NSAIDs, Osteoarthritis, Rheumatoid arthritis

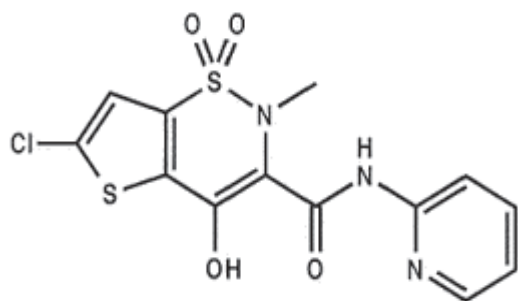
**Abbreviations used:** COX-Cyclooxygenase, NSAID-Non Steroidal Anti-inflammatory Drug, PG-Prostaglandins, TNF-Tumor Necrosis Factor, IL-Interleukin, NO-Nitric oxide, cGMP-Cyclic Guanosine Monophosphate, PDGF-Platelet Derived Growth Factor, TOTP- Total Pain Relief Score,  $C_{max}$ -Maximum Concentration, AUC-Area Under Curve

## Introduction

Lornoxicam, a congener of tenoxicam, is a new NSAID belonging to the oxicam class. It is a strong analgesic and anti-inflammatory NSAID as compared to other NSAIDs. Its analgesic activity is comparable to that of opioids. Studies have shown that it is more effective than 10 mg morphine when used at doses  $> \text{ or } = 8 \text{ mg}$  to control pain after oral surgery. Lornoxicam combines the high therapeutic potency of oxicams with an improved gastrointestinal toxicity profile as compared to naproxen which is probably due to the short half-life of lornoxicam as compared to the other oxicams. Clinical investigations have established it as a potent analgesic with excellent anti-inflammatory properties in a range of painful and/or inflammatory conditions, including postoperative pain and RA.<sup>1,2</sup> Lornoxicam has shown protective effects on the development of myocardial infarction in rats under conditions of ischemia and ischemia-reperfusion.<sup>3</sup> Recently, an experimental study in mice has demonstrated its protective effects against herpetic stromal keratitis (HSK), presumably through the down-regulation of nuclear factor kappa B (NF-kappa B) activation. Lornoxicam treatment significantly decreased the incidence of recurrent HSK, attenuated the corneal opacity scores, and also effectively suppressed both NF-kappaB activation and TNF-alpha expression in biological analysis.<sup>4</sup> Other potential indications of lornoxicam are being investigated.

## Chemistry

The active drug substance is 6-chloro-4-hydroxy-2-methyl-N-2-pyridyl-2H-thieno-[2,3-e]-1,2-thiazine-3-carboxamide-1,1-dioxide (Fig. 1). It is a yellow crystalline solid with a pKa of 4.7. It is highly ionized at physiological pH and has relatively low lipophilicity thereby preventing distribution to fatty tissues. It has a molecular weight of 371.82 Da.<sup>5</sup>



**FIG. 1.** Chemical structure of lornoxicam ( $C_{13}H_{10}ClN_3O_4S_2$ ).

### Mechanism of action

Like all NSAIDs, it acts by inhibiting the metabolites of COX branch of arachidonic acid pathway. It inhibits both isoforms in the same concentration range i.e. COX-1/COX-2 = 1. Thus, a perfectly balanced inhibition of COX-1 and COX-2 is achieved. COX-1 is a constitutive enzyme expressed in many cells as a house keeping enzyme and provides homeostatic prostaglandins. COX-2 is an inducible enzyme, which is expressed at the onset of inflammation in many cell types involved in inflammatory responses. It differs from other oxycam compounds in its potent inhibition of prostaglandin biosynthesis, a property that explains the particularly pronounced efficacy of the drug. Prostaglandins are involved in all phases of inflammatory events including fever, pain reactions and physiological functions like intestinal motility, vascular tone, renal function, gastric acid secretion etc. The inducing events include phorbol esters, cytokines and endotoxins.<sup>6</sup> It might produce the peripheral analgesic effects by NO-cGMP pathway and the opening of  $K^+$  channels.<sup>7,8</sup> It also acts by inhibition of spinal nociceptive processings, elevation of plasma levels of dynorphin and  $\beta$  endorphin following IV administration. *In vitro* tests have shown that lornoxicam also inhibited the formation of nitric oxide. It has also shown marked inhibitory activity on endotoxin induced IL-6 formation in THP 1 monocytes with less activity on TNF alpha and IL-1.<sup>9</sup>

### Pharmacokinetics

Lornoxicam is absorbed rapidly and almost completely from the gastro-intestinal tract. Peak plasma concentration is attained within 2.5 hrs. On repeated administration,  $C_{max}$  is increased in dose related manner. No evidence of drug accumulation on repeated drug administration has been reported. Food reduces the absorption of the drug. The absolute bioavailability of lornoxicam is 90-100%. Almost 99% is protein bound exclusively to albumin. No first-pass effect has been observed. Lornoxicam is found in the plasma in unchanged form and as its hydroxylated

metabolite. The hydroxylated metabolite exhibits no pharmacological activity.<sup>5,10</sup> CYP2C9 has been shown to be the primary enzyme responsible for the biotransformation of the lornoxicam to its major metabolite, 5'-hydroxylor noxicam.<sup>11</sup> Approximately 2/3 is eliminated via the liver and 1/3 via the kidneys as inactive substance. Unlike other oxycams, it has a relatively short plasma half-life (3 to 5 hours). It is eliminated following biotransformation to 5'-hydroxy-lornoxicam, which does not undergo enterohepatic recirculation. Glucuroconjugated metabolites are excreted in urine and faeces with a half-life of about 11 hours. Lornoxicam and its metabolites bind extensively to plasma albumin. It readily penetrates into synovial fluid, the proposed site of action in chronic inflammatory arthropathies. Lornoxicam synovial fluid: plasma AUC ratio is 0.5, after administration of 4 mg twice daily.<sup>12</sup>

### Therapeutic uses

#### Analgesia: Acute and Chronic Pain

Lornoxicam has been shown to produce dose related analgesia. 16 mg and 32 mg were significantly superior to 4 mg with respect to pain relief. The total pain relief score after 6 hours of intake of lornoxicam are highest at 32 mg. Hence it is a useful agent in the treatment of postoperative pain and other acute traumatic painful conditions such as fractures.<sup>13</sup> In pain following oral surgery and post thyroidectomy; lornoxicam in a dose of 8 mg gives better pain relief than aspirin 650 mg, has higher response rate, faster onset of action and longer duration of action. The duration of analgesic effect of lornoxicam is approx 4.5 hrs with maximum pain relief occurring at approximately 2 hrs. The analgesic effects of parenteral lornoxicam is not immediate as some time is required to inhibit the arachidonic acid pathway, thus pre operative administration may be more appropriate for those requiring procedures under 2 hrs. Lornoxicam is found effective in acute sciatica, lumbosciatica and chronic low back pain. Lornoxicam can decrease the opioid requirement when used as an adjunctive analgesic in patients with cancer pain. Lornoxicam decreases the number of headache episodes and also reduces the analgesic intake in migraine attacks.<sup>13-15</sup>

#### Anti Inflammation

In osteoarthritis, 8mg twice daily improves pain and functional disability. Other area where lornoxicam is found useful is ankylosing spondylitis and Rheumatoid arthritis.<sup>16,17</sup> Anti inflammatory and antipyretic effects of lornoxicam include prevention of the degenerative bone loss seen in chronic inflammation by inhibiting polymorphonuclear leucocyte migration (for this effect an additional dose of 0.1 mg/kg is required). Antipyretic

effect is observed at a dose 10 fold higher than that required for inflammation.<sup>18</sup>

#### Reduction of myocardial infarction volume

Activation of inflammation and enzyme cyclooxygenase with formation of proinflammatory prostaglandins is a key element of development of myocardial infarction in patients with acute coronary syndrome. Lornoxicam has shown protective effects on the development of myocardial infarction in rats under conditions of ischemia and ischemia-reperfusion.<sup>3</sup>

#### Herpetic Stromal Keratitis

An experimental study in mice has demonstrated its protective effects against herpetic stromal keratitis (HSK), presumably through the down-regulation of NF-kappa B activation. Lornoxicam treatment significantly decreased the incidence of recurrent HSK, attenuated the corneal opacity scores, and also effectively suppressed both NF-kappa B activation and TNF-alpha expression in biological analysis.<sup>4</sup>

Other effects of lornoxicam include inhibition of release of superoxide from polymorphs and inhibition of the release of platelet derived growth factor (PDGF) from the platelets, both of which are involved in the pathogenesis of RA. Thus lornoxicam can have protective effects in the management of RA. Lornoxicam also stimulates proteoglycan synthesis suggesting possible reparative effects in RA.<sup>19</sup>

#### Dosage and Route

It is available in oral and parenteral formulations. Its oral dose is 4mg thrice daily or 8mg twice daily.<sup>20</sup>

#### Safety Pharmacology & Toxicological studies

Prostaglandins play an important role in gastrointestinal mucosal protection by strengthening the mucosal barrier for acid and in inhibiting gastric acid secretion. Thus the adverse effects of the acidic NSAIDs are mainly because of inhibition of prostaglandin production. The gastric side effects range from mild dyspepsia and heartburn to ulceration and hemorrhage. Lornoxicam does not increase the serum pepsinogen levels (a marker of morphological and functional state of gastric mucosa in contrast to other NSAIDs e.g. indomethacin, ibuprofen which increase the serum pepsinogen levels). Risk factors for NSAIDs induced gastropathy include smokers, old age, history of peptic ulcer and those receiving oral corticosteroids and oral anticoagulants. Clinical investigations done so far have suggested its improved gastrointestinal toxicity profile. This is probably due to the short half-life of lornoxicam as compared to the other oxicams.<sup>21-23</sup> Renal side effects can range from acute

and chronic renal failure to edema and electrolyte imbalance which play only a minor role in normal person. And when the renal function is compromised drug side effects are pronounced to a greater extent. Lornoxicam because of its short half-life is less liable to nephrotoxicity on repeated drug administration. No evidence of nephrotoxicity on administration of doses upto 8 mg twice daily, have been found in either in healthy volunteers or patients with mild to moderate renal impairment.<sup>20,24,25</sup> Hematological effects of lornoxicam include interference with platelet aggregation leading to prolonged bleeding time.<sup>24</sup> The preclinical studies for its chronic oral toxicity and carcinogenic potential suggested that the drug-related toxicity mainly comprised mortality, reduced body weight gain, clinico-pathological changes indicative of anaemia resulting from blood loss, and renal damage, renal papillary necrosis and gastrointestinal mucosal lesions. The kidney-associated changes were not completely reversible during the recovery period. Toxicokinetic investigations demonstrated a dose-linear absorption of the drug. In female rats, the terminal half-life was about twice that in males which led to a higher exposure of this gender to lornoxicam. A dose of 0.01 mg/kg/day was established as no-observed-effect level. In a 104-wk carcinogenicity study, lornoxicam was administered by oral gavage to male and female rats. Drug-related changes were similar to those in the chronic studies and consistent with the anticipated side-effects of NSAIDs. No carcinogenic potential was revealed.<sup>26</sup>

#### Drug Interaction

Like other NSAIDs, it appears to interact with warfarin, sulphonylureas, digoxin and furosemide. It is not affected by the co-administration of ranitidine, aluminium, magnesium and calcium containing antacids. Cimetidine co-administration inhibits elimination of lornoxicam resulting in significant increase in steady state  $C_{max}$  and AUC (area under curve) values and a reduction in apparent plasma clearance.<sup>27</sup> Lornoxicam displaces glibenclamide from its protein binding site leading to enhanced glibenclamide effect.<sup>28</sup> It increases the concentration of warfarin leading to increased coagulation time. Lornoxicam decreases the plasma digoxin clearance and increases methotrexate concentration.<sup>29</sup>

#### Clinical Studies

Clinical investigations focusing on efficacy and tolerability of lornoxicam have been carried out. Comparison of lornoxicam and rofecoxib in patients with activated osteoarthritis (COLOR Study) was carried out in 2520 patients for over 25 days on average. Before and after treatment patients documented their individual scores for pain on movement, at rest and during the night, and their

individual duration of morning stiffness as well as the consequent grade of restriction. Pain on movement (-45.3%), at rest (-42.0%) and at night (-42.5%) was reduced by rofecoxib, whereas improvements after treatment with lornoxicam exceeded those effects significantly (-55.8%, -55.8% and -59.9%, respectively). Shortening of the duration of morning stiffness was significantly ( $p < 0.001$ ) more pronounced with lornoxicam (-66.6%) than with rofecoxib (-50.2%). Adverse events were reported in 5.4% of all lornoxicam patients compared with 12.0% of the rofecoxib recipients ( $p < 0.001$ ). GI symptoms showed a slight trend of being less frequent following rofecoxib therapy. All improvements in each efficacy parameter were clinically relevant in each treatment group and significantly superior ( $p < 0.001$ ) in the lornoxicam group. The results of this study confirmed that both lornoxicam and rofecoxib are effective in the treatment of patients with activated osteoarthritis; the analgesic and anti-inflammatory effects of lornoxicam are significantly superior to those of rofecoxib without inferiority in tolerability.<sup>30</sup>

In another randomized, double blind clinical study; lornoxicam was investigated as a treatment for RA versus naproxen. Lornoxicam (4 mg t.i.d. and 8 mg bi.d.) and naproxen (500 mg b.i.d.) were given to 225 patients for 12 weeks. Grip strength and scores on the Ritchie Articular Index improved similarly in all the treatment groups.<sup>17</sup> In a further multicenter, double blind clinical trial, lornoxicam was as potent as diclofenac sodium with comparable tolerability.<sup>31</sup>

## Conclusion

The data available from clinical studies have demonstrated that lornoxicam has advantageous profile in moderate to severe pain in combination with an anti inflammatory efficacy comparable to other NSAIDs. In addition, it may be an alternative to other NSAIDs for the treatment of painful arthritic and inflammatory diseases. Furthermore, it possesses superior gastrointestinal safety profile as compared to other NSAIDs.

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# Myasthenia Gravis in a Patient with HIV

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## Abstract

A 25 year old female presented with facial weakness and symmetrical proximal weakness of the extremities which was aggravated on exertion. Clinical examination and laboratory investigations were diagnostic of myasthenia gravis. Moreover, the patient tested positive for HIV. Management with anticholinesterase medication showed marked improvement in overall strength and performance of activities of daily living (ADL). The possibility of simultaneous affection with myasthenia gravis should be borne in mind when HIV patients present with weakness.

**Key Words:** HIV, Myasthenia Gravis.

## Introduction

Myasthenia gravis is a disorder of neuromuscular junction, where, as a result of antibody mediated depletion of acetylcholine receptors, there is weakness of the face and extremities. Though muscle weakness is common in HIV patients due to various causes, association with myasthenia gravis is rare with only a few cases reported so far in the literature. This report documents a patient who was affected with both.

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## Case Report

A 25 year old unmarried female from a hill district of Manipur, working in a metropolis, reported to the OPD of the Department of Physical Medicine and Rehabilitation, RIMS, Imphal, with complaints of generalized weakness especially affecting all extremities for the last one year.

Her presenting symptoms started one year back when she had episodes of weakness of her extremities which was usually felt more during the daytime. She was easily fatigued on exertion. Her weakness gradually increased and involved the face with complaints of double vision and tiredness while chewing food.

She had no relevant past medical, surgical or family history.

Examination of the patient showed bilateral ptosis, diplopia, slurred speech, normal muscle bulk and tone, symmetrical proximal weakness of the extremities (MRC 2-3/5) with other neurologic symptoms preserved. Forward Arm Abduction Time test was only 3 seconds. Most of the ADL were affected.

Investigations showed normal CBC, urine RE, blood sugar, ECG, LFT, KFT, serum electrolytes, CPK, thyroid profile, ANA, Rheumatoid Factor, CXR, USG abdomen and CECT thorax. Her HCV Ab and HBs Ag were also negative. EMG (Repetitive nerve stimulation) however showed decremental response. NCV was normal. Acetylcholine Receptor Autoantibody assay showed a high titre (31.45 nmol/L. Positive => 0.40 nmol/L). Test with Neostigmine 1.5 mg/ml i.m showed marked improvement of symptoms within 15 minutes.

Moreover, based on her possible risk behavior, we assessed her retrovirus status after pre-test counseling, which was found to be positive for HIV and the CD4 count was 248/cumm. The patient admitted to having sexual contact 3 years back.

Initially, the patient was started on Tab. Neostigmine 15 mg orally five times daily. There was improvement in overall weakness. The patient was able to perform her ADLs independently and had no difficulty in chewing food. She no longer had symptoms of diplopia. Her Forward Arm Abduction Time test also increased to 40 seconds to 2.4 mts in subsequent follow up assessments.

After post-test counseling, she was also put on anti-retroviral therapy by the ART centre, RIMS.

The present status of the patient is stable with 4 hourly doses of Tab. Neostigmine 15 mg and Anti-retroviral therapy.

## Discussion

Myasthenia Gravis is a neuromuscular disorder characterized by weakness and fatigability of skeletal muscle. It results from a decrease in the number of available acetylcholine receptors at the neuromuscular junction due to an antibody mediated attack. It is prevalent in 1: 7500 population. It usually affects women in their 20s and 30s and men in their 50s and 60s with a woman preponderance<sup>1,2</sup>. The patient who was under our care was a female and her age fell in the common age group.

The main features are weakness and fatigability of muscles on exertion and improves following rest or sleep. Muscles affected are cranial muscles like the lids and extraocular muscles resulting in diplopia and ptosis, mastication muscles resulting in chewing difficulties, slurred speech due to tongue weakness, muscles of extremities especially proximal muscles. Other neurologic functions are preserved<sup>1,2</sup>. This same clinical picture was also observed in our patient.

Diagnostic tests involves baseline investigations, ruling out thyroid disease, myopathies, periodic paralysis, SLE and presence of thymoma through CECT thorax. Tensilon test or Neostigmine test is highly predictive while EMG (repetitive nerve stimulation) showing decremental response is confirmatory. Acetylcholine receptor autoantibody assay is 90 % positive<sup>1-3</sup>. Most of the clinical and laboratory tests were suggestive of myasthenia gravis in our patient and she was responding well with anticholinesterase medication.

Muscle involvement in HIV infected patients is not uncommon in the form of myopathies (Disease related or drug related like Zidovudine)<sup>4</sup>. However, occurrence of myasthenia gravis in HIV patients is rare<sup>5</sup>. There are few case reports of association of myasthenia gravis with HIV in the literature till date<sup>5-8</sup>.

The association of myasthenia gravis and HIV infection may be by chance or maybe due to involvement of the thymus gland. It is theorized that the thymic epithelial atrophy and decrease in thymopoiesis that occurs in myasthenia gravis and HIV-1 infection may in part derive from cytokines or other factors produced by peripheral immune cells within the thymic perivascular space. These two disorders share similar histology and their coexistence may suggest an unknown immunopathogenetic mechanism which comes into play in some cases of HIV

infection leading to the development of myasthenia gravis<sup>9,10</sup>.

HIV infected patients presenting with muscle weakness should also be investigated for possible simultaneous affection of myasthenia gravis.

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# Contractures and Drug Abuse

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## Abstract

Contracture is limitation of complete range of motion, active or passive, due to joint, muscle or soft-tissue limitations. Myogenic contractures can be due to trauma, inflammation, degenerative changes, ischemia, and spasticity. A 32-year-old patient presented with complaints of inability to sit on the floor and limitation of multiple joint movements which progressed over the past three years. He had a history of multiple drug injections (pentazocine) for the past six years at multiple sites throughout the body. He was started on narcotic analgesics for chronic abdominal pain following pancreatitis. Deltoid, quadriceps, hamstring and calf muscles were indurated and contracted. Bilateral winging of scapula was present. Contractures are commonly associated with joint diseases; but normal radiographs and indurated muscles support a myogenic pathology in this case. Myogenic contracture due to parenteral narcotic abuse is a rare entity.

Key words: Contracture, Pentazocine, Substance-Related Disorders

## Introduction

Contracture is the lack of full active or passive range of motion due to joint, muscle, or soft-tissue limitations.

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Contractures have major impact on mobility, activities of daily living, and nursing care of skin. They cause increased energy consumption in ambulation, difficulties in dressing, grooming, eating and hygiene. Myogenic contractures are due to trauma, inflammation, degenerative changes, ischemia, spasticity and mechanical factors. Myogenic contracture due to parenteral narcotic abuse is a rare entity. One such case was reported by Das et al.<sup>1</sup>

## Case Report

A 32-year-old male patient presented with complaints of abnormal posture, inability to squat, and difficulty in some activities of daily living. He had progressive restriction of movement around both the shoulders, elbows, hips and ankle joints for the past 3 years. Restriction of movement started at all the joints at about the same time. He had no muscle weakness within the available range of motion. He had been addicted to injection of Fortwin (pentazocine) for the past 6 years. He used to take several injections of pentazocine every day. The sites of injections were bilateral shoulders, arms, buttocks, thighs and calf muscles. He had a history of alcohol dependence for the past 10 years, and history of tobacco abuse for the past 18 years. He had past history of chronic pancreatitis, pseudocyst of pancreas, splenic artery aneurysm, pulmonary tuberculosis, and diabetes mellitus. Due to pancreatitis, he had chronic abdominal pain for which he was initially prescribed and given pentazocine injection by the medical practitioners but he continued taking this drug on his own and got addicted to this.

Physical examination revealed a moderately-built man standing with abducted shoulders, flexed elbows, flexed and abducted hips and flexed knees (Fig 1). He walked with a broad based gait with decreased step length. He had multiple puncture marks throughout the body, more



Fig 1. Arms resting in abduction due to deltoid contracture.

Fig 2. Multiple puncture marks, right buttocks smaller than left.



Fig 3. Winging of scapula due to deltoid contracture. Fig 4. Radiograph of shoulder joint was normal

so around the hips and shoulders (Fig 2). He had bilateral winging of scapula (Fig 3) and indurations of the deltoids, biceps, glutei, quadriceps, and gastro-soleus. Range of motion, which were abnormal, were as follows: bilateral shoulder abduction 35°-180°, right elbow flexion 0°-55°, left elbow flexion 0°-65°, right hip flexion 0°-45°, and left hip flexion 0°-50°. Terminal flexion was mildly restricted in bilateral knees. Ankle flexion and dorsiflexion were restricted on both sides allowing a range of motion of around 25°. Distal joints were normal. Muscle power was normal. There was a mild sensory deficit in bilateral foot (stocking pattern).

Laboratory studies revealed the following values: hemoglobin 12.0 g/dl; PCV 33%; RBC  $3.56 \times 10^6/\text{mm}^3$ ; white cell count  $7200/\text{mm}^3$  (neutrophils 70%, lymphocytes 27%, eosinophils 2%, monocytes 1%); platelets  $412 \times 10^3/\text{mm}^3$ ; erythrocyte sedimentation rate 55 mm 1st hour; blood sugar (random) 294 mg%; serum urea 14 mg%; serum creatinine 0.6mg%; uric acid 4.2 mg%; aspartate transaminase (SGOT) 22 U/l; alanine transaminase (SGPT) 15 U/l; alkaline phosphatase 87 U/l; creatine kinase 51 IU. Hepatitis B and HIV tests were negative.

Radiography revealed normal joint architecture and multiple areas of calcification at L1 due to chronic pancreatitis (Fig 4-6).

The patient received active and passive stretching exercises for muscles around the shoulder, elbow, hip, knee and ankle joints. He was started on a drug rehabilitation program at the same time. At 6 weeks follow-up there was a minimal increase in the range of motion at all joints. Later on the deaddiction program, under the department of psychiatry, however failed as the patient was lost to follow up.

## Discussion

Contractures are commonly associated with joint diseases; but normal radiographs and indurated muscles support a myogenic pathology in this case. Winging of scapula was found to be due to deltoid contracture. Normal CPK value ruled out ongoing muscle destruction.

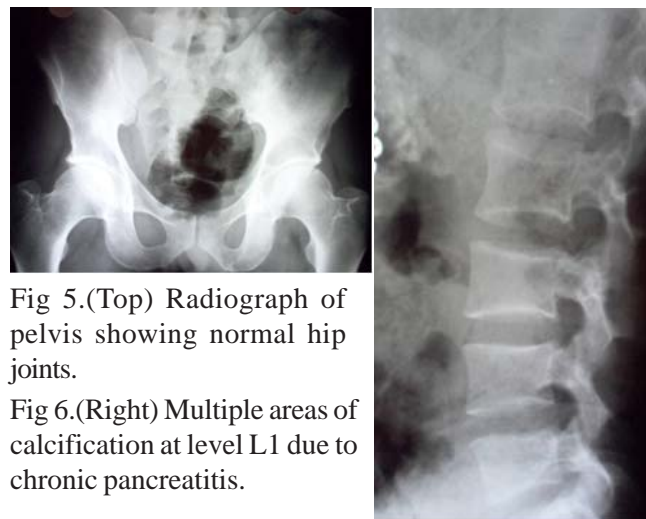


Fig 5.(Top) Radiograph of pelvis showing normal hip joints.

Fig 6.(Right) Multiple areas of calcification at level L1 due to chronic pancreatitis.

In this case, contracture had been induced by pentazocine abuse. It has been proposed that pentazocine precipitates in extracellular tissue resulting in inflammation.<sup>2</sup> Fibrosis, endarteritis, vascular thrombosis, granulomatous inflammation and fat necrosis are known histopathological changes seen in muscles after chronic use of parenteral pentazocine.<sup>3</sup> Surgical release of contractures may have to be contemplated in cases such as this which respond poorly to stretching exercises.

Management of chronic pain with parenteral narcotic agent like pentazocine is a common practice. Pentazocine has been known to cause sclerotic ulcers and myopathy in chronic use. Contracture, as a complication, must be considered and patients must be advised to do range of motion exercises before the condition ensues. Monitoring the patients for addiction and physical examination including the range of motion of joints become important in this clinical setting.

Pentazocine abuse is a growing problem in the society<sup>4</sup> and hence history of drug abuse is a must for all patients reporting with localized contractures.

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## Caregiver- Is There A Hidden Patient?

*In our routine practice it is not a uncommon site to attend to the patients attendants' musculoskeletal and psychological problems. The patients may be an in-patient or out-patient, attending hospital for rehabilitation or any other chronic diseases like Coronary Artery Disease, cancer, depression, child hood disabling conditions etc. What we deal with is only the tip of the iceberg but deep down there lies the whole problem which as yet has not achieved much attention in the routine health care. Adding to the above issue is the fact of increased guilt and anger in the caregiver if the cared patient is not improving and the physician scolds the caregivers. The issue becomes more amplified if the caregiver is a family member, be it a parent, child or spouse although the professional caregivers like doctors, nurses, attendants and other caregivers are not immune from it. The psychological and physical impact of care-giving on caregivers' health has now been established and there are many support groups now formed on the internet and otherwise. This is even more in case of caring for person with disability with higher care needs, behavioral problems and depression, financial stress, lower levels of social support and disturbed family functioning. Care-giving can also have its positive effects and can give better satisfaction and feeling of well being to some. May be the coping mechanisms and the basic psychological profile of the caregivers can make some difference. The role of caregivers in medical practice is complex and extended and they may feel high level of commitment or total detachment but doing it out of expected social norms. The latter may be hidden and may result in cared or caregivers deterioration in physical and mental health. Many caregivers' health risk assessment tools have been developed to assess the impact of care-giving and are undergoing refinement so as to better predict the care-giving burden and its impact and to take the specific measures to prevent the deterioration in patient as well as caregivers health. The family caregivers at times have to leave their jobs or take extra leaves to cope up hence adding to the stress. The coping mechanisms , social support , psychological adjustment , attention to stressors like sleep disturbance, musculoskeletal problems and regular exercise and respite activities can help a caregiver to a great extent. The Physiatrist has a special role to play in this complex relationship and has to ensure due care for the caregiver also. The physical problems like chronic fatigue, fibromyalgia, back pain, neck pain etc and psychological problems such as sleep disturbance,depression, somatization etc. may be co-existent in the same patient. The understanding of various physical, emotional, social, psychological, vocational issues and appropriate counseling and support in these areas can contribute significantly to improvement in the quality of life of both patients and the caregivers.*

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## Save the Earth, Let's go Green

The times have changed. Print media has also changed its colors. The earth is spoilt by us. It continues to get spoilt further with our actions, with our practices and our will to hoard more and more. All over the world efforts are made to save the earth. In our schools, children are told how make their parents understand the new concepts. The concept of being green is coming up and has taken the world by storm. Everyone of us has to make an impact and do our part. Trees make a lot of difference to our lives we all know. To prevent trees from falling and planting more trees is our motto. Somewhere there lies the point I wish to make. Save the trees, use less paper. Hence, use the modern media, the electronic media to send articles, review articles and read them too. Why not try to reduce the use of paper, hence making less trees to be felled and making the earth greener, let it only be a drop in the ocean, every drop counts.

You would notice a lot of change in the guidelines for the contributors. We have tried to omit the requirement of sending the hard copies of the articles submitted for publication. Similarly, I would also request most of our reviewers to be modern and use the electronic modes for reviewing the articles unless it is absolutely mandatory to send to such a reviewer who is not familiar or comfortable with this media, only then we shall use the articles printed on paper. Thus economizing on everything as far as we can.

From here comes something more. Can we dispense with the need for printing the journal. I don't think that we can do that entirely. It would mean a lot of change in the world we live in. I don't think that it is the time that we can have only the electronic version of the journal even though the future may guide us to do only that. We have not reached that stage as yet. It might come in the near future. Perhaps we may start doing that from now in a phased manner. I remember, the Journal of Rehabilitation Research and Development, brought out by the Veterans Administration, many years ago announced that there are two things that make a lot of impact on the finances required to support the journal. One is the printing cost and second is the postage. Now we have also realized that paper cost is not just drained from the pockets of the publisher but also drains the resources of the earth. Keeping that idea in mind, I am proposing an idea to all the members of the association. I understand that as per the membership rules, all life members of IAPMR are supposed to get the journal for their lives, free of cost. I would like to respect that. But

let us also respect the earth, our mother, which gives everything to us. Let us do our part by saving the earth by saving trees. Those of us who are good net users and are comfortable to read the journal online, why not do our part by opting out of the print copies of the journal. The journal shall be available on the net. We can read it, download and print the copies if needed to be attached somewhere with applications etc. It would save us not only the trees but the precious space on the earth needed to store the print version. Not just the space on the earth but look at the limited space in your almirahs in your homes or offices. You would consider it a disrespect to throw old copies of the journal which are 'occupying' precious space you would like to keep something else.

Those of us, who agree to be a part of 'save the earth' campaign and would like to opt out of receiving the print copies of the journal may please write an email to me (EditorIJPMPR@gmail.com) and say that they would not like to have the hard copy of the journal. I shall thank them and not send them any copy. It is purely voluntary.

The print copies shall still be printed and sent to those who do not opt out and also to those who have subscribed and to the libraries where I think it is still needed. It shall be continued to be printed till the time the whole world wakes up to this. Maybe, where internet cannot reach, in future we may even think of sending the CDs or similar things that come up in the future.

I am sure that many of us would like to do this little thing for the sake of all of us, for humanity. I shall be waiting. More suggestions are welcome.

I am not sure how many would read this. But still I am hopeful that those who care would read and act too. I shall feel fortunate to have initiated this if most of us agree.

Don't forget to send me an email either to opt out of receiving the print copies or for any suggestions. If I don't receive a positive no from any, they shall feel assured that they shall continue to get the print copies as always. Just think of the earth, postage, storage space and what not. I propose to start this from the October 2009 issue.

Thanks very much for reading this to this end. Do your part in saving the earth.

*Dr U Singh*  
Editor