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To Study the Impact of Yoga on Pulmonary Functions, Immune Response and Quality of Life in Chest Trauma Patients at Trauma Centre

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1. Summary

Trauma is an everyday event which is natural and widespread in the modern era. It is the leading cause of mortality and morbidity, especially during the productive age and has been projected to be the third most common cause of death by 2010.

Trauma is a major cause of chest injury around the world. In developed nations, trauma usually occurs as a result of industrial accidents, farming accidents, or motor vehicle accidents, which include automobiles, motorcycles and trains.

The complexity of injury in trauma patients makes it challenging to provide an optimal oxygenation while protecting the lung from further ventilator-induced injury to it. Health care personnel can help people with Chest trauma, their families and communities to understand the care that is needed following chest injury and the process of rehabilitation that can reduce the impact.

Conventionally chest physiotherapy in the form of breathing exercises and vibrations are employed in chest trauma patients to avoid complications (decreased lung volumes, atelectasis, pneumonia, respiratory failure). Chest physical therapy is used in the intensive care unit (ICU) to minimize pulmonary secretion retention, to maximize oxygenation, and to re-expand atelectatic lung segments. Chest physical therapy usually consists of postural drainage, percussion, vibration, coughing and cough stimulation techclinicsofsurgery.com

niques, breathing exercises, suctioning, and patient mobilization.

Exercise based as well as mindful yogic practices have shown great benefit in improving pulmonary function, exercise capacity, cardio-respiratory system performance, systemic inflammation as well as post-traumatic stress disorders particularly when used as adjunct therapies combined in a multidisciplinary format. Respiratory complications develop with rib fractures as a consequence of restricted movements of the thorax from pain and mechanical instability resulting in inadequate ventilation. Even an isolated rib fracture is associated with significant consequences, particularly in the older population. This causes decreased lung volumes, atelectasis, and may progress to pneumonia, respiratory failure, need for prolonged ventilation and possible death.

Negative impacts of Chest trauma (e.g. depression, anxiety) have formed the central focus of most of the research. Despite this emphasis, there is little consensus regarding the prevalence of clinically significant psychological dysfunction following chest trauma, either in the short or longer terms and understanding of the processes through which favorable outcomes emerge is limited.

Damage to the osseous structure of the thorax by rib and sternum fractures destabilizes the rib cage and impairs spontaneous breathing mechanics substantially. This condition is amplified by pain, which further reduces breathing function. Direct traumatic damage

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to the lung (i.e., lung contusion), in combination with a concurrent increase in vascular permeability of the lung capillaries in the injured area, leads to an extravasation of protein-rich fluid with an altered surfactant composition, eventually resulting in slow but progressive respiratory failure.

The present study will assess the role of Yoga in the clinical recovery and outcome of chest trauma patients by evaluation of the immune response and pulmonary functions in these patients.

2. Introduction

2.1. Origin of the proposal

According to World Health Organization, India has the highest number of road accidents in the world with 16.8 fatal injuries per 100,000 population, and 38.9 non-fatal injuries per 100,000 populations (Global status report on road safety World Health Organization; 2009). Hence traumatic road accidents would be a significant cause of chest trauma.

80-90% of patients with severe chest trauma have multiple additional injuries (Ullman et al., 2003). The incidence of systemic inflammatory response syndrome (SIRS), infectious complications (e.g., pneumonia), adult respiratory distress syndrome (ARDS), and multiple organ dysfunction syndrome (MODS), is substantially higher in multiply injured patients with severe chest trauma (Jones et al., 2001).

Due of these causes, chest trauma brings a dramatic change in the life situation of an individual in almost all aspects of daily living and functioning. Quality of life (QoL) of chest trauma patients gets affected due to life threatening injuries which are diagnosed during primary survey like laryngeotracheal injuries, tension pneumothorax, open pneumothorax, flail chest with pulmonary contusion, massive hemothorax, cardiac tamponade and potentially life threatening injuries which are diagnosed during secondary survey like tracheobronchial injuries, simple pneumothorax, hemothorax, pulmonary contusion, blunt esophageal injury, aortic disruption and great vessel injuries, blunt cardiac injuries, diaphragmatic injuries and other injuries including fractures of clavicle, sternum and scapula.

2.2. Definition of the Problem

Chest trauma is a significant cause of morbidity and mortality amongst polytrauma patients. The causes and pattern of chest trauma have been reported in literature to vary from one part of the world to another partly because of variations in infrastructure, civil violence, wars and crime. It is a major problem for India also due to a very high incidence of vehicular accidents (6% of global vehicular accidents), other accidental injuries, crime and violence. Irrespective of the cause of chest trauma, it brings a significant and drastic change in a person's life, and one goes from a stage of shock, to acknowledgement, and finally adjustment (Seymour R. et al 2002).

2.3. Objective

To evaluate impact of yoga on post injury outcome in chest trauma patients in relation to:

- i) Pulmonary functions of the chest trauma patients.
- ii) The immune response of chest trauma patients.
- iii) Quality of life of the chest trauma patients.

3. Review and Status of Research and Development in the Subject

3.1. International Status

Chest trauma contributes 25 % of all trauma. In various citations, it is mentioned that more than half of these injuries occurs in the third and fourth decades of life, and males are often involved in injuries than the females (Recep. et al.,2009, Dalal. et al.,2009). According to the WHO, RTIs are the second most important cause of death for 5 to 29 years old.

3.1.1. Quality of life: Quality of life (QoL) is each individual's perception of his/her position in life, in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns [(WHOQOL GROUP, 1996; WHO, 1997). It is a broad-ranging concept, affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs, and relationship to salient features of the environment (WHO, 1997).

3.1.2. Yoga: Yoga is an Art and Science of healthy living. It is a spiritual discipline based on an extremely subtle science, which focuses on bringing harmony between mind and body. The holistic approach of Yoga is well established and it brings harmony in all walks of life and thus, known for disease prevention, promotion of health and management of many lifestyle related disorders. Breathing exercises are popular tools with public and healthcare providers. They are used increasingly in complementary and alternative medicine to promote health and wellness. Recently yoga has been seen with positive outcomes. Yoga derived breathing has been applied as therapeutic method for patients with COPD. Because of pain, patients face problem in breathing properly after chest trauma so deep breathing is encouraged through yoga (pranayama) and asanas.

3.2. National Status

According to National Crime Records Bureau (NCRB data 2014) 4, 51,757 accidental deaths occurred in India. 52 accidental deaths took place every one hour during the year 2014. A total of 4,81,805 'Traffic Accidents' were reported during the year 2014 comprising 4,50,898 'Road Accidents', 2,547 'Railways Crossing Accidents' and 28,360 'Railway Accidents'. The traffic accidents caused injuries to 4, 81,739 persons and 1, 69,107 deaths during 2014. 51 cases of road accidents took place every one hour during 2014. In Delhi, approximately 2000 died in road traffic accidents. A survey suggests that in every 5-6 minutes one person dies due to road accidents in India.

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3.3. Importance of the Proposed Project in the Context of Current Status

Prime minister of India is emphasizing on Yoga which is an ancient art of Indian culture but less explored in relation to modern medicine. Giving due importance to Yoga, United Nations declared 21st June as" World Yoga Day". Chest trauma due to road traffic accidents leads to morbidity & poor quality of life. Rib fractures constitute a major part of blunt chest trauma and each additional rib fracture is associated with an increasing likelihood of developing complications. In elderly patients, a minor trauma can cause a more serious injury due to the increased stiffness of the rib cage as a function of advanced age. In contrast, in children, the elasticity of the osseous structures of the chest can lead to an underestimation of parenchymateous injuries. Each additional rib fracture in the elderly population increases the odds of mortality by 19% and of developing pneumonia by 27%. Respiratory complications develop with rib fractures as a consequence of splinting of the thorax from pain and mechanical instability resulting in inadequate ventilation. Even an isolated rib fracture is associated with significant consequences, particularly in the older population. This causes decreased lung volumes, atelectasis, and may progress to pneumonia, respiratory failure, need for prolonged ventilation and possible death. Moreover, reduced mobility in blunt chest trauma increases the likelihood of venous thrombosis.

Benefits of yoga have been documented in many studies in patients of Asthma, Parkinsonism, multiple sclerosis etc but there is no literature available for the benefit of yoga in chest trauma patients. So, this study is intended to see the beneficial effects of Yoga in chest trauma patients in terms of pulmonary function testing, biomarkers and quality of life.

3.4. Review of expertise available with proposed investigating group/institution in the subject of the project

The JPNATC, AIIMS is functional since Nov 2006 and it is the only stand-alone trauma centre in the country catering to city of Delhi and neighbouring states. The annual foot fall in the Emergency Department was more than 60,000 in 2014. More than 6000 patients are admitted annually. The division of Surgery and Critical Care at JPNATC, AIIMS has 5 surgeons and 2 critical care experts managing all trauma patients. The Trauma Centre has Department of Lab Medicine that has all types of diagnostic facilities. Department of Physiotherapy is well equipped with all state of art physiotherapy equipment.

3.4.1. Patient Recruitment

• All those patients, who will be admitted with isolated chest trauma and managed non-operatively with or without chest tubes.

4. Workplan

A yoga-based lifestyle intervention program for 12 weeks will be used. During hospital stay, supervised intervention program each day will be performed for duration of upto maximum 1 hour under the direct guidance of yoga instructor and medical experts. The Yoga intervention will start with the basic Pranayama and further according to patient's health condition Asanas will be also incorporated. After discharge the patient will be provided with a booklet to continue yoga at home up to 12weeks. Patient will be advised to come once a week for follow-up and supervised Yoga session for duration of upto maximum 1 hour. Pulmonary function test will be performed on day 0 and after 4, 8, and 12 weeks and the parameters would be measured and analyzed (Table 1).

Table 1:

Inclusion Criteria	Exclusion Criteria	
· Admitted patients	· Neurotrauma and/or Orthopedic patients with restricting mobility.	
Patients with isolated chest trauma with or without chest tube	· Children and pregnant women	
· Age 18-65	· Patient with malignancies, coagulation and bleeding disorders	
· Both gender	· Patient not giving consent	
	· Pre- existing disability which may interfere with yoga therapy.	

4.1. Methodology

Study design: Prospective randomized controlled trial.

Patients who will meet the inclusion criteria will be enrolled in the study. Informed consent will be obtained. Randomization will be done by a person who is not involved in the trial. Random sequence generation will be done with a computer-generated list of random numbers obtained from a Microsoft Excel spreadsheet to ensure a 1:1 allocation ratio; a blocked randomization will be performed (random permuted blocks with randomized order of block sizes) with block sizes of 6 and 4 with the same spreadsheet. Allocation concealment will be achieved with sequentially numbered

and sealed opaque envelopes that will be concealed from the researchers. The envelopes will contain the numbers that indicate the group to which the patient would be allocated and will be taken by the patients after signing the informed consents. The researcher will recruit the patients and he/she will explain the nature of the study to the patients and their relatives using photographs of the appliances.

4.2. Sample Size

Sample size was calculated taking into consideration that Yoga will reduce the hospital stay by 1 day in patients with isolated chest trauma.

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Sample size was calculated considering the β -power of 80% and α -power of 5%. 66 chest trauma patients will be enrolled in the studyand they will be recruited to any of the group 1(Undergoing Conventional physiotherapy) and group 2(Undergoing Conventional physiotherapy along with Yoga based intervention).

4.3. Statistical Analysis

Statistical analysis will be performed using appropriate statistical tests like Chi square test, Fischer's test or Mann-Whitney test etc. Unpaired student's t-test will be used to determine the significance of difference between the two independent groups among continuous variables like age and operative time. For skewed data a corresponding non-parametric test, that is Mann-Whitney test will be applied to see the difference between the two independent groups. For qualitative data Chi –square test was used to see the significant difference in proportion between the two groups. Univariate and multivariate analysis will be done using logistic regression technique for analyzing the risk factors associated with failure and difficulty of surgery. Significance was set at 5% level and a p-value less than 0.05 will be taken as significant. Statistical comparisons will be undertaken only between those patients who received treatment in accordance with the random allocation. Intent to treat analysis will be done.

The study will comprise of baseline assessments before yoga-based lifestyle intervention program, intervention program and post assessment. During the study period, the treatment of the patient shall continue as usual and no interference shall be made at any point in the treatment process. Further, the research team will be separate from the clinical care team of the patient.

4.4. Parameters to be Measured

- 1.Biomarkers and cytokines in serum.
- 2. Pulmonary function test (PFT): FEV1/FVC, FEV1, FRC, TV
- 3. Quality of Life Analysis (Figure 1)

Group I patients will be given conventional physiotherapy treatment which includes positioning, postural drainage, percussion, vibration, coughing and cough stimulation techniques, breathing exercises, suctioning, and patient mobilization.

Patients in Group II will be given added Yoga based intervention along with conventional physiotherapy treatment. Yoga training will be delivered by a trained yoga instructor at bed side. Yoga based therapy will include Pranayama and Asanas which is needed to extend and elongate the muscles and soft tissues used in breathing. Pranayama includes Nadi Sodhav Pranayama (Alternate nostril breathing), Bhramari Pranayama (Bee breathing technique) and Surya Bhedan Pranayama. Asanas includes Gomukhasana (Cow's face pose), Matsyasana (Fish pose) and Bhujangasana (Cobra pose) which will help patients by expanding the thoracic regions limited mobility, easing the tightness of muscles and improving pulmonary function.

All the outcome variables will be assessed before and after the therapy sessions.

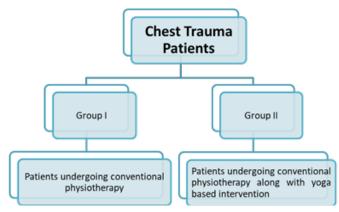


Figure 1:

5. Procedure

5.1. Assessment of Immune response

The immune response will be assessed by measuring the levels of cytokinesIL-2, TNF- α , IFN-Y, IL-4, IL-5, IL-10 and IL-12. Blood samples will be collected (3 ml in plain vial), one hour before and after yoga intervention and/or physiotherapy treatment on day 0, 1, 2, 3, 4, 5 and on the day of discharge.

Analysis of serum cytokines would be done by ELISA, as per manufacturer's instructions.

Serum cytokines will also be measured at each follow up.

Pulmonary functioning, Immune response and quality of life will be evaluated before the therapy protocol starts and also at the end of the protocol (Table 2).

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Table 2: Physiotherapy treatment

Technique	Description	Benefits
Positioning	Positioning the patient for physiotherapy with good lung down.	Changes in ventilation perfusion relationships
Postural Drainage	Positioning the patient according to the bronchopulmonary segment involved.	Helps in removal of secretions, enhances peripheral lung clearance
Percussion and Vibration	Technique given over affected area except the area over the fractured ribs	Enhance muco ciliary clearance from both central and peripheral airways
Breathing Exercises (Diaphragmatic breathing and lateral costal and segmental costal expansion exercises)	Patient relaxed comfortable explaining the patient to inhale deeply for 2-3 seconds and then exhale for 4-sec. Ensures collateral ventilation	Increases tidal volume, improve thoracic- cage mobility, increases inspiratory capacity, enhance cough efficacy, and assist in removal of secretion
Incentive spirometry Coughing	Patient explained to inhale deeply and then exhale forcibly against closed glottis	Coughing removes secretions from the trachea, main stem bronchi, and up to the fourth generation of segmental bronchi

5.2. Pulmonary Function Test (PFT)

Pulmonary Function Tests (PFTs) are non-invasive diagnostic tests that provide measurable feedback about the function of the lungs. Pulmonary Function Test is an inclusive term that refers to several different procedures that measure lung function in different ways. Some of the more common values that will be measured during pulmonary function testing are:

- Tidal volume (VT). This is the amount of air inhaled or exhaled during normal breathing.
- Functional residual capacity (FRC). This is the amount of air remaining in lungs after normal expiration.
- Forced vital capacity (FVC). This is the amount of air exhaled

forcefully and quickly after maximum inspiration.

• Forced expiratory volume (FEV). This is the volume of air expired during the first, second, and third seconds of the FVC test (Figure 2).

Parameters will be recorded by independent observers of respective speciality at bedside.

QOL (Quality of Life) assessment chart shall be filled for all the patients enrolled in the study.

After three weeks of active yoga intervention, the participants will be advised to follow-up the same at their home at least up to next 12 weeks. Patients will be followed up at intervals of 4, 8, and 12 months and the parameters shall be measured and analysed.

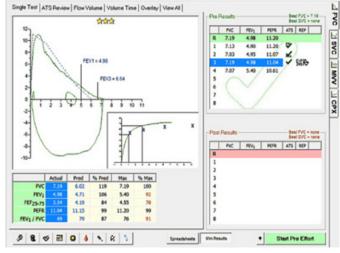




Figure 2:

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5.3. The Yoga Protocol for chest trauma patients is as follows:

5.3.1. Types of Pranayama

1. Nadi Sodhav Pranayama (Alternate nostril Breathing)

Procedure: Sit comfortably and press your thumb down on the right nostril and breathe out gently through the left nostril. Now breathe in from left nostril and then press the left nostril gently with the right finger and little finger. Removing the right thumb from the right nostril, breathe out from the right. Breathe in from the right nostril and exhale from the left. This is onecomplete round of Nadi Pranayama (Figure 3).

2. Bhramari Pranayama (Bee Breathing technique)

Procedure: Sit up straight and place your index fingers on your ears. Place your index fingers on the cartilage of ear. Take a deep breath in and as you breatheout, gently press the cartilage and make loud humming sound like a bee (Figure 4).

3. Surya Bhedan Pranayama

Procedure: Sit comfortably and make the trunk and spine straight and place the handson the knees. Raise the right hand and place the forefinger and the middle finger on the forehead between the eyebrows. Close the left nostril with the ring finger. Breathe in slowly through the right nostril and fill the lungs entirely. Close the both nostrils and hold the breath, Exhale through left nostril keeping the right nostril closed. This is one complete round (Figure 5).



Figure 3: Cycles: 9 rounds in one sitting **Benefits:** 1. It calms and center the mind.

- 2. Maintains body temperature.
- 3. Works therapeutically for circulatory and respiratory problems.



Figure 4: Cycles: 6-7 times in one sitting. **Benefits:** 1. It calms down the agitated mind.

- 2. Helps in reducing blood pressure.
- 3. Improves breathing and circulation



Figure 5: Cycles: 5-10 rounds in one sitting.

Benefits: 1. It destroys all diseases that are caused by insufficiency of oxygen in the blood.

2. It activates the body and the bodily functions.

5.4. Types of Asanas

1. Gomukhasana (Cow's face pose)

Procedure: Sit in a position so that the right knee is directly above the left knee. Place the left arm behind the back and the right arm over the right shoulder. Try to clasp the fingers of both hands behind the back. Bring the raised elbow behind the head so that the head presses against the inside of the raised arm. Stay in this position for 2 minutes and repeat the same process with the left knee uppermost and left arm over the left shoulder (Figure 6).

2. Matsyasana (Fish pose)

Procedure: Stretch both legs and lean backward using the arms for support and rest head on the surface. Relax the arms and the whole body, allowing the head, buttocks and legs to support the weight of the body. Close the eyes and breathe slowly and deeply. Return to the normal position. This is one complete round (Figure 7).

3. Bhujangasana (Cobra pose)

Procedure: Lie flat on the stomach with the legs straight, place the palms of the hand on the surface. Rest the forehead on the floor and close the eyes. Relax the whole body. Slowly raise the head, neck and shoulders like a cobra. Return to the original position. This is one complete round (Figure 8).



Figure 6: Cycles: 3-5 times in one sitting.

Benefits: 1. Induces relaxation.

- 2. Strengthens the muscles of chest, back and triceps.
- 3. Improves posture by opening the Chest area.

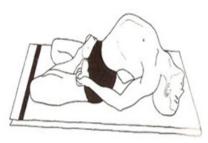


Figure 7: Cycles: 3-4 times in one sitting. **Benefits:** 1. Encourages deep respiration.

2. Regulates the function of thyroid gland boosting the immune system.



Figure 8: Cycles: 3-5 times in one sitting. **Benefits:** 1. More effective for lung diseases. 2. Helps in keeping the spine flexible.

3. Improves circulation.

6. Quality of Life (QOL)

World Health Organization Quality Of Life –BRIF (WHO-QOL-BREF)

WHO-QOL-BREF (Hindi translated version also available) is a standardized instrument comprising of 26 items, measures overall quality of life and quality of life in physical, psychological, social relationships and environment domains.

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