Effect of ginger oil application on functional status among patients with severe osteoarthritis: a quasi-experimental clinical trial

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Osteoarthritis (OA) also known as degenerative joint disease or osteoarthrosis is a worldwide health problem increasing nowadays especially among elderly people. It is the most common and frequently disabling of the joint disorders. The primary clinical manifestations of OA are pain, stiffness, and functional impairment. This article is a report of a study evaluating the effect of applying freshly prepared ginger oil on the functional status of patients with severe osteoarthritis for 4-consecutive weeks. The study was conducted at Rheumatology and Rehabilitation unit, associated with a university hospital. Nonequivalent control group pretest-posttest time series design was utilized, hence, a convenient sample consisting of 60 adult male and female patients assigned randomly to either study or control groups. Data was collected using two tools, the first one was Short Arthritis Severity Assessment Scale (SAS), and the second was Arthritis Impact Measurement Scales 2 (AIMS2). The study results revealed observable improvement in the study group functional status mean scores in comparison to a control group two and four weeks after ginger application as follows; (4.53±0.48 vs. 6.067±0.50); (2.71 ± 0.51 vs. 5.33 ± 0.52). Ginger oil application has the potential to relieve pain, and accordingly, the overall functional status of patients with severe osteoarthritis.

Key words: Ginger (Zingiber officinale) oil; Functional status; Severe osteoarthritis.

INTRODUCTION

Osteoarthritis (OA) is a chronic degenerative disease of the articular cartilage primarily affecting the hips, knees, and hands. It is the most common form of arthritis and the leading cause of disability among elderly people. The disease is associated with significant pain; limitation in mobility and basic daily activities. In fact, OA accounts for more problems while climbing stairs and walking as well as lost efficacy at work than any other joint diseases (Therkleson, 2014; Bartholdy et al., 2016). The chronic pain and disability caused by OA often lead to compounding health issues, such as chronic tiredness, anxiety, and depression that need to be considered in the overall management of the disease (Marks, 2015). Current therapeutic treatments for OA are mostly palliative and focus on the relief of signs and symptoms, however, treating OA pain is complex as pain is a multifactorial biopsychosocial phenomenon that is not completely understood. Additionally, pain and other symptoms of OA are not correlated to radiographic evidence of the disease (Thysen et al., 2015). Osteoarthritis management pathway could be divided distinctly into different categories and ordered as: Holistic approach and self-management; core treatment including information, exercise and weight loss; and additional treatment options such as non-pharmacologic, pharmacologic, and surgical. Therapeutic management should be holistic as well as individually tailored to the patients' expectations; the levels of function and activity; the joints involved; the severity of the patient’s
disease; occupational and vocational needs; and to the nature of any coexisting health problems (Funk et al., 2016).

Pharmacologic interventions such as analgesics, NSAIDs and steroid injections, can ease the pain, though are incapable of repairing damaged tissues in addition to its significant adverse events including gastritis, increased risk of cardiovascular disease, kidney dysfunction, hepatic dysfunction, hematologic abnormalities and reappearance of symptoms after discontinuation of therapy (Lapane et al., 2015).

Ginger is one of the most important and God gifted natural rhizome that is used in the various purposes in medicinal as well as a home remedy for over 25 centuries (Aborehab et al., 2017). Actually, ginger is an important plant with several ethno-medicinal and nutritional values, mentioned in the Holy Quran and Hadith Sharif by Holy Prophet Mohammad (PBUH) and other Islamic and scientific literature; therefore, it is used extensively worldwide as a spice, flavouring agent and herbal remedy (Marwat, et al., 2015; Aryaeian and Tavakkoli, 2015).

Recently, Ginger extract are used to manage arthritis symptoms in Chinese folk and European hospitals specializing in complementary healthcare (Therkleson, 2014). The scientific rationale for the wide utilization is the fact that, ginger easily penetrates into the body due to its volatile nature as well as it has moderate solubility in water and oil. Two study conducted by (Mashhadi et al., 2014) and (Afshin et al., 2013) supported the trans-derm absorption of ginger. The former study evaluated the therapeutic effect of ginger oil through human epidermis, while the latter one evaluated the ginger oil effect through its application on plaster.

Many of the bioactive constituents of ginger have been identified and the mechanistic aspects of the health effects have also been investigated in many studies. Its active ingredients showed the presence of gingerol and gingerol related compounds, paradol, shogoal, zingerone, zerumbone, terpenoids (Nile and Park, 2015; Srinivasan, 2017). Actually Shogaols are important biomarkers used for the quality control of many ginger containing products, due to their diverse biological activities (Semwal et al., 2015; Fan et al., 2015).

The anti-inflammatory activities of ginger are empirically related to inhibition of cyclooxygenase (COX) enzyme particularly the inducible form (COX-2), rather than the constitutive form (COX-1) (Rahmani et al., 2014), inflammatory leukotrienes suppression (Fan et al., 2015; Bartels et al., 2015) and reduction in nitric oxide (NO) and hs-C reactive protein (hs-CRP) concentration (Hsiang et al., 2015; Naderi et al., 2015). Recently, Nanoparticles derived from ginger have been developed as the novel natural delivery mechanism for improved prevention and treatment of inflammatory bowel disease (Zhang et al., 2016). Nursing is a central changing agent in health care delivery as it is the largest occupational group. Moreover, nursing is one of the most multipurpose occupation in health care; not only do nurses have knowledge in the science of diagnosis and disease treatment, but they play also crucial roles in assessing and triaging acute needs; monitoring; care planning; coaching; providing self-management support; educating and supporting caregivers; and coordinating with community, medical, and social resources. Nurses should also determine the patient's functional status and health care needs. Hence, advocating and encouraging the proper utilization of updated evidence based practice in health care management is an integral part of the nursing care. Therefore, the aim of this study is to evaluate the effect of freshly prepared ginger oil application on functional status of patients with severe osteoarthritis.

Study hypotheses
The following two research hypotheses were postulated:

H1: The functional status mean score of patients with severe OA who receive warm ginger oil application will be different than the functional status mean score of a control group two weeks after application.

H2: The functional status mean score of patients with severe OA who receive warm ginger oil application will be different than the functional status mean score of a control group four weeks after application.

MATERIALS AND METHODS

Design:
Non-equivalent control group pretest-posttest time series design was utilized in this study.

Participants and procedure
Convenient sample consists of sixty male and female adult patients who met the below mentioned inclusion criteria were randomly assigned to either study group - receiving warm ginger oil application - or control group - receiving
routine oral and topical NSAIDS. Randomization was sequential in time as participants were recruited with a 1:1 allocation to each of the two groups.

The sample size was calculated using power of .80 (β = 1-.80 = .20) at alpha .05 (one-sided) with effect size (0.5) as the significance level, as these levels have been suggested for use in the most areas of behavioral science research (Suresh and Chandrashekara, 2012).

Inclusion criteria:
Requirement for the potential participants was that; (a) they score on Short Arthritis Severity Assessment Scale (SAS) more than 28/40, (b) their ages were more than 18 years old, (c) had a confirmed diagnosis of chronic symptomatic osteoarthritis for at least one year, (d) they don't follow any complementary strategies, (e) and they don't manifest any signs and/or symptoms of skin reaction or allergy to ginger oil. Patients with joint replacement, fibromyalgia, and cancer were excluded from the study. When participants met the selection criteria and signed the consent form, Arthritis Impact Measurement Scale 2 (AIMS2) was completed by the researcher before the intervention for the first time.

Procedure
The intervention was carried out for 4-consecutive weeks using freshly prepared ginger oil by experts in complementary medicine (F. M. A. Soliman, personnel communication, June, 20, 2016). The researcher provided each participant in advance with an adequate amount of fresh ginger oil (20 to 30 ml) depending up on the number of joints affected. Clear and comprehensive instructions for usage were explained individually to each participant, including though not limited to; the bottles must be stored far from light, only the needed amount of oil is to be pre warmed prior to application to the affected joints using warm water bath. Participants were instructed also, to spread oil evenly with gentle massage movement over the affected joints when they wake up in the morning for four consecutive weeks.

Arthritis Impact Measurement Scale 2 was completed for each participant by the researcher for the second and third time after two and four weeks of application, respectively. It was completed during participants’ designated follow up visits to the outpatient clinic. In between visits, the researcher followed the participants by telephone to ensure appropriate oil application and answer any related inquiries.

Data Collection Measures
Two adapted tools were utilized to collect data pertinent to this study. The first one was SAS; it is used for participants’ selection. This tool asks four simple questions; the first two are about pain and its severity, while the other two are about difficulty going down stairs and difficulty shopping, each scored on a 10-point Likert-type scale, with 0 for no problem and 10 for very severe problem (Wolfe et al., 2004).

The second tool was (AIMS2) which has proven reliable for assessing the outcome of various treatments and programs in the arthritis diseases (Meenan et al., 1992). It consists of 70 items questionnaire. The first six items deal with socio-demographic data and the seventh explore comorbidity. On the other hand, the second 57 items (items 8 - 64) are broken down into 13 categories including: mobility level, walking and bending, hand and finger function, arm function, self-care tasks, household tasks, social activity, support from family and friends, arthritis pain, work, level of tension, mood and patients satisfaction in relation to the previously mentioned thirteen health status categories. The number of indicators in each category ranges between 4 and 5 indicators.

The AIMS2 scales are scored in a consistent fashion so that a low value indicates a high health status. The range of scores depends upon the number of items in each scale. In order to express these scores in similar units, a normalization procedure is then performed so that scores per scale can be expressed in the range 0-10, with 0 representing normal functional status, 1 > 3 represent mild functional status, 3 > 5 represent moderate functional status, 5 > 7 represent severe functional status, 7 > 9 represent very severe and 10 representing worst functional status.

Validity and reliability
The translated Arabic version of the tools was submitted to a panel of five experts in the field of Medical-Surgical Nursing as well as Rheumatology and Rehabilitation Medicine in order to assure content validity. Experts were asked to examine the instrument for content, clarity wording, length, format and overall appearance. Modifications were carried out according to experts’ feedback. Reliability was established using Cronbach’s alpha which showed a satisfactory level for the two tools as follows (0.70 for AIMS2 and 0.85 for SAS).
Ethical consideration
Primary approval was obtained from the Research Ethics Committees at Faculty of Nursing, Cairo University. Also an official permission was obtained from hospital/units administrators to conduct the study. Each participant was informed about the purpose of the study and its significance. They were informed also that participation in the study is completely voluntary, as well as they have the right to withdraw from the study at any point without any penalty. Additionally, all participants were guaranteed their anonymity and confidentiality through coding of all data. Subjects who chose to participate in the study were asked to sign the consent form.

Statistical analysis
Obtained data was tabulated, computed and analyzed using Statistical Package for the Social Sciences (SPSS) version 22. Descriptive statistics included frequency, mean and standard deviation. Additionally, Chi square and t-test were used to study the difference between groups. Hypotheses were accepted or rejected at .05 level of significance.

RESULTS
Table (1) presents comparison of the demographic characteristics of the participants in both groups. As shown, there was no statistical significant difference between the two groups in terms of age, gender, marital status, educational level, and occupation.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Group</th>
<th>Test</th>
<th>* P- value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exp. (N= 30)</td>
<td>Control (N= 30)</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 - &gt;40</td>
<td>6</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>40 - &gt; 60</td>
<td>14</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>60 &amp; above</td>
<td>10</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>49.2±10.5</td>
<td>50.7±9.55</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>22</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>19</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>6</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>5</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Educational level:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can’t read and write</td>
<td>9</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Read and write</td>
<td>10</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Prep &amp; secondary School</td>
<td>8</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>University&amp; High studies</td>
<td>3</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual work</td>
<td>8</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Writing Administration Work</td>
<td>5</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>School work</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>House work</td>
<td>15</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

* P value ≤ 0.05
Furthermore, the participants were predominantly women, married, housewives and their age between 40-60 years. Table (2) displays comparison of functional status means' score between study and control groups 2 & 4-weeks after intervention. As can be seen from the table that a considerable decrease was observed in functional status mean score of participants receiving ginger oil in comparison to the control group after 2-weeks (4.53 ± 0.48 vs. 6.067 ± 0.50). The same table also demonstrates decline in functional status means' scores in the two groups after 4-weeks, nevertheless, the marked decrease was in favor of participants receiving ginger oil (2.71±0.51 vs 5.33 ± 0.52).

Table (3) demonstrates the significant difference between the study and control groups 2-weeks after intervention (T= 12, 13 & P < .05), therefore the first research hypothesis was supported. The same table demonstrates also there was statistical significant differences between the two groups 4-weeks after intervention (T= 19.63 & P < .05). As a result, the second research hypothesis was supported, as well.

On the other hand, figure (1) displays the functional status means' scores between the study and control groups before application as well as 2 & 4-weeks after application. As apparent from the figure, there is improvement in functional status in both study and control group along four consecutive weeks of intervention, however, the obvious improvement was in those participants receiving ginger oil application.

**Table (2) Means and Standard Deviations of Functional Status Two and Four Weeks after Intervention (n=60).**

<table>
<thead>
<tr>
<th>(Functional status)</th>
<th>Groups</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exp. (N= 30)</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>2-weeks after application</td>
<td>4.53 ± 0.48</td>
<td>6.067 ± 0.50</td>
<td></td>
</tr>
<tr>
<td>4-weeks after application</td>
<td>2.71±0.51</td>
<td>5.33 ± 0.52</td>
<td></td>
</tr>
</tbody>
</table>

* P value ≤ 0.05

**Table (3) T-Test of Functional Status Means Score between Study and Control groups 2 and 4-Weeks after Intervention (n=60).**

<table>
<thead>
<tr>
<th>(Functional status)</th>
<th>T</th>
<th>*P- value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-weeks after intervention</td>
<td>12,136</td>
<td>0.031*</td>
</tr>
<tr>
<td>4-weeks after intervention</td>
<td>19.63</td>
<td>0.024*</td>
</tr>
</tbody>
</table>

* P ≤ 0.05

**Figure (1) Functional Status Means Scores between Ginger Oil and Control Groups prior to and after 2 & 4 Weeks of Intervention (n=60).**
DISCUSSION

This paper presents findings from a study evaluating the effect of ginger oil application on the functional status of patients with severe osteoarthritis. The study findings revealed that, the majority of the participants were over 40 years old; this finding is consistent with recent research findings by (Naderi et al., 2015) they reported that the mean age of their participants was more than forty years old, too.

In addition, National Clinical Guideline Centre (2014) stated that a diagnosis of OA can be made without investigations if a person is aged 45 years or over. In fact, several studies confirmed the high correlation between age and OA as a consequence of several biologic changes that occur with aging due to decreased joint capacity to adapt to different abuses and weaken chondrocytes ability of repairing itself (Mobasher et al., 2015).

The study findings displayed also that, the majority of the participants were females. This finding is congruent with findings of previous studies by Musumeci et al., 2015; Glass et al., 2014). These findings could be interpreted in the light of the fact that, after menopause women are more susceptible to OA because of increasing level of osteocalcin (a protein that is found in the extracellular matrix of bone and in the serum of circulating blood), a marker of bone turnover and bone resorption.

Among the studied participants, the most common occupations were manual and administrative type of work. This findings supported by (Chang et al., 2014) who reported that occupations in which a considerable amount of time is spent in kneeling position and/or lifting heavy loads are the high risk occupations for OA development. The study findings have empirically reported that the functional status of participants with severe OA who received warm ginger oil application was significantly higher than functional status of control group after 2-weeks and the improvement sustained to the 4th week which in turn support the two study research hypotheses.

These findings are supported with several studies on ginger extract and its ability to relieve pain. For example, (Therkleson, 2014) reported that Ginger therapy achieved marked relief of osteoarthritis symptoms that progressively improved over the 24 weeks. Furthermore, in a recent study that evaluated the effect of ginger on pain reported that after the intervention, pain scores declined in both groups, but it was greater among ginger group (Alipour et al., 2017).

Additionally, Yip and Tam, 2008, compared the effectiveness of aromatic ginger oil with orange essential oil for moderate-to-severe knee pain among the elderly in Hong Kong, and declared that there was improvement in physical function and pain which was superior in the intervention group post 1-week. Speaking in the same line, (Sritoomma et al., 2014) reported that aromatic ginger oil was effective in reducing pain among older adults suffering from chronic low back pain.

Several factors may have played a role in the observed phenomenon of the improved functional status among participants applying ginger oil. One possible factor is the mechanistic effect of ginger constituents as anti-inflammatory which is supported by Nile and Park, 2015 who indicated that ginger rhizome fractions and its active constituents having promising anti-inflammatory properties through inhibiting Cyclooxygenase-2, Lipoxygenase-5, prostaglandin synthesis and the release of substance P, a mediator of inflammation and pain, accordingly, it can be used as a potential natural drug against inflammatory related diseases (Aryaeian and Tavakkoli, 2015).

The application of freshly pure warm ginger oil could be postulated as another possible factor in these findings as warm oil helps to dilate the blood vessels; and thereby triggers the movement of stagnated fluids. Moreover, it liquefies or softens mucus stagnations, fatty accumulations and also has a tendency to break up mineral crystallizations. Last but not least, it increases local circulation to the stiffened joint which enhances chemical conjunction of ginger constituents with inflammatory mediators such as interleukin-1 (IL-1), tumour necrosis factor (TNF) and (COX-2).

Other possible explanations that might plausibly account for the differences in the functional status between the study and control group could be the proper instructions of application as mentioned in section (3-2). In addition to the previously discussed factors, there is a potential factor which is the duration of ginger oil application; once per day for four consecutive weeks that allows sufficient time for interaction (Therkleson, 2014).

Increasing awareness among participants suffering from OA for the use of non-conventional or alternative medicine due to lack of adequate current traditional treatment efficacy besides its significant drawback, and the purposive sample used -participants suffering from severe OA - may partially account for the difference between the
study and control group as they may perceive complementary medicine as the last hope for alleviating their suffering.

CONCLUSION
The study concluded that:
- Warm ginger oil application induces significant reduction in the level of functional status mean score among patients with severe osteoarthritis.
- Ginger oil application is a convenient, simple and economical option that needs to be considered in the nursing management.
- It is timely to call attention to the importance of incorporating ginger oil as either an adjunct or an alternative treatment to the traditional treatment of that group of patients.
- Further researches are needed on a large probability sample acquired from different geographical areas to support the generalization of the findings.
- A longitudinal study should be designed to determine the long term effect of ginger oil on functional status of patients with osteoarthritis.
- A qualitative research study should be conducted to understand in depth the lived experiences of patients with OA as they perceive them.
- The sample wasn't randomly selected; therefore it is not necessary representative of the general population of osteoarthritis.
- The scope of the study is also limited; it was restricted to those patients suffering from severe OA and who choose to participates in the study.
- The study findings are limited in generalisability due to the fact that the sample was selected from one geographic area in Egypt.

CONFLICT OF INTEREST
The authors declared that present study was performed in absence of any conflict of interest”.

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AUTHOR CONTRIBUTIONS
AIA designed and performed the nursing intervention as well as wrote the preliminary manuscript. BOA reviewed and approved the final version of manuscript as for HAA helped with data analysis and writing the discussion

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Ginger oil and functional status

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