Effectiveness of 2 Weeks Qigong Exercise Therapy Vs Conventional Physiotherapy Management in Post Surgical Breast Cancer Survivors: A Randomized Clinical Trail

Authors
Dr VC. Naik¹, YS. Patil², AR.Pandya³
MPT, Lecturer, KLE University Institute of Physiotherapy, Belagavi, India
KLE University Institute of Physiotherapy, Belagavi

ABSTRACT
Background- Breast cancer being the most prevalent cancer amongst women has the highest survival rates amongst all cancer. Surgery is a part of therapeutic process that helps in preventing metastases. However, it can significantly diminish functional capacity in patients, hamper the quality of life and causes pain. Conventional physiotherapy contributes to its treatment with the use of different techniques that have been developed over years. Qigong therapy is a traditional Chinese medicine and also a moderate form of exercise that may help in improving the shoulder ROM along with pain reduction and hence improving quality of life.

Patients and methods- 30 breast cancer survivors between age group 25 to 69(p<0.05) years of age were recruited from Dr. Prabhakar Kore K.L.E. hospital and MRC, Nehrunagar, Belagavi, Karnataka and KLE’s society Belgaum Cancer Hospital, Ashoknagar, Belagavi, Karnataka.

Method- Participants were randomly assigned to two group i.e. Group A (n=15) and were treated with Qigong therapy and Group B(n=15) were treated with Conventional Physiotherapy, both groups were treated for 14 sessions. Outcome was measured in terms of pain using VAS(Visual Analogue Scale), quality of life was assessed using Functional Assessment of Cancer Therapy-Breast version+4 (FACT-B+4) questionnaire and Shoulder Range of Motion (ROM) using universal goniometer was recorded pre-intervention and post-intervention.

Results- The difference OF VAS scores was highly significant with p value of 0.0212*. the difference of FACT-B+4 score was highly significant with p value of 0.0175* and difference in terms of shoulder ROM showed highly significant with p value of 0.0001* in group A than Group B

Conclusion- Qigong therapy is better than conventional physiotherapy in reduction of pain improving quality of life and shoulder range of motion in post-surgical breast cancer survivors.

Keywords- Qigong therapy, Conventional physiotherapy, Functional Assessment of Cancer Therapy-Breast version+4 (FACT-B+4), Visual Analogue Scale(VAS), Shoulder Range of Motion(ROM).
INTRODUCTION
Breast tissue is defined as a modified cutaneous exocrine gland consisting of skin, subcutaneous tissue, ducts, lobules, along with stoma which includes ligaments, arteries, veins, nerves, and lymphatic's[1].

Breast cancer is one of the most common cancer seen in India. Breast cancer is expected to record 2 million females suffering by year 2030 throughout the world. Worldwide breast cancer occupies for 23% among all the cancers in females. In India, 25.8 per 1,00,000 is the incidence and mortality of 12.7 per 1,00,000 which is high as compared to united kingdom’s incidence of 95 per 1,00,000 and mortality of 17.1 per 1,00,000[2]. Breast cancer is known to be the most prevalent cancer100,000 women in Western Europe and about 40 per 100,000 in developing countries[3].

In age group of 25 to 69 year the maximum of number of breast cancer was seen in 50 to 54 years of age group with mean age of 45.64[4].

Physiotherapy plays important role in breast cancer care in terms of pain reduction, improving quality of life and also essential in prevention of secondary lymph oedema in post-surgical breast cancer survivors[5]. Early onset rehabilitation physiotherapy management program after modified radical mastectomy provides improvement in shoulder mobility and functional capacity without causing an adverse effect in postoperative period.[6]

Physical therapy is an approach which used to increase shoulder function in post-operative breast cancer patients when administered for a longer period of time and instituted after the immediate post-operative phase. The standard treatment includes daily demonstrations and instructions in shoulder and vein pump exercise during the first post-operative week[7]. Exercise training has been shown to produce many positive physiological and psychological benefits. Exercise can improve cardiovascular efficiency, increase cardiac output and stroke volume, decrease heart rate, lower exercise heart rate, and improve ventilation and transport of oxygen from the environment to the cell. These have the potential to reverse cancer toxicities and minimize cancer treatment-related fatigue in breast cancer survivors[8].

Shoulder impairment is well known and frequently seen post treatment in breast cancer patients generally due to surgical trauma and scarring as a result of axillary dissection and also occurs due to fibrosing effect of adjuvant radiotherapy[9].

A study was done on Physiotherapy Management of Post-Operative Breast Cancer Patients which incorporated the interventions of Soft tissue techniques, Shoulder stretches, gleno-humeral joint range of motion exercises, strengthening exercises, hydrotherapy, passive mobilisations, electro physical agent modalities, neural tension techniques[10]. The present study is incorporated with conventional physical therapy group of post-surgical breast cancer survivors.

A study concluded that initiation of physiotherapy exercises in post surgical breast cancer patients will result in better achievement of short term goals i.e., of shoulder mobility and overhead activities but early initiation of physiotherapy protocol may also increase the wound drainage and increase the duration of drainage, another study concluded that there was a better recovery seen in the averages of the flexion, abduction and external rotational movements of the shoulder[11].

Exercises have been found to be safe method for enhancing quality of life by dealing with various post surgical breast cancer complications and improving various domains of functional capacity of an individual[12].

Qigong therapy is believed to be the basis of traditional Chinese medicine which is known to be an ancient form of health maintenance dating back thousands of years.[13] Qigong is subdivided into two categories i.e., internal qigong and external qigong. Qigong exercise or internal qigong works on self directed harmonious flow of...
energy by using gentle movements, posture of exercise and controlled breathing. External qigong is performed by trained practitioner using their hands to cultivate energy (qi) onto the patient’s body for therapeutic purpose.\textsuperscript{14}

Qigong therapy works on basis of ‘qi leads the blood circulation’ i.e., it improves blood circulation by smooth flow of energy and hence causing regulation of blood flow thus providing essential nutrients and sufficient oxygen leading to removal of waste products and relieving the diseased cell and improving the functional efficiency of the person\textsuperscript{15}.

There is increasing evidence of qigong therapy reducing symptoms and improving quality of life of breast cancer patients. Qigong therapies also less exertive than conventional aerobic exercises. Qigong exercises have also shown positive results in improving sleep patterns and reducing insomnia caused due to various psychological issues in post surgical breast cancer patients. As compared to Yoga exercises and Tai-chi, qigong exercises are easy to learn and practice. A study has shown positive result of Tai-chi on physical function, mental health, and biomarkers of inflammation but not on sleep and fatigue hence in another study qigong therapy was given to breast cancer patients and improvement was seen thus proving various benefits of qigong therapy.

According to recent research qigong therapy works on two pathways that is by focussing on meditation and deep breathing which increases melatonin in body and also works on stress response pathway\textsuperscript{16}.

Qigong therapy is has shown improvement in cancer patient regarding Quality of life, mood status, and also produce physical benefit\textsuperscript{18}.

Qigong was proved as an effective nursing intervention for reduction of fatigue, difficulty of daily activities and some of symptoms of chemotherapy side effect as nausea, vomiting and stomatitis\textsuperscript{17}.

Qigong is helpful to some extent to ameliorating the symptoms, improving appetite, strengthening constitute and increasing the ability of self-cure\textsuperscript{20}. There is increase in evidence of qigong on overall health of human body.\textsuperscript{21}The studies also lacked validated outcome measures with large scale RCT’s\textsuperscript{14}. Hence the present study is designed to evaluate the effectiveness of 2 weeks qigong exercise therapy vs. Conventional physiotherapy management in post-surgical breast cancer survivors.

**METHOD**

Participants- 30 post-surgical breast cancer survivors were recruited in the study. The inclusion criteria for the above subjects were

a) Post- surgical breast cancer patients.
b) Brachial plexopathy Grade 1, 2, 3.
c) Third post operative day,
d) Subjects willing to participate.

The exclusion criteria were a) metastases to bone, b) unstable vitals, c) wound infection, d) axillary web syndrome.

The study was carried out in KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehrunagar, Belagavi and K.L.E.’s Society Belgaum Cancer Hospital, Ashoknagar, Belagavi. The study was approved by Institutional Ethical Committee of KLES Institute of Physiotherapy, Belagavi.

**OUTCOME MEASURES**

The outcome measures used were Visual Analogue Scale (VAS) for evaluation of pain and quality of life using Functional Assessment of Cancer Therapy-Breast version+4 (FACT-B+4) questionnaire and shoulder range of motion (ROM) using universal goniometer. Pain was measured using VAS by asking the patient to mark a point as per the severity of her pain on a 0-10 cm scale, where 0 symbolized no pain and 10 symbolized worst pain. The FACT-B+4 questionnaire consists of 42 items, divided under 5 components the subjects were asked to rate their experience of symptom on a 5-point scale,
ranging from “not at all” to “very much.” Shoulder Range of motion of flexion, extension, abduction and adduction, medial and lateral rotation was recorded pre and post intervention using universal goniometer.

**INTERVENTION**

The subjects were randomly allocated to two group i.e Group A-Qigong therapy (n=15) and group B-Conventional Physiotherapy (n=15). Group A was treated with qigong therapy which included following exercises 1. Feudal lord pulls the bow, 2. Immortals push the stone tablet, 3. Baby bird receives the food, 4. Swinging the arms, whereas group B of conventional physiotherapy was given with active Range of motion exercises of shoulder along with shoulder shrugs and hand behind the back exercises. Both the group exercises were given in standing position (fig.1) and (fig.2), the participants received treatment for 40-50 minutes once for 2 weeks in total counting to 14 sessions.

**RESULTS**

**Age:** In this study, the age of participants allocated in both the group A and B was between 25-69 years. The mean age of the participating individuals in group A was 50.80± 8.68 and that in group B was 51.93± 8.31. The difference between mean ages of the 2 groups with $p$ value of 0.7176, which is not signify.

**Visual Analogue scale:** The present study showed reduction in VAS score with pre-intervention and post-intervention mean difference of 3.40± 0.91 in GROUP a and a mean 2.67±0.72 in group B and with highly significant $p$ value of 0.0001*.(table 1)

<table>
<thead>
<tr>
<th>Groups</th>
<th>Time</th>
<th>Mean</th>
<th>Std.D v.</th>
<th>Mean Diff.</th>
<th>SD Diff.</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>Pretest</td>
<td>6.60</td>
<td>1.24</td>
<td>3.40</td>
<td>0.91</td>
<td>0.0001*</td>
</tr>
<tr>
<td></td>
<td>Posttest</td>
<td>3.20</td>
<td>1.08</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group B</td>
<td>Pretest</td>
<td>6.80</td>
<td>0.77</td>
<td>2.67</td>
<td>0.72</td>
<td>0.0001*</td>
</tr>
<tr>
<td></td>
<td>Posttest</td>
<td>4.13</td>
<td>1.13</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Functional assessment of cancer therapy:** breast +4: The present study showed improvement in FACT-B+4 score with pre-intervention and post-intervention mean difference of 2.47±8.23 in group A and a mean 15.87±10.32 in group B with of $p$-value of 0.0175*.(table 2)

<table>
<thead>
<tr>
<th>Groups</th>
<th>Time</th>
<th>Mean</th>
<th>Std.D v.</th>
<th>Mean Diff.</th>
<th>SD Diff.</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>Pretest</td>
<td>66.27</td>
<td>9.56</td>
<td>-24.47</td>
<td>8.23</td>
<td>0.0001*</td>
</tr>
<tr>
<td></td>
<td>Posttest</td>
<td>90.73</td>
<td>8.97</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group B</td>
<td>Pretest</td>
<td>69.67</td>
<td>10.20</td>
<td>-15.87</td>
<td>10.32</td>
<td>0.0001*</td>
</tr>
<tr>
<td></td>
<td>Posttest</td>
<td>85.53</td>
<td>15.69</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Shoulder Range of motion(table 3):**

<table>
<thead>
<tr>
<th>Shoulder movement</th>
<th>Mean difference in Group A</th>
<th>Mean difference in Group B</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>31.00±10.68</td>
<td>22.73±9.97</td>
<td>0.0369*</td>
</tr>
<tr>
<td>Extension</td>
<td>14.67±7.04</td>
<td>10.33±6.30</td>
<td>0.0864*</td>
</tr>
<tr>
<td>Abduction</td>
<td>29.40±10.72</td>
<td>20.13±9.69</td>
<td>0.0193*</td>
</tr>
<tr>
<td>Adduction</td>
<td>29.40±10.72</td>
<td>20.13±9.69</td>
<td>0.0193*</td>
</tr>
<tr>
<td>Medial rotation</td>
<td>12.47±7.83</td>
<td>12.73±12.29</td>
<td>0.9440</td>
</tr>
<tr>
<td>Lateral rotation</td>
<td>11.53±9.51</td>
<td>13.40±9.60</td>
<td>0.5968</td>
</tr>
</tbody>
</table>

Highly significant
DISCUSSION
The present randomized clinical trial was aimed to find out the effectiveness of two weeks of qigong therapy vs. conventional physiotherapy in post-surgical breast cancer survivors in terms of pain reduction, improvement of range of motion and quality of life using VAS scores, range of motion, FACT-B+4 questionnaire.

The subjects were divided into two groups, group A and group B, Qigong therapy and Conventional Physiotherapy respectively, 30 subjects were randomly assigned to both the groups using envelope method.

The study included visual analogue scale (VAS) which was used as an outcome measure for quantifying pre and post difference in management of pain. As VAS has higher reliability for pain evaluation according to Bijur PE et al. In this study while comparing both the groups, it was noted that Group A - Qigong therapy was significantly better than group B - Conventional physiotherapy (table no.1) it may be because Qigong works on 3 channels i.e., it increases energy flow and strikes over the diseased cell and good health is due to well-balanced and free flowing qi in body, whereas sickness and pain are due to blockage and unbalanced qi in the body systems, due to which the blood flow to the cell is affected and qigong therapy helps it through motivating qi and energy within the body, by breaking the qi blockage and balancing the energy systems. These possible effect is supported by a study done by Kevin chen and Rapheal Yeung where they reviewed more than 50 studies of qigong therapy for cancer in china and concluded that qigong therapy for cancer treatment is a powerful alternative to what is been used currently for treating cancer.

In this study Quality of life was also assessed using (FACT-B+4) as Quality of life in breast cancer survivors is often hampered due to side effects of treatment and symptoms of disease itself. Similarly a study done by Fong SM et al used FACT B questionnaire for analyzing Quality of life in breast cancer patients.

The study also assessed quality of life using FACT-B+4 questionnaire, in group A viz. Qigong therapy it showed better results in improvement of quality of life than group B viz. Conventional physiotherapy (table no.2), the possible result may be due to overall reduction in pain and improvement in shoulder mobility thus helping for daily activities to be performed with more ease and qigong is also believed to diminish the side effects of treatment through gentle exercise and relaxation by meditation and breathing exercise which is also backed by a pilot study done by Oh Byeongsang et al which concluded that medical Qigong along with usual medical treatment can enhance quality of life and reduce inflammation in cancer patients.

In consensus to a study by Richard L Gajdasik and Richard W Bohannon, ROM using universal goniometer was done in a study concluded that clinicians should adopt standardized methods of testing and should interpret and report goniometric results as ROM measurements, thus in this study active shoulder Range of motion was analyzed using universal goniometer, which has good intra-rater reliability and clinical utility according to Perdona M et al.

Similarly When Group A viz. qigong therapy was compared to group B viz. Conventional physiotherapy subjects in terms of Shoulder ROM of flexion, extension, abduction, adduction...
showed better results with group A viz. qigong therapy intervention, whereas medial and lateral rotation showed better results in conventional physiotherapy intervention(table no.3). In consensus to a study, by Fong SM et al which concluded that qigong therapy might improve shoulder muscular strength and functional wellbeing in breast cancer survivors, our study found significant difference in shoulder ROM which contraindicates the finding of study done by Fong SM this may be due to the comparison of shoulder ROM of the breast cancer survivors with a healthy control group however in our study pre-intervention and post-intervention analysis was done of the affected side shoulder.

This study concludes that both Qigong therapy and Conventional physiotherapy are effective in the rehabilitation of post-surgical breast cancer survivors clinically, but when compared for the better outcome, the group receiving Qigong therapy proved to be effective in management of pain, overall shoulder mobility and improving quality of life than the group receiving Conventional physiotherapy.

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