CLINICAL METHODS

CHAPTER 5
A. Selection Criteria of Patients

In order to test the efficacy of the recipe, on disc syndrome in general, spondylosis in particular, clinical trials have been taken. Independent case papers have been maintained which are shown in the text (Table 6.1). The criterion of selection of the patients is based on symptoms supported by X-ray reports of the lumbar and cervical spines. These are precisely, so far as symptoms are concerned, acute pain, tingling sensation of the extremities, stiffness of the neck or back, sense of weakness in the extremities and giddiness in relation to the cervical spine. These symptoms essentially must have been supported X-rays of the cervical region or lumbar region showing narrowing of the intervertebral spaces, loss of curvature of the spine, degenerative changes of the discs, marginal osteophytes and sometimes muscle spasm. The patients who do not fulfill the above criterion barring few symptomatic complaints are only selected for the case paper studies.

The patients after registering on the case paper were first asked to take the X-ray and the X-ray report of the radiologist to ensure the bonafides of the syndrome. And such patients were also examined by orthopedic surgeon to confirm the radiological report. In the present investigations more than 500 patients were examined, out of which 152 genuine patients have been selected so that a proper classification - sexwise, agewise, occupationwise and prakritiwse (Ayurvedically) could be made.
B. **Method of Treatment:**

The enrolled patients were treated for a period of 24 weeks. Each patient was administered Swadāṇstrādi guggul 60 mg twice a day with plain water on empty stomach and Padmak Kitta yog was given in the dose of 60 mg twice a day after meals with water. Since these are outdoor patients the responsibility of taking the drug lied with them, whether the patient is sincerely taking the recommended prescribed drug could be checked by periodic examination every week for symptomatic relief. This was supported by X-ray examination after twelve weeks and 24 weeks wherever possible. Each patient depending upon the symptoms and symptomatic relief, they were given points e.g. those who showed 5 symptoms of the syndrome were given 10 points. Likewise with a decreasing number of symptoms with increasing period of administering the medicine, the score points decreased.

The score points were decided according to the standard norms. The three basic criteria were chosen e.g. pain, restricted movements and tingling sensation in the fingers both feet as well as hands were taken into consideration. 'No pain' was considered as 'zero', 'mild pain' was given point 'one', 'moderate pain' was given points 'two' and 'severe pain' as 'three'. Restricted movements or stiffness of neck or back was another symptom. To assess it from all angles, flexion, extension, lateral movements and side to side movements (in case of back turning movement) were taken into consideration. They were also given points accordingly. Tingling sensation in the fingers is another symptom. It is subjective. Patients were asked to explain the symptom and according to the severity of it, the points were given from 0 to 3. According to recent
studies giddiness is not supposed to be related to the cervical disc syndrome. So it was not taken into consideration for the score.

The total score was the sum of the scores discussed above. After every week each sign and symptom was judged and after each week, the progress of the patient was recorded.

C. Radiological Report:

After making the entry of the patient in the case paper based on the radiological and orthopedic report the drug was administered. After 12 weeks period again X-ray reports were called for. To adjudge whether the drug is acting in the right direction or not following points were considered.

1) Narrowing of the spaces
2) Muscular spasm of the spine
3) Degenerative changes with marginal osteophytes.

D. Subjectivity of Symptoms:

In any clinical trial the efficacy or effectiveness of drug, not only depended upon the physical changes taking place in response of the effect of medicine, but the subjectivity in it. In other words, the patient must feel and sense the recovery i.e. feel better. This point is also taken into consideration while recording the changes.

E. Physical Examination of the Patient:

A thorough physical examination of the patient was done. Patient was examined for general examination and each system was checked. Only positive findings were noted. While examining the stiffness of the
movement of neck or back flexion, extension, lateral movements and side to side movements were seen. For flexion and extension Ganiometer was used (see fig. 5.1). While examining the abdomen palpation and percussion were done. Tenderness over abdominal area was decided according to the pressure required. Abdomen was percussed in splenic (Left hypochondriac) and liver (Right hypochondriac) areas, from dull to tympanic notes were noted. Loss of power was seen according to the standards and it was also given points as 0, 1, 2, 3, 4. While doing physical examination the measures of extremities were also taken. Reflexes were noted. In other systemic examination blood pressure was taken. Wherever necessary in other investigation blood reports were taken for haemoglobin, blood, sugars and R.A. factors.
GANIOMETER

Plate 5.1