# Original Article

# Effect of meditation and relaxation therapy on preoperative anxiety and stress in oral squamous cell carcinoma patients scheduled for oral and maxillofacial surgery: An experimental study

# ABSTRACT

**Context:** The diagnosis of oral squamous cell carcinoma [OSCC] and its treatment phase is emotionally demanding for the patient and challenging for the surgeon. The induction of stress and anxiety is unavoidable in these patients. It becomes very important for the patient to have psychological as well as physical stability during this treatment phase. Various studies have reported the beneficial effect of meditation along with relaxation therapy on healthy individuals but the beneficial effect of meditation and relaxation therapy [MRT] to reduce stress and anxiety preoperatively in OSCC patients has not been reported in scientific literature.

Aim: The aim of this study was to study the effect of MRT on preoperative anxiety and stress in OSCC patients undergoing for oral and maxillofacial surgery.

Settings and Design: An experimental, parallel study design was carried out with randomization of patients into experimental[25] and control group[25] with allocation ratio 1:1 in 50 patients diagnosed with OSCC [stage II or III] scheduled for oral and maxillofacial surgery with general anesthesia.

**Materials and Methods:** The biopsy which was the prerequisite for the diagnosis was taken. Twenty-one days before surgery in experimental group, patients were oriented about meditation and relaxation exercises. The reorientation of MRT was done from the day of admission twice a day till the day of surgery. Physiological parameters for stress and anxiety like heart rate [HR], blood pressure [BP], pulse rate [PR], and respiratory rate [RR] were evaluated on 1<sup>st</sup> day of MRT at 9 am and on the day of surgery. The serum cortisol which was quantitative parameter for stress was evaluated 1<sup>st</sup> day of MRT at 9 am fasting and on the day of surgery. The qualitative analysis for anxiety was done preoperatively using visual analog scale on the 1<sup>st</sup> day before MRT and compared with the values on the day of surgery after MRT at a specific time.

Statistical Analysis: Paired *t*-test analysis was used intragroup whereas unpaired *t*-test was used intergroup between experimental and control groups with significance at *P* = 0.05 and highly significant

at *P* = 0.0001.

**Results:** The serum cortisol was significantly less in the experimental group over control group with t = 7.04 and P = 0.0001. The systolic and diastolic BP, pulse rate, respiratory rate, and anxiety in the experimental group reported significantly less rate compared to the control group with t = 5.66, t = 22.2, t = 11.93, t = 27.71, and P = 0.0001.

**Conclusion:** In our study, MRT in the form of Sukhasana, Anulom Vilom, Omkar chanting, and Shavasana for 30 min twice daily has shown positive effect to reduce stress and anxiety. The serum cortisol as a quantitative parameter has been effectively evaluated in this benchmark study.

**Keywords:** Life style, meditation, relaxation therapy, squamous cell carcinoma of head and neck

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# **INTRODUCTION**

Oral squamous cell carcinoma [OSCC] ranks 12th in the world. India has the most cases, with 1% of the population suffering from premalignant lesions. The prevalence is higher in developing countries due to lifestyle risk factors with a male-to-female ratio of 3:1.<sup>[1,2]</sup> Both the hospital environment and surgical exposure contribute to anxiety and stress. The counseling of the patients becomes an integral part of OSCC as they are filled with anxiety and stress regarding treatment-related morbidity. Nature and humans have been designed to work according to the circadian rhythm controlled by the suprachiasmatic nucleus, the so-called master clock.<sup>[3]</sup> Cortisol is a key hormone in the regulation of stress and has a circadian rhythm. This is due to its catabolic action during the day and anabolic action during the night having an impact on the cardiovascular and neuroendocrine systems. It is regulated by a feedback inhibition mechanism. The normal levels of blood serum cortisol are between 8 am and 10 am.<sup>[4]</sup> The raised levels of blood serum cortisol, which are a result of stress, have been linked to an advanced disease state in cancer related to the oral cavity. The various studies on imbalanced cortisol secretions indicate elevated levels of cortisol in patients with OSCC.<sup>[5]</sup> Thus, it plays a key role in the body's response to stress by reducing inflammation, improving the immune system, promoting analgesia, and maintaining vitals.<sup>[6]</sup> It is very important to have psychological stability in these patients during the journey to survival, which can be achieved with preoperative and postoperative MRT.<sup>[7-9]</sup> Meditation is the merging of the idiomatic and universal selves.<sup>[10,11]</sup> Preoperatively, this plays a crucial role in surgery as it not only helps the patient be psychologically prepared for the surgery but also has beneficial physiological effects on the surgical procedure.<sup>[8-10,12-15]</sup> They can be evaluated by physiological markers like blood pressure (BP), heart rate (HR), and hormonal markers such as increased secretions of cortisol and epinephrine, along with psychological markers like the stress measurement scale and a psychological questionnaire.[16-19] Meditation and relaxation therapy (MRT) help to combat anxiety and stress by increasing oxygen supply to the body and gaining control over one's own body, which in turn helps improve psychological and physical stability and the quality of one's lifestyle ahead.<sup>[20]</sup> The combination of meditation with relaxation therapy and spiritual exercises gears up self-healing, which should be included in the preoperative and postoperative preparation programs for OSCC patients scheduled for surgery under general anesthesia. Thus, the patient's anxiety and stress management are the cornerstones for the best outcome of the treatment and improving their overall physiologic responses.<sup>[8,9,16]</sup> The null hypothesis

of this study was that there was no significant difference between the experimental and control groups with respect to preoperative anxiety and stress in OSCC patients undergoing oral and maxillofacial surgery. Hence, the purpose of this study is to assess the effectiveness of MRT on preoperative anxiety and stress in patients with OSCC scheduled for surgery with general anesthesia.

### MATERIALS AND METHODS

An experimental, parallel study design was carried out with randomization of patients into an experimental and control group with an allocation ratio of 1:1 in 50 patients diagnosed with OSCC of the mandible [stage II or III] and scheduled for oral and maxillofacial surgery with general anesthesia as the primary treatment without prior radiotherapy or chemotherapy in the same institution. The sample size was calculated using G power 3.1.9.2 software with  $\alpha$  0.05, power 80%, and effect size = 0.78. The inclusion criteria were the patients reporting a confirmed clinical, radiological, and histopathological diagnosis of OSCC scheduled for surgery with general anesthesia; patients according to AHA guidelines with normal-to-mild hypertension in stage 1; and patients willing to participate in this study. The exclusion criteria were patients suffering from psychiatric disorders, those on steroid therapy, patients with history of endocrine disorders, and patients with a history of chemotherapy/radiotherapy. The ethical clearance was obtained from institute Ethical Committee with Ref no. DYPDCH/ IEC/123/116/19 dated 25.09.2019. This study was carried out in accordance with the ethical standards of the committee and with the Helsinki Declaration of 1975, as revised in 2000. According to the parallel study design, every patient was divided into two groups, experimental group[25] with MRT and the control group[25] without MRT with computer-generated simple random sampling allocated by sequentially numbered, opaque, sealed envelope [SNOSE] technique in which both the investigator and the statistician were blinded.

A detailed case history was taken of all the enlisted participants and a written informed consent was obtained for the same. The biopsy which was the prerequisite for the diagnosis was taken around 21 days before surgery and patients were oriented about meditation and relaxation exercises on the same day. The reorientation of MRT was done on the day of admission which was 3 days before surgery was planned twice a day till day of surgery for its maximum effect on anxiety and stress of the patient. Preoperatively before beginning with MRT, vitals such as BP, pulse rate, and respiratory rate were physiological parameters for stress and anxiety while blood sample for serum cortisol to measure stress was collected in morning 9 am on first day of admission along with anxiety assessment by visual analog anxiety scale in fasting state of both the groups to reduce diurnal variability. Prior to the intervention, the participants of experimental group were again explained about the MRT exercises. The participants of both groups were taken into empty room where experimental group was subjected for 30 min MRT in the sequence of Sukhasana, Anulom Vilom, Aum, and Shavasana carried out according to Patanjali Yoga. The main aim of these practices was based on the principles of attention diversion and relaxation to cope with preoperative anxious and stressful phases. The Sukhasana was carried out by asking the participants to sit on the yoga mat with legs straight out in front, hands on the floor beside the hips with palms down and fingers pointing forward along with legs crossed at the ankles with the left leg on top and the right leg below simultaneously concentrate on breathing for 5 minutes [Figure 1a]. Anulom Vilom followed the Sukhasana. The participants were instructed to take gyan mudra. Then the thumb of the right hand was placed on the right nostril to inhale deep breath in slowly from the left nostril [Puraka] for 1 s with pressed left nostril with the ring finger while the thumb on left nostril hold the breath for 4 s [Kumbhaka]. Later the right nostril was opened to exhale for 2 s [Rechaka]. The ratio of Puraka, Khumbhaka, Rechaka was 1:4:2 [Figure 1b-d]. The cycle of Anulom Vilom was carried out for 15 min. The Vaikhari Aum chanting was performed, in which participants were instructed to take a deep breath to pronounce "Aum" by parting their lips sufficiently in a low voice and pitch for 6 s, followed by closing their lips, "M" was automatically produced which is nasal in nature for 10 s. The length of "U" should be 1/3 and the length of "M" should be 2/3 of the total time for Aum in one breath, which completes one cycle [Figure 1e and f]. This was done for 10 repetitions in a stretch in 1 sitting which were rhythmic and slow. The MRT was concluded by Shavasana in which participants were lying on the yoga mat with back on ground, palms facing the sky, eyes closed, and body relaxed for 5 min. The control group participants were asked to sit comfortably for 30 minutes with closed eyes[Figure 1g]. The day of surgery was 3 days after admission. MRT was conducted all three days, twice daily. On the day of surgery, after MRT, in participants in both groups, vitals such as BP, pulse rate, respiratory rate, serum cortisol blood sample, and anxiety using visual analog scale (VAS) were assessed again at 9 am in a fasted state to reduce diurnal variability. The obtained data were compiled on an MS Office Excel sheet [2010, Microsoft Office, Washington, DC, USA] and subjected to statistical analysis using a Statistical Package for the Social Sciences [SPSS v 21.0, IBM, Chicago, IL, USA]. The statistical analysis intragroup was done using paired t-test and intergroup was done using the unpaired *t*-test by a statistician.

#### RESULTS

This experimental study was conducted between January 2020 and September 2021. A total of 50 patients were evaluated, with 32 males and 18 females ranging in age from 32 to 57 years with stage II and III of OSCC. [Figures 2 and 3]. In this study, males from rural backgrounds made up the majority of the patients. The majority of the patients were from economically challenged sections of the community and had very low monthly family incomes. Nearly every patient who was recruited for the study has a history of addiction in chewing form of tobacco.

The baseline value in each group is day 1 of surgery of each patient compared to day of surgery values. The mean values of the parameters in the experimental and control group on day 1 and say of surgery are presented in Table 1. Unpaired *t*-test analysis keeping significance at P = 0.0001 and confidence interval of 95% revealed that the serum cortisol level was significantly less in the experimental group over the control group with t = 7.04 and P = 0.0001. This is the key indicator of reduced stress levels amongst the experimental group compared to control group. .The same was observed for anxiety level with a significant low score of anxiety in the experimental group over control group with t=27.71and P = 0.0001 measured using Visual Analogue Scale (VAS). Systolic and diastolic BP was noted to be significantly low in the experimental group with t = 5.66 and P = 0.0001. The pulse rate in the experimental group reported significantly less rate compared to the control group with t = 22.21and P = 0.0001. A significant difference was observed for respiratory rate with the experimental group presenting a low respiratory rate over the control group with t = 11.93and P = 0.0001. Overall, the MRT resulted in reducing the stress and anxiety amongst experimental group by lowering the parameters of BP, pulse rate, respiratory rate, and serum cortisol levels. Figure 4 gives the graphical analysis of parameters on day of surgery between both groups.

#### DISCUSSION

Stress is the combination of fear and physical tension. In short term, it helps individual but in long term, it not only affects mental but also physical state. High level of cortisol mostly detected in Cushing's syndrome, pituitary gland tumors, and adrenal gland tumors. Tsigos C *et al.* studied elevated cortisol levels on stress, trauma or anxiety disorders.<sup>[21]</sup> Vadiraja HS *et al.* used saliva samples to estimate the cortisol levels as stress mediator along with a Hospital Anxiety and Depression Scale [HADS] to evaluate anxiety in breast cancer patients. According to the study's findings, yoga had a good impact on patients



Figure 1: (a) Patient in Sukhasana posture. (b) Patient placing the thumb of the right hand on the right nostril and inhaling deep breath slowly from the left nostril. (c) Patient pressing the left nostril gently with the ring finger while keeping thumb on left nostril holding the breath. (d) Patient opening the right nostril and exhaling through the right nostril. (e) Patient pouncing "Aum" by parting lips sufficiently in low voice and pitch. (f) Patient pouncing the consonant "M" by closing the lips. (g) Patient lying in Shavasana posture



Figure 2: Flow diagram of the progress through the phases of the study (enrolment, intervention, allocation, follow-up, and data analysis)

with early breast cancer getting adjuvant radiation.<sup>[22]</sup> Our study aimed to evaluate the effect of MRT on preoperative stress among OSCC patients scheduled for surgery by evaluating serum cortisol levels with baseline on day 1 and day of surgery. The result of the study with t = 7.04 and P = 0.0001 of serum cortisol level signified the positive effect on MRT group to reduce preoperative stress in OSCC patients. Sharma P et al. in the study made observation that the presence of oral cancer can be associated with an imbalance in the body's stress hormone, cortisol.<sup>[5]</sup> Similarly in our study, serum cortisol was evaluated on the day 1 and on the day of surgery at 9 am in the morning. MRT in the form of Anulom Vilom and Omkar chanting improved the overall function of central and peripheral nervous system. When anxiety was compared between MRT group and non-MRT group, there was observable mean difference of 6.4 while serum cortisol mean difference 2.82 [Figure 4]. The effect of circadian rhythm of cortisol on cardiovascular system had been reviewed by Mohd Azmi NAS et al.<sup>[4]</sup> In our study, vitals like BP, PR, and RR were evaluated as they were indicative of both stress and anxiety levels. According to the statistics, serum cortisol levels were lower on the day of surgery in the MRT group compared to the non-MRT group.

Rao MR *et al.*<sup>[23]</sup> conducted a qualitative study to evaluate anxiolytic effect of yoga therapy in 98 patients with stages II and III breast cancer undergoing conventional treatment used state trait anxiety inventory. [STAI]<sup>[23]</sup> Our study aimed to evaluate effect of MRT on preoperative anxiety in patients



Figure 3: Site of lesion

with stage II and stage III of oral squamous cell carcinoma undergoing surgery as primary treatment. In total, 32 male patients were studied, with males being affected more than females when quantitative parameters were used [Figure 1]. Adair M *et al.*<sup>[24]</sup> used the HADS to evaluate anxiety and depression in a pilot study on the feasibility and preliminary efficacy of tailored yoga in survivors of head and neck cancer (HNC) and concluded that yoga could reduce anxiety in HNC survivors. In our study, pranayama in the form of Anulom Viloum was practiced for 15 min and OM chanting for 10 min



Figure 4: Graphically presentation comparing the parameters on day of surgery between experimental and control groups

Table	1: I	Descriptive	data	with	respect	to	the	parameters	in	the	experimental	and	control	group
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Parameters	Day	п	Experimental group		Cor	Significance P	
			Mean	Std. deviation	Mean	Std. deviation	
Serum cortisol	Day 1	25	14.1384	1.79214	14.9800	0.69940	0.0001*
	Day of surgery	25	12.3904	1.81726	15.2200	0.85489	
Systolic BP	Day 1	25	130.4000	2.00000	130.0000	0.00000	0.0001*
	Day of surgery	25	124.8000	5.09902	132.4000	4.35890	
Diastolic BP	Day 1	25	91.2000	3.31662	90.0000	0.00000	0.0001*
	Day of surgery	25	84.8000	5.09902	92.4000	4.35890	
Pulse rate	Day 1	25	76.2800	3.75855	75.6000	1.32288	0.0001*
	Day of surgery	25	72.6000	1.00000	78.8400	0.98658	
Respiratory rate	Day 1	25	16.4400	1.15758	15.3600	0.48990	0.0001*
	Day of surgery	25	12.9200	0.95394	17.4400	1.6350	
Anxiety	Day 1	25	8.4400	0.50662	7.8800	0.92736	0.0001*
	Day of surgery	25	2.6000	0.64550	9.0000	0.95743	

\*statistically significant difference (P<0.001), #non-significant difference (P>0.05) for all tables

twice daily with evaluation of physiological parameters like systolic and diastolic BP, pulse rate, and respiratory rate along with psychological parameter anxiety which was assessed using VAS. There was statistically consequential difference present in SBP and DBP between MRT group and without MRT group with mean difference of 7.60 with P = 0.0001 [Figure 4]. MRT has indubitable effect on BP to reduce stress and anxiety levels.

Mooventhan A *et al.* reported that Om chanting with Bhramari pranayama enhanced sympatho-vagal balance, with 5 minutes of deep breathing improved lung function.<sup>[13]</sup> In our study, the mean difference between both groups was 4.52 with P = 0.0001; thus, respiratory rate affected stress and anxiety levels [Figure 4]. Singh MP *et al.*<sup>[1]</sup> retrospectively studied clinical epidemiology of OSCC in India on 611 patients which reported more prevalence in males than in females. In our study, there were 32 men and 18 women among the 50 participants with a majority from rural backgrounds. Zetzl T *et al.*<sup>[25]</sup> and Pattnaik SJ *et al.*<sup>[26]</sup> conducted a qualitative questionnaire study to evaluate the yoga intervention and reminder e-mails for reducing cancer-related fatigue. The

authors proposed yoga as a holistic approach for stress management in OSCC patients. Shukla M et al.[27] compared various breathing exercises by using parameters like breath holding time and rating of perceived exertion. The study reported that Anulom Vilom improved the duration of inspiration, thus had a beneficial effect on autonomic nervous system. In our study, the MRT was began with proper posture in form of Sukhasana which was preceded by Anulom Vilom for 15 min followed by Om chanting for 10 min and the session ended with Shavasana for 5 min. This MRT exercise was trained for 21 days and was found to be effectively practiced as a habit as proposed by Morselli.<sup>[28]</sup> MRT reduced levels of serum cortisol, BP, RR, PR, and anxiety in MRT group when equated to non-MRT. This suggested that MRT had a beneficial impact on stress along with somatic symptoms of anxiety. The scientific literature currently provides very little data about the effectiveness of yoga for patients with oral squamous cell carcinoma [Table 2]. This might be the first study to scrutinize the effect of MRT on preoperative stress and anxiety in OSCC patients based on quantitative analysis. However, it has to be supported, nonetheless, by more focused research in oncology settings.

Table 2: S	Studies cor	iducted on	yoga and	oral	cancer
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Title	Author and year	Participants	Intervention	Type of study	Parameters assessed	Results
1. Feasibility and preliminary efficacy of tailored yoga in survivors of head and neck cancer: a pilot study	Adair M. <i>et al.</i> <sup>[24]</sup> 2018	35 patients of head and neck cancer survivors	Yoga 3 times a week for 4 weeks then 2 times a week for 4 weeks	A pilot study Qualitative questionnaire	Hospital Anxiety and Depression Scale (HADS) Brief Pain Inventory (BPI-SF) The Vanderbilt Head and Neck Symptom Survey (VHNSS–Version 2) Body Image Quality Life Instrument (BIQLI)	Efficacy measures of yoga indicated potential benefit for reducing anxiety in head and neck cancer survivors
2. Yoga as a holistic approach for stress management in oral cancer patients. A prospective study	Pattnaik S <i>et al.</i> <sup>[26]</sup> 2020	200 patients diagnosed with oral squamous cell carcinoma	Yoga 1 month	Prospective study Qualitative questionnaire	10-point questionnaire	Reduction in stress levels following a month of yoga practice
3. Clinical yoga trial aim to improve quality of life at advanced stages of oral cancer	Bakshi J <i>et al.</i> <sup>[29]</sup> 2021	26 patients of advanced stages of oral cancer Stage III or stage IV	Yoga 1 h per day/5 days per week for 3 months for 45±10 min duration The preoperative and postoperative assessments were done at 2 weeks before surgery and completion of 2-month yoga after the surgery	Qualitative questionnaire, randomized study	Perceived Stress Scale (PSS) Stress and Anxiety Inventory (STAI)	The study revealed no significant change in stress level between control and experimental group. The anxiety level was not found to be significantly decreased in the experimental group
4. Effect of yoga therapy on psychological distress and quality of life in head-and-neck cancer patients undergoing radiotherapy	Joshi AM <i>et al.</i> <sup>[30]</sup> 2021	20 patients of head and neck cancer (stage III) patients undergoing radiotherapy	Yoga therapy for 6-week, 45 min each	Qualitative questionnaire	Quality of life by European Organization for Research and Treatment of Cancer [EORTC] QLQ-C30 QoLQuestionnaire and QLQ-H&N35 Psychological distress by distress thermometer	In HNC, patients receiving radiation, yoga therapy intervention substantially decreased psychological distress, enhanced quality of life, enhanced functioning, and decreased symptoms

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# Limitations

Several limitations of the current study had to be acknowledged. The sample size was limited due to the stipulated time period for the study, so the beneficial effect of MRT could not be generalized to all patients. The baseline value for anxiety was significantly higher in the experimental group on day 1, while on the day of OT, the anxiety was found to be higher in the control group. Patients' compliance was the major limitation factor encountered in the study which might be due to preexisting clinical conditions of OSCC and future surgical treatment; patient took time to understand the process and effect of MRT on their anxiety and stress. This study was carried out during peak COVID-19, so many participants were in a dilemma about the surgery.

### Lacunae

Knowing which components of the MRT were beneficial to these individuals would have been an useful information. Many patients were not ready to participate as they assumed MRT was only a physical form of exercise and not the priority of their lives considering their diagnosed condition. Lack of financial support for holistic approach in treatment of OSCC patients.

# **Future prospective**

This study should be carried out at many centers along with larger sample around the world to understand the efficacy of MRT on OSCC patients. There can be organized framework where the supportive care and cancer treatment both can be adopted simultaneously.

### **CONCLUSION**

In congruence with the result of this experimental study, it can be concluded that MRT was effective in reducing anxiety and stress in OSCC patients. Most cancer patients cannot afford to obtain treatment, and there is no framework for providing supportive care and cancer support groups. This study would be the benchmark for further research.

#### **Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for images and other clinical information to be reported in the journal. The patient understands that names and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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### **Conflicts of interest**

There are no conflicts of interest.

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