# Effect of integrated yoga therapy on pain, morning stiffness and anxiety in osteoarthritis of the knee joint: A randomized control study

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#### ABSTRACT

Aim: To study the effect of integrated yoga on pain, morning stiffness and anxiety in osteoarthritis of knees.

**Materials and Methods:** Two hundred and fifty participants with OA knees (35–80 years) were randomly assigned to yoga or control group. Both groups had transcutaneous electrical stimulation and ultrasound treatment followed by intervention (40 min) for two weeks with follow up for three months. The integrated yoga consisted of yogic loosening and strengthening practices, *asanas*, relaxation, *pranayama* and meditation. The control group had physiotherapy exercises. Assessments were done on 15<sup>th</sup> (post 1) and 90<sup>th</sup> day (post 2).

**Results:** Resting pain (numerical rating scale) reduced better (P<0.001, Mann–Whitney U test) in yoga group (post 1=33.6% and post 2=71.8%) than control group (post 1=13.4% and post 2=37.5%). Morning stiffness decreased more (P<0.001) in yoga (post 1=68.6% and post 2=98.1%) than control group (post 1=38.6% and post 2=71.6%). State anxiety (STAI-1) reduced (P<0.001) by 35.5% (post 1) and 58.4% (post 2) in the yoga group and 15.6% (post 1) and 38.8% (post 2) in the control group; trait anxiety (STAI 2) reduced (P<0.001) better (post 1=34.6% and post 2=57.10%) in yoga than control group (post 1=14.12% and post 2=34.73%). Systolic blood pressure reduced (P<0.001) better in yoga group (post 1=-7.93% and post 2=-15.7%) than the control group (post 1=-1.8% and post 2=-3.8%). Diastolic blood pressure reduced (P<0.001) better in yoga group (post 1=-7.6% and post 2=-16.4%) than the control group (post 1=-2.1% and post 2=-5.0%). Pulse rate reduced (P<0.001) better in yoga group (post 1=-8.41% and post 2=-12.4%) than the control group (post 1=-5.1% and post 2=-7.1%).

**Conclusion:** Integrated approach of yoga therapy is better than physiotherapy exercises as an adjunct to transcutaneous electrical stimulation and ultrasound treatment in reducing pain, morning stiffness, state and trait anxiety, blood pressure and pulse rate in patients with OA knees.

Key words: Anxiety; osteoarthritis; pain; stiffness; yoga.

# **INTRODUCTION**

Patients with osteoarthritis (OA) of knee are characterized primarily by articular cartilage degeneration and a secondary peri-articular bone response.<sup>[1]</sup> Worldwide, the prevalence rate of OA is 9.6% for men and 18% for

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women >60 years.<sup>[2]</sup> In India OA is the second most common rheumatologic problem and has a prevalence rate of 22 to 39.<sup>[3]</sup> Clinically it presents as pain in and around the joint, joint stiffness usually after rest, crepitation and restricted joint movements associated with muscle weakness.<sup>[4]</sup> The strongest risk factors for OA are age<sup>[5]</sup> and genetics.<sup>[6]</sup> Other risk factors include female gender, obesity, cigarette smoking, intra-articular fractures, chondrocalcinosis, crystals in joint fluid/cartilage, prolonged immobilization, joint hypermobility, instability, peripheral neuropathy, prolonged occupational or sports stress.<sup>[7]</sup>

Chrousos and Gold observed that the development of age-related diseases occurs at different rates in different

individuals and psychological distress appears to be an important factor promoting earlier onset of age-related diseases.<sup>[8]</sup> Aging being a strong risk factor for OA, psycho emotional stresses would also have a contributory role in initiation and aggravation of degenerative changes of OA. It has been suggested that the presence of depressive symptoms predicts future musculoskeletal disorders but not vice versa.<sup>[9]</sup> Linton S.J reviewed the psychological risk factors in back and neck pain which indicated a clear link between psychological variables with neck and back pain. Stress, distress or anxiety as well as mood and emotions, cognitive dysfunction and pain behavior were found to be significant factors.<sup>[10]</sup>

Relieving pain and stiffness and improving physical function are the important goals of present day therapy for OA.<sup>[11]</sup> Non-opioid analgesics such as acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs), including cyclo-oxygenase II inhibitors have been the mainstay of drug treatment.<sup>[12]</sup> They reduce both pain and inflammation quite effectively, but their long-term use is associated with increased risk for gastrointestinal bleeding,<sup>[13]</sup> hypertension<sup>[14]</sup> congestive heart failure,<sup>[15]</sup> renal insufficiency and other adverse effects.<sup>[16]</sup> Before deciding on specific non-pharmacologic and pharmacologic options. it is important to understand the degree of the patient's symptoms, concerns, disability, and what the arthritis means to him or her.<sup>[17]</sup> Emotional responses are a component of any pain and hence the first step in osteoarthritis pain management is to respect pain, treat it intensively and address the psyche. Inadequately treated pain can lead to other serious co-morbidities, including depression, sleep disturbances, anxiety, fatigue, impaired ambulation, decreased socialization and poor quality of life.<sup>[18]</sup>

Yoga is an ancient Indian science and way of life which talks about the origin of diseases.<sup>[19]</sup> The texts describe the mechanism of how the suppressed emotions (called *adhis*) percolate into the physical body manifesting as diseases (*adhija vyahdis*). These texts go on to describe the conceptual basis for reversibility of mind body disease (*prasava-pratiprasava* model) and offer the necessary principles to design specific postures, breathing and meditation techniques for different diseases.<sup>[20]</sup> Hence, yoga is fast advancing as an effective therapeutic tool in physical, psychological and psychosomatic disorders.

Several studies point to the psychological benefits of yoga during health and disease. In a study on healthy adults, Vempati *et al.* showed that the yoga-based guided relaxation can reduce the sympathetic activity as measured by autonomic parameters, oxygen consumption and breath volume.<sup>[21]</sup> Medical and pre-medical students showed lesser anxiety and stress during an examination period after eight weeks of meditation.<sup>[22]</sup> The relaxation component of yoga has shown significant reduction in heart rate and blood pressure in different conditions.<sup>[23]</sup> Transcendental meditation (TM) was compared to muscle relaxation in its effectiveness in controlling stress with significantly better reduction in blood pressure in the TM group.<sup>[24]</sup> Yogitha *et al.* showed reduction in blood pressure, pulse rate and state anxiety levels in patients with common neck pain after integrated yoga.<sup>[25]</sup>

Yoga therapy has shown significant reduction in pain, functional disability with improved strength, balance and gait, when used as an adjunct in the management of rheumatoid arthritis,<sup>[26]</sup> hand OA<sup>[27]</sup> and OA knees.<sup>[28,29]</sup> Although we know that the psychological components such as depression and anxiety are important aspects to be addressed in pain management and yoga has shown its contributory role, there are no yoga studies that have looked at the relationship between anxiety and pain in patients with OA knees. Hence the present study was planned.

# MATERIALS AND METHODS

Patients with OA knees from the outpatient department of Ebnezar Orthopedic Center, Bengaluru were recruited for the study. A sample size of 250 was obtained on G power software by fixing the alpha at 0.05 powered at 0.8 and an effect size of 0.38 considering the mean and SD of an earlier study.<sup>[30]</sup> Two hundred and fifty patients, 76 males and 174 females in the age group of 35 to 80 years  $(\text{voga} - 59.56 \pm 9.54)$  and  $(\text{control} - 59.42 \pm 10.66)$ with OA knees(one or both joints) satisfying the ACR Guidelines<sup>[31]</sup> for diagnosis were included. The inclusion criteria were (i) persistent pain for three months prior to recruitment, (ii) moderate to severe pain on walking, (iii) Kellegren and Lawrence<sup>[32]</sup> radiological grading of II to IV in X-rays taken within six months prior to entry, and (iv) those fully ambulant, literate and willing to participate in the study. Those with (i) grade I changes in X-ray (ii) acute knee pain, (iii) secondary osteoarthritis due to rheumatoid arthritis, gout, septic arthritis, tuberculosis, tumor, trauma or hemophilia were excluded. The study was approved by the institutional review board (IRB) and ethical committee of SVAYSA university. Signed informed consent was obtained from all the participants.

# Design

This was a prospective randomized parallel active control study on patients with OA knees in the age range of 35 to 80 years. After the initial screening, patients who fulfilled the entry criteria were assigned to either yoga or control group. A computer generated random number table (www.randomizer.org) was used for randomization. Numbered envelopes were used to conceal the sequence until the intervention was assigned. Both groups were given the conventional physiotherapy using transcutaneous electrical stimulation and ultrasound followed by supervised practices at the center for 40 min daily (6 days/week) for two weeks. The study group was taught integrated yoga and the control group the non-yogic physiotherapy exercises by certified therapists. After this, they were asked to practice only the supervised practices of 40 min daily at home for the next three months. Compliance was supervised by telephone calls once in three days and a weekly review class at the center. All patients were asked to tick the practices daily after the home practice in the diary provided for the purpose; at every visit their clinical progress and therapy received on the day were documented. All assessments were carried out on  $1^{st}$ ,  $15^{th}$  and  $90^{th}$  days.

# **Blinding and masking**

As this was an interventional study, double blinding was not possible. The answer sheets of the questionnaires were coded and analyzed only after the study was completed. The statistician who did the randomization and data analysis and the researcher who carried out the assessments were blinded to the treatment status of the subjects.

# Intervention for yoga group

The daily routine practiced at the center in the yoga group included 40 min of integrated yoga therapy practice after 20 min of physiotherapy with transcutaneous electrical stimulation and ultrasound for 15 days. The integrated yoga therapy practice included *shithilikarana vyayamas* (loosening practices), *sakti vikasaka* (strengthening practices) followed by yogasanas and relaxation techniques with devotional songs. Later patient was advised to continue the integrated yoga therapy practice of 40 min at home for the next three months.

The concepts used to develop a specific module of an integrated approach to yoga therapy (IAYT) for knee pain were taken from the traditional yoga scriptures (*Patanjali Yoga Sutras, Yoga vasishtha* and *Upanishads*) that highlight a holistic life style for positive health at physical, mental, emotional and intellectual levels.<sup>[33]</sup> Yoga is defined as mastery over the modifications of mind (*Chitta Vritti Nirodhah*-definition of yoga by *Patanjali*). It helps to remove the unnecessary surges of neuromuscular activation resulting from heightened stress responses that may contribute to aging<sup>[34]</sup> The daily routine included a 1 h practice as follows [Table 1]:

• Yogic sukshma vyayamas (loosening and strengthening practices): These are safe rhythmic repetitive stretching movements synchronized with breathing. These practices mobilize the joints and strengthen the periarticular muscles.

#### Table 1: Yoga module for osteoarthritis of knees

Conventional physiotherapy was carried out		20.0 min						
TENS- 10 min								
Ultrasound- 10 min								
Integrated yoga practice- This was made		40.0 min						
to practice by the patient at the center for								
40 min for 15 days after the conventional								
physiotherapy and later advised to continue								
at home for the next three months. This								
included the tollowing practices:		100						
Shimilikarana vyayama (loosening exercises):		10.0 min						
Passive rotation of each too	10 rounds	1.0 min						
(clockwise and anticlockwise)	TO TOUTIOS	1.0 11111						
Toe bending	10 rounds	0.5 min						
<ul> <li>Passive rotation of ankle</li> </ul>	10 rounds	0.5 min						
(clockwise and anticlockwise)								
Ankle bending	10 rounds	0.5 min						
Ankle rotation	10 rounds	0.5 min						
(clockwise and anti-clockwise)								
2. Knee loosening practices								
<ul> <li>Bending the knee in prone position</li> </ul>		1.0 min						
<ul> <li>Knee bending – both sides</li> </ul>	10 rounds	0.5 min						
<ul> <li>Knee rotation – both sides</li> </ul>	10 rounds	0.5 min						
Passive patella rotation		0.5 min						
Helf butterfly	10 roundo	0.5 min						
<ul> <li>Full butterfly</li> </ul>	10 rounds	0.5  min						
Hin rotations	10 rounds	0.5 min						
(both internal and external)	10 1001103	0.0 11111						
4. Upper limbs loosening practices								
Finger loosening	10 rounds	0.5 min						
Wrist loosening	10 rounds	0.5 min						
Wrist rotation	10 rounds	0.5 min						
(clockwise and anticlockwise)								
5. Neck loosening practices								
<ul> <li>Forward and backward bending</li> </ul>	10 rounds	1.0 min						
Neck rotation	10 rounds	0.5 min						
(both clockwise and anticlockwise)		1.0						
o. Insidiil relaxation lechnique- is a 17 siep		1.0 min						
from toes to the head and letting it ap								
7. Strengthening exercises (sakti vikagsaka		5.0 min						
suksma vyayama)								
<ul> <li>Back exercises (kati sakti vikaasaka)</li> </ul>	5 rounds	0.5 min						
<ul> <li>Thigh exercises (jangha sakti vikaasaka)</li> </ul>	5 rounds	0.5 min						
<ul> <li>Straight leg raise breathing- single</li> </ul>	10 rounds	1.5 min						
and both legs								
<ul> <li>Knee cap tightening – single and</li> </ul>	10 rounds	2.0 min						
both legs	<i>с</i> 1	05.						
Ankle fightening exercises	5 rounds	0.5 min						
of 3 phase of observing the abdoming		5.0 min						
movements synchronizing it with								
breathing and chanting of 'U kara								
9. Yogasanas		10.0 min						
A. Standing asanas								
• Tadasana								
Ardha Kati Chakrasana								
Ardha Chakrasana								
Prasarita padahastasana								
B. Lying Asanas								
<ul> <li>Bhujangasana</li> <li>Shulu</li> </ul>								
<ul> <li>Shalabasana</li> <li>Dhanurasana</li> </ul>								
Dianorasana		contd						

#### Table 1: contd/-

10.	Deep relaxation technique (DRT) is a guided relaxation technique with relaxation from toes to the head, feeling of letting go, chanting OM and	5.0 min
	feeling of limitless expansion through	
	visualization.	
11.	Nadi Shudi Pranayama (With Nasik	3.0 min
	Mudra) - Nadishuddhi Pranayama is	
	a slow rhythmic technique of alternate	
	nostril breathing involving the phases of	
	inhalation and exhalation using nasika	
	mudra.	
12.	OM meditation is done seated in any	2.0 min
	comfortable meditative posture repeating	
	the syllable OM mentally.	

- *Relaxation techniques*: Three types of guided relaxation techniques were interspersed between the physical practices of *sukshmavyayamas* and *asanas*.
- Asanas (physical postures): Asanas are featured by effortless maintenance in the final posture by internal awareness. We selected asanas in standing and supine position that would relax and strengthen the knee joints.
- *Pranayama*: The practice of voluntary regulated breathing while the mind is directed to the flow of breath is called *Pranayama*. These practices promote autonomic balance through mastery over the mind.<sup>[35]</sup>
- *Meditation*: Patanjali defines meditation (*dhyana*) as effortless flow of a single thought in the mind without distractions (*pratyaya ekataanata dhyanam*). This has been shown to offer physiological benefits through alertful rest to the mind body complex.<sup>[36]</sup>
- Lectures and Counseling: Yogic concepts of health and disease, yama, niyama, bhakti yoga, Jnana yoga and karma yoga were presented in the theory classes. These sessions were aimed at understanding the need for life style change, weight management and prevent early aging by yogic self management of psychosocial stresses.

#### Intervention for control group

The daily routine practiced at the center in the control group included 40 min of a therapeutic exercise practice after 20 min of physiotherapy with transcutaneous electrical stimulation and ultrasound for 15 days. The therapeutic physical exercises (40 min) included loosening and strengthening practices for the hands, elbows, arms and shoulders followed by a brief period of rest and specific knee practices followed by supine rest with light music. Later patient was advised to continue the therapeutic exercise practice of 40 min at home for the next three months [Table 2].

#### Measurements

a. Numerical pain rating scale (NRS): Pain at rest was recorded by the patient on numerical pain rating scale

# Table 2: Control module for osteoarthritis of kneesConventional physiotherapy was carried out20.0 minonly at the center for 15 days which includedTENS- 10 min

•	Ultrasound- 10 min		
The	rapeutic practices- This was made to		40.0 min
pra	ctice by the patient at the center for		
40	min for 15 days after the conventional		
phy	siotherapy and later advised to continue		
at t	he home for next three months. This		
incl	uded the following practices:		
100	sening exercises		10 min
1	Foot and ankle		
	<ul> <li>Passive rotation of the toes</li> </ul>	10 rounds	0.5 min
	(each toe clockwise and anticlockwise)	10 1001100	0.0
	Passive rotation of the ankle	10 rounds	0.5 min
	(both clockwise and anticlockwise)		
	Toe bending	10 rounds	0.5 min
	Ankle bending	10 rounds	0.5 min
	<ul> <li>Ankle rotation (clockwise and</li> </ul>	10 rounds	0.5 min
	anti-clockwise both sides)	10 1001100	0.0
2.	Knee		
	<ul> <li>Knee bending – both sides</li> </ul>	10 rounds	0.5 min
	<ul> <li>Knee rotation – both sides</li> </ul>	10 rounds	0.5 min
3.	Hip and waist loosening practices		
	Half butterfly	10 rounds	0.6 min
	Full butterfly	10 rounds	0.6 min
	Hip rotations	10 rounds	0.5 min
	(both internal and external)		
4.	Upper limbs loosening practices		
	Finger loosening	10 rounds	0.6 min
	Wrist loosening	10 rounds	0.6 min
	Wrist rotation	10 rounds	0.5 min
	(both clockwise and anticlockwise)		
	<ul> <li>Elbow loosening</li> </ul>	5 rounds	0.5 min
	Arm loosening-forward and backward	10 rounds	0.5 min
	movements		
5.	Neck loosening practices		
	<ul> <li>Forward and backward bending</li> </ul>	10 rounds	0.5 min
	Sideward bending	10 rounds	0.5 min
	Sideward tilting	5 rounds	0.5 min
	Neck rotation	5 rounds	0.5 min
	(both clockwise and anticlockwise)		
6.	Quick pause		2.0 min
7.	Strengthening exercises		5.0 min
	Palm exercises	5 rounds	0.5 min
	Elbow exercises	10 rounds	0.5 min
	Arm exercises	5 rounds	0.5 min
	Back exercises	5 rounds	0.5 min
	Thigh exercises	5 rounds	0.5 min
	Calf exercises	5 rounds	0.5 min
8.	Rest		3 min
9.	Specific knee practices		15.0 min
	• Flexion and extension with and		3 min
	without resistance		
	• Knee cap tightening- self and against		3 min
	small pillow		
	• Straight leg raising – single and both		5 min
	– 30/60/90 degrees		
	Cycling		4 min
10.	Supine rest		5.0 min

prepared for the purpose by drawing a 10 cm line in the center of a white sheet with '0' as nil pain and '10' as worst possible pain.<sup>[37-39]</sup> Separate sheets were used at each assessment time.

- b. Early morning stiffness in minutes as reported by the patients during clinical interview was documented.
- c. State and trait anxiety inventory (STAI-1 and STAI-2): STAI developed by Spielberger et al.,<sup>[40]</sup> consisting of 2 forms each comprising of 20 items rated on a four point scale (0-3) was used for assessing the anxiety levels. Form STAI-1 assesses the state anxiety which is defined as 'a transitory emotional state that varies in intensity, fluctuates over time and characterized by feelings of tension and apprehension and by heightened activity of the autonomic nervous system'. It evaluates how respondents feel 'right now' at this moment. Form STAI-2 evaluates trait anxiety, which is defined as 'a relatively stable individual predisposition to respond to situations perceived as threatening'. It assesses how the respondents feel most of the time. The scores for each of the forms range from 20 to 80, with high scores indicating presence of high levels of anxiety. We used both Y1 and Y2 in our study.

Quek *et al.*,<sup>[41]</sup> have reported a high degree of internal consistency for STAI with Cronbach's alpha of 0.38 to 0.89 for each of the 40 items and 0.86 for the total scores. test-retest correlation coefficients for the 40 items score were highly significant. Intra-class correlation coefficient was also high (ICC=0.39 to 0.89).

- Blood pressure (BP): BP was measured using a mercury sphygmomanometer (Diamond Company) on day one, 15<sup>th</sup> day and on 90<sup>th</sup> day.
- e. Pulse rate (PR) Pulse rate was counted manually for 1 min on first,  $15^{th}$  day and on  $90^{th}$  days.

It was ensured that the BP and pulse were recorded after completing the intervention in both groups at all points of time.

# Statistical methods

The data were analyzed using SPSS Version 16. The base line values of the two groups were checked for normal distribution by using Shapiro-Wilk's test. The baseline values were not normally distributed. Hence Wilcoxon's signed ranks test and Mann –Whitney U test were used to compare means within and between the two groups respectively. Spearman's Rho test was used to observe the correlations between all variables at all three points in time (pre,  $15^{th}$  and  $90^{th}$  days). Figure 1 shows the trial profile. 7 patients dropped out in the yoga group and 8 in the control group. Table 3 denotes the demographic data. There was no significant difference between groups at baseline on all variables (P>0.05, Mann–Whitney test for pre values).

# RESULTS

Table 4 shows the results within yoga group and between the groups. Table 5 shows the results within control group and between the groups after  $15^{th}$  and  $90^{th}$  days.



Figure 1: Trial profile

Tab	e	3:	Demo	ograp	ohic	data

Characteristics	Yoga (n=125)	Control (n=125)		
Age				
(Mean±SD)	$59.56 \pm 9.54$	$59.42 \pm 10.66$		
Sex				
Males	37	39		
Females	88	86		
Occupation				
Skilled workers	28	32		
Semi-skilled workers	34	31		
Unskilled workers	3	5		
Others	60	57		
Associated diseases				
Diabetes	22	16		
Hypertension	30	19		
Overweight/obesity	98	73		
Osteoporosis	78	67		
Others	26	30		

# **Resting pain**

Mann–Whitney U test showed a significant difference between and within groups in resting NRS (Wilcoxon's, P < 0.001) after the intervention on  $15^{\text{th}}$  and  $90^{\text{th}}$  day with higher effect sizes in yoga than control group.

# Early morning stiffness

There was a significant difference in early morning stiffness within groups (Wilcoxon's, P<0.001) and between groups (Mann–Whitney, P<0.001) after the intervention at

VB	Pre and post	Mean ± SD	95% CI		ES	% change
			LB	UB		•
Resting pain	Pre	6.89 ± 0.69	8.15	8.48	3.74	
	Po1	4.53 ± 0.92 (*+)	4.74	5.13	5.37	-33.6
	Po2	$1.94 \pm 1.11$ (*+)	1.81	2.24	4.20	-71.8
Early morning stiffness	Pre	$16.47 \pm 5.22$	15.51	17.42	2.41	
, ,	Po1	5.17 ± 3.97 (*+)	4.44	5.89	3.13	-68.6
	Po2	$0.31 \pm 1.27 (*+)$	0.07	0.54	1.35	-98.1
Systolic blood pressure	Pre	$138.48 \pm 16.1$	135.52	141.43	1.64	
	Po1	127.49 ± 12.50 (*+)	125.19	129.77	2.24	-7.93
	Po2	116.72 ± 11.06 (*+)	114.69	118.744	2.04	-15.7
Diastolic blood pressure	Pre	86.96 ± 7.17	85.64	88.27	1.56	
	Po1	80.27 ± 6.37 (*+)	79.10	81.44	2.74	-7.6
	Po2	72.63 ± 7.50 (*+)	71.25	74.00	1.69	-16.4
Pulse rate	Pre	79.41 ± 5.29	78.44	80.37	2.87	
	Po1	72.73 ± 4.89 (*+)	71.84	73.62	3.18	-8.41
	Po2	69.56 ± 4.67 (*+)	68.71	70.41	0.99	-12.4
STAI-1	Pre	62.39 ± 6.82	61.15	63.63	3.01	
	Po1	$40.19 \pm 4.49 (*+)$	39.37	41.01	4.28	-35.5
	Po2	25.96 ± 4.80 (*+)	25.08	26.83	2.74	-58.39
STAI-2	Pre	62.20 ± 6.07	60.10	61.42	2.54	
	Po1	40.63 ± 4.54 (*+)	38.20	40.22	40.22 3.20 -	-34.6%
	Po2	26.68 ± 5.71 (*+)	24.10	25.50	1.55	-57.10

#### Table 4: Results within yoga group

Po1 - Post (15<sup>th</sup> day); Po2 - (90<sup>th</sup> day), SD - Standard deviation, CI - Confidence interval, LB - Lower bound, UB - Upper bound, ES - Effect size, % - Percentages. \*P<0.01 for Wilcoxon's test (within groups). \*P<0.01 for Mann–Whitney 'U' test (between groups)

#### Table 5: Results within control group

VB	Pre and post	Mean ± SD	95% CI		ES	% change
			LB	UB		-
Resting pain	Pre	6.68 ± 0.70	8.01	8.35	1.77	
	Po1	5.78 ± 1.12 (*+)	5.70	6.15	2.24	-13.4
	Po2	$4.17 \pm 1.51$ (*+)	4.01	4.61	2.18	-37.5
Early morning stiffness	Pre	$16.53 \pm 5.45$	15.53	17.53	1.93	
	Po1	$10.14 \pm 5.40 (*+)$	9.15	11.13	3.11	-38.6
	Po2	4.68 ± 4.63 (*+)	3.83	5.53	2.18	-71.6
Systolic blood pressure	Pre	133.13 ± 12.68	130.78	135.47	1.24	
	Po1	$130.64 \pm 12.12$	128.40	132.88	1.58	-1.8
	Po2	$128.05 \pm 12.28$	125.78	130.32	1.20	-3.8
Diastolic blood pressure	Pre	84.49 ± 6.93	83.20	85.76	0.68	
	Po1	82.68 ± 6.81	81.41	83.93	1.24	-2.1
	Po2	80.24 ± 6.99	78.95	81.53	0.71	-5.0
Pulse rate	Pre	79.30 ± 4.23	78.52	80.07	1.65	
	Po1	$75.23 \pm 4.66$	74.38	76.08	1.84	-5.1
	Po2	73.66 ± 4.94	72.75	74.56	0.96	-7.1
STAI-1	Pre	$62.37 \pm 8.93$	60.73	64.00	1.18	
	Po1	52.62 ± 8.70(*)	51.02	54.21	2.23	-15.6
	Po2	$38.17 \pm 5.88(*)$	37.09	39.25	1.59	-38.8
STAI-2	Pre	60.17 ± 9.35	59.73	64.00	1.00	
	Po1	51.67 ± 8.19 (*)	52.02	53.21	1.80	-14.12
	Po2	39.27 ± 5.88 (*)	40.09	42.25	1.43	-34.73

Po1 - Post (15<sup>th</sup> day), Po2 - (90<sup>th</sup> day), SD - Standard deviation, CI - Confidence interval, LB - Lower bound, UB - Upper bound, ES - Effect size, % - Percentages.\*-P<0.01 for Wilcoxon's test (within groups). +-P<0.01 for Mann–Whitney 'U' test (between groups)

both points in time with higher effect sizes in yoga than control group.

#### State and trait anxiety scores

Systolic and diastolic blood pressure

There was significant difference within (Wilcoxon's, P < 0.001) and between groups (Mann–Whitney, P < 0.001) in the systolic and diastolic blood pressure in the two groups with better reduction in yoga group.

There was better reduction in both state and trait anxiety scores (Wilcoxon's, P < 0.001) and between groups (Mann-Whitney, P < 0.001) in the yoga group with significant differences within and between yoga and control groups at two weeks and three months.

#### Pulse rate

There was significant reduction in both groups with (Wilcoxon's, P < 0.001) and between groups

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(Mann–Whitney, P < 0.001) significantly better reduction in yoga than control group at  $15^{\text{th}}$  and  $90^{\text{th}}$  days.

# Correlations

There was a significant positive correlation (Spearman's Rho test) between early morning stiffness and pain at 2 weeks (P<0.001, r=0.35). Pulse rate also showed positive correlation with pain (P=0.05, r=0.18) at 2 weeks. State anxiety (STAI-1) was positively correlated with pain (P<0.001, r=0.34) at 90<sup>th</sup> day; Trait anxiety also showed a positive correlation with pain (P=-0.013. r=0.23) at 90 days.

# DISCUSSION

This randomized two armed parallel control trial on 250 patients with osteoarthritis of knees of both genders (F=175) in the age range of 35 to 80 years showed significantly better improvement in yoga than control group on all variables (P<0.001, Mann– Whitney) including resting pain, early morning stiffness, state and trait anxiety scores, blood pressure and pulse rate.

# **Resting pain**

In a pilot study on OA of knees, Kolasinski et al.,[28] used a specific sequence of asanas based on the teachings of Iyengar for eight weeks. They measured only the pain and physical functions by WOMAC with a significant reduction (P=0.04) in pain by 46.7%. In another pilot study on yoga for OA knees, Ranjita et al.,[42] used a set of integrated yoga therapy program in a non-residential camp set up for one week without any physiotherapy intervention. She showed a 40% reduction in resting pain after yoga. In our study, we added yoga after the standard physiotherapy which showed a reduction in resting pain scores by 33.6 and 71.8% after 15 and 90 days respectively. Looking at the degree of changes in all the three yoga studies which is similar (37-47%), we may speculate that yoga is beneficial when used with or without a session of physiotherapy.

# Early morning stiffness

Haslock *et al.*,<sup>[26]</sup> showed the beneficial effects of specific integrated yoga practices in patients with rheumatoid arthritis who had secondary OA in several joints. They observed better increase in hand grip strength (63%, left, 66% right) in yoga group than non yoga controls (8% left and 5% right) indicating reduced stiffness. Our study showed a reduction in early morning stiffness scores by 69 and 98% after 15 and 90 days respectively. None of the other yoga studies have noted morning stiffness as an outcome variable.

# State trait anxiety

There was better reduction in state and trait anxiety scores in the yoga group with significant differences within and between yoga and control groups at two weeks and three months. In our earlier study on patients with chronic neck pain,<sup>[25]</sup> we had observed significant 19.3% reduction in STAI-1 scores as compared to 8.2% in control group within 10 days of intervention. In the present study, we used both state and trait anxiety measures since this was a long-term follow up of three months. The reduction in anxiety scores after yoga in both STAI-1 (36% -post 1 and 58% -post 2) and STAI-2 scores (post 1-35% and post 2-57%) were much higher in these patients with chronic knee pain as compared to those with neck pain.

# Blood pressure and pulse rate

In a randomized controlled study in patients with chronic neck pain, we observed a reduction in both systolic and diastolic blood pressure by 16% after ten days' of add -on IAYT for neck pain.<sup>[25]</sup> In the present study also, we observed similar reduction of 16% in both systolic and diastolic BP after 90 days of intervention. The pulse rate reduced by 10% in the chronic neck pain study which is similar to the present study with 12.4% reduction after 90 days of IAYT for knee pain. A significant correlation observed in this study between pain and early morning stiffness after yoga points to the global improvement in the patient's condition. Again, a significant correlation between pulse rate and anxiety with pain shows the mind body interaction.<sup>[43]</sup> We know that there exists an etiological relationship between an aging disease such as OA and life style, obesity and stress.<sup>[5]</sup> Whether this positive correlation has an etiologically predictable relationship needs to be studied in future studies.

There are some studies that have looked at anxiety and autonomic variables in normal healthy volunteers after yoga for promotion of positive heath. Raghuraj *et al.*,<sup>[44]</sup> observed significant reduction in heart rate variability and blood pressure immediately after 20 min practice of alternate nostril breathing (*nadishuddhi pranayama*).

In a study by Vempati *et al.*,<sup>[21]</sup> in healthy adults, the yoga-based guided relaxation was shown to reduce the sympathetic activity as measured by reduced heart rate and skin conductance, oxygen consumption and breath volume. Reduction in heart rate has also been observed after meditation.<sup>[36,45]</sup>

The immediate effect of a 30 min practice of a meditation technique called cyclic meditation on STAI 1 was measured in normal healthy volunteers, which showed significantly better reduction in state anxiety after the cyclic meditation session as compared to a session of supine rest. Studies on different types of meditation have consistently shown increased mental alertness even while the patients are physiologically relaxed. These autonomic changes of reduced sympathetic arousal, reduced anxiety and alertful rest points to stress reduction after yoga both in health and disease which seems to be the inner healer.<sup>[36]</sup>

## Mechanisms

The experience of pain in OA patients is not only due to activation of sensory nociceptive fibers in the arthritic joint but it is compounded by other factors such as affective, behavioral and cognitive factors.<sup>[17]</sup> Stress reducing effect of yoga seems to be a major mechanism of its efficacy in pain management in patients with OA knees.<sup>[46]</sup> The multi-factorial approach of yoga includes not only physical practices (asanas) but also has the components of breathing (pranavama), meditation (dharana and dhyana), introspective intellectual (jnana yoga) and emotional (bhakti yoga) practices. These practices help in bringing about mastery over the modifications of the mind (chittavritti nirodhah) which is the definition of yoga according to Patanjali.<sup>[21]</sup> This may contribute to a consistent change in behavior and life style that can reduce anxiety and the resultant effect on pain reduction.

Baser *et al.*<sup>[47]</sup> have shown the association between cognitive behavioral therapy (CBT) with physical, psychological and social well being. The concepts in philosophy of yoga are similar to those of CBT which says that chronic pain is not simply a neurophysiologic state but is influenced by the way a person sees the world and attributes meaning to the events. Lip chick *et al.*,<sup>[48]</sup> showed that the increased sense of personal control over pain following a pain management program of CBT was accompanied by a reduction in negativity. Thus the present study gives evidence to the relationship between reduction in pain, anxiety and sympathetic tone after yoga in patients with OA knees. This may offer preliminary evidence to the reversibility theory of yoga in a degenerative disease.

# Strengths of the study

Good sample size, randomized control design, active supervised intervention for the control group for the same duration as the experimental group and follow up for three months with good compliance (6% dropout) are the strengths of this study. The result of this study that has shown marked differences between groups on all variables offers strong evidence for incorporating this module of IAYT for OA knees by the clinicians.

## Limitations of the study

The study was on a selected group who presented to a specialty orthopedic center and hence not generalizable.

#### Suggestions for future work

A longer follow up of  $\geq 12$  months is necessary to check the long-term efficacy and acceptability. Studies using MRI and biochemical variables may throw light on the mechanisms.

#### **CONCLUSIONS**

Adjunctive program of integrated approach of yoga therapy for OA knees reduces 'rest pain', early morning stiffness, anxiety, and blood pressure and pulse rate. Yoga offers a good value addition as a non-pharmacological intervention in management of OA knees.

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