EFFECTS OF ACUPUNCTURE IN NECK PAIN PATIENTS: A COMPARISON OF REAL AND SHAM ACUPUNCTURE

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SUMMARY

The aim of this project was to see the effects of acupuncture in neck pain patients. Two aspects were seen: first of all the effect of acupuncture on blood flow of hands, secondly what are the differences in real and placebo acupuncture?

In the first part of the 30 patients with neck pain for more than 3 months were taken. These patients were not having any cervical myelopathy, radiculopathy, malignancy, diabetes mellitus or were taking any vasoactive drugs. The patients were given a course of 10 sessions of acupuncture. During 1st, 3rd, 5th , and 10th session temperature of their hands were taken using infrared camera. Following a resting period of 20 minutes temperature was recorded before acupuncture (T0) was given, during the course of acupuncture at an interval of 5 minutes (T5, T10, T15, T20, T25) and 5 minutes after acupuncture (T30). It was seen there was an increase in temperature of the hands from the baseline, peaking at 20 minutes. Along with this the baseline temperature at 1st, 3rd, 5th, and 10th sessions were compared. It was seen that there was a significant rise in temperature of the hands at 10th session in comparison to the 1st session. A control group of 18 subjects with no neck pain was used for comparison. They were not given acupuncture and their temperature was recorded after a resting period of 20 minutes in a similar manner to above. In this group there was a significant decrease rather than increase in temperature over a period of 30 minutes. Another significant feature was that the baseline temperature of the neck pain patients was significantly lower than the normal control subjects, which became slightly normal following a course of acupuncture.

In the second part of the study, neck pain patients with similar complaints were recruited. These were randomly allocated into real and sham group using block randomization. Both group had 30 patients and they were very much similar to each other in the baseline values compared. These patients were given a course of 7 sessions of real or sham acupuncture. The outcome measures considered were: primary or subjective- VAS and NPAD score, secondary or objective- temperature of the hand and the pain pressure threshold. Temperatures of the hands were measured at 1^{st}, 3^{rd}, 5^{th} and 7^{th} session. Pain threshold was measured at 1^{st}, 5^{th} and 7^{th} session at four points: mid-trapezius, infraspinatus, mid-deltoid and mid-tibia. VAS score was noted at 1^{st}, 3^{rd}, 5^{th}, and 7^{th} session and the NPAD index was filled up at 1^{st} and 7^{th} session. Of the 30 patients in real group there were only 2 patients who did not complete the course but these two were pain free when they came for there 6^{th} session, in total 24 patients had improved and 6 had not improved. Whereas in the placebo group out of 30, 19 patients completed all 7 sessions, 11 patients came for 3-5 sittings. These patients did not continue, as they were not finding any improvement in their pain status. Of the 19 patients who completed all 7 sessions 10 were relieved and 9 patients did not improve. So in total of 30 patients 10 patients improved and 20 did not get relieved. We took the best-case scenario sensitivity analysis and considered that the patients who did not continue did not get relieved.

The VAS and NPAD score changes were significant in both groups but the change in VAS score was more significant in the real acupuncture group. The objective measures were different in the groups- in the real group there was a significant increase in temperature within the session as well as in the baseline temperature and pain pressure threshold also augmented. These changes were not seen in the placebo group.

Conclusion: Real acupuncture is superior to sham acupuncture in all the aspects measured in our study. As the other group also had pain relief suggests a strong placebo subjective effect. But this placebo effect does not bring about any objective changes.

ABBREVATIONS

TCA- Traditional Chinese acupuncture

DNIC- Diffuse noxious inhibitory control

ACTH- Adrenocortical tropic hormone

MTrP- Myofascial trigger point

m-RNA- Messenger ribonucleic acid

LTR- Local twitch response

SEA- Spontaneous electrical activity

EPN- End plate noise

ReP- Referred pain

EPM- Energetic placebo model

MPM-Metameric placebo model

VAS- Visual analogue score

NPAD- Neck pain and disability index

LV- Left ventricle

BDI- Beck's depression Inventory

EA- Electro-acupuncture

INTRODUCTION

1.1 Neck Pain

Neck pain is a common complaint with a point prevalence of 10-18% and lifetime prevalence of 30-50%. This leads to sick leave, cost of which is considerable (1,2). It is more commonly found in women then in men, the reason being women making a larger number of the elderly population, their smaller physical size and strength. (3)

Neck pain is caused by various reasons such as mechanical strain, whiplash injury, disc herniation, systemic disorders etc. The most common cause is cervical spondylosis/. It has got various synonyms as degenerative disc disease, degenerative spondylosis, osteophytosis and spondolytic deformans. It is a vertebral ankylosis (immobility of a joint) (4). Spondylosis is a term applied to changes noted in spine radiologically which are significant as narrowing of disc height, presence of osteophytes arising from disc margins, osteoarthritic changes in post zygapophyseal joints. The etiology for the formation of osteophytes is still unknown and also whether these osteophytes are mechanically responsible for encroachment upon neural tissue resulting neurological symptoms. The latest theory for the formation of osteophytes is that because of the presence of uncovertebral joints of von luschka, osteophytosis is of greater incidence in cervical spine than in lumbar spine where these joints do not exist. As these joints are pseudo joints – essentially exostoses- they have no cartilage intervening and being approximating articulating osteoarthroses, they enlarge and deform from repeated friction, compression and abrasion.

1.2 Symptoms following changes in the vertebra-

Anterior narrowed disc space and posterior longitudinal ligament thickening- This leads to limitation of normal range of motion. This range of limited motion is not noted until upon examination as 30-40 degree of flexion – extension and 75-90 degrees of rotation occur at occipital level where similar changes do not occur.

Pain- pain occurs if there is superimposed trauma, acute recurrent tension, anxiety or faulty postural changes. The osteoarthritic changes do not cause pain.

Reduction in the width and depth of intervertebral foramina along with the presence of osteophytes- leads to nerve root entrapment symptoms as numbness, tingling, and needle pricking sensation. Motion- extension and or rotation intensify the pressure of osteophytes on nerve root. Faulty posture also clearly intensifies the propensity of nerve root entrapment.

Cervical radiculopathy- sensory manifestations are more noted by the patient rather than motor. As the sensory root lies in proximity to posterior zygapophseal joints which leads to earlier sensory symptoms and that is why electromyography results are usually negative. Nerve root symptoms according to the region – interscapular C5, C6; upper extremity C5, C6; thumb C6; ring & little finger C7, C8. Commonest nerve root involvement is at C6-C7 levels causing paraesthesia and pain radiating to radial side of arm to fingers.

1.3 Treatment remedies available-

1. Restoration of physical posture- decrease forward head posture and decrease excessive lordosis.

2. Supine traction with the angle, force, and duration of traction, which is determined by the tolerance and response reaction of the patient. (5,6,7)

3. Neck brace to avoid excessive motion and provide proper posture. This should be used for limited time period only to allow inflammation to subside but not too long which might lead to disuse or dependence. (8)

4. Anti-inflammatory drugs or antidepressants, whenever indicated and considered to contribute to excessive pain and to influence posture.

5. Acupuncture

6. Spinal manipulation is the use of high velocity, short amplitude thrust to move the joint passively beyond the point at which it could be moved actively by the patient. (2)

1.4 Patient Distribution

Of all the patients who attended the National University Hospital (NUH) acupuncture clinic in the year 2001-02 with complaint of pain, neck pain formed up to 25-30% of patients, the rests had complaints of low back pain, migraine, headaches, knee, ankle pain, tennis elbow, frozen shoulder etc. The following bar chart shows depictive representation of patient distribution in NUH acupuncture clinic. (Figure1)

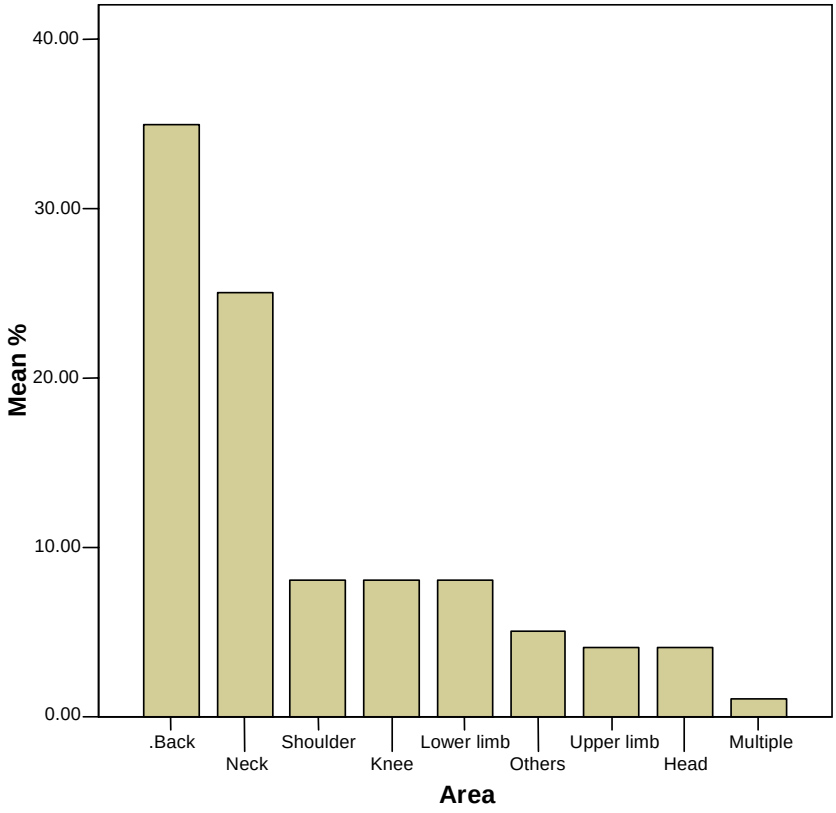

Figure 1: Bar chart showing patient complaints distribution at NUH acupuncture clinic. (Data collected from NUH pain clinic in 2001-02)

1.5 **History of acupuncture**

Acupuncture is a part of traditional Chinese medicine. It is believed to have originated in China and has history in literature dated back to 200 B.C continuing till present (9-11). Use of acupuncture in china has had its waxing and waning periods. The oldest known text is the Yellow Emperor's *Classic of Internal Medicine. (Huang Ti Nei Ching)*. Acupuncture flourished in China during the Ming dynasty. (1368-1644). It was forbidden during the rule of Emperor Dao Guang, as he considered it as an insignificant and petty skill. In the early part of twentieth century there was conflict in two factions of China, one wanting to rid China of everything superstitious and unscientific, and the other not wanting to surrender Chinese culture to western influence (12) It was reintroduced with full force by the communist government in 1950s to cater its huge population It was presented to Japan in 552 AD and flourished over next 200years. It arrived in Europe by Jesuit missionaries in sixteenth century. It has been present in Northern America since early 19th century but a great interest in acupuncture following President Nixon's visit to China in 1971. (13) It was given recognition by W.H.O in 1975 for specific indications and contraindications. Since 1975, W.H.O along with China opened up international training courses in Beijing, Shanghai and Nanjing. These training centers have trained acupuncturist for many countries. (14) Many researches are being done to justify the scientific use of acupuncture and not just a placebo effect.

Acupuncture is derived from Latin word 'acu'- meaning needle and 'puncture' meaning to put in. It is a loose translation of the Chinese term 'zhen jiu' which actually means 'zhen'- needle (therapy) and 'jiu'- cauterization (moxa therapy). It refers to the insertion of dry needles at specifically chosen sites, for the treatment or prevention of symptoms

and conditions. Indications include acute and chronic pain syndromes, allergic disorders, addictions, psychosomatic and psychosexual illness and acupuncture anesthesia and analgesia.

1.5.1 The contraindications for use of acupuncture are-

- Acute bacterial infections
- Cancer
- Bleeding or coagulation disorders
- Patients with pacemakers cannot receive electro-acupuncture therapy.

1.5.2 The list of 43 conditions recommended by W.H.O in 1979 are as follows (15)

- *Respiratory*

  Acute sinusitis, acute rhinitis, Common cold, acute tonsillitis

- *Bronchopulmonary diseases*

  Bronchial asthma, acute bronchitis,

- *Eye disorders*

  Acute conjunctivitis, Cataract, Myopia, Central retinitis

- *Disorders of mouth cavity*

  Toothache, Pain after tooth extraction, Gingivitis, Pharyngitis

- *Orthopedics*

  Per arthritis humeroscapularis, Tennis elbow, Sciatica, Low back pain, Rheumatoid arthritis.

- *Gastrointestinal*

  Spasm of esophagus, Hiccups, Gastroptosis, Gastric hyperacidity, chronic duodenal ulcer, Acute and chronic colitis, acute bacterial dysentery, Constipation, Diarrhea, Paralytic ileus.

- *Neurological*

  Headache, Migraine, Trigeminal neuralgia, Facial paralysis, Paralysis after apoplectic fit, Peripheral neuropathy, Paralysis by polio, Meniere's syndrome, Neurologic bladder syndrome, Nocturnal enuresis, Intercostals neuralgia.

1.5.3 The adverse effects of acupuncture are very few - (provided given by qualified acupuncturists**)**

1. Delayed or missed diagnosis (16)
2. Deterioration of disorder under treatment (17)
3. Pain- persistent pain at the needle insertion site
4. Syncope- vasovagal attack (18)
5. Drowsiness
6. Septicemia (19)
7. Hepatitis- not prevalent these days as sterile needles are used
8. Cardiac tamponade (20)
9. Pneumothorax- this is the most frequently reported injury, either unilateral or bilateral. (21)

Studies conducted by Ernst et al, pointed out that the incidence of these side effects are negligible when compared to drug-induced complications / side effects, as drugs are between 4th and 6th leading cause of death in U.S.A (22).

1.6 Mechanisms of action of acupuncture

Several physiological mechanisms of acupuncture have been proposed accounting for its pain relief. Spinal and supraspinal endorphins and even activation of Diffuse Noxious Inhibitory Control (DNIC) has also been proposed. (23) Researches have shown that electro acupuncture of varying intensity has different changes in the m-RNA expression of (pre)proopiomelanocortin, preproenkephalin and preprodynorphin (24, 25). Other neurochemicals such as serotonin, noradrenaline and ACTH have also been involved.

1.6.1 Acupuncture physiology has been summarized as follows:

1. ***Acupuncture needle inserted within the segment of pain (Spinal gate control mechanism).***

Melzack & Wall introduced the gate control theory in 1965. (26) The pain carrying fibers are A delta II (skin), III (muscle) which are the myelinated ones; the unmyelinated are C fibers (skin) & IV (muscle). (Figure 1)-→ These fibers reach the spinothalamic tract cells in the spinal tract. (2nd cell)--→ Thalamus (3rd cell)→ Cortex (4th cell).

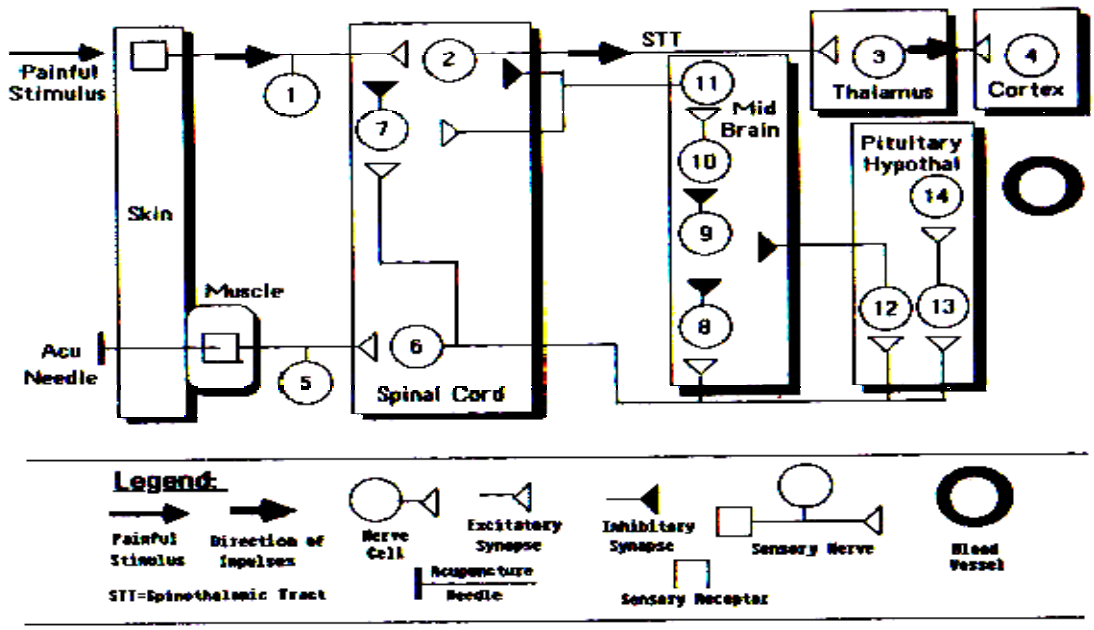

Fig2: Pain transmission pathway (27)

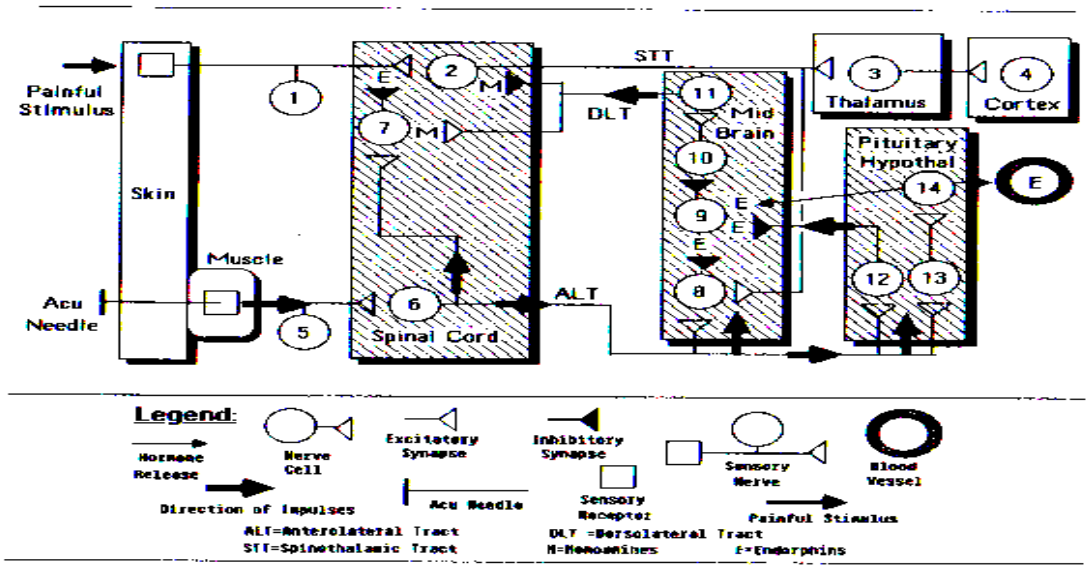

Fig 3: Acupuncture pathway (27)

Legend for Fig.2 and Fig. 3

Cell 1- Cell at painful site; *Cell 2*- Spinothalamic tract cell; *Cell 3*-Thalamus; *Cell 4*- Cortex; *Cell 5*- Muscle afferent nerve; *Cell 6*- Anterolateral tract in spinal cord; *Cell 7*-Endorphinergic cells; *cell 8&9*- Periaqeductal cell; *Cell 10*- Cells in the mid brain; *Cell 11*- Raphe nucleu; *Cell 12 &13 &14*-Pituitary hypothalamic complex

Acupuncture when applied**,** sends impulses to spinal cord via type II & III muscle afferent nerves (5^{th} cell). These are thought to signal numbness (II) and fullness (III) sensation of de qi needling sensation. Along with this the fibers from skin via A delta and C fibers reach anterolateral tract in the spinal cord (6^{th} cell). From here impulses are sent to spinal cord, mid brain and pituitary hypothalamic complex. The cell in the spinal cord (6^{th} cell) sends a short segmental branch to an endorphinergic cell (7^{th} cell) which releases enkephalin or dynorphin but not β endorphin. This endorphin causes presynaptic inhibition of pain carrying fibers (1st cell), preventing transmission of painful message from cell 1 to cell 2. This probably works by reducing calcium inflow during the action potential, resulting in reduced release of pain transmitter.

The projection from the anterolateral tract to mid brain excites cells in the periaqeductal grey (8^{th} & 9^{th} cell), which release enkephalin to disinhibit the cell 10 (which is thus excited) and this in turn activates the raphe nucleus (11^{th} cell) (located in the caudal end of medulla oblongata). Impulses from raphe nucleus (11th cell) are sent down to dorsolateral tract to release monoamines (serotonin and nor epinephrine) onto the spinal cord cells. The spinal cord cell (2^{nd} cell) is inhibited by postsynaptic inhibition while the pain-stimulated cell (1^{st} cell) is presynaptically inhibited via the endorphinergic cell (7^{th} cell). (The endorphinergic cell is excited while the spinal cord cell is inhibited by monoamines). (Figure 2.)

2. Non- segmental effect

Cell from the anterolateral tract (6^{th} cell) sends impulses on to the cells in the pituitary hypothalamic complex (12^{th} &13^{th} cell). Cells in this complex activate raphe nucleus

via endorphin and cell 13 stimulates the pituitary gland to release β-endorphin. As to how the β-endorphin from pituitary reaches the brain to cause analgesia is not known, while it has been shown that elevated levels of β-endorphins in C.S.F and blood accompany acupuncture analgesia. The amount in the blood is too little to cross the blood brain barrier. Some evidence suggests that the pituitary-portal venous system can carry hormones in a retrograde direction directly to brain. The release of pituitary β-endorphin is correlated with an equimolar release of ACTH and MSH, as all of them have a common precursor. Acupuncture has been found to be similar to physical activity, stress as in these conditions also there is release of ACTH and MSH. This complex is stimulated not at high but on only at low frequency stimulation (27).

1.6.2 Practical features of acupuncture -

1. Local segmental needling usually gives a more intense analgesia than distal non-segmental needling, as it uses the entire 3 centres (spinal cord, midbrain, hypothalamic pituitary complex). Generally the two approaches are used together to enhance the effect of one another.

2. Difference in the frequency and intensity of stimulation: Low frequency (2-4 Hz), high intensity needling works through the endorphin system and activates all the 3 centres, which produces analgesia of slower onset of long duration, outlasting the 20 min stimulation session. Its effects are cumulative, become increasingly effective after several treatments. High frequency (50-200 Hz), low intensity needling only activates cells in the spinal cord and midbrain, bypassing the endorphin system. This is rapid in onset, but of very short duration, with no cumulative effects.

The above pain relief mechanism by acupuncture has been accepted on the fact that, it was reversed by giving naloxone (endorphin antagonist). (28, 29)

1.6.3 Modes of treatment -

The methods of treatment range from strict Traditional Chinese Acupuncture (TCA) approach based on meridians with needling sensation elicited at multiple sites to an orthodox diagnostic approach followed by superficial brief needling. The majority of medical acupuncture practitioners trained by eastern or western schools practice somewhere between these approaches, using a combination of trigger points, tender points, segmental points and the most commonly used traditional points referred to as 'strong' points.

Other acupuncture techniques in common use in the west is electro- acupuncture and use of semi permanent indwelling needles.

Western-based acupuncture treatment is used in the following conditions-

1. Painful conditions: Myofascial pain- trigger points approach to treatment

2. Non-myofascial pain: nociceptive pain and visceral pain- best approached with segmental acupuncture

3.Neurogenic pain- where direct segmental stimulation may be effective or may exacerbate symptoms, in which case an extra segmental approach may be used.

4. Acute or post-surgical pain.

5. Non-painful conditions-commonly treated with a local or segmental approach or for generalized conditions a selection of well known traditional points.

1.6.4 Myofascial trigger points (MTrP) -

A myofascial trigger point as defined by Travell and Simons (30) is a hyper irritable focus within a taut band of skeletal muscle or its associated fascia. The trigger point is painful on compression and can exhibit a characteristic referral pattern of pain or autonomic dysfunction and may also exhibit a jump sign and twitch response.

In our study we used pressure algometer as an objective mean to identify the muscle pain threshold of some predetermined muscle points before and after treatment.

Neurophysiological evidence of tender point -

Hubbard and Berkoff demonstrated that myofascial tender point showed increased electrical activity within an area of 1 or 2mm around the tender point relative to a normal area of same muscle. (31) Such similar results were also shown by Ward (32), who demonstrated spontaneous electrical activity in tender points at 2 locations that were also acupuncture points. Further studies showed that a physiological stressor significantly increased the electrical activity of trapezius tender point compared to a non-stressful control task. (33,34)

There are multiple MTrP loci in an MTrP region. An MTrP locus contains a sensory component (sensitive locus) and a motor component (active locus). A sensitive locus is the site from which pain, referred pain (ReP), and local twitch response (LTR) can be elicited by needle stimulation. Sensitive loci are probably sensitized nociceptors based on a histological study. They are widely distributed in the whole muscle, but are concentrated in the endplate zone. An active locus is the site from which spontaneous electrical activity (SEA) can be recorded. Active loci are dysfunctional endplates since

SEA is essentially the same as endplate noise (EPN) recorded from an abnormal endplate as reported by neurophysiologists. Both ReP and LTRs are mediated through spinal cord mechanisms, demonstrated in both human and animal studies. The pathogenesis of MTrPs appears to be related to the integration in the spinal cord (formation of MTrP circuits) in response to the disturbance of the nerve endings and abnormal contractile mechanism at multiple dysfunctional endplate to a physiological stressor. (35)

1.7 Effect of acupuncture on the nervous system

1.7.1 Autonomic nervous system

Acupuncture, through activation of beta endorphinergic system, affects vasomotor areas in the brainstem, thereby regulating sympathetic tone. This occurs in two phases. 1st phase is the excitation phase, which leads to increased sympathetic tone with increased heart rate, blood pressure and cardiac output. 2nd phase of depression following continuing sensory stimulation for about 20-40 min leads to the release of endogenous opioids, which produce central inhibition of sympathetic outflow. This inhibition is dependent on the functional state of the body. Thus, acupuncture decreases the sympathetic activity in hypertension (resulting in a decreased blood pressure) but gives the opposite effect in the hypotensive state resulting in increased blood pressure. This is probably related to the regulatory function of the baroreceptor reflex and different sensitivity of baroreceptor in hypotension and hypertension. The majority of work concerning sensory stimulation on cardio vascular system highlights the importance of sympathetic, not vagal nerves as the efferent reflex limb. But Nishijo et al (1991) demonstrated that increased parasympathetic activity was also due to increased vagal tone, rather than just decreased sympathetic activity. (36)

A recent study showed that acupuncture at sishencong points located on the vertex of the head enhanced cardiac vagal and suppressed sympathetic activities in humans, implicating its importance in stress in which there is vagal withdrawal and/or sympathetic over activity. (37). Knardahl et al showed a significant transient increase in muscle sympathetic nerve activity, along with moderate increase in pain threshold. Such changes were not seen in placebo control group in which only needles were inserted with no stimulation. (38)

Another recent study shows that sympathetic and parasympathetic stimulation in healthy individuals depends on the site of sensory stimulation and period of observation. This study used power spectral analysis, the low frequency and high frequency components of heart rate, which was used to measure the sympathetic and parasympathetic neural activity. Stimulation of the ear induced a significant increase in the parasympathetic activity during the stimulation period of 25 min and persisted during the post-stimulation period of 60 min. No significant changes were observed in the sympathetic activity, blood pressure or heart rate. Stimulation of the thenar muscle resulted in a significant increase in the sympathetic and the parasympathetic activity during the stimulation period and during the post-stimulation period. A significant decrease in the heart rate frequency at the end of the post-stimulation period was also demonstrated. The superficial needle insertion into the skin overlying the right thenar muscle caused a pronounced balanced increase in both the sympathetic and parasympathetic activity during the post stimulation period of 60 min while no changes were observed during the stimulation period. (39). These suggest that at different times and at different locations effect of acupuncture on autonomic nervous system is different.

1.7.2 Peripheral blood flow

Peripheral blood flow is correlated to the autonomic (sympathetic) tone of the body, as increased sympathetic activity leads to decrease blood flow whereas decreased sympathetic tone leads to increased blood flow. Therefore we can use the change in skin blood flow to reflect the state of the autonomic tone. Ernst & Lee (40) using thermography found electro-acupuncture produced a temporary increase in sympathetic activity locally during stimulation, followed by a sustained decrease in sympathetic tone as shown by vasodilatation, in the whole body especially in both hands.

Moehrle and colleagues (41) did a randomized controlled trial in patients with Raynauds syndrome and showed a significant reduction in the rates of attacks and increased blood flow. Blood flow during cold stress was gauged by red cell velocity, measured with Doppler flow meter and capillaroscopy.

A recent study done by Sanberg et al in patients with fibromyalgia showed a significant increase in blood flow in the muscle. Such significant increase in blood flow was not seen in the skin of healthy females suggesting a greater sensitivity to pain and other somatosensory input in patients of fibromyalgia. (42) Blood flow impedance in the uterine arteries of infertile women was seen reduced following a course of electro-acupuncture (8 sessions) and even 10-14 days after last session. Along with this skin temperature of the forehead and lumbosacral area was also significantly increased during the session. This suggests a central inhibition of the sympathetic activity. (43)

Following up the previous studies on neiguan (P 6) point on the forearm, overlying the trunk of median nerve, which showed that electro-acupuncture, had a depressor response (in myocardial ischemic dysfunction) as well as presser response (in hemorrhagic hypotension). Syuu et al showed that neiguan EA achieved the antihypotensive effect by improving left ventricular (LV) filling of the hemorrhage depressed LV performance despite the inhibition of the hemorrhage increased plasma catecholamines. This presser effect seemed to accompany an increase in venous return by neiguan EA increased vasomotor tone and muscle pump as administration of vecuronium (a neuromuscular blocking agent) blocked this effect. (44)

1.7.3 Effect of acupuncture on other organs

Acupuncture was seen to improve changes in external respiration function, psychological status and bronchial permeability in patients with bronchial asthma, thus correcting the disorders of the autonomic nervous system. The placebo control group did not show any improvement. (45) Acupressure has also been shown to be of benefit in children with psycho autonomic neurotic disorders. Relative augmentation of sympathetic activity was observed in patients with initial vagotonia, while those with initial sympathicotonia exhibited a relative increase in parasympathetic activity. (46)

1.8 Various types of controls for acupuncture studies

The methodological difficulty and challenge in finding suitably acceptable controls for acupuncture trials is probably the biggest obstacle to the acceptance of this technique by the conventional medical community. The possible choices of control can be-

- *No treatment or waiting list*

  This is considered ethically justifiable in trials of chronic, stable conditions.

- *Comparison with alternative treatment or standard care*

  These trials require acupuncture to be at least as good as standard care to establish its efficacy and have the advantage of treating all the patients in the study.

- *Invasive placebo controls*

  Controlled needling techniques available is used for needling at non-acupoints located either intra- or extrasegmentally, or superficial needling at non-acupoints intra- or extrasegmentally or at the correct points. Clinical studies with placebo acupuncture as placebo, which consists of needling outside the meridian, but near to classical acupoints (45 trials) was classified as energetic placebo model (EPM). Another 45 studies using a placebo treatment consisting of needling within a segmental zone far away from the active points were classified as neurophysiological or metameric placebo model (MPM). Studies using EPM as placebo failed more frequently to show any differences between real acupuncture and placebo treatment than those using MPM as placebo control. On the other hand, placebo acupuncture appeared almost as active as 'real' acupuncture. These results suggest that the design and the way of performing the placebo procedure can influence the outcome, i.e. success or failure of a clinical trial in obtaining differences among the patients groups, in case they actually exist. (47)

- *Non-invasive placebo acupuncture controls*

  The simulated acupuncture procedure represents a reasonable control treatment for acupuncture-naive individuals in randomized controlled trials assessing the efficacy of acupuncture. (48). A placebo needle has been designed which telescopes instead of penetrating the skin. The Park Sham Device involves an improved method of supporting

the sham needle. Results have suggested that the procedure using the new device was indistinguishable from the same procedure using real needles in acupuncture naive subjects, and is inactive, where the specific needle sensation (de qi) is taken as a surrogate measure of activity. It was therefore a valid control for acupuncture trials. The findings also lend support to the existence of de qi, a major concept underlying traditional Chinese acupuncture. (49)

White et al found that most patients were unable to discriminate between the needles by penetration; however, nearly 40% were able to detect a difference in treatment type between needles. No major differences in outcome between real and placebo needling could be found. The fact that nearly 40 % of the subjects did not find that the two were similar raises some concerns with regard to the wholesale adoption of this instrument as a standard acupuncture placebo. (50-52)

- *Inactivated Transcutaneous Electric Nerve Stimulation (TENS)*
- *Laser therapy*

This therapy has the advantage that, whether active or inactive they cannot be felt by the patient. The operator can also be unaware whether the instrument is active, and therefore true double blind studies can be performed.

- *Local anesthetic prior to needling*

We cannot be sure whether all sensation are blocked or not, incomplete blockade.

1.9 Systematic reviews of clinical trials on acupuncture for neck pain

White and Ernst (53) included all randomized control trials, which were suitable according to Jadad score. Of 32 relevant trials conducted, only 14 were of acceptable

quality and these also were highly heterogeneous among themselves. Out of these 14 trials, 2 studies used laser acupuncture. Overall, the outcomes of the 14 randomized controlled trials were equally balanced between positive and negative. Acupuncture was superior to waiting list in one study, and either equal or superior to physiotherapy in three studies. Needle acupuncture was not superior to indistinguishable placebo control in four out of five studies. Of the eight high-quality trials, five were negative and 3 were positive. The authors conclude that acupuncture is efficacious in the treatment of neck pain is not based on the available evidence from sound clinical trials. Further studies are needed to justify its use.

In another meta analysis conducted by Lesley et al (54) all included trials were scored using a five-item 0-16 point validity scale (OPVS). The individual RCT was ranked according to their OPVS score to enable more weight to be placed on the trials of greater validity when drawing an overall conclusion about the efficacy of acupuncture for relieving neck and back pain. Thirteen RCTs met the inclusion criteria. Five trials concluded that acupuncture was effective, and eight concluded that it was not effective for relieving back or neck pain. There was no obvious difference between the findings of trials using traditional and non-traditional points. With acupuncture for chronic back and neck pain, they found that the most valid trials tended to be negative. There was no convincing evidence for the analgesic efficacy of acupuncture for back or neck pain.

Aker et al conducted a Meta analysis on various modalities present for the treatment of neck pain and also concluded that more studies need to be done to pin point one specific modality to be superior to another.(1)

However, a recent RCT for neck pain on 24 females has shown a long-term effect up to 3 yrs. (55)

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1.10 Thermography

Infrared thermography is a technique to assess body temperature. Every object whose temperature is above absolute zero emits infrared energy in the form of invisible light; this self-emitted energy may be collected optically, transformed into proportional electrical impulses and then converted to visible light to form a picture or thermogram. Since the amount of infrared light given off by any object is a function of its temperature, such thermograms are in reality quantitative representation of the objects surface temperature. Electronic thermogram can measure the skin surface temperature to an accuracy of 0.1°centigrade. Other techniques, which can measure temperature directly or indirectly, are contact thermography, video thermography and laser doppler.

Sherman et al (56) compared effectiveness of video thermography, infrared thermography and contact thermography and concluded that contact thermography was unable to accurately image many areas with curved surfaces and was unable to produce accurate recordings when several sensors with differing temperature ranges had to be used on the same subject. It was relatively inaccurate when measuring heat producer. Video thermography was easy to use and produced excellent recording but was difficult to transport, required liquid nitrogen and 110V of electricity. In contrast advantages of infrared thermography are: non- contact method, can cover wide area, requires no external illumination or irradiation of object or may be made in total darkness, easy to operate and portable, stored images which can be processed later.

Laser Doppler, which can measure the flow, can also be used but is very expensive, as it requires separate probe for separate patients.

Various studies conducted on the use of infrared thermography have come to a conclusion that thermography is a good adjunct to diagnose any musculoskeletal disorder but not as a complete diagnostic tool (57- 61).

In this study on acupuncture for neck pain using thermography, we want to see whether there is any difference in real and placebo acupuncture regarding the changes in the autonomic tone and are there any difference in the normal group of people and patients with neck pain with respect to their baseline autonomic tone.

1.11 Algometry

The term 'algometer' was coined by Head and Keele (62). Pressure algometer is a very sensitive device designed to measure forces applied to very specific locations on the patient. The size of the tip used can be 0.5 cm^2 or 1 cm^2.

Pressure threshold is defined as the minimum pressure (force) required for causing minimal amount of pain. The average pressure thresholds for males and females at various points have been done by Fischer (61- 64). The specific locations used in our study were - upper trapezius, infraspinatus, middle deltoid and mid tibia. These points were chosen in our study, as patients with neck pain frequently complain pain over the trapezius muscle; infraspinatus and deltoid muscles are supplied by cervical nerves (C5,6) correspond to the

same spinal cord segment of the neck pain; mid-tibia point was taken as a reference point, to see whether there was any change in the pain threshold at the distant points.

Algometry has been used clinically to document fibrositis (65), fibromyalgia (66), identification of trigger points sensitivity (67, 68), quantification of joint tenderness in arthritis condition, evaluation of pain sensitivity, and abdominal pain. It has also been shown effective for evaluating the results of pain relieving modalities such as anaesthetic blocks, heat manipulation, and anti-inflammatory and for documenting long-term effectiveness of treatment.

Fischer has demonstrated an excellent reliability and reproducibility with pressure threshold measurements using the algometer. Reeves et al has also demonstrated a high inter- and intra related reliability for testing marked trigger points and for locating unmarked trigger points in the temporo-mandibular region. (67)

1.12Neck Pain Questionnaires (Table 1)

In contrast to scales measuring overall health issues, region specific functional status can concentrate on a more restricted body function; they are expected to have greater responsiveness and better content validity than the more general or global scales. The Neck Pain and Disability Index (NPAD) differ from other measures of neck pain because it is more responsive to the multidimensional nature of the pain experience. Chronic pain is acknowledged to be a complex perceptual experience with a number of underlying factors that include sensory, affective and intensity dimension. This questionnaire permits a comprehensive assessment of the patient's neck pain. Although NDI demonstrates

reliability and validity as a disability scale, there is no evidence that it addresses all aspects of pain experience. Also, the Neck Disability Index (NDI) included 10 items geared towards assessing disability following injury to cervical spine, which were not relevant to our patients.

NPAD is a 20-items questionnaire (appendix 1) that measures problem with the neck, intensity of pain, its interference with functional aspects of life and the presence and extent of emotional factors. The strong correlation between the Becks Depression Inventory (BDI) and NPAD confirmed the association between depression with the patient's perception and report of pain and disability. This indicates NPAD is an emotionally receptive measure. The patients respond to each item by marking on a10 cm scale. Items score range from 0-5 in quarter point increment. The VAS score provides immediate information, is simple to use, does not require physical measurement and is sensitive to varying pain intensities. Although the use of VAS score rating has been questioned, the NPAD combines scales and descriptive terms allows the patient to express some dimensions of his or her pain beyond pain intensity. The NPAD score is the sum of the item scores. Higher scores correlate with greater disability. The time required to fill up the questionnaire is less than 5 minutes. (69)

No.	Name of the Questionnaire	Author	Administration	Constructs Measured	Reliability & validity	Assessment
1	Neck disability index (NDI)	Vernon H.S. Moir 1991	10 items	Neck pain & disability score using a% of max pain & disability	.6-.7 correlation with other indices. Ceiling effect for very sick patients	Elderly who do not drive will have missing data.
2	Copenhagen	Jordan A.C., Manniche, C,(1998)	15 items	Neck dysfunction for individual with chronic neck pain	Test-retest reliability excellent. Validity measured by comparison of the scale score with self reported pain and physician assessment.	none
3	Northwick park neck pain questionnaire	Leak A.M., J.Cooper, S.Dyer, K.A.Williams (1994)	Nine five part Questionnaire	Neck disability in patients with long term neck pain	Correlation coefficient .8 3-day test retest reliability good. No validation	Rheumatology patients up to age 85 were tested

TABLE 1: Comparison of the neck pain specific questionnaire (70)

No	Name of the questionnaire	Author	Administration	Constructs Measured	Reliability & validity	Assessment
4.	Neck pain and disability scale	Wheeler A.H., P.Goolkasian, A.C.Baird, B.V.Darden (1999)	20 item self assessed questionnaire using visual analogue scale	4 dimensions neck problem. Pain intensity ,emotional and cognitive effects of pain, and interference with life activities	Reliability of entire scale was excellent, but was not determined separately for each of the dimensions. No validity comparisons have been made	None
5.	Patient specific functional scale self reports with neck dysfunction	Westaway M.D., P.W.Stratford, J.M.Binkley (1998)	Patients list activities, which they are unable to do or have difficulty with performing. Activities are ranked according to a dysfunction level on a scale 0(unable) to 10(no problem).3sections:pain affected activities, functional limitations, pain intensity	None since patients self define the items reported	Total score are correlated with pain scores and the neck disability index. 72 hr test retest reliability is high. Very responsive to change	None

TABLE 1: Comparison of the neck pain specific questionnaire (70)

1.13 Aims of our study

1. ***To evaluate the effects of electro acupuncture (EA) on visual analogue scale (VAS) for pain, and skin temperature of both hands, in patients with chronic mechanical neck pain.***

2. ***To compare needle and placebo EA in patients with chronic mechanical neck pain; using VAS score, neck pain and disability index (NPAD) scores, muscle pressure pain threshold and skin temperature of both hands as the outcome indicators.***

CHAPTER 2

MATERIALS AND METHODS

This study was done in two parts. The first part was a pilot study, the objectives were to evaluate the effect of a course of EA therapy on patients with chronic mechanical neck pain, and the changes in skin temperature following acupuncture compared to the control.

The second part was a single blind, randomized, placebo controlled study comparing acupuncture with placebo in the treatment of mechanical neck pain.

2.1 Pilot study to evaluate the effects of acupuncture in patients with mechanical neck pain

In the pilot study, 30 adult patients consisting of 22 female and 8 males were recruited. The patients enrolled into this study had come to the NUH acupuncture clinic with the complaint of neck pain. The Institution Review Board approved the research protocol and written informed consent was obtained from the patients.

2.1.1 Inclusion criteria

1.Patients with neck pain with ≥ 3 months duration.

2.VAS score of ≥ 3.

2.1.2 Exclusion criteria

The patients included were not having cervical myelopathy, malignancy, diabetic neuropathy, and were not taking any vasoactive medications. Patients having history of whiplash injury were also not included.

2.1.3 Treatment schedule

Patients were given a course (10 sessions) of acupuncture for pain relief. They were advised to come 2 times in a week. Recording of the infrared thermogram and VAS score will take place on the 1st,3rd, 5th and 10th treatment session.

During the treatment session, temperatures of the dorsum of both hands were taken before, during (at 5 min interval till 25 min), and 5 min after EA treatment. Thermographs (Tsk) of the hands were taken using Infrared camera THERMACAM™ PM575 (Sweden), in a draft free and quiet room with soft light, room temperature was controlled between 23-25℃. Subjects were instructed not to eat, drink or smoke anything for at least 2 hours prior to the treatment session. Subjects were tested in a comfortable sitting position with hands at pronated position and resting on a cushion, below heart level. The thermo graphic assessment was done after 20 minute rest period to acclimatize the subjects to the experimental setting and to stabilize their Tsk. The thermo grams for the dorsal aspect of both hands were taken with the camera at a standardized position (distance and height) in relation to the subjects. The distance was kept constant at 1.5 meters.

The recordings were taken just before acupuncture, followed by an interval of every 5 min during electro acupuncture for 25 min, till 5 minutes after EA was stopped.

***Recordings*:**

1) **T0**: Recorded immediately after rest period.

An acupuncturist treated patients with standard acupuncture needles (Hwato, China, Φ0.25 mm, L 25-40 mm) and de-qi sensation was induced. The number of the needles used varied from 7-14. Needle acupuncture was performed at GB 20 (Feng Chi), GB 21(Jian Jing), and Huatuojiaji at C5 (this is a series of 28 pairs of acupoints, located 0.5 cm lateral to the lower border of the spinous process) bilaterally and any trigger points and / or tender points the patient might have**.** Distal points on the forearm and hands were avoided. Following placement of the needles, an electric stimulator (HANS LY 275, Singapore) was used to deliver a 15 Hz alternating with 2 Hz stimulation, with the intensity adjusted to suit the patients. The patients were not given any moxibustion or external heat source as these therapies could increase the temperature.

2) **T5**: Recorded after 5 minutes of acupuncture stimulation.

3) **T10**: Recorded 5 minutes after T5

4) **T15**: Recorded 5 minutes after T10.

5) **T20**: Recorded 5 minutes after T15.

6) **T25**: Recorded 5 minutes after T20.

Needles were removed after the T25 reading.

7) **T30**: Recorded 5 minutes after removal of the needles.

Mean temperatures were calculated after drawing the outline of both hands using AGEMA Thermo vision 2.1 software (Secaus, New York).

2.1.4 Outcome Measures

1. Severity of neck pain as assessed on VAS (0-10).
2. Temperature of both hands as measured by thermography.

2.1.5 Control group

Similar temperature measurements in the same environment were taken from a group of healthy volunteers without EA for comparison. In the control group of 18 people, 12 were female and 6 male. Most of the people recruited were the staff working in NUH. This group of subjects had no history of neck pain. For this group the readings were just taken once.

Recording

The subjects were advised not to eat, drink or smoke at least 2 hours prior to the recordings. They were made to acclimatize in the similar draft free environment, 23-25°C. They were not given any acupuncture. Thermo graphic readings were recorded at T0, T5, T10, T15, T20, T25, and T30 at 0, 5, 10, 15, 20, 25, 30 minutes, after 20 minutes of acclimatization.

2.2 Comparison of needle and placebo acupuncture

2.2.1 Subject selection

In the 2nd part of the study the inclusion and exclusion criteria's for the patient were same as the pilot study. The enrolled subject should be having neck pain for more than or equal to 3 months duration and a VAS of more than or equal to 3 and should not be having cervical myelopathy, malignancy and not taking any vasoactive drugs.

2.2.2 Randomization

With block randomization patients were allocated into the needle or placebo group.

60 patients were enrolled into the study. The Institution Review Board approved the research protocol and written informed consent was obtained from the patients.

Blinding

It was a single blind study with the patient being unaware whether he or she is in the needle or placebo group.

2.2.3 Outcome measures

1. VAS score
2. Temperature changes
3. NPAD index questionnaire
4. Muscle pressure pain threshold readings at mid trapezius, infraspinatus, mid-deltoid and mid-tibia point.

2.2.4 Treatment schedule

The patients recruited for the RCT were advised to come for 7 sessions, twice a week. The course of treatment was shortened to seven sessions (compared to ten in the pilot study) as almost half the patients participated in the pilot study could only attend up to 6 to 7 sessions due to their work commitment. Furthermore, results from the pilot study showed that significant improvement could be expected by the 6^{th} session.

Sessions

First session: Following history and physical examination, the patient was assigned to needle or placebo group according to the block randomization chart. The readings were recorded in a case record form. (Appendix 2) The patient was asked to fill up the NPAD questionnaire and the VAS score was noted. Digital pressure algometer was done on 4 sites: mid-trapezius, infraspinatus, mid-deltoid & mid-tibia to measure the muscle pressure pain threshold. Subsequently the patient was made to rest for 20 min in a draft free environment so to stabilize his/her body temperature. After all this, the thermo graphic pictures of the dorsum of hands were taken (T0).

Thermo graphic pictures were then repeated every 5 min T5, T10, T15, T20, T25, and T30 as described above.

1) **T0**: Recorded immediately after rest period.

2) **T5**: Recorded after 5 minutes of acupuncture stimulation.

3) **T10**: Recorded 5 minutes after T5.

4) **T15**: Recorded 5 minutes after T10.

5) **T20**: Recorded 5 minutes after T15.

6) **T25**: Recorded 5 minutes after T20.

Needles were removed after the T25 reading.

7) **T30**: Recorded 5 minutes after removal of the needles.

Third session: Following a resting period of 20 min thermo graphic picture was taken T0. VAS score was noted. Followed by which needle or placebo acupuncture accordingly

was given. Thermo graphic pictures were taken every 5 minutes till EA was in progress for 25 min.

Fifth session: VAS score was noted; Digital algometry was repeated at the same 4 sites. The patient was made to rest for 20 min and then T0 was taken. After this the patient was given acupuncture and thermo graphic pictures were taken as above.

Seventh session: Digital algometry was repeated at the same 4 sites. The patient was made to rest for 20 min and then T0 was taken. After this the patient was given acupuncture and thermo graphic pictures were taken as above.

After the completion of all this, the patients were finally asked to fill up the neck pain disability index again.

2.2.5 Acupuncture technique

Placebo

The difference in needle and placebo acupuncture was the type of needle used. Placebo acupuncture was performed using the Park placebo device, which consisted of a blunt telescoping placebo needle and a purpose-designed Park tube. The body of the needle retracted back into the handle during needle 'insertion' by the acupuncturist. This gave the sensation of pinprick but without actually penetrating the skin. EA was performed initially by increasing the intensity of the stimulation until the patient could feel a very mild tingling sensation. The stimulating intensity was than turned down to zero, the patient was than informed that the stimulating frequency is very high that the patient may

or may not feel the same tingling sensation. The light indicators of the stimulator were left on thus gave an impression that the stimulator is still working.(55-57)

Needle acupuncture

Needle acupuncture was given using acupuncture needles, which look no different from the placebo device. The real needle on the other hand did not shorten and so penetrated the skin. De-Qi sensation was not specifically sorted for. In case of needle acupuncture electrical stimulator at 15 Hz frequencies with intensity comfortable to patient was given. The number of the needles varied from 4-10. Needle acupuncture was performed at GB 20 (Feng Chi), GB 21(Jian Jing), and Huatuojiaji at C5 (this is a series of 28 pairs of acupoints, located 0.5 cm lateral to the lower border of the spinous process) bilaterally and any trigger points and / or tender points the patient might have. Distal points on the forearm and hands were avoided. The patients were not given any external heat or moxibustion.

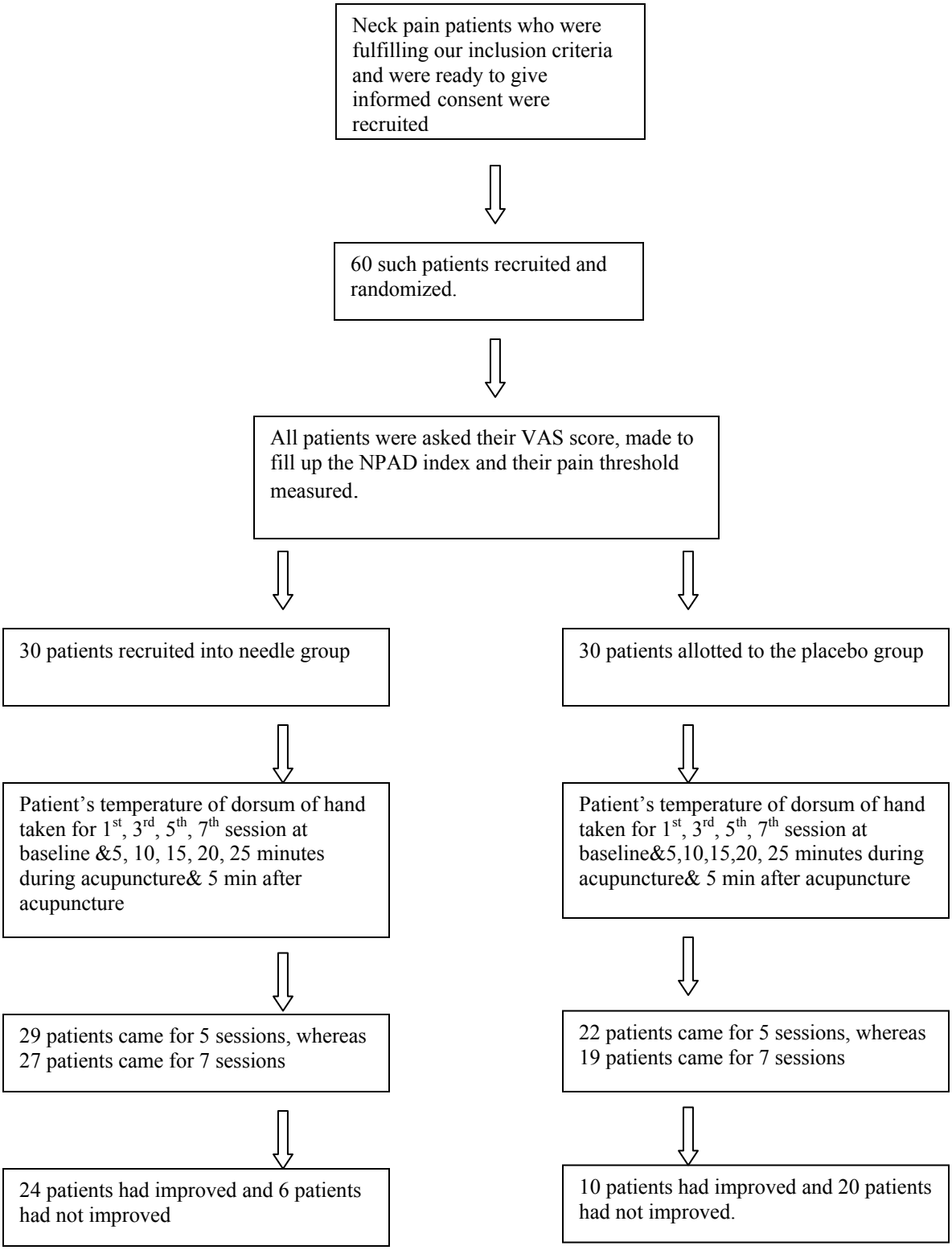
2.2.6 NPAD index

The patient filled up the neck pain disability index either with or without assistance. The index was available in English as well as in Chinese. The patient was asked to choose any of the above. The time taken to fill up the questionnaire was less than 5 minutes. The patients were required to fill up the same form on the 1st and the 7th treatment session.

Follow up

After the completion of the course the patients whom had improved, whether in needle or placebo, were advised not to go for any other treatments. This was to see how long the effect of acupuncture lasts.

Flow Chart 1: Showing the study flow for the second part of the thesis (Comparison of needle and placebo acupuncture)



2.3 Materials

2.3.1 ThermaCAM™ PM575 (Figure 4)

This is an infrared camera used to measure surface temperature of any object. The ThermaCAM™ PM575, (Danderyd, Sweden) infrared condition monitoring system consists of an infrared camera with a built in 24º lenses, a removable battery pack and a range of accessories. This camera measures and images the emitted infrared radiation from an object. This is a portable camera, lightweight and operates for more than 1.5 hours on one battery pack. A high-resolution colour image is provided in real time in integral viewfinder or an external monitor. The images were stored in a 512 Mb PC card for later analysis. Voice comments can also be saved along with the image. The images could be analyzed either in the field using the real time functions built into the camera, or in a PC using the AGEMA™ report software. The measurement accuracy of the camera is ±2%; thermal sensitivity is <0.1º C, detector type is focal plane array 320×240 pixels, colour LCD viewfinder, 14 bit digital storage capacity, two rechargeable nickel-metal hydride batteries. It can operate in the environmental temperature range of –15 to +50º C; weighs 2.3 kg with the battery and the size is 220×133×140mm.

Principle of thermo graphic camera

The camera measures and images the emitted infrared radiation from an object. The fact that radiation is a function of object surface temperature makes it possible for the camera to calculate and display this temperature. The radiation measured by the camera does not only depend on the temperature of the object but is also a function of emissivity. Radiation also originates from the surroundings and is reflected in the object. The radiation from the object and the reflected radiation will also be influenced by the

absorption of the atmosphere. The camera does the necessary compensation for all these different radiation sources automatically. But the parameters such as emissivity of the object, ambient temperature, distance between the object and the camera, relative humidity has to be supplied for the camera. For this reason in our study the distance as kept constant at around 1.5 meter and the temperature of the surrounding was kept around 23-25º C.

Emissivity

Emissivity is a measure of how much radiation is emitted from the object, compared to that from a perfect black body. Human skin exhibits an emissivity close to 1.

Ambient temperature

This parameter is used to compensate for the radiation reflected in the object and the radiation emitted from the atmosphere between the camera and the object.

Distance

This is the distance between object and the front of the lens. This parameter is compensated as the radiation is being absorbed between the object and the camera and transmittance drops with distance. This was kept around 1.5 m.

Fig 4: ThermaCAM™ PM575, infrared camera used for taking pictures of the dorsum of the hands.

2.3.2 Irwin OLE 1.1

The feature of this program is its ability to exchange infrared information with other applications e.g.: AGEMA 2.1. It is a copyright for AGEMA infrared systems AB 1997-1998.

OLE stands for "Object Linking and Embedding" which helps information exchange between programs running in a computer. It is useful in copying an IR image to the clipboard and pastes it into a drawing program, copy a measurement value to the clipboard and link it to the spreadsheet.

2.3.3 AGEMA ™ Research 2.1

Thermo graphic pictures taken were analyzed using AGEMA Thermo vision 2.1 software (Secaus, New York). The mean temperature of both the hands was calculated after drawing the outline of both hands and fingers up to the styloid process. (Figure 5) The readings taken were in ◦C.

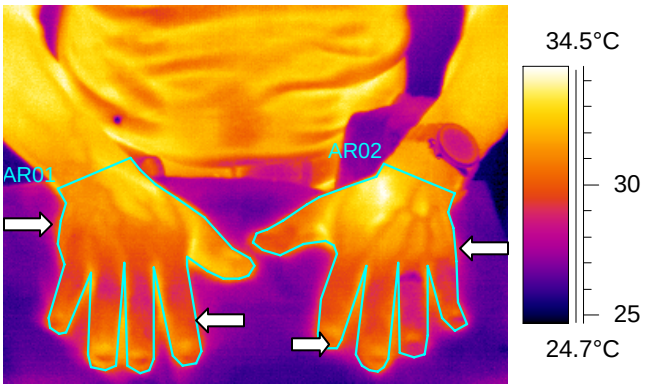


Figure 5: Thermo gram with the outline drawn (indicated by arrows) around it to calculate the temperature. As shown in the scale the dark areas represented by black, blue, red represent lower temperature areas whereas as the temperature increases it becomes more on the yellowish side.

Basic principle

Its main purpose is to deal with live IR images or IR images from PC card hard discs. It shows IR images, records them on disc and analyzes them later.

The measurements are made with the following analysis tools: isotherm, spot meter, area and line. The results produced by these can be displayed within the IR image, in the profile window or result table. For our research we used the polygon area, this was used to draw an outline on the infrared image as in our case the dorsum of the hand. With the help of this program the mean temperature of the hands were measured.

Isotherm type, it can be interval, above or below. If interval is chosen, all pixels with a temperature that lies within the set interval will be coloured with the same isotherm colour. If above is chosen, all pixels with a temperature higher than a set temperature will be coloured with the same preset isotherm colour. We chose the interval isotherm type in our study. Isotherm width was set from 24-40 º C.

To get good images the camera was set at a temperature range of 24-40º C, put on auto-adjust and images were clearly focused. Parameters as emissivity, ambient temperature, atmospheric temperature, relative humidity of air and distance were to be kept in mind while taking a picture. These parameters value had to be correct otherwise the scale temperatures and displayed colourings would be wrong, thus we would get incorrect temperatures and colours.

2.3.4 Algometer

The algometer used was *ALGOMETER ™ COMMANDER & DIGITRACK ™ COMMANDER* to measure the muscle pressure pain threshold of the patients. (Figure 6) Digital pressure algometer readings were taken in lb/cm^2. The size of the probe used was 1 cm^2. (Figure 7). To reduce variance, the test was repeated 3 times at each muscle point. The mean reading was then taken. The tests were performed on 1^{st}, 5^{th} & 7^{th} session. Average mean muscle pressure pain thresholds of the right and left side were calculated.

Fig 6: ALGOMETER ™ COMMANDER with the probe

Fig 7: The two probes of different sizes, on the left is 1 cm^2 and on the right is .5 cm^2

Method of measuring muscle pressure pain threshold

The patient was made to wear a gown open at the back after taking off the street clothes. After that he or she was made to sit comfortably on a chair with no side arms, hands resting on a cushion. The procedure was explained to the patient, that the four points

chosen for the threshold measurement will be pressed by the algometer, on both sides three times. The moment the patient started feeling pain he or she had to say “pain”. The pain did not have to unbearable for the subject to say “pain”. That’s how the muscle pressure pain threshold was measured.

The locations used to determine the muscle pressure pain threshold for the four muscles were standardized as follows-

Mid-trapezius point is the centre of the line joining the spinous process of C7 and the acromion process.

Mid-deltoid is the centre of the line-joining the tip of the shoulder and the deltoid insertion at the humerus.

Infraspinatus is the depression of the subscapular fossa at the level of T 4 on the scapula.

Mid-tibia is the centre of the line joining the lateral epicondyle of the femur and the lateral malleolus.

The applicator force was applied at these points perpendicular to the skin’s surface, at an increasing rate of 2 pounds per second. The applicator was removed the moment the patient said, “pain”.

2.3.5 Needles

Needles

The needles used were sterile disposable needles for single use only (HUANQIU acupuncture medical appliance co Ltd. Suzhou, China), 0.25×25mm. (Figure 8)

Park Device

The needles used in placebo had a similar external appearance to that of the real needles. The placebo needles were sterilized needles from DONGBANG, .25×50mm in size originally but shorten upon them when pricked. (Figure 9 & 10).

It consists of a plastic base with self adhesive tape, which enables it to stick on the skin during needle insertion. An opening in the base will provide support for an insertion tube loaded with the placebo needle. (Figure 7) (48- 52)

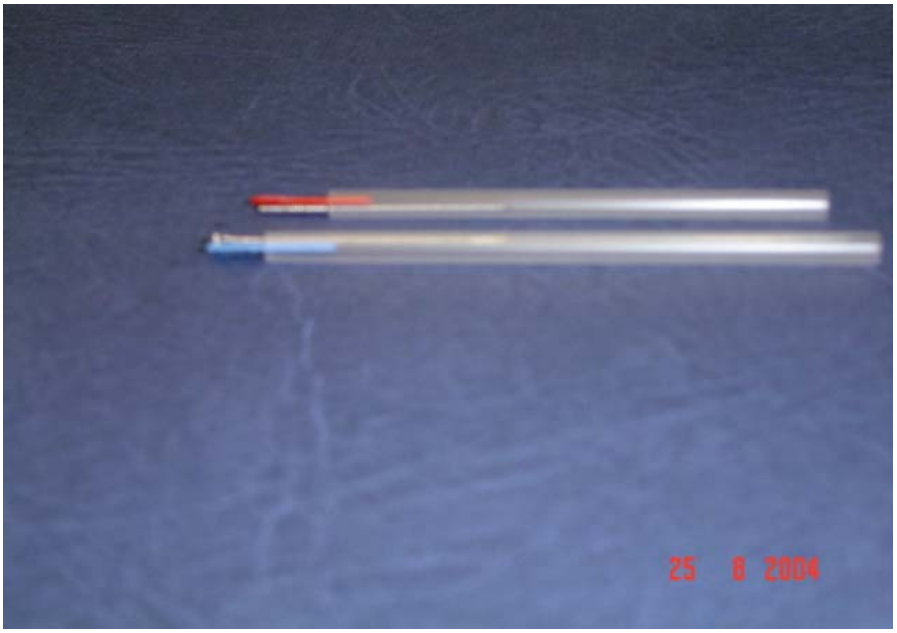


Fig 8: The needle above in the picture (red) is placebo needle; below (blue) is real needle

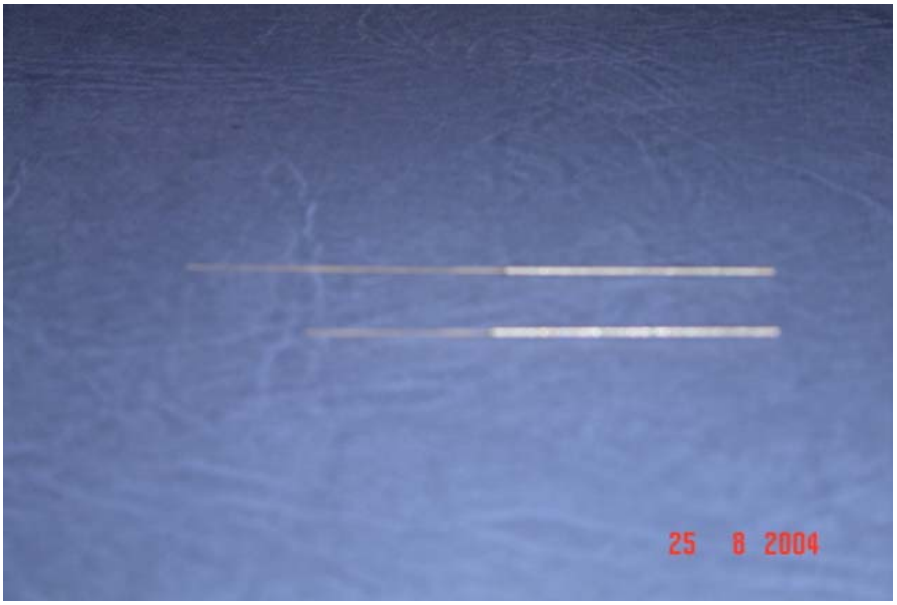


Fig 9: Shortening of the placebo needle once it is pricked. Above in the picture is placebo needle that is not used below is the needle that has been used.

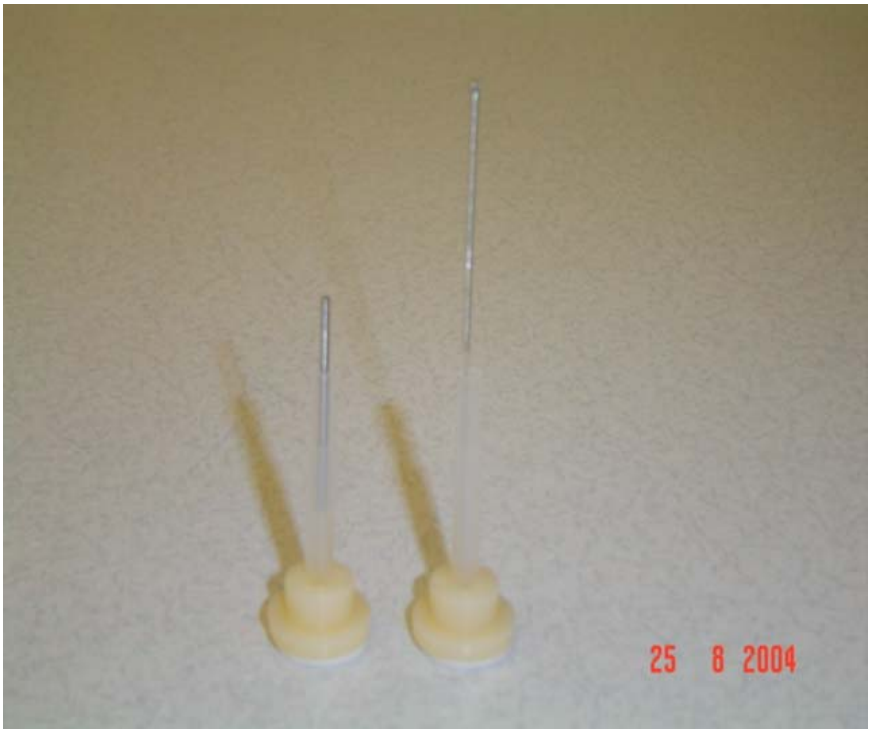


Fig 10: Park sham device with needles. Left: placebo needle after 'insertion'; Right: placebo needle before 'insertion'.

2.4 Statistics

All values were presented either as mean ± S.D or median (interquartile range) as appropriate. The statistical analysis was performed using the SPSS (version 12.0) statistical software; both parametric and non-parametric tests were used as appropriate. For K-related samples Friedman test, for 2 related samples Wilcoxon tests and for 2 independent samples Mann Whitney U test was used. A *P* value of < 0.05 will be taken as statistically significant.

Variations in skin temperature

The thermo graphic readings were compared within the session using Friedman tests. The baseline temperatures of all the 4 sessions were also compared using Friedman test.

In the 1st part of the study the readings of all the 4 sessions were also compared to the control group using non-parametric tests. Man-Whitney U test was used to compare the baseline temperatures, VAS score, NPAD score, and muscle pressure pain threshold between the two groups.

Variations in muscle pressure pain threshold changes

The pain threshold readings of the 4 muscle points (mid trapezius, infraspinatus, mid-deltoid, mid-tibia) were compared for all the 3 sessions using Friedman non-parametric test. After taking the measurements for the right and left sides, mean value was calculated for further analysis.

NPAD and VAS scores

The total scores of the NPAD for the first session were compared to the total of 7th session using non-parametric Wilcoxon tests. The changes in VAS score were compared using Friedman test.

A patient was deemed to have improved when there was a reduction in 50% of the VAS score (compared to baseline) or it was less than or equal to 3.

The improvement in VAS and NPAD score for both groups were compared by Mann-Whitney U test. (Non-parametric test for 2 independent samples)

CHAPTER 3 :

RESULTS

3.1 Pilot study to evaluate the effects of acupuncture in patients with mechanical neck pain

30 adult patients consisting of 22 females and 8 males were recruited through referrals from the orthopaedic outpatient clinic at NUH. The mean age of this patient group was 50.5±10.5 years. The control group consisted of 18 adults, 12 females and 6 males. The mean age of this was 42.5±8.2 years. The unpaired t- test for the two age groups was not significant different. (P>0.05)

The median baseline temperature of the control group was 34º C (27.60 – 36.00 range) [30.875 – 35.025 IQR], which was significantly higher than that of the patient group, which was 32.2 º C (28.80 – 34.60) [31.0 –33.5] (P < 0. 01).

In the patient group the median baseline temperature in the **1st session** was 32.2ºC (28.80 – 34.60) [31.0 – 33.5], which increased and peaked to median temperature of 33.45ºC (28.05 – 35.25) [32.45 –34.65] at 20 min during the acupuncture session.(Fig 15) The increase in temperature was significant (P < 0.01). In the **3rd session** the median baseline temperature was 32.9ºC (29.10 – 34.50) [31.30 – 33.725], which peaked to median temperature of 34.1ºC (31.90- 35.30) [33.52 – 34.70] at 20 minutes (P < 0.01).(Fig 16) Similar increases were seen in the **5th session** from median temperature of 33.1ºC (30.55 – 35.20) [31.50 – 33.55] at baseline to a median temperature of 34.3ºC (32.10 – 35.20) [33.75 – 34.75] (P < 0.01) at 20 minutes (Fig 17) and **10th** session from a median of

33.8ºC (31.60 – 34.60) [32.55 – 33.97] at baseline to a median temperature of 34.5ºC (32.50 – 35.00) [33.80 – 34.75] at twenty minutes ($P < 0.01$)(Fig 18)**.** (Table 2)

The graphs show that in a few sessions, there was initially a slight but insignificant decline in temperature followed by a significant increase, which most of the time peaked at 20 minutes.

The baseline temperature of all the four sessions was compared using Friedman test. As only 16 patients had completed all the 10 sessions, the data was compared for these 16 patients only. The baseline temperature at the 1st session was 32.2ºC and increased to 33.8ºC at the 10th session ($P < 0.01$). (Fig 19)

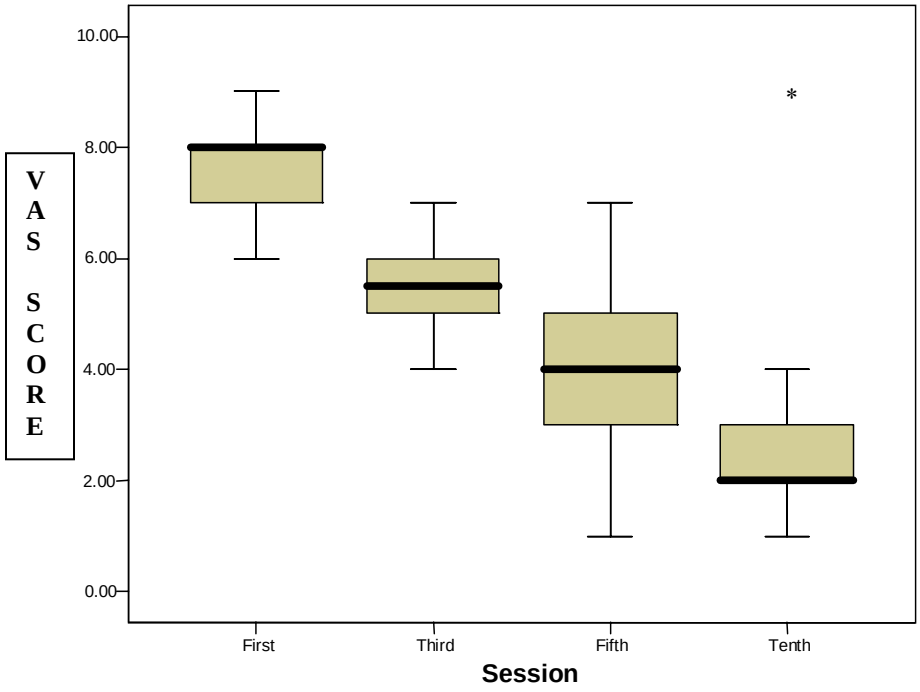
TABLE 2: Temperature at the baseline and at 20 minutes at all the four sessions.

	First session	**Third session**	**Fifth session**	**Tenth session**
Baseline	**32.2°C** (28.80 -34.60 range) [31.0 – 33.5 IQR]	**32.9°C** (29.10 – 34.50 range) [31.30 – 33.725 IQR]	**33.1°C** (30.55 – 35.20 range) [31.50 – 33.55 IQR]	**33.8°C** (31.60 – 34.60 range) [32.55 – 33.975 IQR]
Twenty minutes	**33.45°C** (28.05 – 35.25 range) [32.45 –34.65 IQR]	**34.1°C** (31.90- 35.30 range) [33.525 – 34.7]	**34.3°C** (32.10 – 35.20 range) [33.75 – 34.75 IQR]	**34.5°C** (32.50 – 35.00 range) [33.80 – 34.75 IQR]
***P* values**	<0.01	<0.01	<0.01	<0.01

In control group, there was a slight but statistically significant drop in skin temperature at the end of the observation period compared to baseline values. ($P = 0.032$) (Fig 14).

Out of the 30 patients, 5 patients did not improve as per our criteria of improvement. Of the 14 patients who stopped treatments prior to the 10th session, 5 were not showing any improvement and 9 had improved so they did not want to continue because of work commitments.

The VAS score showed a significant improvement and changed from a median of 8 (5.0 – 9.0 range) [6.75 – 8.0 IQR] in the first session to a median of 2 (1.0 – 6.0 range) [2.0 – 3.0 IQR] in the tenth session. (Fig 11)



*$P < 0.01$ compared to the first session

Fig 11: VAS score changes over ten acupuncture sessions

Baseline temperature changes at the first and tenth session (Figure 12 & 13).

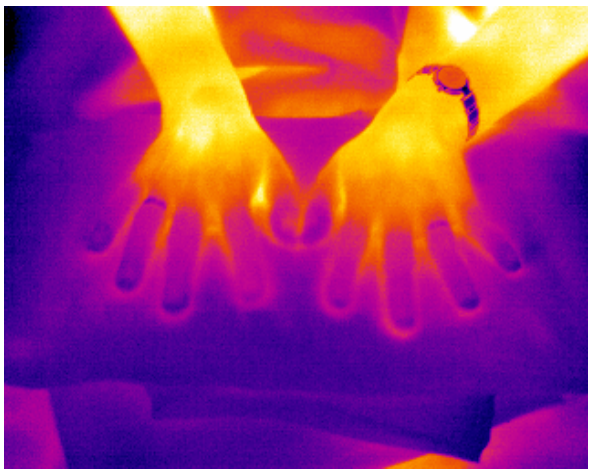


Fig 12: Thermograph before EA at 1st session (Temp: 29.1 °C)

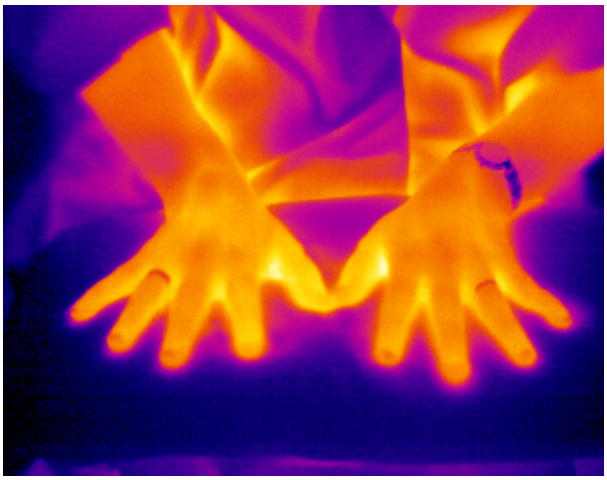
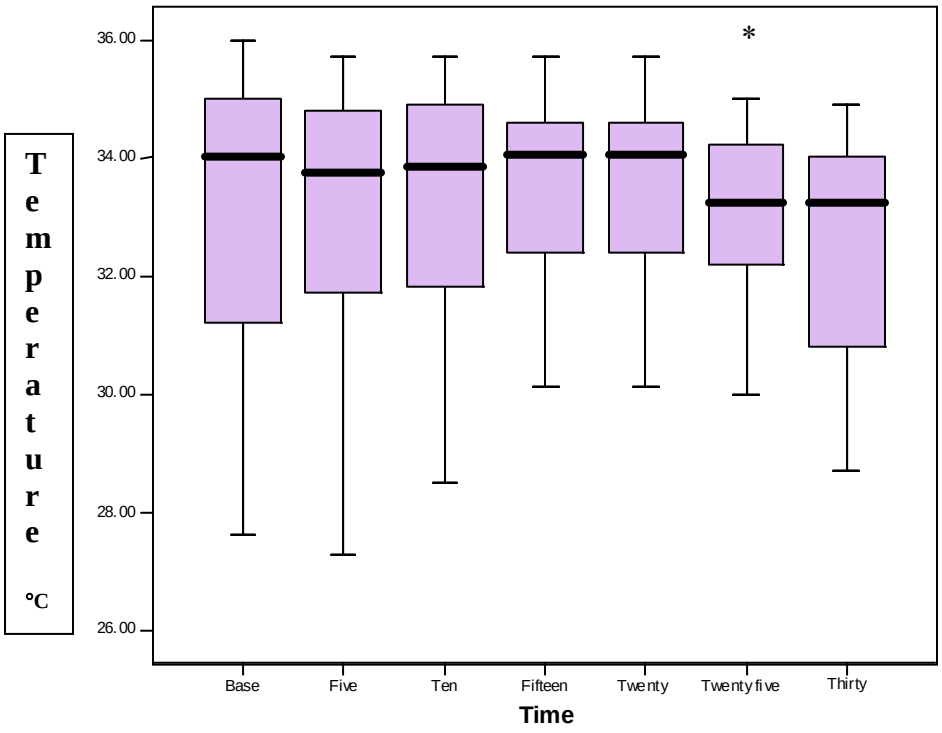
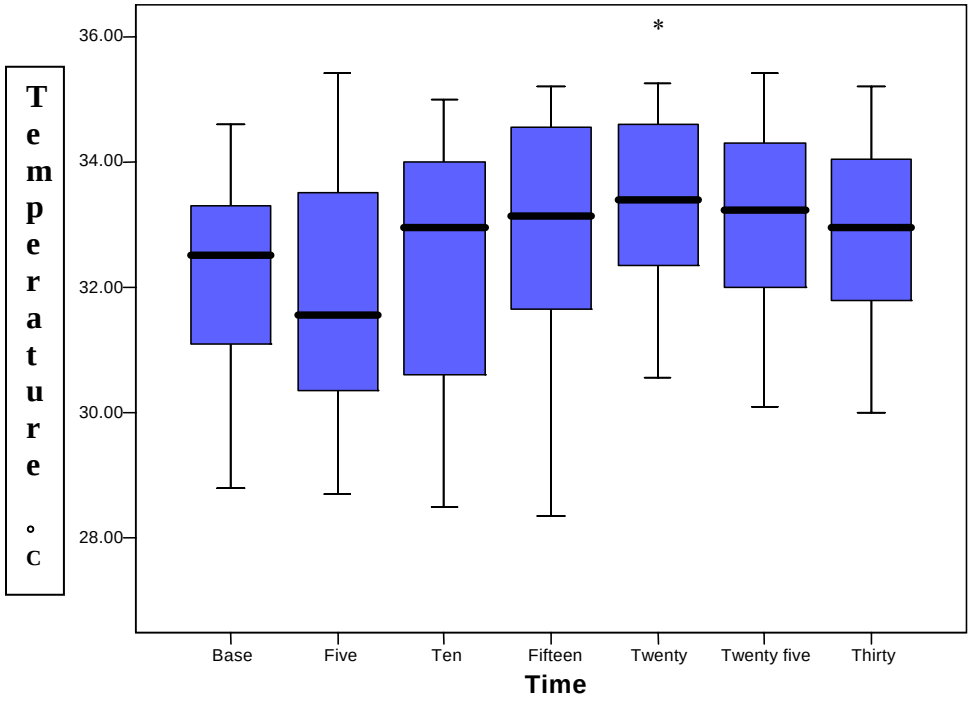


Fig 13: Thermograph (same patient as in Fig12) before EA at 10th session (Temp: 32.0 °C)



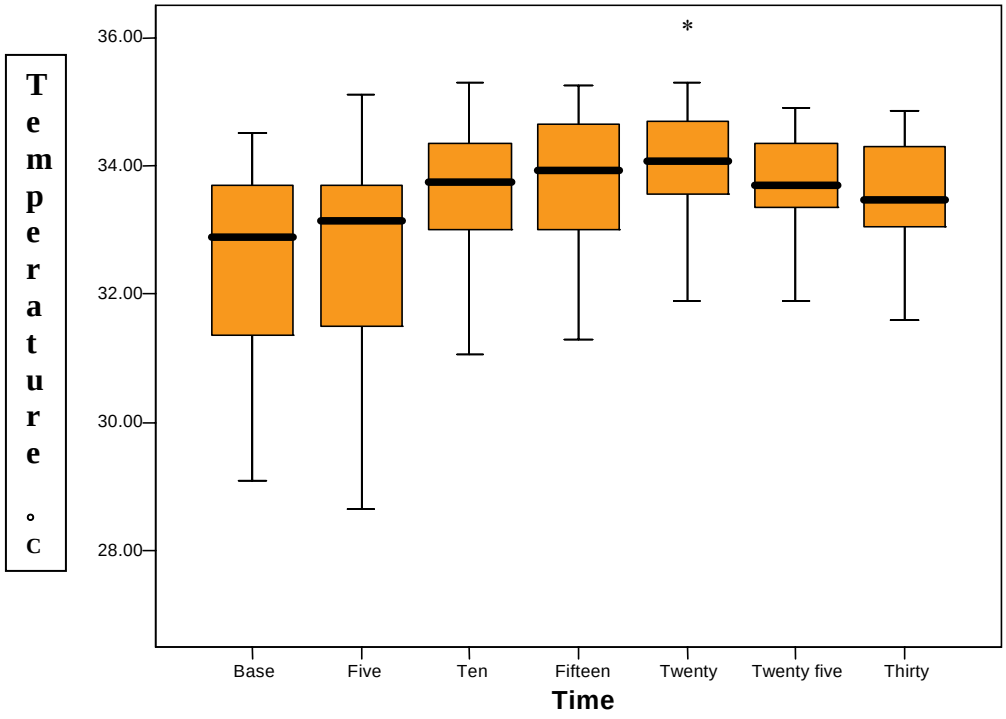
* P < 0.01 compared to the baseline

Fig 14: Temperature changes in control group over time without acupuncture



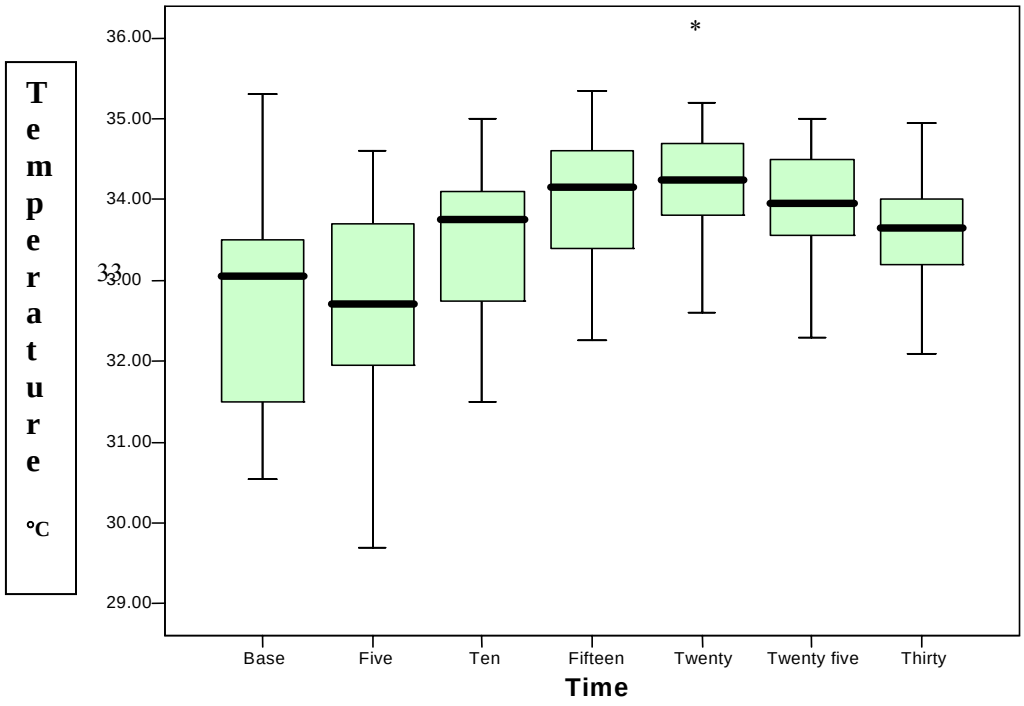
* P < 0.01 compared to the baseline

Fig15: Temperature changes in neck pain patients at first session over time during acupuncture



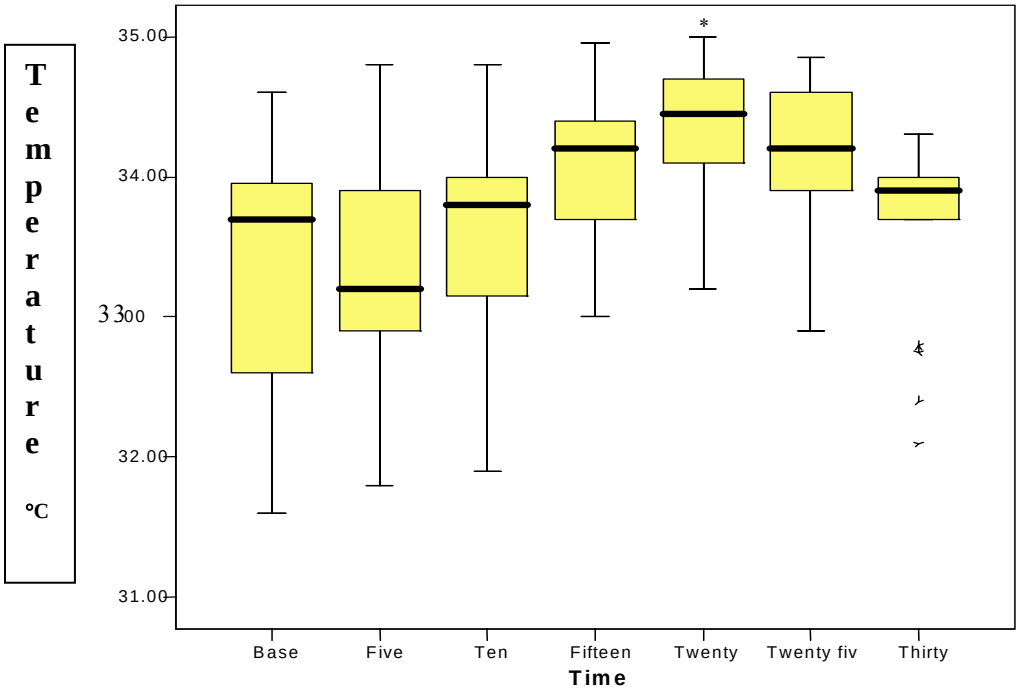
* P < 0.01 compared to the baseline

Fig16: Temperature changes in neck pain patients at third session over time during acupuncture



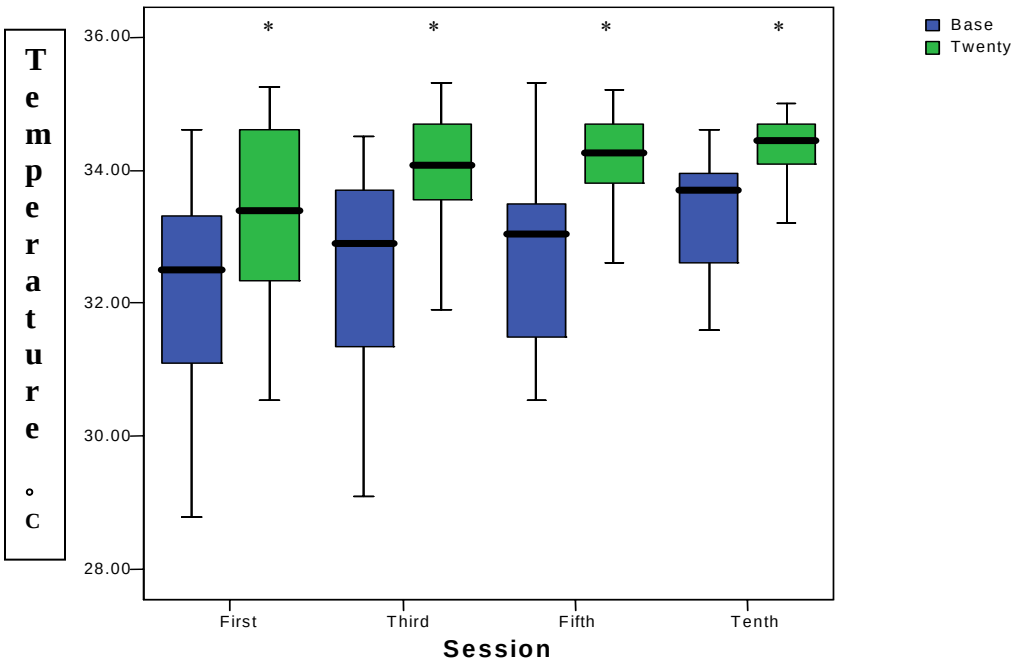
* P < 0.01 compared to the baseline

Fig17: Temperature changes in patients at fifth session over time during acupuncture



* P < 0.01 compared to the baseline

Fig18: Temperature changes in patients at tenth session over time during acupuncture



* P < 0.01 compared to their respective baseline temperature

Fig 19: Box plot showing the baseline and 20 min temperature at all the four sessions

3.2 Comparison of needle and placebo acupuncture

3.2.1 Comparison of the two groups at baseline level

The needle group consisted of 30 patients with 22 females and 8 males. The mean age of this group was 45.9±9.7 years. The placebo group had 30 patients, 21 females and 9 males. The mean age was 46.8±10.7 years. There was no significant difference in age and sex distribution between the two groups.

The demographic data and other values of the two groups randomly chosen were quite similar to one another in all the aspects as shown in Table 3.

TABLE 3: COMPARISON OF THE DEMOGRAPHIC DATA AND BASELINE VALUES OF TWO GROUP

S. NO		NEEDLE	PLACEBO	P VALUE
1.	NO.OF MALES/FEMALES	8/22	9/21	
2.	AGE (YRS) (Mean ± Std. Dev)	45.9±9.7	46.8±10.7	0.323
3.	DURATION OF NECK PAIN (Months) (Mean ± Std. Dev)	3.9 ± 1.4	4.2 ± 1.1	0.137
4.	VAS SCORE	7	6.5	0.235
5.	NPAD SCORE	49.5	45	0.609
6.	BASELINE TEMPERATURE (ºC)	32.15	32.9	0.34
7.	MUSCLE PRESSURE PAIN THRESHOLD AT MID TRAPEZIUS RT/ LT (lbs/cm^2)	8.05	8.00	0.29
8.	MUSCLE PRESSURE PAIN THRESHOLD AT INFRA-SPINATUS RT/LT (lbs/cm^2)	8.13	7.00	0.45
9.	MUSCLE PRESSURE PAIN THRESHOLD AT MID DELTOID RT/LT (lbs/cm^2)	7.93	7.58	0.36
10.	MUSCLE PRESSURE PAIN THRESHOLD AT MID TIBIA RT/LT (lbs/cm^2)	12.4	11.75	0.55

* Items 3 – 9 are quoted in median values. Their range and inter quartile values are mentioned in the text.

3.2.2 Outcomes

In the needle group, out of the 30 patients, 27 patients completed all 7 treatment sessions, whereas 3 patients came for 5-6 sittings. Out of these, 2 patients came for 6 sittings and could not come because of their work constraints; both of them reported good pain relief when they came for their 6^{th} session; whereas one patient came till 5^{th} session and reported no significant pain relief. In total of 30 patients, 24 reported significant improvement and 6 did not find any improvement.

In the placebo group, out of the 30 patients, 19 completed all 7 sessions, whereas 11 came for 3-5 sittings. These patients did not continue, as they were not finding any improvement in their pain status. Of the 19 patients who completed all 7 sessions, 10 reported significant pain relief and 9 did not improve. So in total of 30 patients, 10 patients improved and 20 did not.

We took the best-case scenario sensitivity analysis and have assumed that the patients in the placebo group who stopped coming had not improved as according to the VAS score of their last visit. (Table 4)

TABLE 4: Proportion of patients improved / not improved in the two groups.

	NEEDLE	PLACEBO	TOTAL
IMPROVED	24	10	34
NOT IMPROVED	6	20	26
TOTAL	30	30	60

The chi-square test for these two groups was significant ($P< .01$).

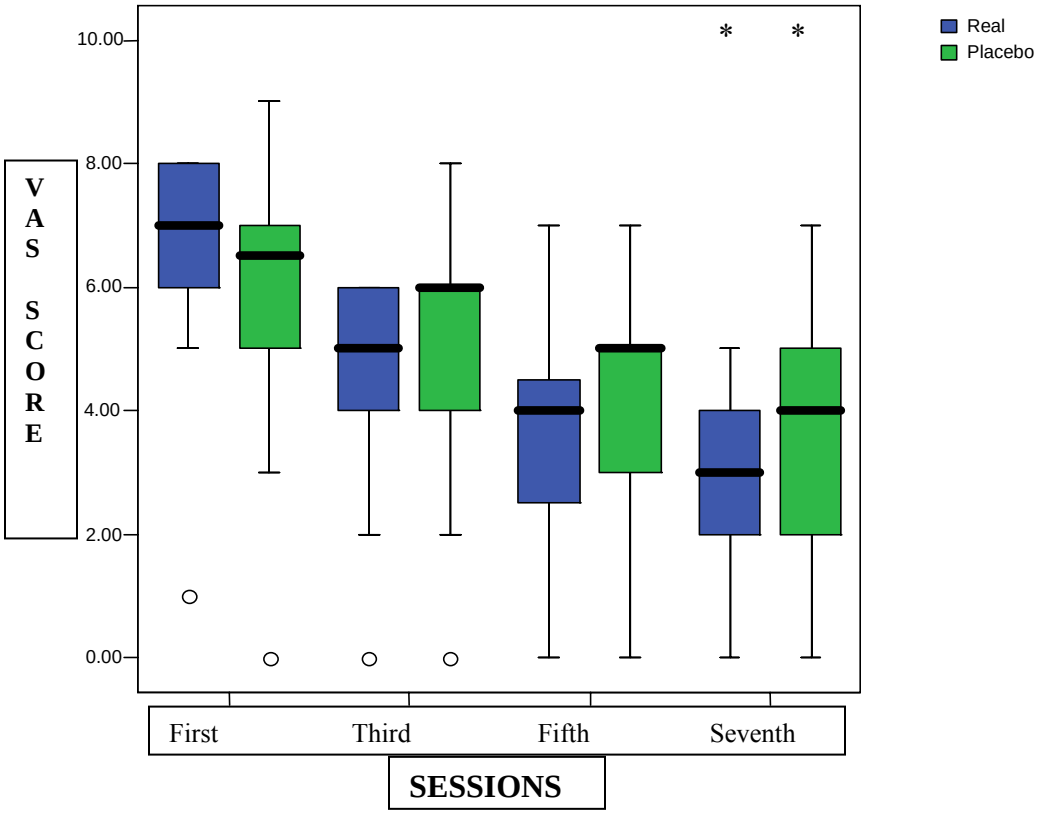
3.2.3 VAS score and NPAD score changes

The changes in the median VAS score in the needle group were from 7 (4.0 – 8.0 range) [6.0 – 8.0 IQR] in the first session to 2.0 (0.00 – 5.00 range) [1.25 – 4.0 IQR] in the final session, which was significant ($P< .01$). The change in the placebo group was from a median of 6.5(4.00 – 9.00 range) [5.0 – 7.25 IQR] to 3.5 (0.00 – 7.0 range) [2.0 – 5.0 IQR], which was also significant ($P< .01$) (Figure 20).

However, the median improvement in the VAS score in the needle group was 4 (1.0 – 7.0 range) [3.0 – 5.0 IQR], which was significantly better than the placebo group median of 2.5 (0.00 – 5.0 range) [1.0 –4.0 IQR] ($P< .01$).

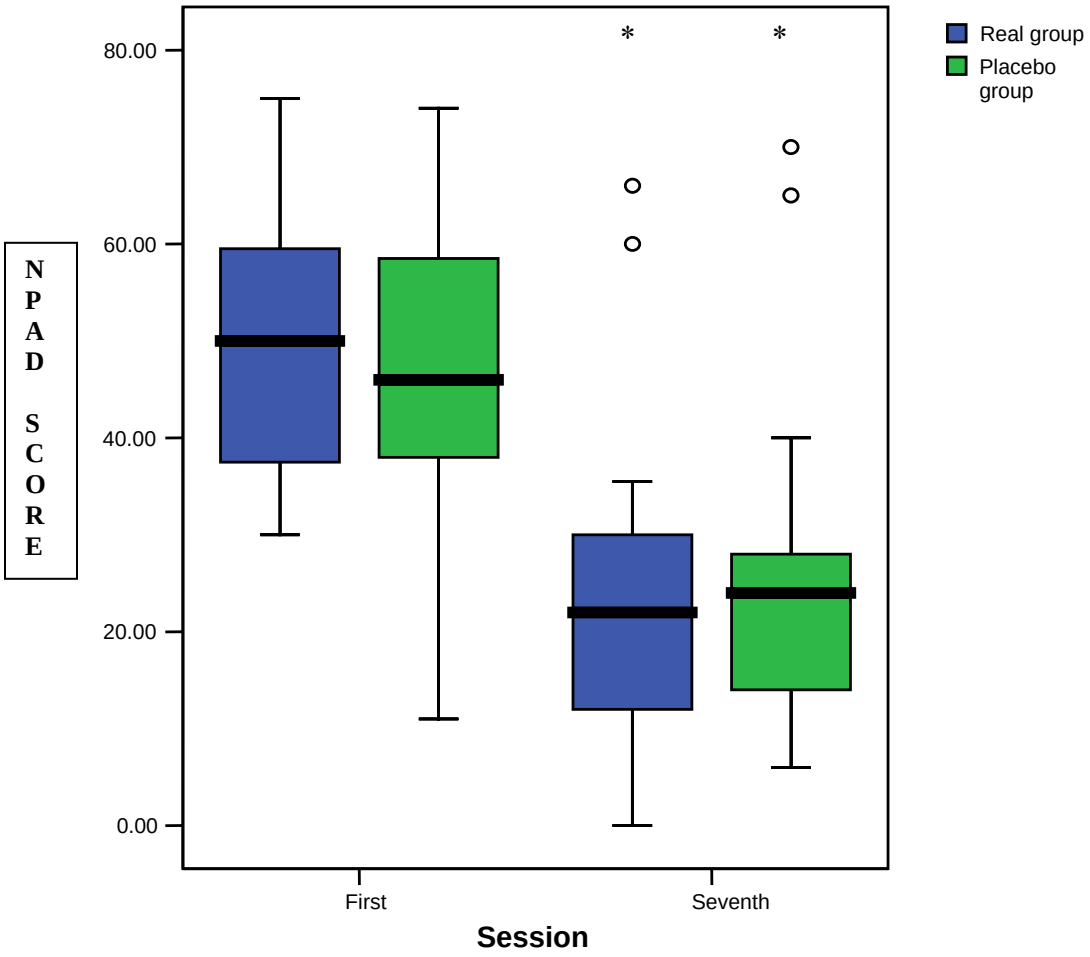
The NPAD score was significantly reduced from a median of 50.0 (25.0 –75.0 range) [37.0 – 60.0 IQR] in the first session to a median of 20.50 (0.00 – 66.00) [10.75 – 30.0] after the seventh session ($P<. 01$). For the placebo group, the score reduced from a median of 45.00 (11.00 – 74.00 range) [35.5 – 58.625 IQR] to a median of 24.00 (6.00 – 70.00 range) [14.00 – 30.00 IQR] ($P < 0.01$).

The median improvement of NPAD score in needle group was 29.5 (0.00-56.0 range) [22.75-36.25 IQR], which was significantly better than for the placebo group median of 20 (-6.00 –30.50 range) [11.25-30.00 IQR] (P<. 01) (Figure 21).



*P < 0.01 compared to their respective first session scores

Fig 20: VAS score in needle and placebo group over 7 sessions



* P < 0.01 compared to their respective first session scores baseline

Fig 21: Box plot showing NPAD score changes in the two groups of patient

3.2.4 Muscle pressure pain threshold changes

Needle group

At the mid-trapezius point the median of mean of right and left side muscle pressure pain thresholds measured was **8.05** (4.15 – 15.20 range) [6.38 – 9.26 IQR], **9.35** (4.30-14.70 range) [7.82 – 10.63 IQR], and **9.98** (4.00 – 17.20 range) [7.27 –10.83 IQR] lbs/cm^2 at 1st, 5th and 7th session.

At the infraspinatus point the median of mean recording of right and left side recordings at 1st, 5th and 7th session were **8.13** (4.25–19.95 range) [6.45 –9.79 IQR], **8.88** (5.55 –

15.10 range) [7.33 - 10.73 IQR] and **9.38** (4.55 – 19.15 range) [7.78–11.35 IQR] lbs/cm^2 respectively (P<0.01).

At the mid-deltoid point the recordings were **7.93** (3.30 – 19.25 range) [6.23 –10.20 IQR], **8.6** (4.35 –13.45 range) [7.44 –10.69 IQR] and **9.7** (4.45 –15.95 range) [8.24 – 11.13 IQR] lbs/cm^2 at 1st, 5th and 7th session respectively (P< 0.001).

At the mid-tibia point the readings were **12.4** (4.85-22.50 range) [9.58-14.59 IQR], **12.30** (6.75-23.1 range) [10.59-14.64 IQR] and **12.18** (7.15- 22.70 range) [10.31-14.11 IQR] lbs/cm^2 at 1st, 5th & 7th session respectively. (P=0.717).

Placebo group

At the mid-trapezius point the median of mean of right and left side muscle pressure pain thresholds measured was **8.0** (3.65-10.55 range) [5.85-8.90 IQR] lbs/cm^2 1st session, **7.0** 4.00-8.55 range) [5.9-8.15 IQR] lbs/cm^2 in 5th and **5.55** (4.2-12.75 range) [5.05-7.8 IQR] lbs/cm^2 in 7th session (P=0.265).

At the infraspinatus point the median of the mean of the right and left side changed from **7.65** (3.9- 13.60 range) [5.3-9.00 IQR] lbs/cm^2 in the first session, to **7.00** (4.00-11.55 range) [5.10-8.65 IQR] lbs/cm^2 at fifth session and **6.15** (3.4-17.05 range) [5.2-8.85 IQR] lbs/cm^2 (P=0.149).

At the mid deltoid point the readings at the 1st session were **7.58** (3.75-11.45 range) [4.81-9.11 IQR] lbs/cm^{2,} **6.43** (4.5-11.55 range) [5.41-7.90 IQR] lbs/cm^2 at 5th and **7.02** (4.65-14.85 range) [5.48-9.8 IQR] lbs/cm^2 at the 7th session (P=0.384).

At the mid tibia point the median of the average of the readings were **11.75** (6.3- 19.70 range) [9.40-14.2 IQR], **10.35** (6.6-20.3 range) [9.15-11.60 IQR] and **11.5** (5.00-19.70 range) [9.3-12.55 IQR] lbs/cm^2 (P=0.550) at 1^{st}, 5t and 7^{th} session respectively. (Figure 22)

Before the start of the treatment sessions there was no significant difference of muscle pain pressure threshold on the right and left sides of the two groups of patients.

The changes in the placebo group were not significant at any of the points. In the needle group, muscle pain pressure threshold increased statistically significant at the mid trapezius, infraspinatus and the mid-deltoid point. There was no significant change at the mid-tibia point in the needle group. (Table 5)

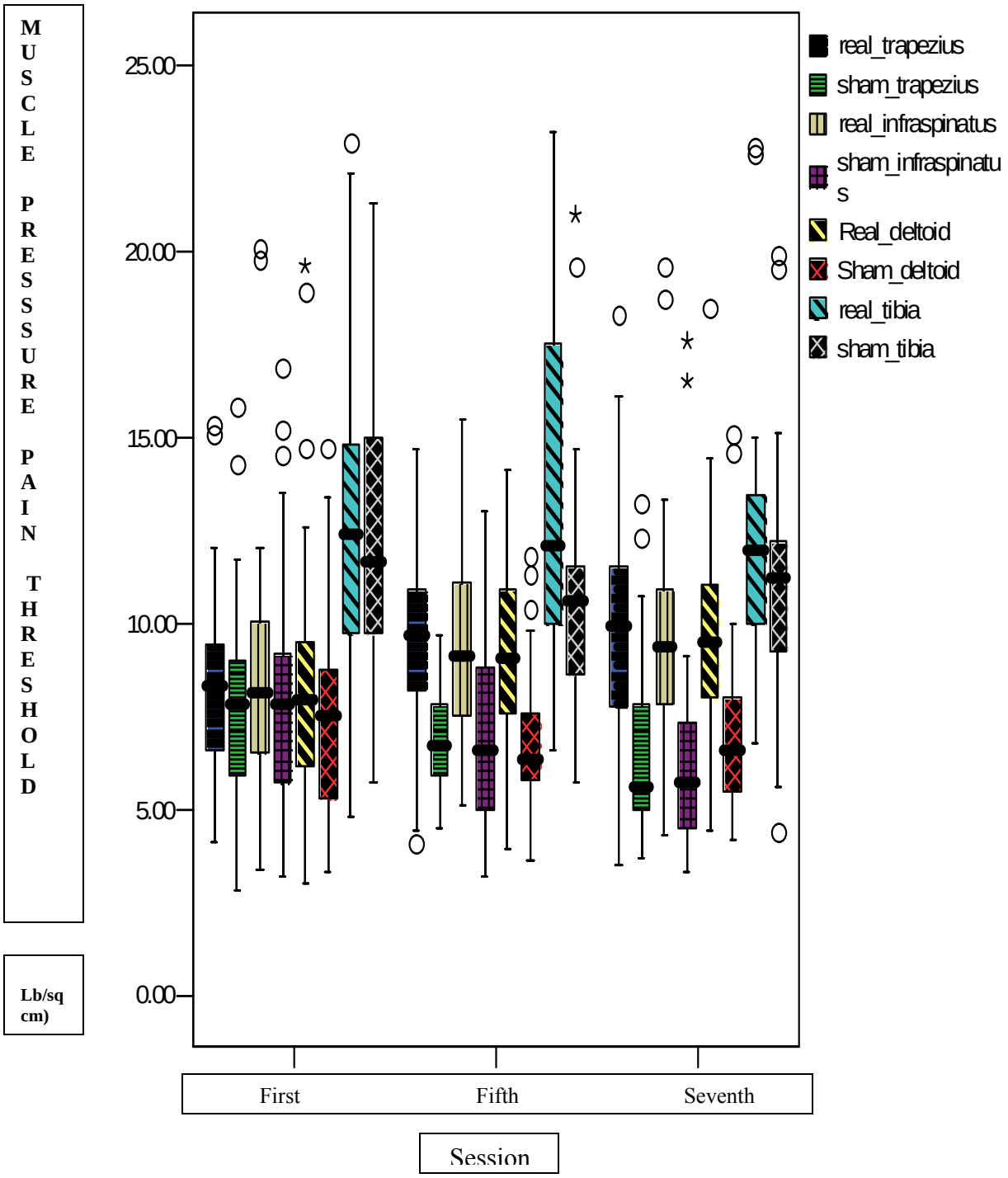


Fig 22: Box plot showing the muscle pressure pain threshold changes in two groups of patient at the first, fifth and seventh session

TABLE 5:Muscle pain pressure threshold changes in needle and placebo group

POINTS	FIRST SESSION		FIFTH SESSION		SEVENTH SESSION		p-value over the sessions.	
	NEEDLE	PLACEBO	NEEDLE	PLACEBO	NEEDLE	PLACEBO	NEEDLE	PLACEBO
MID TRAPEZIUS (lbs/cm^2)	8.05	8.00	9.53	7.00	9.98	5.55	<. 01	>.05
INFRA-SPINATUS (lbs/cm^2)	8.13	7.65	8.88	7.00	9.38	6.15	<. 01	>.05
MID-DELTOID (lbs/cm^2)	7.93	7.58	8.6	6.43	9.7	7.02	<. 01	>.05
MID-TIBIA (lbs/cm^2)	12.4	11.75	12.3	10.35	12.18	11.5	>.01	>.05

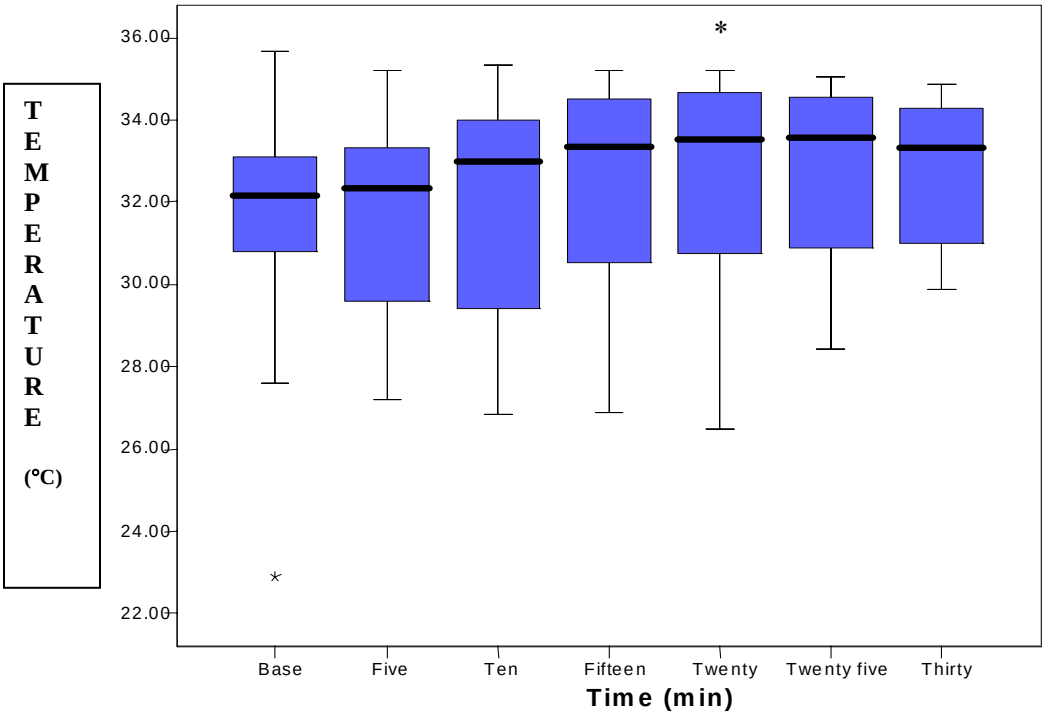
3.2.5 Temperature changes

Needle group

Temperature changes within the session

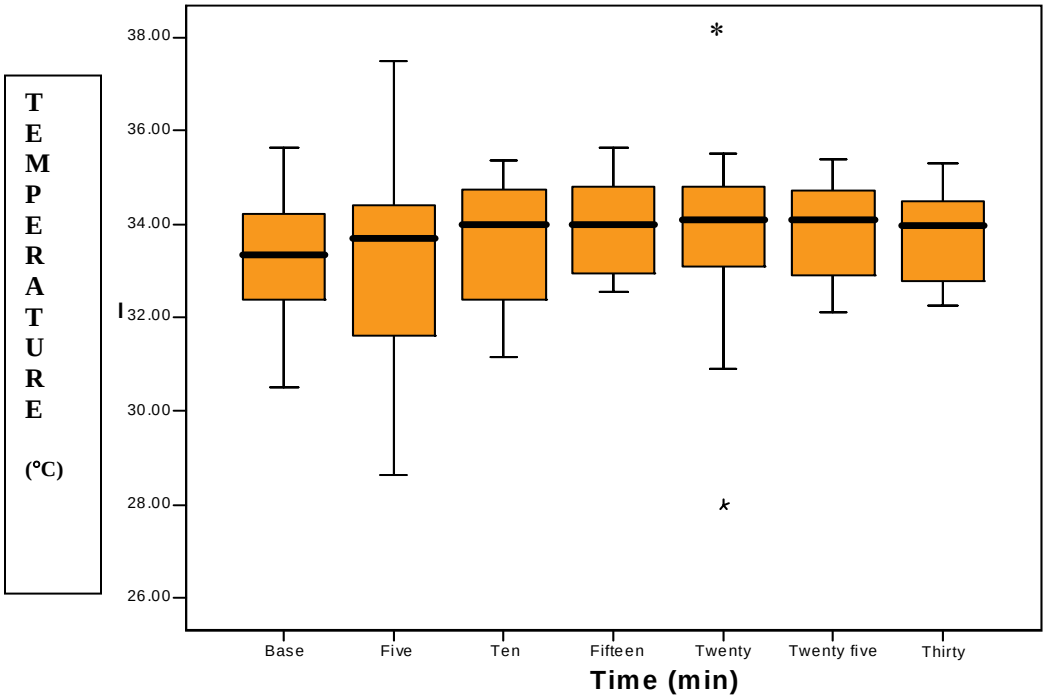
There was an increase from the baseline temperature in all the 4 sessions for which the recordings were taken. In the **1st session** the baseline temperature increased from a median of **32.4ºC** (22.90 – 64.00 range) [30.90 – 33.75 IQR] at baseline to a median of **33.55 ºC** (18.0 – 35.5 range) [30.67 – 34.65 IQR] at twenty minutes. ($P < 0.01$). In the **third session** the median temperature changed from **33.5 ºC** (29.45 – 68.50 range) [32.25 – 34.5 IQR] at baseline to median of **34.07 ºC** (24.0 – 35.50 range) [33.02 – 34.80 IQR] at twenty minutes. (P < 0.01). In the **fifth session** the median temperature changed from **33.45ºC** (30.15 – 36.00 range) [32.61 – 34.45 IQR] at baseline to median of **34.22 ºC** (30.55 – 36.00 range) [33.63 – 34.80 IQR] at twenty minutes. ($P < 0.01$). In the **seventh session** the median temperature changed from **33.85 ºC** (31.15 – 35.30 range) [32.96 –

34.87 IQR] at baseline to **34.50 ºC** (29.70 – 35.60 range) [33.65 – 35.07 IQR] at twenty minutes. ($P < 0.01$). (Figure 23, 24, 25, 26)



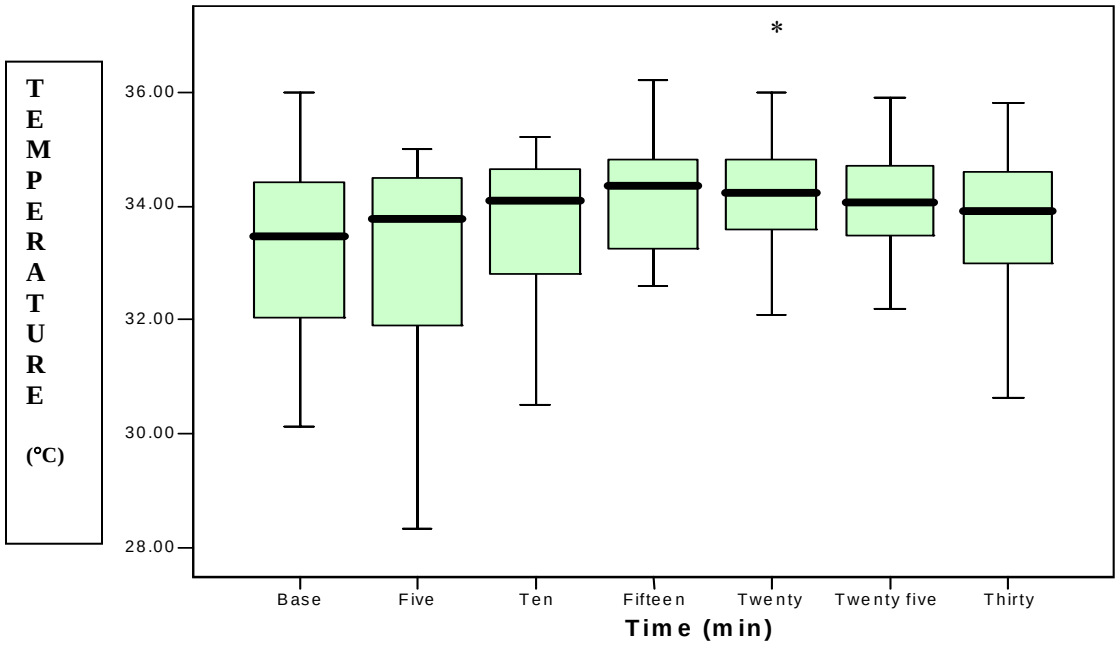
* P < 0.01 compared to the baseline

Fig 23: Temperature changes over time in needle group at first session



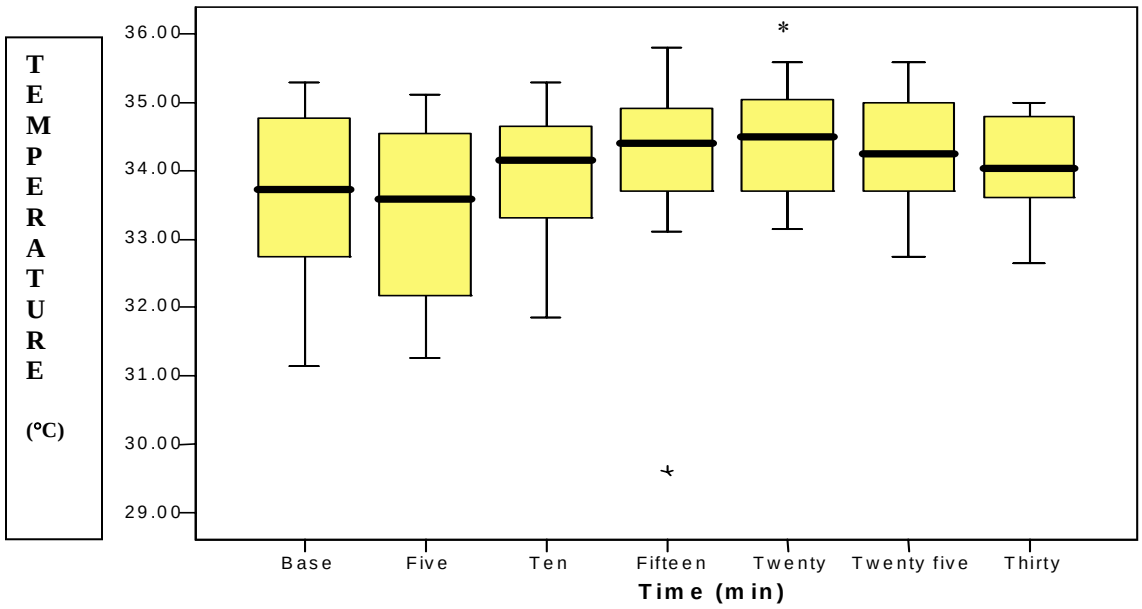
* P < 0.01 compared to the baseline

Fig 24: Temperature changes over time in needle group of patients at third session



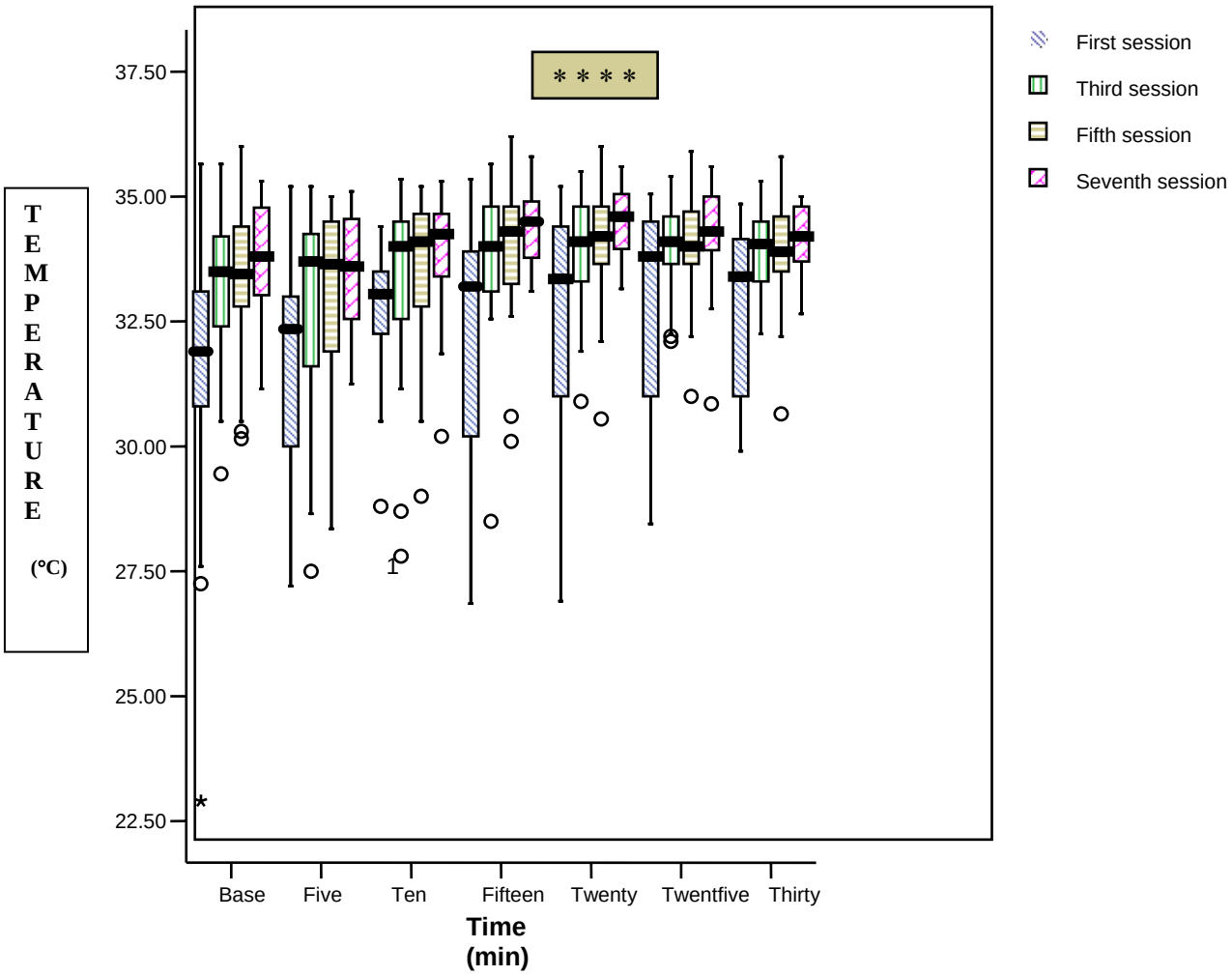
* P < 0.01 compared to the baseline

Fig 25: Temperature changes over time in needle group of patients at fifth session



* P < 0.01 compared to the baseline

Fig 26: Temperature changes over time in needle group of patients at seventh session



***P < 0.01 compared to their respective baseline values**

Fig 27: Box plot showing temperature changes in all the 4 sessions in needle group.

Baseline temperature in needle group

When the baseline temperatures of all the 4 sessions were compared, the median increased from 32.4ºC at 1st session to 33.5ºC at 3rd, 33.45ºC at 5th and 33.85ºC at 7th session. (Ranges and IQR mentioned above).

This increase in baseline temperature was significant ($P < 0.01$) (Figure 28, 29, 30, 31)

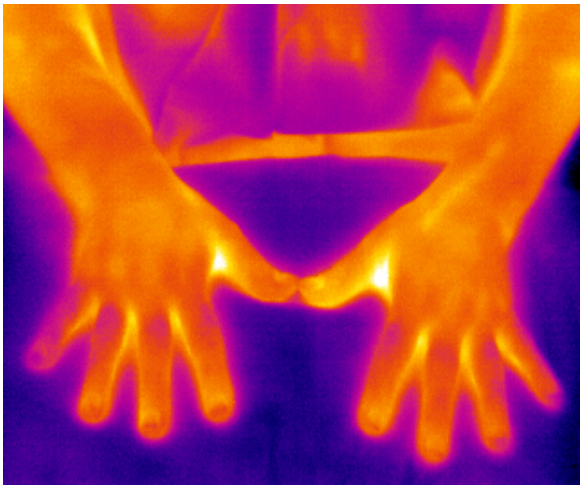


Fig 28: 20 minutes after rest period, before acupuncture in the first session. (Temperature 30.8ºC)

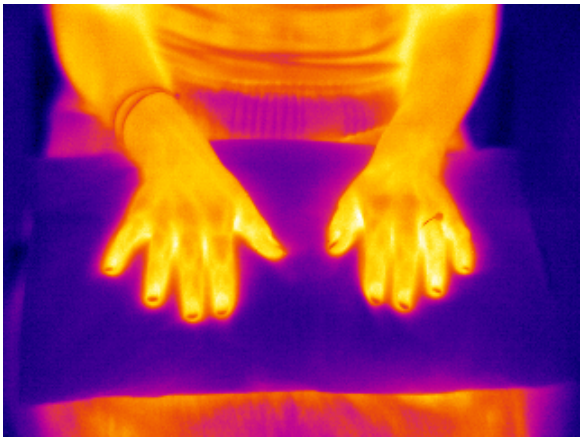


Fig 29: 20 minutes after rest period, before any acupuncture in the third session for the same patient as above. (Temperature 33.2ºC)

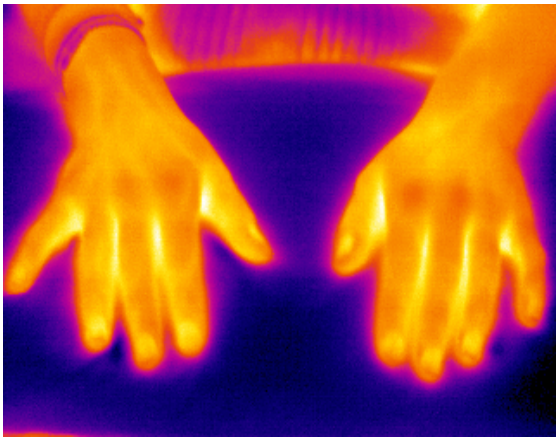


Fig 30: 20 minutes after rest period, before any acupuncture in the fifth session for the same patient as above. (Temperature 33 °C)

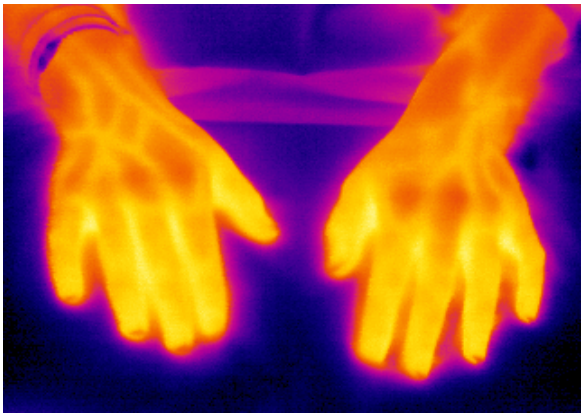


Fig 31: 20 minutes after rest period, before any acupuncture in the seventh session for the same patient as above. (Temperature 34.2 °C)

Placebo

Temperature changes within the session

There was no significant change in temperature in any of the sessions in the placebo group.

In the **first session** the median temperature changed from 33.00 ºC (29.80 – 34.25 range)

[31.95 – 33.62 IQR] at baseline to a median of 32.75 ºC (26.60 –34.30 range) 32.11 –

33.52 IQR] at twenty minutes. (P = 0.25). For **third session** these values changed from 32.95 ºC (30.50 – 33.95 range) [32.15 – 33.41 IQR] to 33.1ºC (31.50 – 33.95 range) [32.05 – 33.40 IQR] (P = 0.315). For **fifth session** these values were 33.00 ºC (28.00 – 34.70 range) [32.32 – 33.45 IQR] to 33.2 ºC (30.10 – 34.45 range) [32.55 – 33.55 IQR]. (P = 0.554). For **seventh session** these values were 32.75 ºC (29.50 –33.80 range) [31.65 – 33.12 IQR] to 32.67 ºC (29.90 – 33.90 range) [31.17 – 33.55] (P =0.417)

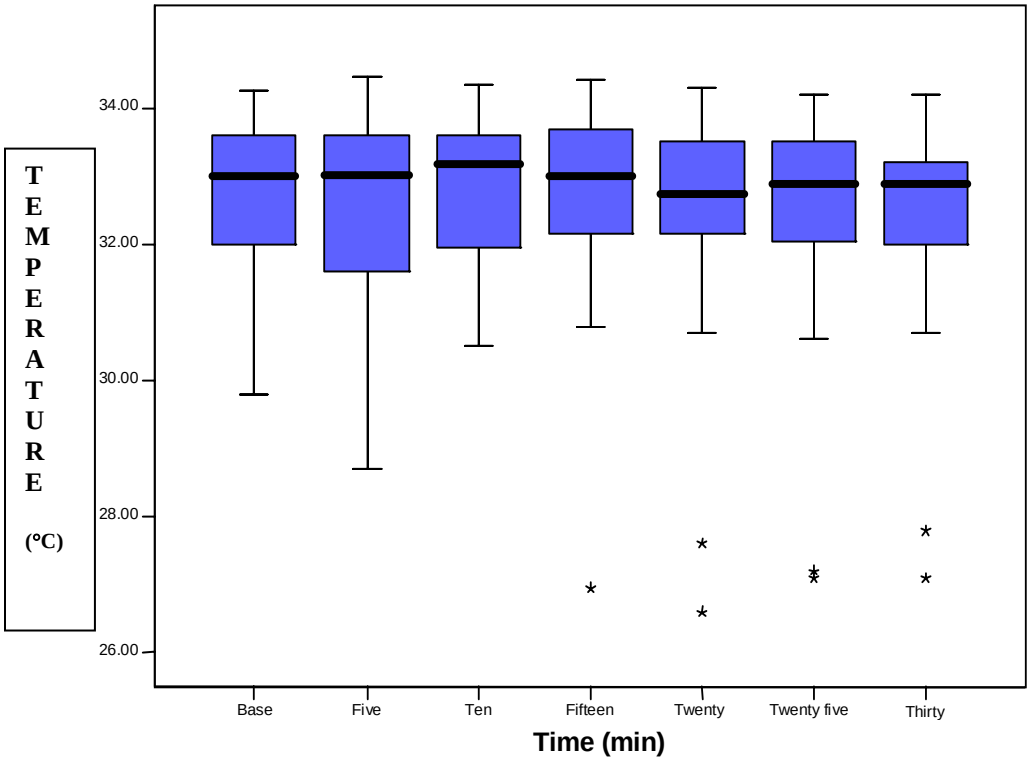


Fig 32: Box plot showing temperature changes in first sessions of placebo patients

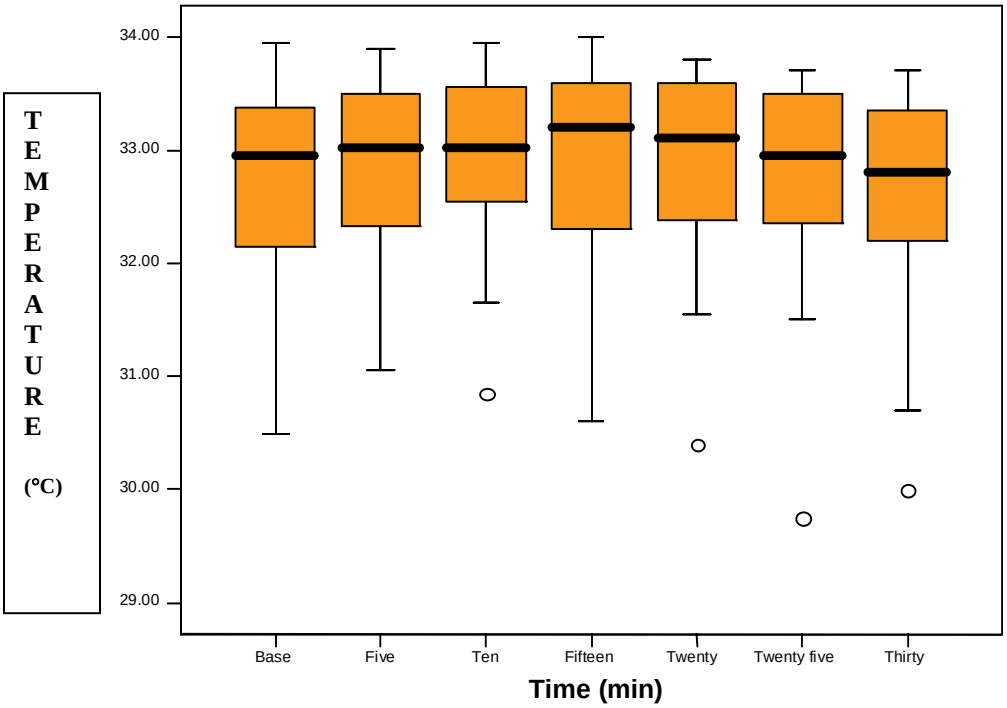


Fig 33: Box plot showing temperature changes in third sessions of placebo patients

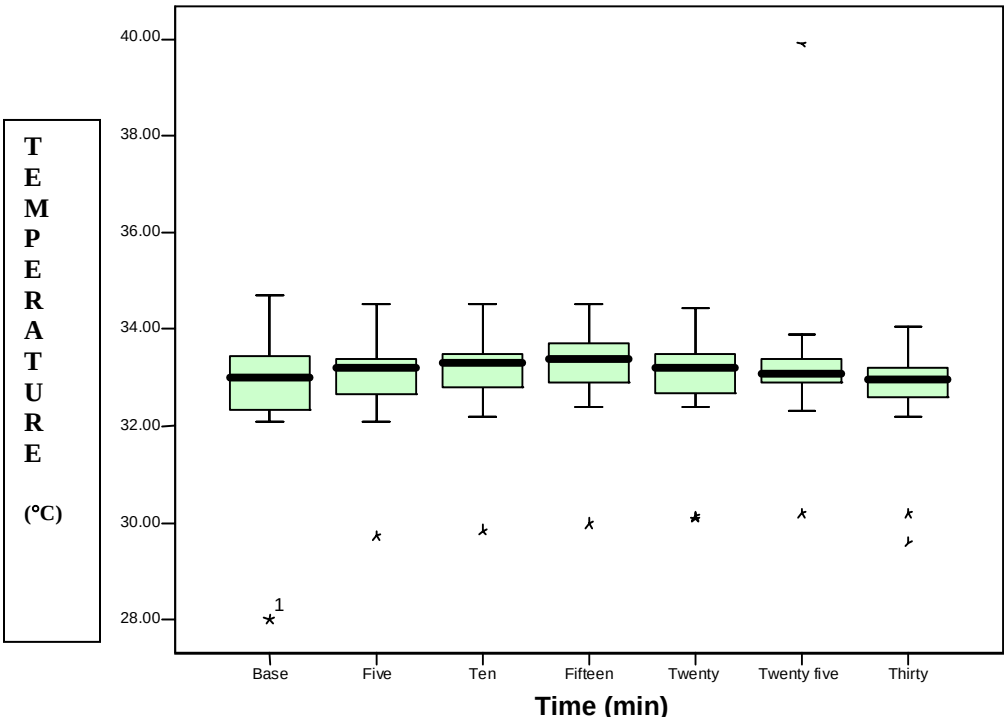


Fig 34: Box plot showing temperature changes in fifth sessions of placebo patients

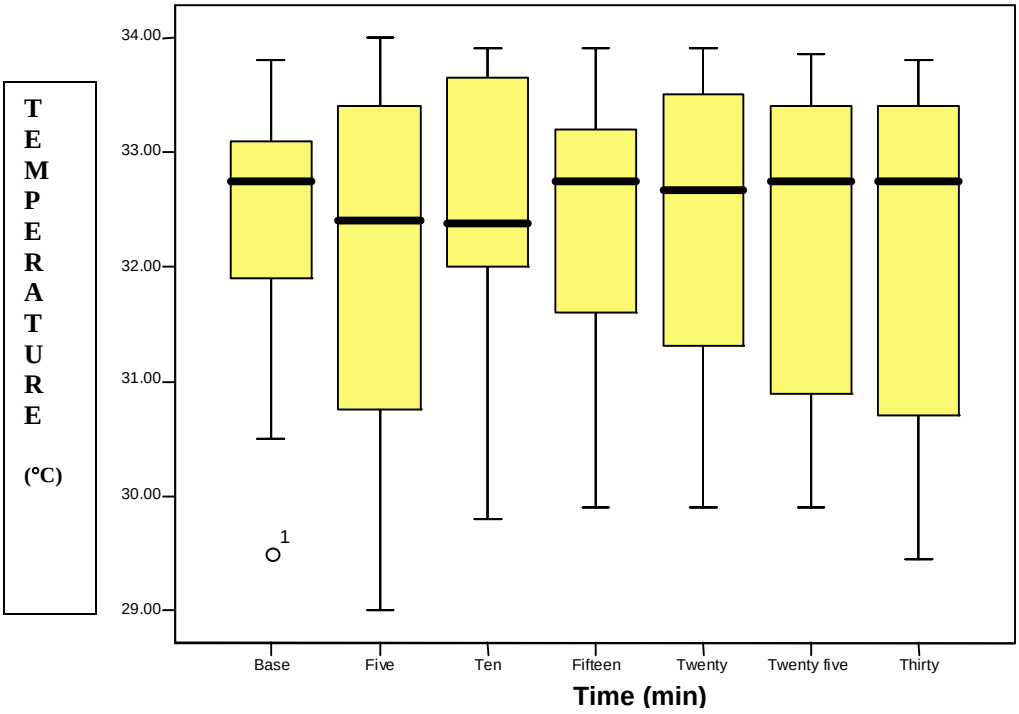


Fig 35: Box plot showing temperature changes in seventh sessions of placebo patients

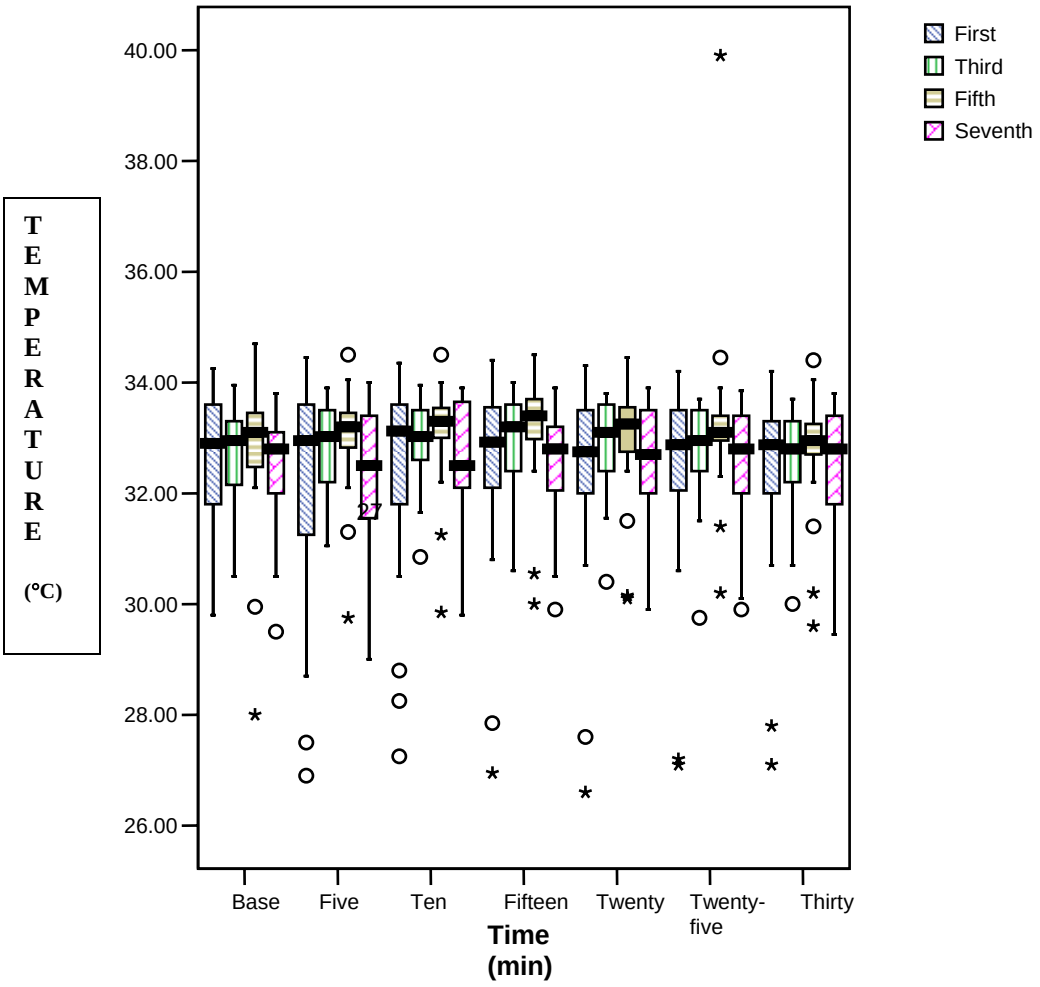


Fig 36: Box plot showing temperature changes in all 4 sessions of placebo patients

Baseline temperature in placebo group

There was no significant change in the baseline temperature. It changed from 33.0 ºC in 1st, 32.95 ºC in 3rd, 33.0 º C at 5th and 32.75 º C at 7th session. (P = 0.42) (Ranges and IQR mentioned above)

TABLE 6: Showing temperature at the baseline and at 20 minutes in needle and placebo group

	1ST SESSION	3RD SESSION	5TH SESSION	7TH SESSION
NEEDLE BASE°C	32.15	33. 35	33.45	33.8
NEEDLE 20MIN°C	33. 52	34.10	34.225	34.6
P-VALUE (Wilcoxon's test)	<0 .001	<0 .001	<0 .001	< 0.001
PLACEBO BASE°C	32.9	32.95	33.1	32.8
PLACEBO 20 MIN°C	32.75	33.1	33.1	32.8
P-VALUE (Wilcoxon's test)	0.25	0.315	0.554	0.417

TABLE 7: COMPARISON OF THE OUTCOMES IN THE TWO GROUPS

Outcome	Needle Acupuncture	Placebo acupuncture	P value
VAS Score (0-10)			
1st session	7.0	6.5	>.05
3rd session	5.0	5.5	-
5th session	4.0	5.0	-
7th session	2.0	4.0	-
Median improvement in VAS Score	4.0	2.5	<. 01
Temperature of hands (°C)			
1st session (baseline)	32.4°C	33.0	>.05
At 20 min	33.5°C	32.75	-
3rd session (baseline)	33.5°C	32.95	-
At 20 min	34.07°C	33.1	-
5th session (baseline)	33.45°C	33.0	-
At 20 min	34.22°C	33.2	-
7th session (baseline)	33.85°C	32.75	<. 001
At 20 min	34.5°C	32.65	-
NPAD score (0-100)			
1st session	50.00	45.0	>.05
7th session	20.5	24.0	-
Median improvement in NPAD score	29.5	20	<. 01
Muscle pressure pain threshold (lb/cm2)			
Mid Trapezius			
1st session	8.05	8.0	>.05
5th session	9.35	7.0	-
7th session	9.98	5.5	<. 001
Infraspinatus			
1st session	8.13	7.65	>.05
5th session	8.88	7.00	-
7th session	9.38	6.15	<. 001
Mid deltoid			
1st session	7.93	7.58	>.05
5th session	8.6	6.43	-
7th session	9.7	7.02	< .001
Mid tibia			
1st session	12.4	11.75	>.05
5th session	12.3	10.35	-
7th session	12.18	11.50	>.05

CHAPTER 4

DISCUSSION

Mechanical neck pain is a common complaint amongst patients who seek acupuncture treatment at our clinic. As previous systematic reviews (53,54) did not conclusively prove that acupuncture is effective for this symptom, we conducted a pilot study and followed by a randomized, single blind, placebo-controlled study (RCT) to evaluate the role of acupuncture in mechanical neck pain of more than three months duration. In addition to using the VAS score for pain as the conventional primary outcome measure, we also compared the NADP index before and after treatment in the RCT. Furthermore, we also studied changes in skin temperature and muscle pressure pain threshold, before and after a course of acupuncture. The results will give us further ideas on the mechanisms of action of acupuncture.

The results from the pilot study and the RCT showed that the type of acupuncture therapy as employed by us was effective in reducing the pain symptom, as evidenced by the significant reduction in the VAS scores at the end of a course of acupuncture therapy, when compared to their respective pre-treatment values. Although the VAS scores were also significantly decreased in the placebo group, the absolute reduction in the VAS scores in the needle group was significantly better than the placebo group. In addition, chi-square test analysis also showed a significant improvement (defined as a 50% reduction in VAS score or VAS score of 3 or less) amongst patients who received needle acupuncture compared to patients who received placebo acupuncture.

Many previous studies comparing needle acupuncture and placebo acupuncture could not detect a significant difference between the two groups (71, 72), this is because the placebo acupuncture techniques involved actual penetration of skin and muscle tissues (same as needle acupuncture), except that they were carried out at 'non-acupoints' or acupoints which were not known to have the therapeutic effects for the clinical condition being studied. This 'control method' for studying pain condition has been known to be flawed, as there are no universally accepted inert control points. Moreover, any penetration of skin and muscle anywhere on the body would have elicited certain physiological effects both locally and distally (e.g. endorphins release), hence requiring a very big sample size to detect a significant difference.

We used a validated sham needle (48-52) which does not involve skin penetration, hence eliminated the non-specific effects elicited by skin penetration. It is well known that all treatment modality will carry some degree of placebo effect; this is especially so when it comes to complementary and alternative therapy such as acupuncture. This is illustrated in our results that patients who received placebo acupuncture also experienced a significant reduction in their VAS scores. However, there were significantly higher numbers of patients in the needle group who had significantly improved. Moreover, the needle group also had a significantly more absolute reduction in VAS scores. Taken together, our results showed that needle acupuncture has a therapeutic effect in patients with mechanical neck pain. The mechanisms of acupuncture analgesia could be multiple; these may involve both a spinal (trigger points release; gate-control mechanism; activation of descending inhibitory pathways) and supra-spinal mechanisms (release of endorphins and inhibition of central sympathetic control) [see above]

Chronic pain has been acknowledged to be a complex perceptual experience, with a number of underlying factors that include sensory, affective and intensity dimension. We evaluated the Neck Pain and Disability Index questionnaire in our study. We hypotheses that this questionnaire might permit a more comprehensive assessment of our patient's neck pain. Our results showed that the NADP index improved in both groups but the needle group had more significant reduction in NPAD score than the placebo group. (70)

In addition to the improvement in VAS scores. Our study also demonstrated some other physiological effects of needle acupuncture; namely needle acupuncture at the neck and shoulder areas were accompanied by a significant increase in skin temperature of both hands, and a significant increase in muscle pressure pain threshold of the neck and shoulder muscles. Both these parameters did not varied significantly in the placebo group.

The results from our pilot study showed that EA caused an increase in skin temperature of both hands as recorded by infrared thermography. The increase in temperature is due to vasodilatation involving at least the cutaneous blood vessels; this in turn is most probably due to a reduction in the sympathetic tone exerted on the skin vessels. As the skin blood vessels are known to supply by only the sympathetic fibres, this strongly suggests that EA as administered in this study is able to cause a sympatholytic effect. The increase in temperature was statistically significant and was consistent during the four recorded EA treatment sessions; the temperature usually peaked at 20 minutes following the start of EA. For those patients who completed ten sessions of EA, a significant

increase in the baseline hand temperature was also observed at the tenth session as compared to the first session before EA started. The same results were confirmed in the RCT. These changes were not observed in the normal controls (pilot study) and the placebo group (RCT).

We also postulate that there is an increase in the basal sympathetic tone in patients who suffer from chronic neck pain; this is supported by the significantly higher hand temperature in a group of healthy volunteers without neck pain (pilot study). Although we could not rule out that some increase in sympathetic tone observed in patients was due to anxiety and / or stress associated with the impending EA; whereas the volunteers are free from such mental stress. The consistent finding of an increase in temperature during each session of EA would support the sympatholytic effect of EA on these patients.

The sympathetic inhibition observed can be due to either a centrally mediated reflex, a presynaptic inhibition of sympathetic nerves or release of endogenous opioids including β endorphin. (28,29,73,74). Anatomical, physiological and pharmacological observations have indicated features common to the central endogenous analgesic system and the thermoregulatory system. (75, 76,77) The opiate receptors are found in high concentration in brainstem and in the hypothalamic thermoregulatory centers while the serotoninergic system (78) implicated in acupuncture analgesia is also believed to be a part of central thermoregulatory pathway.

Generalized or localized vasodilatation following EA had been demonstrated previously (40,43,79,80). However, Scudds et al (81) showed a cooling effect of EA on skin

temperature following acupuncture at LI4 & SI3 points. This contradictory result could be due to the use of a higher strength of stimulus (causing pain) and the use of different points for acupuncture.

A positive correlation between an increase in skin temperature and acupuncture analgesia had been reported by Cao et al (79). They also showed that nor-epinephrine (NE) release in brain and plasma NE were decreased by EA suggesting mainly central inhibition of NE system by EA. The inhibitory effects on NE system are accompanied by a rise in pain threshold, suggesting inhibition of sympathetic activities playing a favorable role in acupuncture analgesia. Collins (81) also found an association between pain relief and reduced vasomotor activity in 20 neck and arm patients who were given acupuncture. On the other hand, Dyrehag et al (79) followed up a group of patients who were given a series of acupuncture session, although they found that the baseline temperature was more than 1°C above baseline at all locations, but they could not find a correlation with pain relief.

We postulate that a vasodilatory response to EA in patients with mechanical neck pain may be a good screening test to predict who will be responsive to EA therapy, this will save time and money for the patients who will be assigned other treatment modalities.

The other interesting finding is the significant increase in muscle pressure pain threshold (MPPT). The MPPT increased over the trapezius, infraspinatus and deltoid muscles (C5, 6) in the needle group but not the placebo group. There was no significant change in the MPPT measured over the tibialis anterior muscle in both groups. As the trapezius,

infraspinatus and the deltoid muscles shared the same spinal segments as the painful areas (C5, 6), which EA were applied; whereas the lumbar segments supply the tibialis anterior muscle. This finding strongly supports the segmental acupuncture mechanism for pain relief (see section 1.6 Mechanisms of action of acupuncture). This mechanism involves the stimulation of acupuncture points, which share the same spinal segments as the symptomatic areas. The needle sensation basically activates (via A δ fibres) the inhibitory interneurons at the spinal dorsal horn, which inhibit transmission of noxious impulses to the CNS (gate-control theory). The same needle sensation can also activate of the descending inhibitory pathways, which will further modulate the noxious sensation at the dorsal horn.

Although very few of our patients presented with classic trigger points, applying acupuncture at these trigger points and other tender areas have been shown to be effective in treating myofascial pain. This thesis only report the immediate treatment outcome of our patients, it would be clinically more useful to report a longer term follow-up, a 1 year post treatment follow-up by telephone interview is being conducted.

CONCLUSION:

Needle acupuncture (as compared to placebo acupuncture) is effective in improving the VAS and the NADP scores of patients with chronic mechanical neck pain. The analgesic effect of acupuncture is partly contributed by an increase in the local MPPT, as evidenced by the significant increase in MPPT measured on the neck and shoulder muscles (trapezius, infraspinatus and deltoid), which share the same cervical segments as the

painful area (C5, C6). There was no change in the MPPT of the tibialis anterior muscle, which is supplied by the lumbar spinal segment. Deactivation of the trigger points will also contribute to the improvement of the pain symptom.

Additional analgesic effect can also be contributed by acupuncture induced endorphins release from the central nervous system, (82) which has been shown to exert an inhibitory effect on the sympathetic centre in the medulla. (83) This will lead to an increase in skin blood flow (control exclusively by the sympathetic system) as evidenced by the significant increase in hand temperature measured during and after EA. Other neurological mechanisms involved may include the gate-control mechanism and activation of the descending inhibitory pathways.

Significant increases in MPPT and skin temperature were not observed in patients who received placebo acupuncture.

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Appendix – I

NECK PAIN AND DISABILITY VISUAL ANALOGUE SCALE

Name: _____ Date: _____/_____/_____

ID Number: _____ Chart Number: _____ Examiner's Initials: _____

PLEASE MAKE AN "X" ALONG THE LINE TO SHOW HOW FAR FROM NORMAL TOWARD THE WORST POSSIBLE SITUATION YOUR PAIN PROBLEM HAS TAKEN YOU.

1. How bad is your pain today? SCORE

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____15

NO PAIN MOST SEVERE PAIN

2. How bad is your pain on the average?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____15

NO PAIN MOST SEVERE PAIN

3. How bad is your pain at its worst?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____15

NO PAIN CANNOT TOLERATE

4. Does your pain interfere with your sleep?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____15

NOT AT ALL CAN'T SLEEP

5. How bad is your pain with standing?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____15

NO PAIN MOST SEVERE PAIN

6. How bad is your pain with walking?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____15

NO PAIN MOST SEVERE PAIN

7. Does your pain interfere with driving or riding in a car?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____15

NOT AT ALL CAN'T DRIVE

OR RIDE _____

8. Does your pain interfere with social activities?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____15

NOT AT ALL ALWAYS

9. Does your pain interfere with recreational activities?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____15

NOT AT ALL ALWAYS

\10. Does your pain interfere with work activities?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____l5

NOT AT ALL CAN'T WORK

11. Does your pain interfere with your personal care (eating, dressing, bathing, etc.)? SCORE

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____l5

NOT AT ALL ALWAYS

12. Does your pain interfere with your personal relationships (family, friends, sex., etc.)?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____l5

NOT AT ALL ALWAYS

13. How has your pain changed your outlook on life and the future (depression, hopelessness)?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____l5

NO CHANGE COMPLETELY CHANGED

14. Does pain affect your emotions?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____l5

NOT AT ALL COMPLETELY

15. Does your pain affect your ability to think or concentrate?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____l5

NOT AT ALL COMPLETELY

16. How stiff is your neck?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____l5

NOT STIFF CAN'T MOVE NECK

17. How much trouble do you have turning your neck?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____l5

NO TROUBLE CAN'T MOVE NECK

18. How much trouble do you have looking up or down?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____l5

NO TROUBLE CAN'T LOOK UP OR DOWN

19. How much trouble do you have working overhead?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____l5

NO TROUBLE CAN'T WORK OVERHEAD

20. How much do pain pills help?

0l_____:_____l_____:_____l_____:_____l_____:_____l_____:_____l5

COMPLETE RELIEF NO RELIEF

TOTAL SCORE_____

AGE:_____**OCCUPATION**_____

Appendix- II

CASE RECORD FORM

1. NAME:
2. AGE :
3. SEX:
4. IC NUMBER:
5. ADDRESS:
6. CONTACT NO.:
7. REFFERED BY: SELF/ORTHOPAEDICIAN/PHYSIOTHERAPIST
8. OCCUPATION:
9. ETHNIC GROUP: CHINESE/ MALAY/ INDIAN/OTHERS
10. PREDOMINANT LANGUAGE AT HOME/ WORK:
11. MARITAL STATUS: SINGLE/ MARRIED / DIVORCED / WIDOWED
12. RELIGION: NONE/ BUDDHIST/ CHRISTIAN/ HINDU/ MUSLIM
13. DURATION OF NECK PAIN:____ DAYS/WKS/MTHS/ YEARS
14. PAIN SCORE ON A VISUAL ANALOGUE SCALE OF 10:

    0____1____2____3____4____5____6____7____8____9____10

15. HISTORY OF ANY REFFERED PAIN:
16. HISTORY OF ANY NEUROPATHY: NUMBNESS/ TINGLING/ PIN POINT NEEDLES
17. HISTORY OF ANY HEADACHE/ NAUSEA / VOMITTING
18. HISTORY OF ANY PAIN KILLERS BEING TAKEN, AMT, NATURE, FREQUENCY:_____

19. HISTORY OF ANY SUCH PREVIOUS PAIN: Y /N

20. HISTORY OF PAIN IN ANY OTHER PART OF THE BODY:

21. HISTORY OF ANY CONCURRENT THERAPY: PHYSIOTHERAPY/ MASSAGE/OTHERS

22. HISTORY OF ANY MEDICAL ILLNESS: DM/ HT/ HEART DISEASE/ RHEUMATIC DISEASE :

23. HISTORY OF ANY MALIGNANCY:

24. HISTORY OF ANY SURGERY:

25. HISTORY OF ACUPUNCTURE :

Date												
Visit No.												
VAS Score												
Pain threshold at Trigger Point												
	Rt.	**Lt.**	**Avg.**	**Rt.**	**Lt.**	**Avg.**	**Rt.**	**Lt.**	**Avg.**	**Rt.**	**Lt.**	**Avg.**
Temperature Before Acupuncture												
Temperature 5 minutes after Acupuncture												
Temperature 10 minutes after Acupuncture												
Temperature 15 minutes after Acupuncture												
Temperature 20 minutes after Acupuncture												
Temperature 25 minutes after acupuncture												
Temperature 5 minutes after needles are removed												