CHAPTER III

METHODOLOGY
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In this chapter, the procedure adopted for the selection of subjects, study setting, experimental variables, experimental design, outcome measures, pilot study, reliability, procedure of evaluation, procedure of intervention, collection of data and methods employed for statistical treatment have been described.

SUBJECTS – INCLUSION CRITERIA

One hundred subjects were included in the study and they were university level players involved in games like foot ball, volley ball, basket ball, tennis, badminton, table tennis, hockey, high jumpers, long jumpers, shot put, kabadi, kho kho, javelin thrower & runners. Both first & second degree soft tissue injuries were included in the study. The subjects were volunteers, both male & female who were aged between 18 years to 30 years and who were playing not less than 2 year in their relevant sports. Both direct as well as referral patents were included in the study.

The subjects were students of R.K Group of Colleges - Rajkot, Gujarat, students of Masterskill University, Kuala Lumpur, Malaysia, students of Magadh University, Bodhgaya, Bihar. The written consent was taken from all the subjects those who were participated in the study.

STUDY SETTING

The Evaluation and Treatment Intervention was done in the following settings;

i) Out Patient Department, R.K. Physiotherapy Centre, Bakthi nagar circle, Rajkot, Gujarat.

ii) Out Patient Department, R.K. Physiotherapy College Campus, Rajkot, Gujarat.
iii) Out Patient Department, Masterskill University, Kuala Lumpur, Malaysia.

iv) Out Patient Department, Institute of Physiotherapy, Magadh University, Bodhgaya, Bihar.

SELECTION OF VARIABLES

The dependent variables selected for this study as follows Pain, Tenderness, Range of motion and Functional Assessment.

The independent variables selected for this study as follows Ultrasound therapy, LASER Therapy and Taping

The intervening variables of this study as follows Gender, Type of sports and Fitness level

RESEARCH DESIGN

The type of research was experimental research with single blinded randomized controlled study. The experimental design of the study was 5x4 factorial analyses with last factor as repeated measure.

In this study 5x4 factorial design was used to analyse the main and interaction effects. Where the main effect and interaction effect was significant (Factor 'A' and Factor 'B') the Bonferroni Post hoc test was used to find out the paired mean difference (Anne Ruthestin, 1985)
Outcome measures

Subjective assessment

i) Pain assessment was done using numerical rating scale.

Objective assessment

i) Active pain free range of motion was measured by using goniometry.

ii) Local tenderness will be assessed by manual palpation and it was graded according to the subjects response.

ii) Functional level was assessed by using the below mentioned functional scale.
   a. Quick DASH (Disabilities of arm, shoulder & hand) sports module was used to assess the subjects with upper limb.
   b. The Foot & Ankle Disability Index (FADI) Score - Sports Module is used to assess the subjects with lower limb injuries.

PILOT STUDY

A pilot study was conducted to find out the accuracy of measurement tools which were used during the study and the efficiency of the modalities used for the treatment protocol. Ten subjects were randomly allotted to the five treatment groups. The experimental procedures was administered and the data was documented regarding the pain intensity, tenderness, active pain free range of motion, and functional scores. The results were correlated with the hypotheses and it was checked.

RELIABILITY OF DATA

The reliability of data was proved by establishing the instrument reliability, tester’s competency, reliability of tests and subject’s reliability.
RELIABILITY OF THE TESTS

Tester's competency was evaluated together with the reliability of the tests. Reliability of the test was established using test-retest method where by the consistency of the results was obtained by intra-class correlation. The repeated measurement of individuals on the same test was done to determine the reliability as it was univariate, not a bivariate situation. It is the distribution of a single variable it make sense, then to use a univariate statistics like the intra-class correlation co-efficient.

The data were collected from two subjects in each intervention groups who were selected randomly and for each variable calculation of co-efficient of correlation was done. Such obtained intra class correlation co-efficient for test and re test are tabulated in table (3).The very high value of correlation (from 0.92 to 0.98) obtained, demonstrated the competency of the investigator to administer the test as well as the reliability of the tests.

TABLE-3
OBTAINED INTRA CLASS CORELEATION

<table>
<thead>
<tr>
<th>S.NO</th>
<th>TESTED VARIABLES</th>
<th>CO-EFFICIENT OF CORRELETATION(N=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TEST-RETEST SCORES</td>
</tr>
<tr>
<td>1</td>
<td>PAIN INTENSITY</td>
<td>0.99</td>
</tr>
<tr>
<td>2</td>
<td>TENDERNESS</td>
<td>0.98</td>
</tr>
<tr>
<td>3</td>
<td>ACTIVE PAIN FREE ROM</td>
<td>0.94</td>
</tr>
<tr>
<td>4</td>
<td>FUNCTIONAL ASSESSMENT</td>
<td>0.7</td>
</tr>
</tbody>
</table>
INSTRUMENT RELIABILITY

Goniometry is the instrument used in the study for measuring the Range of Motion of the involved joints. The instrument was in good working condition. The calibration was tested and it was found to be accurate enough to serve the purpose of the study.

SUBJECTS RELIABILITY

The above test, re-test co-efficient of correlation values also determined that the reliability of the subject was adequate as the same subjects were used under similar condition by the same tester and no motivated techniques were used with any circumstances.

TESTERS RELIABILITY

Testers reliability was established by test re-test procedures. or this purpose, two subjects from different intervention groups were selected at random on the chosen variables, which were recorded twice under identical conditions on different occasions by the investigator.

The scores thus obtained could be analyzed by using intra class correlations. This could be tested for significance at0.05 level of confidence as shown in table 2.

ORIENTATION OF THE SUBJECTS

Before the assessment and intervention procedures the subjects were oriented about the purpose of the study. The investigator had given explanation about the evaluation and treatment procedure, so that no confusion about efforts required on their part. The researcher instructed the subjects how to record the level of pain intensity in the numerical rating scale. The subjects were oriented regarding their performance in the functional assessment. They were given instruction regarding the treatment procedure and does and don'ts.
ADMINISTRATION OF EVALUATION PROTOCOL

ASSESSMENT OF PAIN

Numerical Rating Scale was used to record subjective reports of pain. The NRS consisted of a 10-cm horizontal line, anchored with “no pain” at the left end (i.e. threshold intensity) and “pain as bad you can imagine” at the right (i.e. maximally tolerable intensity). Subjects were asked to document their pain intensity daily before and after the treatment session.

ASSESSMENT OF TENDERNESS

Tenderness was assessed by the therapist on the Injured joint / Muscle of the subjects by palpation and their responses were documented according to grade of the tenderness scale David.magee et.al (1996).
Grade 0 – No Pain
Grade I - Patient Complains of Pain
Grade 2- Patient complains of pain and winces
Grade 3- Patient winces and withdraw the joint
Grade 4- Patient will not allow palpation of the joint

Tenderness grade was documented daily before and after the treatment session.

ASSESSMENT OF RANGE OF MOTION

Pain free active range of motion of the joint which is relevant to the soft tissue injury was measured using the goniometry which is universally acceptable and reliable instrument to measure the ROM.
In this study Active pain free ROM was measured on the 1st and last day of the treatment session in the following joints according to the relevant condition: Ankle joint, Knee joint, Wrist joint, Elbow joint.

FUNCTIONAL ASSESMENT

UPPER LIMB

Disability of Arm Shoulder and Hand (QUICK DASH) -Sports Module was used to assess the functional level of the subjects with soft tissue injury in the upper limb.

This module consist of 4 questions as follows (1) Using your usual technique for playing your instrument or sport? (2) Playing your musical instrument or sport because of arm, shoulder or hand pain? (3) Playing your musical instrument or sport as well as you would like? (4) Spending your usual amount of time practicing or playing your instrument or sport? The maximum score is 20 it means the subject unable to do any activity and the minimum score is 4 it denotes the subject is normal.

The score was documented on the first day and the last day of the treatment.

LOWER LIMB

The Foot & Ankle Disability Index (FADI) Score - Sports Module was used to assess the functional level of the subjects with soft tissue injury in the lower limb.
FADI Score consist of 8 questions as follows Running, Jumping, Landing, Squatting and stopping quickly, Cutting, lateral movements, Low-impact activities, Ability to perform activity with your normal technique, Ability to participate in your desired sport as long as you would like and score was given according the response of the patient. The maximum score is 100 it means no difficulty and the minimum score is 0 denotes unable to do.

The score was documented on the first day and the last day of the treatment.

The total treatment protocol was extended for the period of 6 days per week for three consecutive weeks and the total number of treatment was 18 sessions. Assessment of pain intensity and tenderness was documented daily. Functional assessment, range of motion and muscle power was documented on the first day, 6th day, 12th day & 18th day.

PASSIVE STRETCHING

Stretching was included in the protocol to gain the following benefits.

- Increased flexibility and range of motion
- Injury prevention
- Preventing DOMS
- Improved posture
- Improvements in sports performance
- Stress relief & Pain relief
STRENGTHENING

Strengthening was included in the protocol to gain the following benefits

- Muscle hypertrophy (increase in size of fibres)
- Increased density of the capillary network surrounding each muscle (this means more blood and so oxygen can reach your muscles)
- Increased mitochondria within the muscles (these are where the majority of your energy is produced)
- Increased motor unit (groups of fibres served by one motor neurone) recruitment
- Improved coordination
- Increased tolerance to lactic acid (which causes fatigue)
- Increases in hormones and enzymes required for energy production
- Increased stores of ATP / PC and glycogen (all needed for energy)
- Improved ligament and tendon strength

All together, these changes result in an increase in muscular strength.

DATA COLLECTION PROCEDURE

Both direct and referral patients were included in the study. Detail assessment was taken (Assessment Form Attached in the Index) and the subjects were made sure that they should have $1^0$ or $2^0$ sprain or strain. For the first 48 to 72 hours treatment administrated was Rest, Ice, Compression and Elevation as a common protocol for all the subjects.

After 48 hours the subjects were randomly allotted to the group and the treatment was administrated as per the group protocol.
Before the collection of data, the subjects were oriented about the purpose of the study. Clear instruction was given to the subjects about the experiment, evaluation method and procedures, so that there was no confusion regarding the efforts required on their part.

The regular treatment protocol which was administered for all the five groups includes soft tissue mobilization, stretching & strengthening. Ultrasound therapy, LASER, Taping and Soft Tissue Mobilization was administered through the treatment session until recovery whereas stretching and strengthening was administered for all the five groups only in the third week of treatment session.

**Group A – Ultrasound Therapy with Taping (n=32)**

**Objective**

The purpose was to find out the efficiency of ultrasound therapy along with taping to reduce the pain intensity, to reduce the tenderness, to improve the active pain free range of motion and to improve the functional score of the subjects.

**Intervention**

The subjects allotted in this group were treated with Ultrasound therapy, Taping, Soft Tissue Mobilization finally stretching and strengthening in the last phase of treatment session.

**Position of the subjects**

The subjects were positioned comfortably and the treatment area was completely exposed for the treatment administration. The subjects were instructed not change position during the treatment.
Dosage

Ultrasound

Continuous ultrasound

Intensity: 1.5 w/cm² with a duty cycle of 20 percent. (Binder et al 1985).

Frequency -1 MHz

Duration of treatment 7 to 10 minutes

Taping

Taping is applied on the appropriate treatment area from the first session of the treatment and re applied once in 24 hours after the treatment session. Taping was continued till the day of recovery.

Material used- Elastic adhesive bandage width of 2 inch (5cm) was used for the soft tissue injury of upper limb and 3 inch (7.5cm) was used for the soft tissue injury of lower limb.

Soft Tissue Mobilisation

The soft tissue mobilisation was given in all the three phase of treatment session. Technique was chosen according to the injured structure.

Stretching and strengthening

Stretching and strengthening was administrated on the second and third phase of the treatment sessions.

Stretching was administrated to stretch the tightened structures and it was maintained for thirty seconds in order to gain good effect.

In order to improve the fitness of the muscle, Delorm’s strengthening programme was administrated. The subjects were done thirty lifts in one session with adequate rest period in between the thirty lifts (10 lifts –Rest- 10 lifts –Rest-10 lifts) with the weight allotted to them.
Total Number of Treatment Session

The total treatment protocol was extended for the period of 5 days per week for three consecutive weeks and the total number of treatment session was 15.

Instruction to the subjects

All the subjects are instructed to maintain the fitness level without stressing injured structure. Subjects are instructed not to do the provocative testing movements it may re injure the soft tissue.

Group B – Ultrasound Therapy (n=32)

Objective

The purpose was to find out the efficiency of ultrasound therapy along with taping to reduce the pain intensity, to reduce the tenderness, to improve the active pain free range of motion and to improve the functional score of the subjects.

Intervention

The subjects allotted in this group were treated with Ultrasound therapy, Taping, Soft Tissue Mobilization finally stretching and strengthening in the last phase of treatment session.
Position of the subjects

The subjects were positioned comfortably and the treatment area was completely exposed for the treatment administration. The subjects were instructed not change position during the treatment.

Dosage

Ultrasound

Continuous ultrasound

Intensity : 1.5 w/cm² with a duty cycle of 20 percent. (Binder et al 1985).

Frequency -1 MHz

Duration of treatment 7 to 10 minutes

Soft Tissue Mobilisation

The soft tissue mobilisation was given in all the three phase of treatment session. Technique was choosen according to the injured structure.

Stretching and strengthening

Stretching and strengthening was administrated on the second and third phase of the treatment sessions.

Stretching was administrated to stretch the tightened structures and it was maintained for thirty seconds in order to gain good effect.

In order to improve the fitness of the muscle, Delorm’s strengthening programme was administrated. The subjects were done thirty lifts in one session with adequate rest period in between the thirty lifts (10 lifts –Rest- 10 lifts –Rest- 10 lifts) with the weight allotted to them.
Total Number of Treatment Session

The total treatment protocol was extended for the period of 5 days per week for three consecutive weeks and the total number of treatment session was 15.

Instruction to the subjects

All the subjects are instructed to maintain the fitness level without stressing injured structure. Subjects are instructed not to do the provocative testing movements it may re injure the soft tissue.

Group C – LASER Therapy with Taping (n=32)

Objective

The purpose was to find out the efficiency of ultrasound therapy along with taping to reduce the pain intensity, to reduce the tenderness, to improve the active pain free range of motion and to improve the functional score of the subjects.

Intervention

The subjects allotted in this group were treated with Ultrasound therapy, Taping, Soft Tissue Mobilization finally stretching and strengthening in the last phase of treatment session.
Position of the subjects

The subjects were positioned comfortably and the treatment area was completely exposed for the treatment administration. The subjects were instructed not change position during the treatment.

Dosage

LASER

Type: Helium Neon (HeNe) laser 632.8 nm combined with infrared diode laser 904 nm pulsed wave

Dosage: 6-8 Joules/cm\(^2\) in the first week & 1 to 4 Joules/cm\(^2\) in the Second and Third week

Treatment Duration: 15 minutes

Treatment Frequency: 1 session per day

Taping

Taping is applied on the appropriate treatment area from the first session of the treatment and re applied once in 24 hours after the treatment session. Taping was continued till the day of recovery.

Material used- Elastic adhesive bandage width of 2 inch (5cm) was used for the soft tissue injury of upper limb and 3 inch (7.5cm) was used for the soft tissue injury of lower limb.

Soft Tissue Mobilisation

The soft tissue mobilisation was given in all the three phase of treatment session. Technique was choosen according to the injured structure.
Stretching and strengthening

Stretching and strengthening was administrated on the second and third phase of the treatment sessions.

Stretching was administrated to stretch the tightened structures and it was maintained for thirty seconds in order to gain good effect.

In order to improve the fitness of the muscle, Delorm's strengthening programme was administrated. The subjects were done thirty lifts in one session with adequate rest period in between the thirty lifts (10 lifts –Rest- 10 lifts –Rest-10 lifts) with the weight allotted to them.

**Total Number of Treatment Session**

The total treatment protocol was extended for the period of 5 days per week for three consecutive weeks and the total number of treatment session was 15.

**Instruction to the subjects**

All the subjects are instructed to maintain the fitness level without stressing injured structure. Subjects are instructed not to do the provocative testing movements it may re injure the soft tissue.

**Group C – LASER Therapy (n=32)**

**Objective**

The purpose was to find out the efficiency of ultrasound therapy along with taping to reduce the pain intensity, to reduce the tenderness, to improve the active pain free range of motion and to improve the functional score of the subjects.
Intervention

The subjects allotted in this group were treated with Ultrasound therapy, Taping, Soft Tissue Mobilization finally stretching and strengthening in the last phase of treatment session.

Position of the subjects

The subjects were positioned comfortably and the treatment area was completely exposed for the treatment administration. The subjects were instructed not change position during the treatment.

Dosage

LASER

Type: Helium Neon (HeNe) laser 632.8 nm combined with infrared diode laser 904 nm pulsed wave

Dosage: 6-8 Joules/cm² in the first week & 1 to 4 Joules/cm² in the Second and Third week

Treatment Duration: 15 minutes

Treatment Frequency: 1 session per day

Soft Tissue Mobilisation

The soft tissue mobilisation was given in all the three phase of treatment session. Technique was choosen according to the injured structure.

Stretching and strengthening

Stretching and strengthening was administrated on the second and third phase of the treatment sessions.
Stretching was administrated to stretch the tightened structures and it was maintained for thirty seconds in order to gain good effect.

In order to improve the fitness of the muscle, Delorm’s strengthening programme was administrated. The subjects were done thirty lifts in one session with adequate rest period in between the thirty lifts (10 lifts –Rest- 10 lifts –Rest- 10 lifts) with the weight allotted to them.

**Total Number of Treatment Session**

The total treatment protocol was extended for the period of 5 days per week for three consecutive weeks and the total number of treatment session was 15.

**Instruction to the subjects**

All the subjects are instructed to maintain the fitness level without stressing injured structure. Subjects are instructed not to do the provocative testing movements it may re injure the soft tissue.

**Group C – CONTROL GROUP (n=32)**

**Objective**

The purpose was to find out the efficiency of ultrasound therapy along with taping to reduce the pain intensity, to reduce the tenderness, to improve the active pain free range of motion and to improve the functional score of the subjects.
Intervention

The subjects allotted in this group were treated with Ultrasound therapy, Taping, Soft Tissue Mobilization finally stretching and strengthening in the last phase of treatment session.

Position of the subjects

The subjects were positioned comfortably and the treatment area was completely exposed for the treatment administration. The subjects were instructed not change position during the treatment.

Soft Tissue Mobilisation

The soft tissue mobilisation was given in all the three phase of treatment session. Technique was choosen according to the injured structure.

SOFT TISSUE MOBLISATION

Plantar Fascitis

The techniques used were light stroking to the top of the foot, spreading the metatarsals, Pettrissage sole of the foot, Deep pressure with the heel of the hand, Circular frictions and Cross friction massage to the heel.

Figure-62 –Pettrissage for foot Figure-63-Deep Pressure Foot
T.A Sprain

The techniques used were stroking, effleurage, Petrissage, Stripping the muscle and Circular frictions

Figure-64-Effleurage for T.A

Figure-65-Stripping for T.A

Ankle Sprain (Lateral Ligament)

The techniques used were stroking, effleurage & Cross frictions.

Figure -66-Cross Friction for Ankle lateral ligament
Quadriceps Strain

The techniques used were stroking, effleurage, Petrissage, Stripping the muscle and Circular frictions

Figure -66-Effleurage for Quadriceps Figure -67-Stripping for Quadriceps

Hamstring Strain

The techniques used were stroking, effleurage, Petrissage, Stripping the muscle and Circular frictions

Figure-68-Stripping for Hamstrings Figure-69-Petrissage for Hamstrings

Medial Collateral Ligament of Knee Sprain

The techniques used were stroking, effleurage and Circular friction.

Medial Epicondylitis

The techniques used were stroking, effleurage and Transverse friction.
Lateral Epicondylitis

The techniques used were stroking, effleurage and Transverse friction

Wrist Sprain (Palmar)

The techniques used were stroking, effleurage, finger Kneading and Circular Friction.

Wrist Sprain (Dorsal)

The techniques used were stroking, effleurage, finger Kneading and Circular Friction.

Stretching and strengthening

Stretching and strengthening was administrated on the second and third phase of the treatment sessions.

Stretching was administrated to stretch the tightened structures and it was maintained for thirty seconds in order to gain good effect.

In order to improve the fitness of the muscle, Macqueen’s strengthening protocol was administrated. The subjects were done forty lifts in one session with adequate rest period in between the thirty lifts weekly three times (10 lifts – Rest- 10 lifts –Rest- 10 lifts-Rest-10 Lifts) with the weight allotted to them.

Total Number of Treatment Session

The total treatment protocol was extended for the period of 5 days per week for three consecutive weeks and the total number of treatment session was 15.
Instruction to the subjects

All the subjects are instructed to maintain the fitness level without stressing injured structure. Subjects are instructed not to do the provocative testing movements it may re injure the soft tissue.

STATISTICAL ANALYSIS

The collected data on the selected variables scored as pretest before the treatment, post test 1 on 6th day during treatment, post test 2 on 12th day after the treatment and post test 3 on 18th day after the treatment intervention were analyzed using 5x4 Factorial Analysis of Variance as recommended by Ann Ruthestin (1985).

The collected data on the selected variables scored as pretest before the treatment and post test scores on 18th day after the treatment intervention were analyzed using Factorial Analysis of Covariance as recommended by Clarke and Khan (1986).

In all the cases 0.05 level was fixed as level of significance which was considered as appropriate. Bonferroni’s post hoc test was calculated to find out the significance of mean difference when the obtained ‘F’ value was greater than the required value to be significant.