EFFICACY OF SLOW NEGATIVE PLEURAL SUCTION IN THORACIC TRAUMA PATIENTS UNDERGOING TUBE THORACOSTOMY - A RANDOMISED CONTROL TRIAL

A Thesis submitted to the

All India Institute of Medical Sciences, Jodhpur

In partial fulfillment of the requirement for the degree of

MASTER OF SURGERY (MS)

GENERAL SURGERY

JULY, 2020 **DR. DEEPAK**

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DECLARATION

I hereby declare that this thesis titled "**Efficacy of slow negative pleural suction in thoracic trauma patients undergoing tube thoracostomy - A Randomised control trial"** is a bonafide and original research work carried out in partial fulfilment of the requirements for the degree of Masters of Surgery in General Surgery under supervision and guidance, in the Department of General Surgery, All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE

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Finally I apologize for all the errors which might have crept in due to oversight. To the best of my efforts, I have tried to minimized them and crave indulgence for those missed.

Date: *Dr Deepak*

DEDICATION

I would like to dedicate this thesis, the first piece of literature written by me, to my guide, and to my parents.

ABBREVIATIONS

ICD	Intercostal drainage tube
ISS	Injury severity Score
WHO	World Health Organization
CXR	Chest X ray
CECT	Contrast enhanced Computed tomography
eFAST	Extended Focused Assessment Sonography for Trauma
SSI	Surgical Site infection
VATS	Video Assisted thoracoscopic Surgery
IQR	Interquartile Range
SDH	Subdural Hematoma
AICU	Adult Intensive care unit
RCT	Randomized Control Trial
hPa	Hectopascal
FC	Flail Chest

SUMMARY

Background: Chest trauma is major cause of morbidity and mortality. Chest trauma lead to hemothorax, pneumothorax and hemopneumothorax and lung contusion. Hemothorax, pneumothorax and hemopneumothorax need to be drained by chest tube placement otherwise can lead to respiratory discomfort, tension pneumothorax, dyspnea and death of patient.

Slow continuous negative suction can affect the ICD duration and hospital stay. Very few studies are there for slow negative suction in trauma patients undergoing tube thoracostomy

Objective: The primary objective was to compare the duration of tube thoracostomy in both groups. While secondary objectives were,

- To compare the duration of hospital stay.
- To compare the incidence of persistent air leak.
- To compare the incidence of re-interventions.
- To compare the incidence of clotted hemothorax.
- To calculate injury severity score.

Methods: Patients undergoing tube thoracostomy in trauma patient for pneumothorax, hemothorax and hemopneumothorax from January 2021 to June 2022 in the Department of General Surgery, AIIMS Jodhpur, were recruited into the study. All patient underwent tube thoracostomy were randomised and negative suction was applied (-20 cm of H2O) in group A (i.e. negative suction group). ICD was removed on basis of ICD output (<200 ml/days), clinically stable patients, no air leak and lungs expanded on Chest X-ray. The patients were discharged when stable. So duration of ICD, hospital stay, ISS, complications, and incidence of reinterventions were calculated.

Results: Duration of ICD was significantly lower in negative suction group (3days) as compared to normal water seal group (5 days), with p value is <0.001. Hospital stay was reduced in the negative suction group as compared to the normal water seal group which was 5 days in negative suction group i.e. group A vs 10 days in normal water seal i.e. group B (p-0.004). ISS in both group were not significantly different,

complications and deaths were lower in the negative suction group as compared to the normal water seal group.

Conclusion:

Application of continuous slow negative suction lead to decrease in ICD duration, hospital stay less complication and reinterventions. So we can apply the slow negative suction on all trauma patient undergoing tube thoracostomy can lead to decrease morbidity, decrease chest pain due to ICD placement, less hospital stay, and early return to work.

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INTRODUCTION

Road traffic accidents are one of the primary causes of death for people between the ages of 5 and 29 and are a significant public health burden. According to the WHO worldwide status report on road safety released in 2018, there are now 1.35 million fatalities caused by traffic each year(1). Trauma is a leading cause of mortality, morbidity, hospitalization, and disability. According to the WHO, this is the second most important cause of death for 15 to 29 year olds. Thoracic injuries occur in a significant percentage of trauma patients, most frequently in male victims in the 20–40 year age.(2) . In India, there were 4,22,659 "Traffic Accidents" in 2021 compared to 3,68,828 in 2020. (The number of people killed in traffic accidents per 1,000 vehicles grew from 0.45 in 2020 to 0.53 in 2021)(3). Males are more likely to experience chest trauma between the second and fifth decades of life, at an average age of 40, which lowers their life expectancy by an additional 40 years during their most productive and active years.(4) After head and spinal injury thoracic trauma is 3rd most common cause of death lead to mortality range from 10%-60%.

The injuries can be penetrating chest trauma and blunt chest trauma. Rib fractures, sternal fractures, thoracic injuries like pneumothorax, hemothorax, lung contusions and even lethal aortic and cardiac injuries commonly seen in chest trauma patients. The magnitude of these thoracic injuries can be noted in various trauma literatures. Rib fractures are present in two-thirds of admitted patients with chest trauma. When three or more consecutive ribs are fractured at different locations, it is referred to as a flail chest (FC), which causes paradoxical chest wall movement, abnormal respiratory mechanics, and frequently respiratory failure(5). Patients with FC often need prolonged ventilatory support and protracted ICU and hospital stays, despite advancements in ventilatory management. Even though it only occurs in a small proportion of patients who experience blunt trauma, 2-4 ribs fractures with flail chest is linked to high rates of morbidity, mortality, and resource consumption.(6)

Advanced Trauma Life Support protocols are used as guideline for initial resuscitation and management for trauma patient. Clinicians should assess and stabilize the patient's airway, breathing, circulation and disability in sequential manner (ABCDs). After addressing the patient's ABCDs, the clinician continues the initial assessment and management based on vital signs, the initial presentation, and the mechanism of injury.

Mechanism is less predictive of injury severity and ultimate disposition as compared to abnormal vital signs in the setting of blunt trauma. Radiological investigations are used during initial assessment and management. Radiological investigations are important in proper evaluation and management of thoracic trauma patients.

Nevertheless, the initially chest X-ray [CXR] continues to be an ATLS recommendation [3] as Pneumothorax and hemothorax can be seen in chest X ray. But the chest radiography is poorly sensitive and less accurate in finding the injuries like occult pneumothorax, small hemothorax, and lung contusions in blunt trauma chest patients. Therefore, a CECT scan of the chest is frequently performed in the trauma bay in hemodynamically stable patients. Although CECT chest is the gold standard for diagnosis but application of CT in all trauma patients has its limitations like exposure to excessive radiation, increase in total costs, and overcrowding of the emergency department. Chest tube should be inserted as early as possible in pneumothorax, hemothorax and hemopneumothorax. In trauma patient eFAST is done and USG chest is a component of that. Chest tube should be inserted under sterile technique, should not be clamped except while the removal of the chest tube, when changing the chest drainage system, when checking for air leaks or gauging the patient's tolerance for the procedure.(7–9) It is removed if patient is stable (RR <22, SPO2 > 95%) no air leak, lung, completely expanded and drain is < 200 ml per day. It is removed by asking the patient to full inspire and holding the breath and abrupt applying gauze pad or closing the wound.

USG is more sensitive as compared to chest x-ray for pneumothorax, hemothorax. Yet CXR is commonly used as the early diagnostic test in patients with thoracic injuries, yet the accuracy of USG is more compared as compared to chest x-ray.(10)

COMPLICATION DUE TO CHEST TUBE CAN BE:

- Pneumonia
- Mediastinitis
- Empyema
- SSI
- Residual pneumothorax
- Residual hemothorax
- Post removal empyema

- Post removal fibrothorax

Recurrent Pneumothorax is most common complication (11). For retained hemothorax either reinsertion of ICD and early VATS can be done(12–14). In our study we compared the chest tube duration in both groups i.e. group A and group B as primary objective. Duration of hospital stay, ISS, complication and reinterventions in both groups as secondary objectives.

Placement of continuous negative suction lead to decreased ICD duration, less hospital stay and lesser complication and reinterventions. So continuous negative suction can be placed in all trauma patients undergoing tube thoracostomy.

Duration of ICD and hospital stay can be affected by other injuries like concomitant bone fracture, neurological injuries, intra-abdominal solid and hollow viscus injuries and in patient is on endotracheal tube and underwent procedure in general anesthesia immediately after ICD insertion.

REVIEW OF LITERATURE

Trauma is leading cause of death in age up to 44 years. It accounts for 6 percent of all death and 4th leading cause of death. For every death 3 people are permanently disabled. Mechanism of injury divided into blunt trauma which is due to motor vehicles related injuries, falls and assaults whereas penetrating injuries due to firearms and stabbing injuries . Trauma related injuries has a tri modal distributions. 50 % are immediate within minutes due to massive blood loss or neurological damage. 30 % within 2 days post injury due to neurological dysfunction. Remaining 20 % die within days to weeks due to sepsis or MODS.(15)

According to ATLS, evaluation of trauma patients should be divided into primary and secondary survey. In primary survey assessment of patient airway is most important, patient with low GCS, intoxicated, suspected traumatic brain injury require artificial airway.

Evaluation of breathing is assessed by chest movement and auscultation of breath sounds. Percussion is used to determine the hemothorax and pneumothorax. 4 life threatening injuries are massive hemothorax, tension pneumothorax, open pneumothorax and flail chest. Massive hemothorax is indication of open thoracotomy.

Thoracic anatomy

The ribs and costal cartilages form the lateral aspects of the thoracic cylinder.

The ribs can be divided into two main groups:

Typical: It attach the spinal column and connect with the sternum anteriorly via the costal cartilages. They have a head, a neck, a tubercle, an articular facet, and a shaft. They articulate with the costal cartilages through a cup at the front end. A notch on the underside carries the neurovascular bundle, the intercostal nerve, an artery, and a vein coursing underneath the rib as shown in fig 1

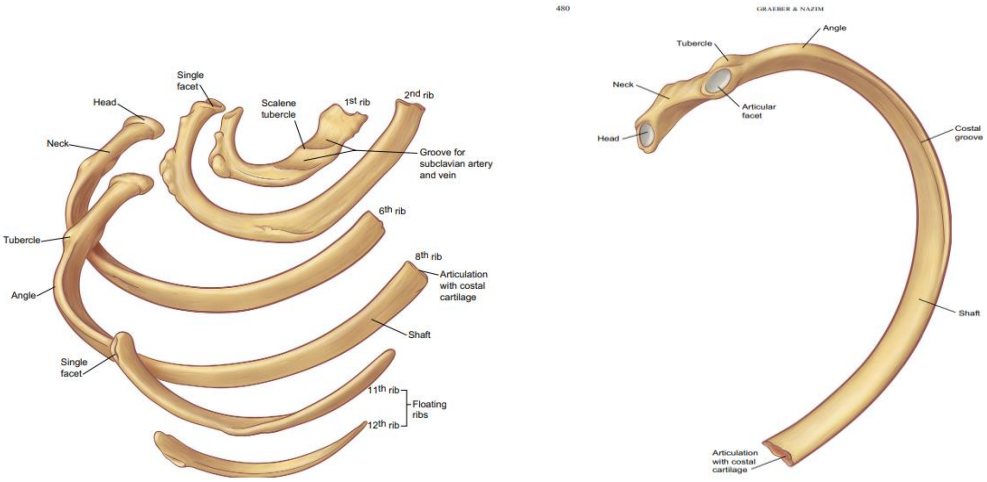


Fig 1

Atypical:

Rib 1st is a very flat rib short, broad, and sharply curved, rib 2nd is a little more developed and is little larger has a poorly developed costal groove, and its tubercle is less well defined and is intimately associated with the serratus anterior muscle. Other atypical ribs, the floating ribs, are ribs 11 and 12.

Their ends taper to rudimentary cartilages. The cartilage is not as joined to the rest of the rib cage; hence the name ‘‘floating ribs.’’. The costal cartilages are an integral part of the articulation of the ribs with the sternum anteriorly. The relationship between the ribs and the sternum is shown in Fig.3. These cartilages join the rib to the sternum in a way that facilitates the action of the ribs with the sternum. As the sternum moves upward, the body moves anteriorly; hence the cartilages articulate with the corresponding ribs to draw the ribs upward when the muscles contract, increasing the diameter of the chest.

Costal cartilages 1 -7 articulate directly with the sternum. Cartilages 7 and 8 are fused at their margins where they articulate with the sternum. Ribs 8, 9, and 10 fuse into the costal arch, which joins with 7^{th} rib cartilage to meet the sternum and articulate with it.

1^{st} rib cartilage articulates with the manubrium of the sternum. 2^{nd} rib cartilage to the angle of Louis, which joins the body with the manubrium as shown in fig 3

The cartilages on the end of ribs 11 - 12 are rudimentary and do not articulate(15).

MUSCULAR STRUCTURES

Intercostal Muscles- 11 intercostal spaces between 12 ribs contain intercostal muscles and membranes that supply neurovascular structures-

External intercostal muscles- fibers run obliquely downward, forward, and insert into the upper border of the rib below. In the upper 2 spaces they do not reach the anterior end of the ribs and in the lower 2 they become continuous with the external oblique muscles as shown in fig 3.

The internal intercostal muscles - fibers run obliquely inferiorly and posteriorly and insert into the upper border of the rib below.

The innermost intercostal - are variable and incomplete, and fibers run in the direction of the fibers of the internal intercostals, but they lie deep to the intercostal neurovascular bundle.

The subcostalis (or infracostal) muscles, which could be considered part of this third group of muscles, lie on the internal surface of the lower ribs, usually in the lower part of the thorax.

The subcostalis muscles arise from the inner surface of one rib near its angle and are inserted into the inner surface of the second or third rib below.

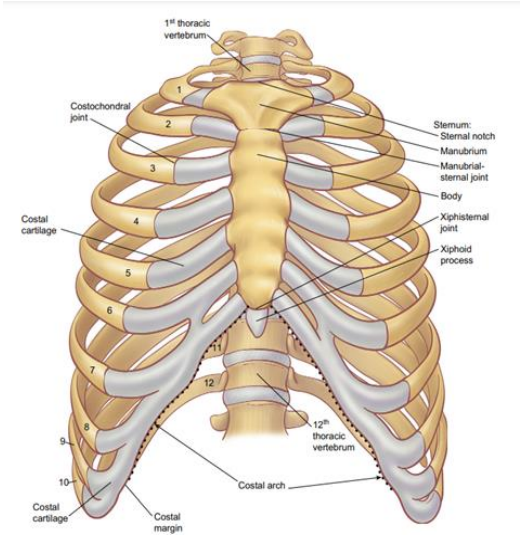


Fig 2

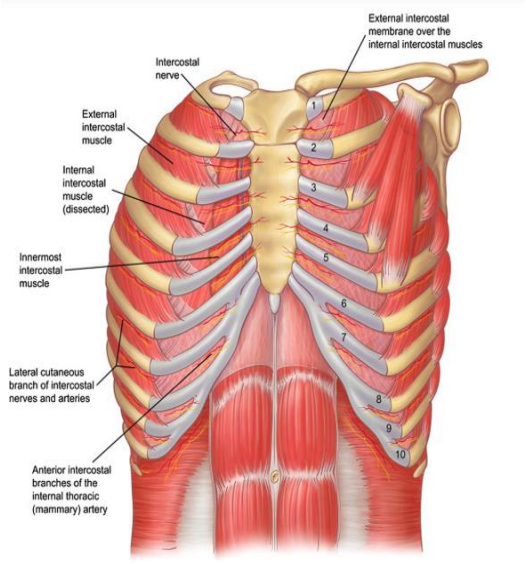


Fig 3

There is an ample collateral blood supply to the thoracic wall. Three different sources of blood supply the thoracic wall in abundance. These are the axillary artery, subclavian artery, and thoracic aorta. One of the arteries listed below that directly supplies the chest wall emerges from each of these major sources:

- Anterior intercostal artery
- Posterior intercostal artery
- Internal thoracic artery

The intercostal gaps, which are bounded by the top and lower borders of the ribs above and below, are where the anterior and posterior intercostal arteries run. A posterior and anterior intercostal artery supplies blood to each of the upper nine intercostal gaps (both of which give off collateral branches).

Only the posterior intercostal arteries supply the 10th and 11th intercostal spaces. The superior epigastric and musculophrenic arteries, as well as the upper six anterior intercostal arteries, all originate from the internal thoracic artery.

Intercostal veins

The thoracic wall is drained by eleven pairs of posterior intercostal veins, nine pairs of anterior intercostal veins, and one pair of subcostal veins. The ipsilateral anterior intercostal veins and each posterior intercostal vein connect via an anastomosis. There are various drainage sites for the intercostal veins:

The brachiocephalic vein receives the first posterior intercostal vein's direct drainage. The left and right superior intercostal veins are created by the anastomosis of the second and third posterior intercostal veins. While the right superior intercostal vein travels through the azygous vein to the superior vena cava, the left superior intercostal vein empties into the left brachiocephalic vein.

The azygous or hemizygous veins are the destinations of the remaining fourth to eleventh posterior intercostal veins.

Direct drainage occurs from the first six pairs of anterior intercostal veins. The seventh to ninth anterior intercostal veins will first drain to the musculophrenic vein, which then drains to the internal thoracic vein.(16)

Lymphatic drainage-

The hemiazygos, acessary azygos, and azygos veins make up the azygos venous system. [15] The left posterior intercostal veins are drained by the hemiazygos and acessary azygos veins, which also connect to the left common iliac vein. The right posterior intercostal veins, hemiazygos, and acessary azygos veins are all drained into the superior vena cava through the azygos vein.

Except for the right upper limb and right side of the head, the lymphatic system of the entire body drains through the thoracic duct. The thoracic duct in the thorax passes through the aortic hiatus in the diaphragm, ascends just anterior to the thoracic vertebral bodies, and empties into the intersection of the left subclavian and internal jugular veins. The right side of the head receives lymphatic drainage through the right lymphatic duct.

Nerve Supply-

The intervertebral foramina are the exit points for the T1 to T12 thoracic spinal nerves, which divide into anterior and posterior ramus branches. In the neurovascular space, the anterior ramus branches (intercostal nerves) move with the posterior intercostal vessels immediately inferior to each rib (between the innermost intercostal muscle and internal intercostal muscle). During their progression, anterior cutaneous, lateral, and collateral branches split off. The muscles of the thoracic wall and the skin around the ribs are innervated by the anterior ramus branches. The skin covering the posterior thoracic wall and the muscles of the spine are innervated by the posterior ramus branches.

The C5 to T1 spinal neurons give rise to the brachial plexus, which is located above the thorax.

Pleura-

It is vital structure of respiratory tract. There are two pleurae, each of which is a two-layered membrane covering each lung. A thin layer of pleural fluid, a viscous (thick) lubricant, separates the layers.

Its function is to cushion the lung and minimise any friction that can form between the lung, rib cage, and chest cavity. Each lung has one pleura, which is a single membrane

that folds back on itself to produce two layers. There are two pleurae in total. A thin, lubricating liquid fills the gap between the membranes (known as the pleural cavity) (called pleural fluid).

Two different layers make up the pleura:

The visceral pleura is a delicate, slick membrane that covers the surface of the lungs and dips into the spaces between the various lobes of the lungs (called the hilum).

The outer membrane that lines the inner chest wall and diaphragm (the muscle dividing the chest and the diaphragm) is known as the parietal pleura as shown in Fig 5.

At the hilum, which also acts as the point of entry for the bronchus, blood vessels, and nerves, the visceral and parietal pleura converge. The intrapleural space is another name for the pleural cavity. It contains pleural fluid that the mesothelial cells have secreted. The fluid enables the layers to move over one another as the lungs expand and contract during breathing (breathing).

The pleurae also act as a barrier between other body organs, preventing interference with lung function and the reverse.

In order to inhale and expel, the lungs require lubricant and cushioning, which the pleura's structure provides. Pleural fluid, which is present in the intrapleural cavity in amounts ranging from 4 to 5 cc, helps to lessen friction as the lungs expand and compress.

Due to the pleura fluid's slightly sticky nature, the lungs are drawn outward during inhalation as opposed to sliding around in the chest cavity. The surface tension it produces keeps the lungs pressed up against the chest wall. The pleurae also act as a barrier between other body organs, preventing interference with lung function and the reverse.(17)

The pleura's self-contained nature can assist in limiting the spread of infection to and from the lung

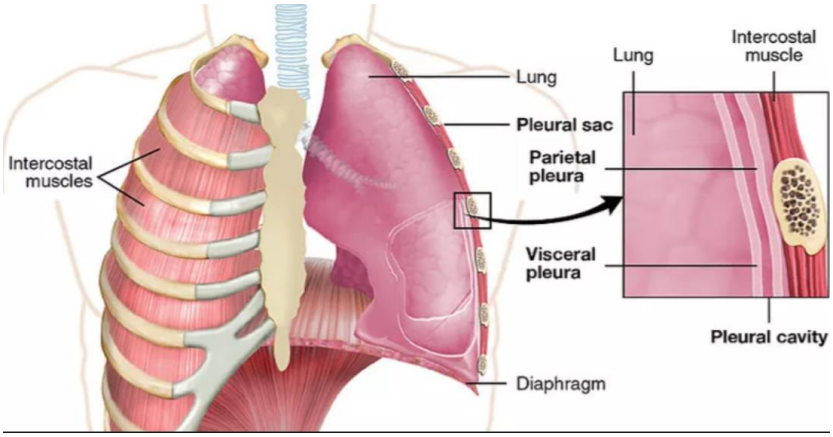


Fig 4

Lungs-

The lung has an apex, three boundaries, and three surfaces anatomically. Above the first rib, the apex is located.

The anterior, posterior, and inferior borders are among the three borders. A cardiac notch is formed in the left lung by the front border of the lung and the pleural reflection. The cardiac notch is a concavity that forms in the lung to house the heart. The costal surface and the base of the lung are separated by a thin inferior boundary. From the C7 to the T10 vertebra, or from the top of the lung to the inferior border, the posterior border is thick.

The costal, medial, and diaphragmatic surfaces of the lung are its three surfaces. The costal pleura protects the costal surface, which runs along the sternum and ribs. Additionally, it connects the diaphragmatic surface to the medial surface at the inferior border as well as the anterior and posterior borders. Anterior and posterior divisions are present on the medial surface. It is connected to the sternum anteriorly and the vertebra posteriorly. The right dome is higher than the left dome due to the liver, and the diaphragmatic surface (base) is concave and rests on the dome of the diaphragm.

While comparable, the structure of the right and left lungs differs. Right upper lobe (RUL), right middle lobe (RML), and right lower lobe (RLL) are the three lobes that make up the right lung (RLL). The left upper lobe (LUL) and left lower lobe (LLL) are the two lobes that make up the left lung (LLL). An oblique and horizontal fissure

separates the middle and lower lobes of the right lobe, whereas the horizontal fissure separates the upper and middle lobes. Only an oblique fissure divides the top from the lower lobe in the left lobe.(16)

The lobes are further divided into segments, each of which corresponds to a particular segmental bronchi. The third-order branches (lobar bronchi) that branch from the main bronchus are known as segmental bronchi.

There are ten parts in the right lung. The RUL has three segments (apical, anterior, and posterior), the RML has two segments (medial and lateral), and the RLL has five segments (superior, medial, anterior, lateral, and posterior). The RLL is divided from the RML and RUL by the horizontal fissure, while the oblique fissure divides the RUL from the RML.

Depending on how the lobe was divided, there are eight to nine segments on the left. Anterior, apicoposterior, inferior, and superior lingula are the four segments in the left upper lobe, and four to five segments can be found in the lower lobe.(18)

Diaphragm-

During contraction, the diaphragm pushes its central tendon downward, enlarging the thorax's vertical diameter. As a result, the thoracic cavity experiences more negative pressure, which causes air to be drawn in. As a result, the diaphragm is the key muscle involved in inspiration. The diaphragm flattens down as it is pulled inferiorly into the abdominal cavity during inhalation. The anterior chest wall is simultaneously raised like the handles of a bucket by the external intercostal muscles that are situated between the ribs. This causes the chest cavity to enlarge and widen, allowing outside air to enter. The chest wall and rib cage begin to sag and return to their initial positions after exhalation. Additionally, there are concurrent relaxation and elevation of the diaphragm. This motion forces the air within the lungs to push out of the body.

Physiology of Respiration-

During contraction, the diaphragm pushes its central tendon downward, enlarging the thorax's vertical diameter. As a result, the thoracic cavity experiences more negative pressure, which causes air to be drawn in. As a result, the diaphragm and other respiratory muscles receive signals from neural and sensory input systems to regulate the mechanical characteristics of respiration. Numerous soft tissues, muscles, and bone

structures in the upper airway regulate the patency for respiratory activities. Cortical moods, sensory input, medications, and passive changes in lung capacity can all have an impact on the upper airway, which ultimately serves to modulate reflex activity and offer defense/protection and maintenance of the airway. The intensity of brain activity in the respiratory centre and the subsequent stimulation of motor neurons during breathing determine the depth of inspiration. More stimulation causes a greater number of motor units to get activated, which causes the breathing muscles to contract more forcefully. Various drugs and addictions like alcohol, opiods, and barbiturates affect the higher centres as well as peripheral receptors lead to decreased in respiratory efforts as shown in fig 6(19–23).

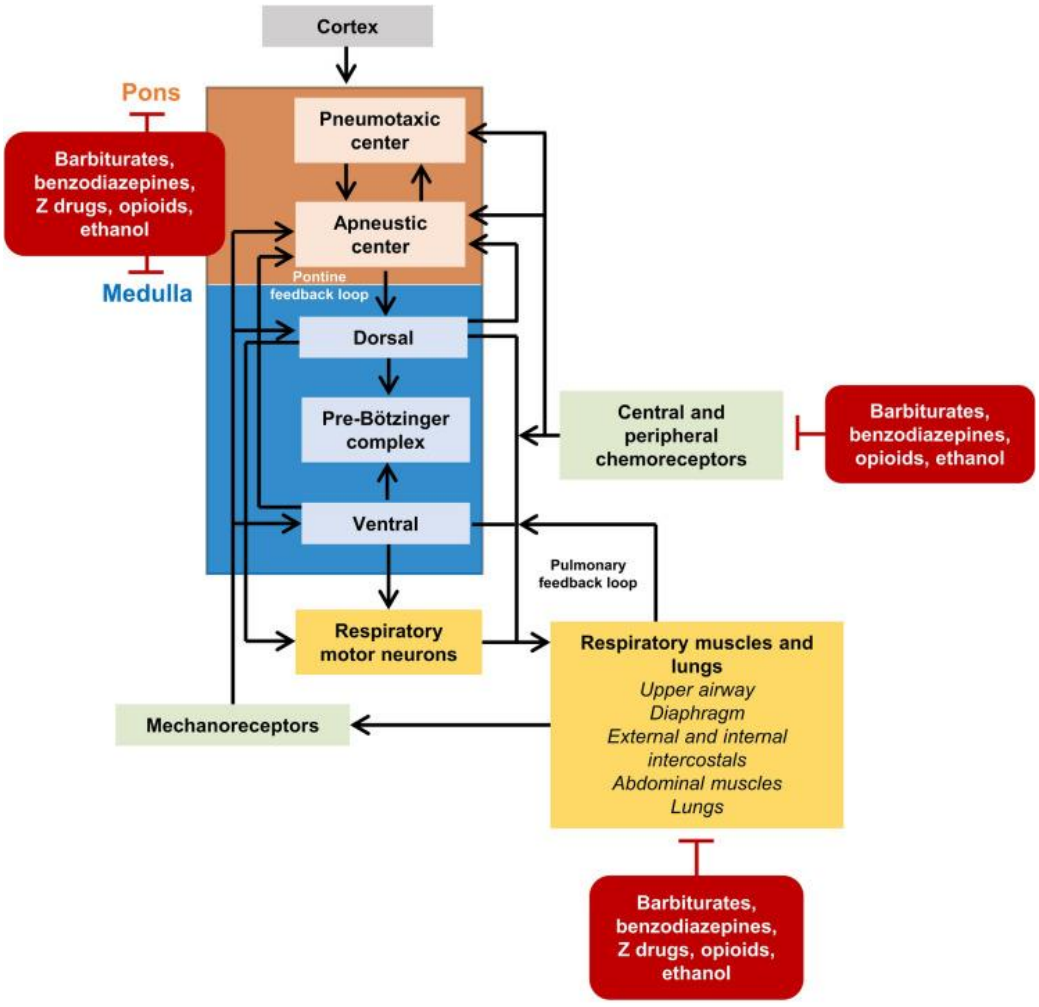


Fig 5

Most pressure changes that lead to inspiration are caused by the diaphragm and external intercostals contracting and relaxing. The scaleni, sternocleidomastoid, and anterior serrati are accessory muscles of inspiration, however they are not involved in passive

breathing. The abdominal muscles and internal intercostals are the most crucial muscles during expiration because they contract and compress the abdominal organs, forcing them up into the diaphragm, increasing pleural and alveolar pressure, and expelling air from the lungs. The lungs' respiratory exchange surfaces move O2 and CO2 from the air to the blood. While CO2 is taken from the blood and deposited to the alveoli before O2 traverses the lungs' alveoli and travels to tissues, prior to exchange to back to environment.

A healthy adult's average resting respiratory rate is about 12 breaths per minute as a result of the interaction of these processes. A normal tidal volume is around 7 mL/kg of ideal body weight (around 500 mL in an average healthy adult man and 400 mL in a healthy adult female), and minute ventilation is the result of respiratory rate and tidal volume. A patient's total respiratory health can be determined by evaluating this and other aspects of breathing.(24)

Chest Tube-

A flexible plastic tube called a chest tube is introduced through the chest wall and into the mediastinum or pleural area. It is used to expel material from the intrathoracic space, including air in the event of a pneumothorax, fluid in the event of a pleural effusion, blood, chyle, or pus in the event of an empyema. It is also called as an intercostal catheter or a Bülau drain.

Principle

The pulmonary pressure is lower than the external atmospheric pressure.

A proper chest drainage system must do the following:

- Remove fluid and air as quickly as feasible.
- Prevent drained fluid and air from returning to the pleural space.
- Restore negative pressure in the pleural space to allow the lung to re-expand.

In order to prevent air and fluid from returning to the chest, a drainage device must

- Allow air and fluid to exit the chest
- Include a one-way valve; and
- Designed so that it is below the level of the chest tube to allow gravity drainage.

Single chamber system-

It comprises of a bottle that gathers and holds the fluid while also plugging air leaks (leakage barrier-water seal). The tip of a hard straw is inserted into the bottle of saline solution such that it is 2 cm below the top of the solution. The thoracic drainage tube, which is positioned in the pleural cavity, is attached to the opposite end of this rigid straw. A one-way decompression valve (vent) opening allows the system to be depressurized in order to relieve the pressure caused by the air leak. This valve cover needs to be taken off before the system is connected to the patient.

It includes a bottle that collects and holds the fluid and seals air leaks (leakage barrier-water seal). The hard straw's tip is put into the saline solution bottle such that it is 2 cm below the liquid's surface. The opposing end of this rigid straw is connected to the thoracic drainage tube, which is positioned in the pleural cavity. To release the pressure brought on by the air leak, a one-way decompression valve (vent) opening enables the system to be depressurized. Before the system is linked to the patient, this valve cover needs to be removed.

It is obvious that the system will not function consistently if the hard straw is above the liquid level in the bottle, leading to pneumothorax.

However, if a substantial amount of liquid is removed from the patient's pleural cavity, the liquid level will rise and more pressure will need to be applied to the rigid straw in order to efficiently transfer more air from the pleural cavity to the bottle. Practically speaking, this system only functions if only air is leaving the chest. If fluid is draining, it will increase the depth of the water seal and add to the fluid therein. As the depth increases, it becomes harder for the air to push through a higher level of water, which may lead to air remaining in the chest. As a result, the one-bottle system works efficiently for uncomplicated pneumothorax.

Another disadvantage of this system is that the positioning of the bottle at a level higher than the patient’s chest causes liquid passing into the pleural cavity.

Two chamber system-

The two-compartment method was established due to the aforementioned reasons for the one-bottle system's ineffective performance in pleural fluid effusion instances. When sizable amounts of liquid are drained from the pleural cavity, this technique is

recommended over the one-bottle system. With this method, the second bottle serves as the water seal and the first bottle (closer to the patient) collects drainage (water seal and air vent). Therefore, as fluid builds up in the drain bottle, the degree of water seal does not rise. As it has a spot for drainage to gather and a one-way valve that prevents air or fluid from returning to the chest, the water-seal bottle is essential for chest drainage.

Gravity is used in both the one and two-bottle chest drainage systems to create a pressure gradient that allows fluid and air to exit the chest. Gravity drainage is improved by keeping the drainage system below the patient's chest; when the patient exhales or coughs, more pressure is produced. Gravity drainage might not be adequate to empty the chest if the patient has a significant air leak into the pleural space, and suction might be necessary instead. This also entails the installation of a suction control bottle as a third bottle to the system.

Three chamber System-

Gravity is used in both the one and two-bottle chest drainage systems to create a pressure gradient that allows fluid and air to exit the chest. Gravity drainage is improved by keeping the drainage system below the patient's chest; when the patient exhales or coughs, more pressure is produced. Gravity drainage might not be adequate to empty the chest if the patient has a significant air leak into the pleural space, and suction might be necessary instead. This also entails the installation of a suction control bottle as a third bottle to the system.

To make it simple to measure and record the time, date, and amount of drainage, the collection chamber must be calibrated and have a write-on surface. The water seal is located in the centre chamber of a conventional chest drainage system. The major function of the water seal is to permit expiration from the pleural space and prevent inhalation into the pleural cavity or mediastinum. A 2 cm water seal is created when the water seal chamber is filled with sterile fluid up to that line. Keep the chest drainage unit upright at all times in order to maintain an efficient seal, and keep an eye on the water level in the water seal to look for evaporation(25)

Charalambos Zisis et al shows that wall suction is not as effective as a water seal at stopping leaks. Water seal is safe and ideal for all patients, including those with pneumothoraxes and air leaks; however, if a patient has a significant leak (greater than an expiratory 3 on the classification system), subcutaneous emphysema, or an expanding pneumothorax that results in hypoxia, some suction (about 10 cm of water) should be applied to the chest tubes.

The height of a water column in the suction control chamber controls the amount of suction in traditional chest drainage machines. Typically, a suction pressure of around 20 cm H2O is advised. Infants, those with friable lung tissue may all require lower pressure. In a wet suction control system, the short suction tubing is linked to a suction source and the suction control chamber is filled with sterile fluid to the appropriate height. The amount of suction placed on the chest cavity won't be much changed by increasing suction at the source of the suction, but it will increase airflow through the system.

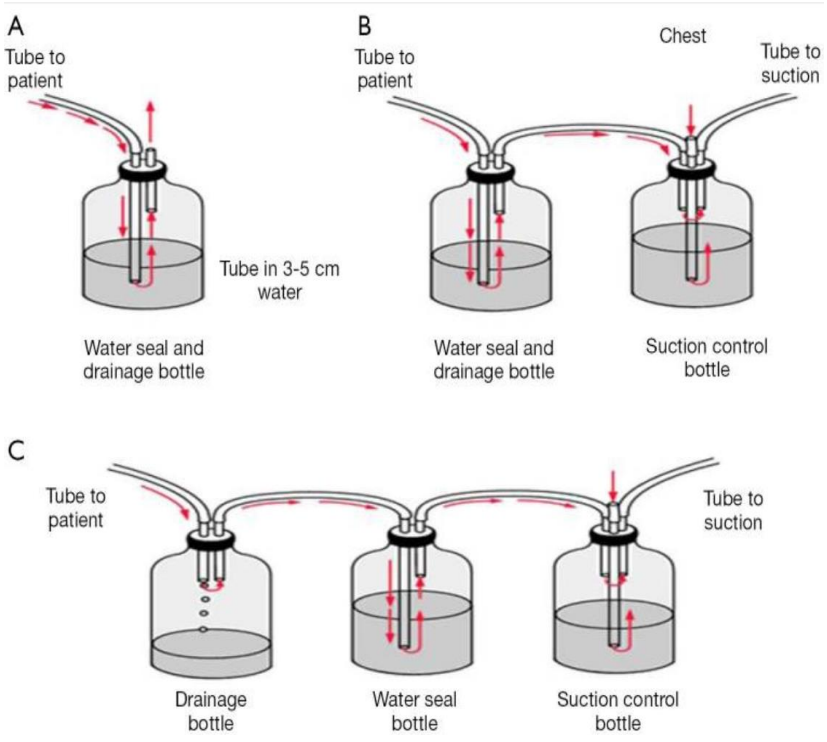


Fig 6

Carlos H. Morales et al(26): This Randomised control study was conducted between March 1 and November 30, 2012 in the Department of General Surgery of the University Hospital San Vicente Foundation of Medellı´n (Colombia), a referral hospital for trauma patients showed that there were 110 patients total, 56 in the suction group and 54 in the non-suction group. The demographic features of each group were identical. In terms of chest tube duration there was not significant difference (In both groups it was 3), p value was 0.35. In terms of hospital stay (p = 0.22), tube thoracostomy duration (3 days in each group), or problems, there were no differences between the groups. However, compared to patients in Group 2 with normal water seal, patients in Group 1 with negative suction were more likely to experience an air leak over time (p = 0.023).

	With suction(n)	Normal water seal(n)	
Outcome	Median	Median	p value
Chest tube	3	3	0.35
Hospital stay	3	3	0.22
Recurrent pneumothorax	0	1	0.49

Table 1

Muhammad Muslim et al(27) – This Randomized clinical controlled trial was conducted in the department of thoracic surgery Post Graduate Medical Institute Lady Reading Hospital Peshawar from July 2007 to March 2008 showed that Each group included fifty patients. Regarding age, sex, pre-intubation Hb, and pre-intubation nutritional status, the two groups did not significantly differ from one another. In group I, 46 patients (92%) and group II, 37 patients (74%), fully expanded their lungs. In group I, 3 (or 60%) people had pneumothorax or partial lung extension, while group II had 10 (20%) such cases. There was no response from 1 patient in group I and 3 (6%) participants in group II. In groups I and II, the mean duration of chest drain removal was 8.2 +/- 3.14 days and 12.6 +/- 4.20 days, respectively. In groups I and II, the hospital stays lasted 7.2 +/- 2.07 days and 12.4 +/- 3.63 days, respectively. Clotted Haemothorax requiring surgery developed in three (6%) patients in group I and 8 (16%) patients in group I. Conclusion was After penetrating chest injuries, placing chest tubes

on continuous low pressure suction aids in blood evacuation, lung expansion, and minimises the formation of clotted hemothorax. In addition, it shortens the time needed to remove chest drains, length of hospital stay, and likelihood of surgery for occluded empyema or hemothorax.

	With suction(n)	Normal water seal(n)	p value
Recurrent Pneumothorax	3	3	<0.05
Duration of chest tube	8.2 days	12.6 days	<0.05
Length of hospital stays	7.2	12.4	<0.05
Clotted hemothorax/ Thoracotomy	3	8	>0.05

Table 2

Majumdar MNI et al (28) This randomized controlled clinical trial was conducted at Combined Military Hospital (CMH) Dhaka and National Institute of Diseases of the Chest and Hospital (NIDCH), Mohakali, Dhaka from April 2012 to March 2013. A total of 60 patients with blunt and penetrating chest trauma fulfilling the selection criteria enrolled in this study.

In group I, the average length of the chest tube was 7.13 days with a range of 5- 16 days, but in group II, the average length was 11.83 days with a range of 6 - 28 days. In group I, the average length of stay was 8.97 days with a range of 6 -18 days, compared to 13.47 days with a range of 8- 32 days in group II. In group I, 96.7% of patients experienced complete lung re-expansion, whereas 3.3% of patients required a thoracotomy and clot extraction due to a clotted hemothorax. 76.7% of patients in group II who were receiving simple chest tube drainage were able to fully expand their lungs, while 23.3% of patients needed a thoracotomy due to a clotted hemothorax. A helpful device in the treatment of traumatic haemothorax and/or haemopneumothorax is continuous low pressure suction. It lowers thoracic surgery morbidity, hospital stay, and expense.

Tim Michael Feenstra et al(29)- This was systematic review and meta-analysis of tube thoracostomy following traumatic chest injury; suction versus water seal. Three RCTs (randomised controlled trials) were included in this review and meta-analysis after evaluation of 120 identified studies. Suction was observed to have a positive

impact on the length of the chest tube procedure (MD (mean difference) 3.38 days, P=0.005, hospital stay (MD 3.90 days, P = 0.0003), and the occurrence of persistent air leak (OR (odds ratio) 0.27, P=0.001). The incidence of clotted hemothorax and (re-)interventions showed no significant difference.

With the exception of a chronic air leak, the GRADE assessment of the evidence's quality was low (moderate). Conclusion shows that suction appears to have a beneficial impact on the length of chest tube therapy, hospital stay, and chronic air leakage in chest trauma. The quality of the evidence, however, was (very) low to moderate according to GRADE, and there were few data points available.

	Suction		Water seal		
Study	Mean	Total(n)	Mean	Total (n)	Mean difference
Majumdar	7.13	30	5.26	30	-4.70
Morales	4.52	56	5.8	54	-1.28
Muslim	8.2	50	12.6	50	-4.40
Total		136		134	-3.38

Table 3

Duration of chest tube

	Suction		Water seal		
Study	Mean	Total(n)	Mean	Total (n)	Mean difference
Majumdar	8.97	30	13.47	30	-4.50
Morales	5.29	56	7.23	54	-1.94
Muslim	7.2	50	12.4	50	-5.20
Total		136		134	-3.90

Table 4

Length of hospital stay

Mohammad Ali Hessami et al (30)- This was randomized control trail conducted from Dec 2007 to April 2008 in all relevant teaching hospitals in Kermanshah, the provincial capital of Kermanshah in western Iran (Imam Reza and Talegani Hospital). This study shows that The 138 eligible patients who required chest tube replacement

due to trauma or cancer were randomly assigned to one of two groups: control (chest tube removal when drainage reached 150 ml/day), or trial (chest tube removal at 200 ml/day). All patients got normal care while they were admitted to the hospital and a follow-up visit 7 days following their release. Then, t-test and chi-squared were used to compare patients' key clinical outcomes. Out of a total of 138 patients, 70 and 68 patients, respectively, were randomly assigned to the control (G150) and trial (G200) groups. The two groups' initial features were comparable. Although the trial group's length of hospital stay (LOS) was shorter on average (4.1 vs. 4.8, p=0.04), the trial group's changes in drainage time were not statistically significant (p=0.1). One week after being released from the hospital, an analysis of the data revealed no statistically significant changes in the rates of radiological re-accumulation, thoracentesis, or decrease in pulmonary sounds (auscultatory). This study showed that when there is 200 ml/day of drainage as opposed to 150 ml/day, it is safe to remove the chest tube and even leads to a shorter hospital stay. This ultimately results in a lower cost.

Characteristics	Control	Trial	P value
Length of stay	4.8	4.1	0.04
Drainage time	3.8	3.4	0.1
Re accumulation	7.1	8.8	0.62
Thoracocentesis	4.3	4.3	0.97

Table 5

AIM & OBJECTIVES

AIM: Efficacy of slow negative pleural suction in thoracic trauma patients undergoing tube thoracostomy – A- Randomised control trial

OBJECTIVES:

PRIMARY OBJECTIVES:-

1. To compare the duration of tube thoracostomy in both groups.

SECONDRY OBJECTIVES:-

2. To compare the duration of hospital stay.
3. To compare the incidence of re-interventions.
4. To compare the incidence of clotted hemothorax.
5. To calculate injury severity score.
6. To compare the incidence of persistent air leak.

MATERIAL & METHODS

I. **Study setting**: This study was conducted in all thoracic trauma patients (undergoing tube thoracostomy) with pneumothorax/ hemothorax / hemopneumothorax admitted to Department of General Surgery, All India Institute of Medical Sciences, Jodhpur.

II. **Study design**: Randomized control trial.

III. Study participants:

A. Inclusion criteria:

All thoracic trauma patients with hemothorax /pneumothorax/ hemopneumothorax.

B. Exclusion criteria:

1. Patients not willing to participate in study
2. Patient undergone thoracotomy/ VATS
3. Patient on mechanical ventilation.

Methodology: This randomized controlled trial was conducted in Department of General Surgery AIIMS, Jodhpur after obtaining the approval of institutional research committee & institutional ethics committee. Patients were kept in 2 different groups by randomization. Randomization was done by computer generated random number table. Then patients were divided into two groups.

Group A: The patients in this group having chest tube underwent slow negative pleural suction.

Group B. The patients in this group were having chest tube with normal water seal drainage.

Group A

In this group patient with pneumothorax/ hemothorax/ hemopneumothorax with chest tube undergoing slow negative pleural suction (-20 cm of H2O = 19.6 hPa) was there as shown in fig 9 and 10.

Chest tube was removed on basis of the following criteria

- Expanded lung on chest X ray
- Drain <200 ml per day
- No air
- Patient clinically stable

If patient satisfied above criteria we removed the chest tube and chest x ray was done after 6 hours of removal. Hence we measured the duration of chest tube placement, duration of hospital stay, treatment success and post procedural complication like residual pneumothorax, empyema, fibrothorax. Patients were followed up to 10 days after discharge.

Fig 7

Fig 8

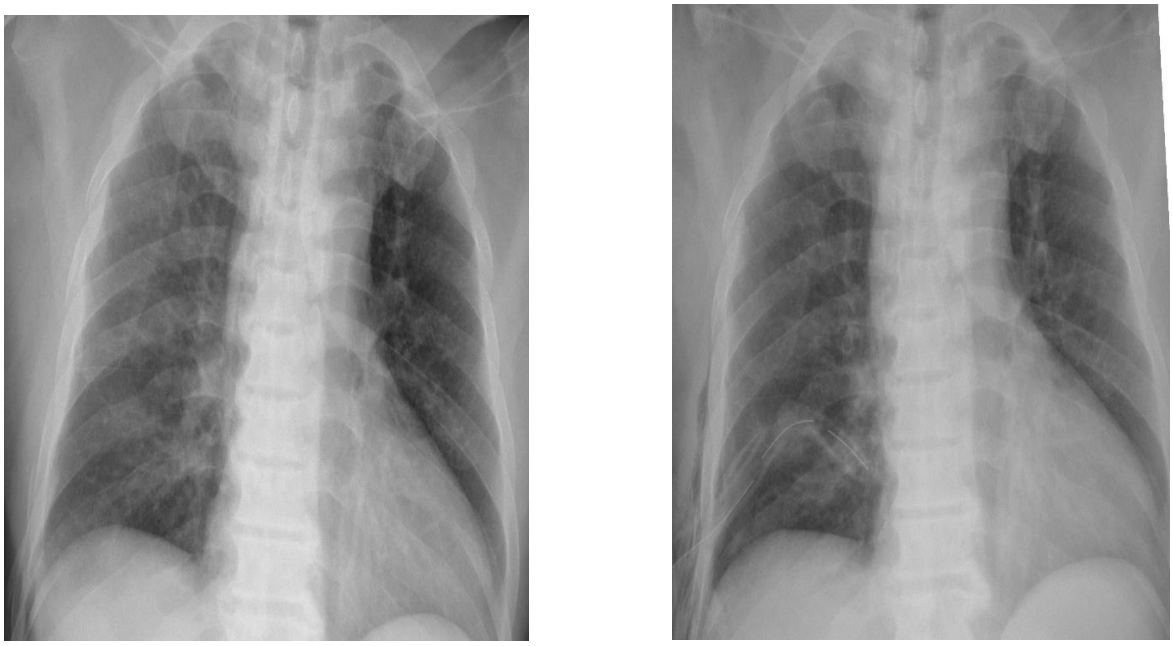


Fig 9

Before ICD insertion **After ICD Insertion**

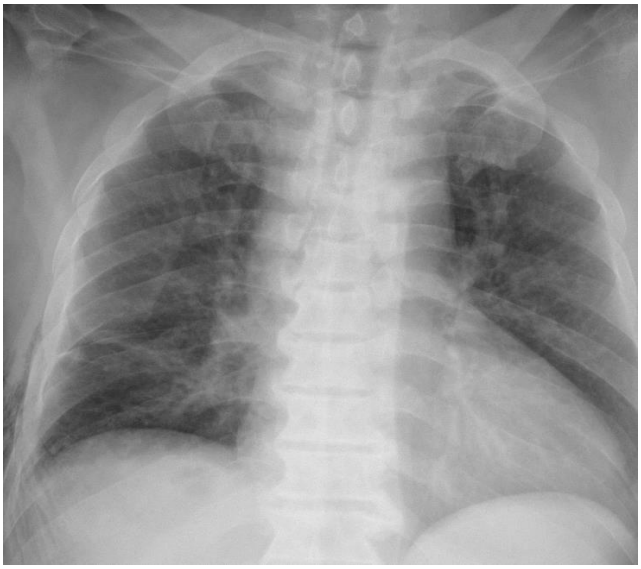


Fig 10

After ICD Removal

Group B

In this group patient with patient with pneumothorax/ hemothorax / hemopneumothorax with chest tube with normal water seal were there as shown in Fig 12

Fig 11

Chest tube was removed on basis of the following criteria.

- Expanded lung on chest x ray
- Drain <200 ml per day
- No air leak
- Patient clinically stable

  If patient satisfied above criteria we removed the chest tube and chest X ray was done after 6 hours of removal(31). Hence we measured the duration of chest tube placement, duration of hospital stay, treatment success and post procedural complication like residual pneumothorax, empyema, fibrothorax. Patients were followed up-to 10 days after discharge.

Re-intervention: Requirement of reinsertion of tube thoracostomy due to residual pneumothorax/hemothorax, requirement VATS/ open thoracotomy.

V. Study duration: 18 months

VI. Sample Size: 60

The sample was calculated based on the pooled results of 3 previously conducted studies on the subjects. (Majumdar-2014, Morales-2014 and Muslim-2008)

We kept the alpha error at 0.05, a power of 90%, and a two sided allocation ratio of 1:1. The mean difference was 3.38 with pooled standard deviation of 2.65(suction) and 4.24 (water seal) and sample size calculated was 52 with attrition of 10%.

Final Sample size=52 rounded up and fixed on 60.

Formula used for calculating sample size by using **Open epi software**

VII. Data collection: Data related to the aim and objective of the study was recorded. Randomisation was done by computer generated random number table. All trauma patient presented to emergency underwent primary survey. All patient of chest trauma with pneumothorax, hemothorax and hemopneumothorax were included in this study. Patient were randomized according to table and negative suction was applied in ward

in group A. Patient were excluded according to exclusion criteria. ICD were removed according to mentioned criteria.

Statistical analysis: Data was analyzed using SPSS version 25 (SPSS, Chicago, IL, USA). Age, Sex, ICD duration, hospital stay, ISS and complication were calculated as median (as data was no normally distributed)

VIII. ETHICAL CONSIDERATION:

Ethical clearance was obtained from the Institutional Ethics Committee (IEC).

This was a randomised control trial. Patients were enrolled after taking informed written consent. No compromise in patient care was made. No pressure or coercion was exerted on subjects for participation in study.

Confidentiality and privacy was maintained in all stages. Enrolment in the study did not pose any additional risk to the patient and did not increase the cost of the treatment.

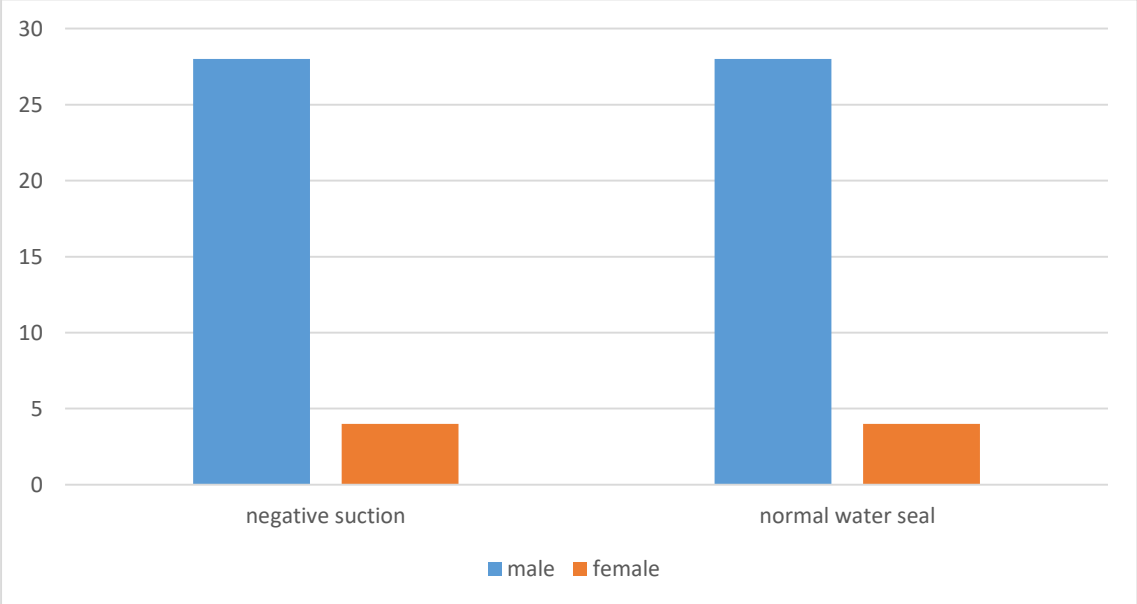
RESULTS

Total 64 patients included 32 patients included in both groups in this Randomized control study. All patients in this study with hemothorax, pneumothorax and hemopneumothorax underwent tube thoracostomy.

	Group A(n=32)	Group B
Male	28 (87.5)	28 (87.5)
Female	4 (12.5)	4 (12.5)

Table 6

The sex distribution was comparable in both the groups. In Negative suction group (group A), it was 28 male and 4 female while in normal water seal group (group B) there were also 28 male and 4 female. There is male preponderance of the chest trauma with 87.5 % as compared with previous studies (88.22 % male)(32).

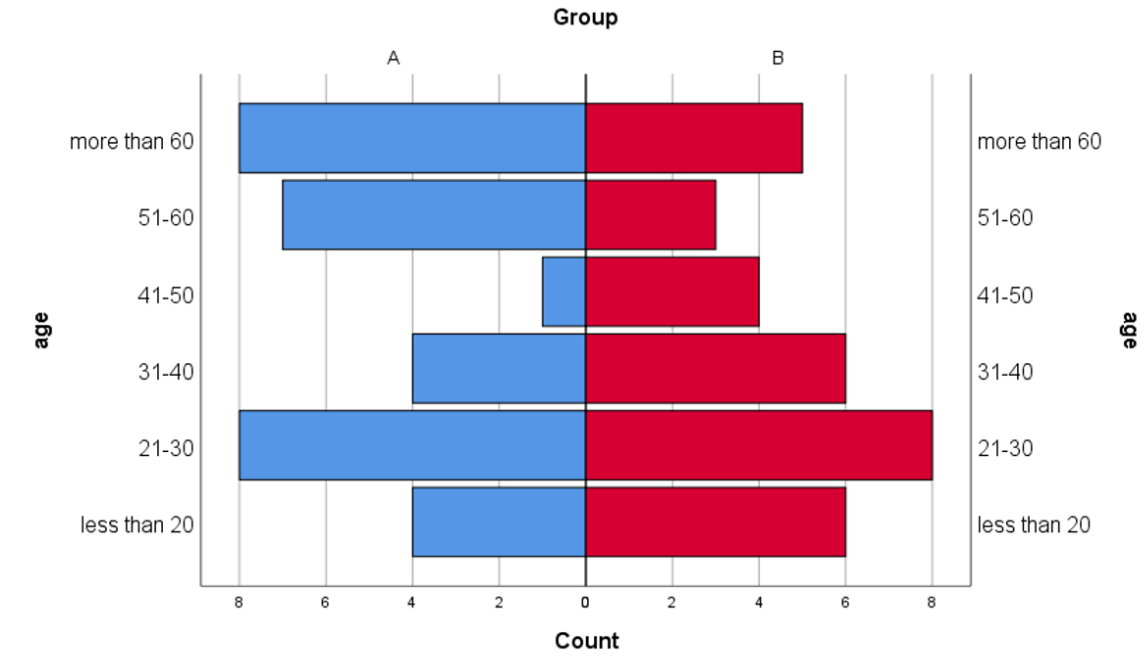


Graph 1: Bar Chart showing distribution of Sex

Objectives	Group A (Negative Suction) n=32 Median (IQR)	Group B (Normal water seal) Median (IQR)	P value*
Age (yrs)	42.5 (23.5-61.5)	35 (22.75-52.25)	0.211

p value calculated by using Mann Whitney U test

Table 7



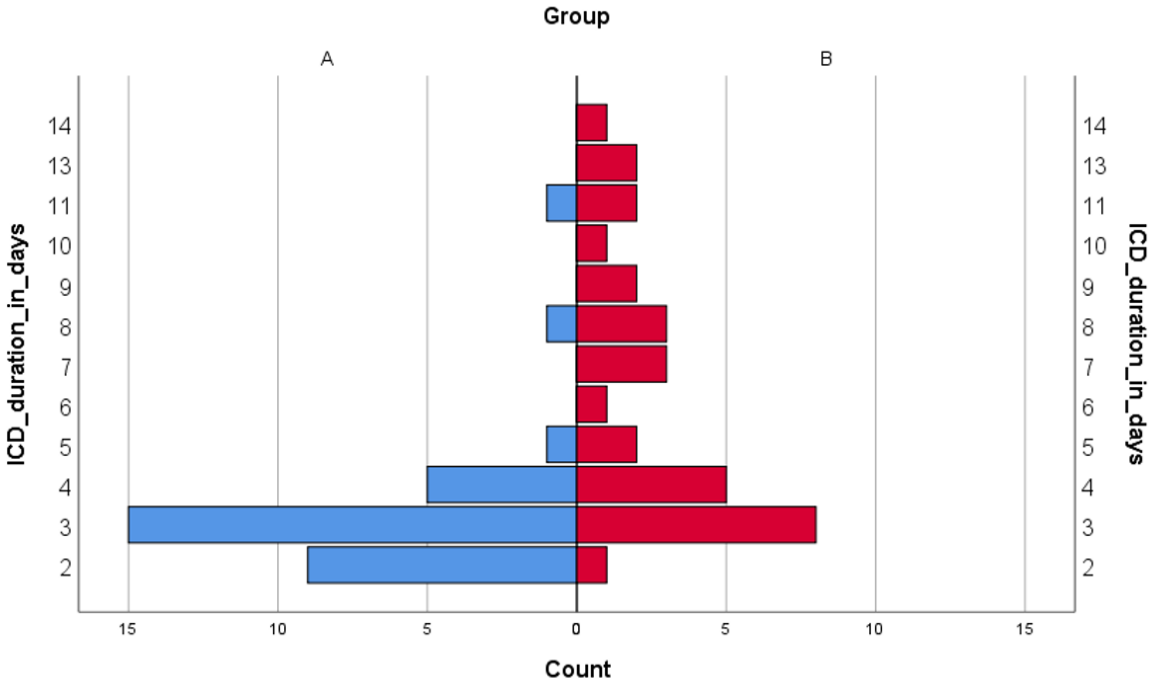
Graph 2: Funnel Chart Showing distribution of Age

Age was comparable in both groups. Median age in negative suction group (Group A) was 42.5 yrs. and in normal water seal group was 35 years

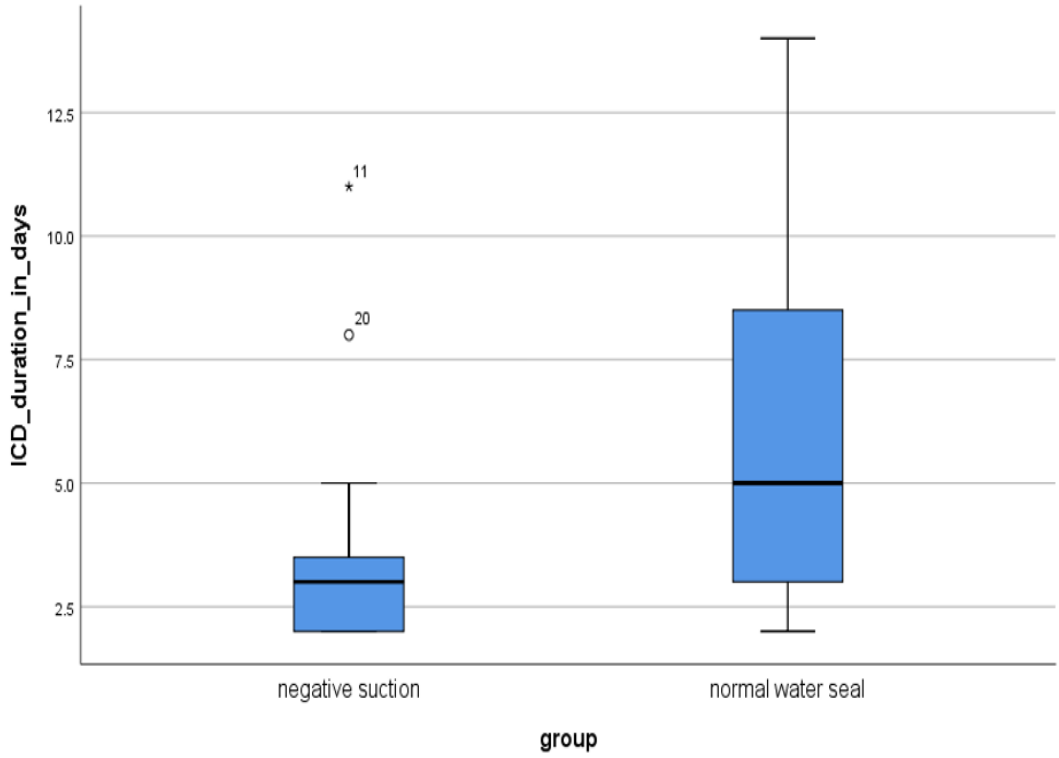
Objectives	Group A (Negative Suction) n=32 Median (IQR)	Group B (Normal water seal) Median (IQR)	P value*
Duration of ICD (Days)	3 (2-3.75)	5 (3-8.75)	<0.001
Hospital Stay	5 (4-8.75)	10 (6-16.75)	0.004
ISS	17 (12.5-22)	17 (12-21.25)	0.609*
* By Mann- Whitney U test			

Table 8

Primary objective duration of ICD was significantly lower in group A (3days) as compared to group B (5 days), p is <0.001

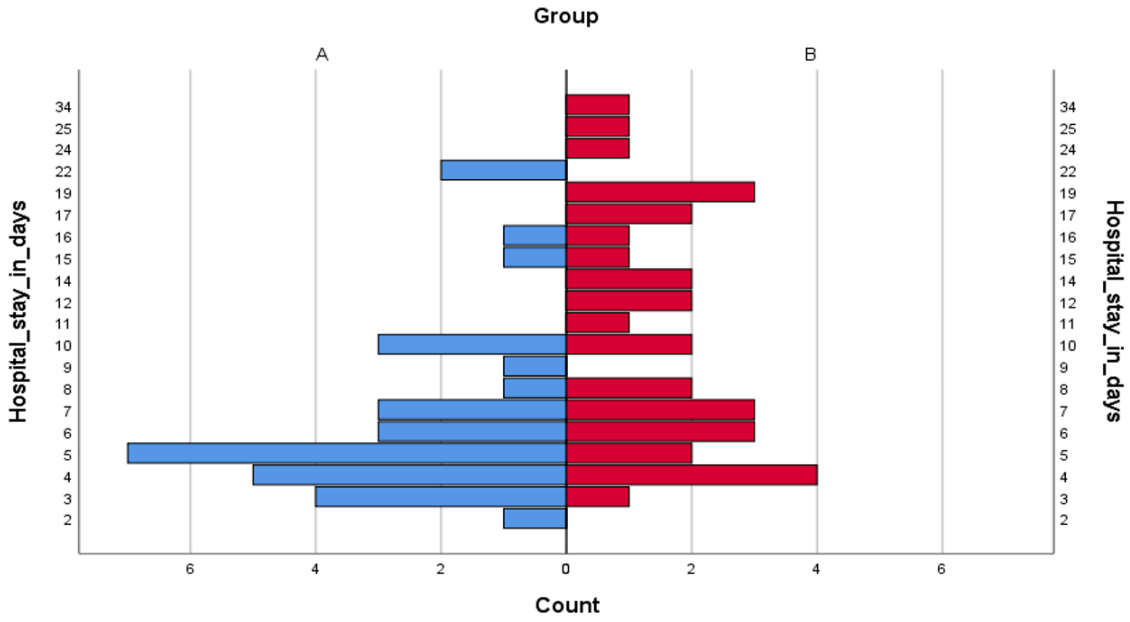


Graph 3: Funnel Chart Showing ICD duration

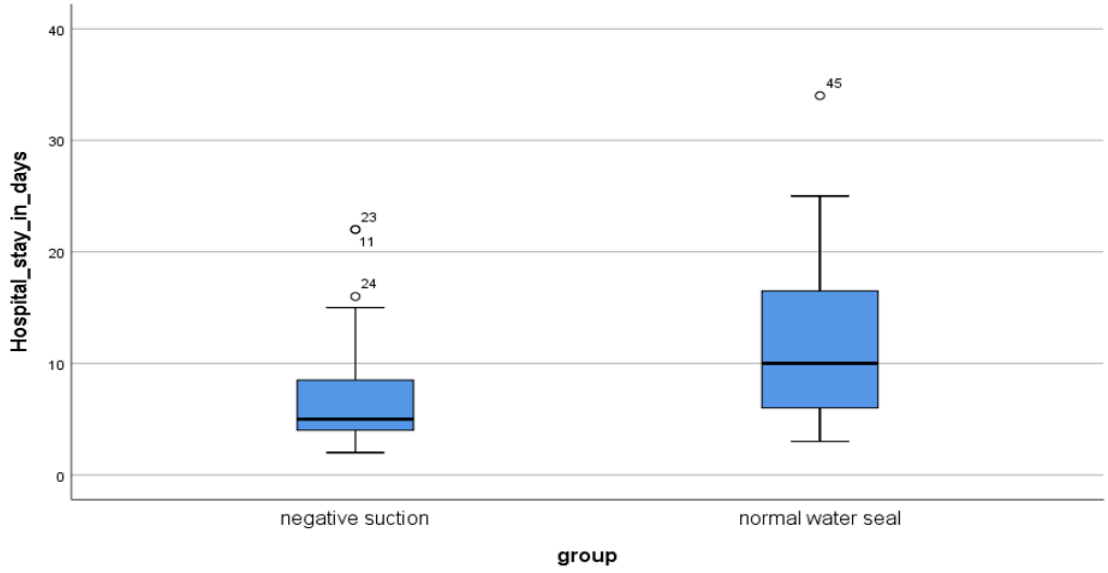


Graph 4: Simple Boxplot Showing ICD duration

Primary objective duration of ICD was significantly lower in group A (3days) as compared to group B (5 days), p is <0.001.

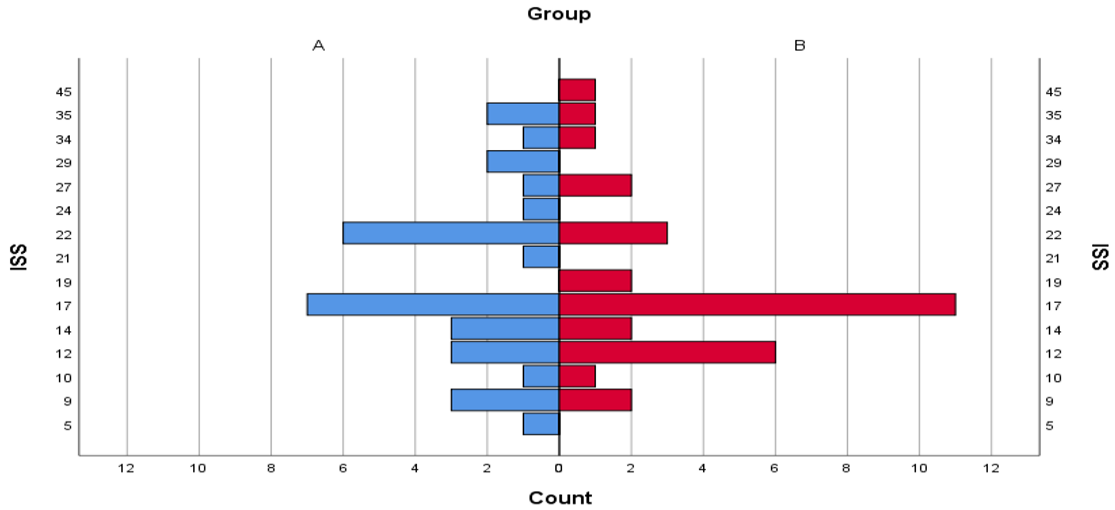


Graph 5: Funnel Chart Showing Hospital Stay

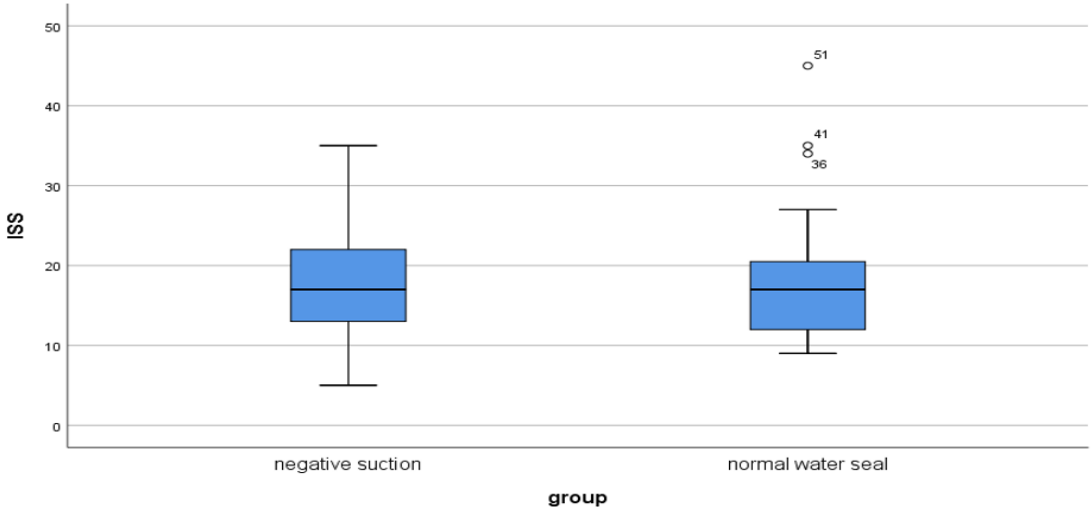


Graph 6: Simple Boxplot Showing Hospital Stay

Hospital stay reduced in negative suction group as compared to normal water seal group which was 5 days in group A vs 10 days in group B (P-0.004).

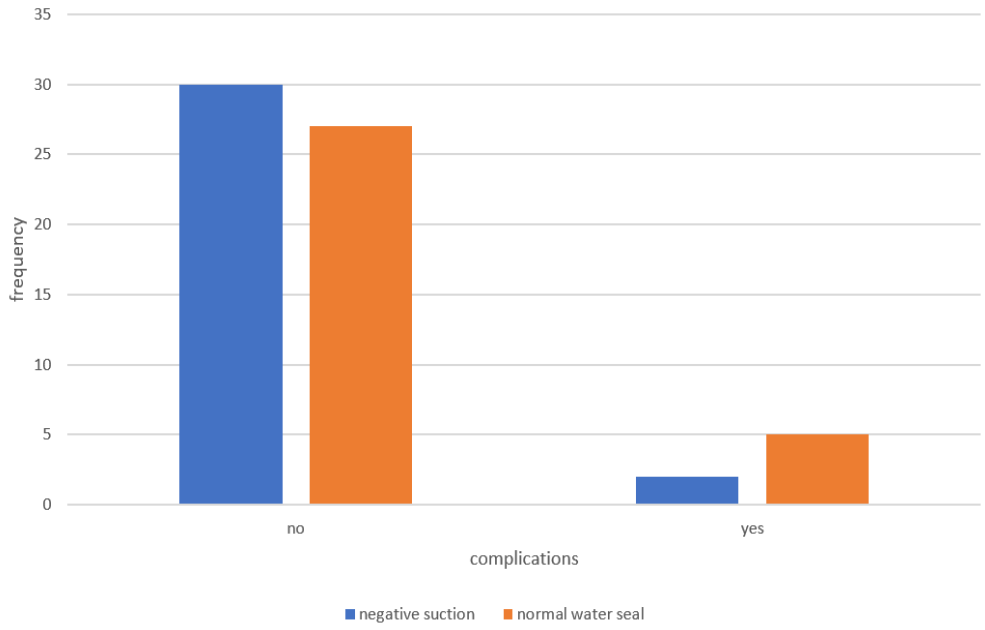


Graph 7: Funnel Chart Showing ISS



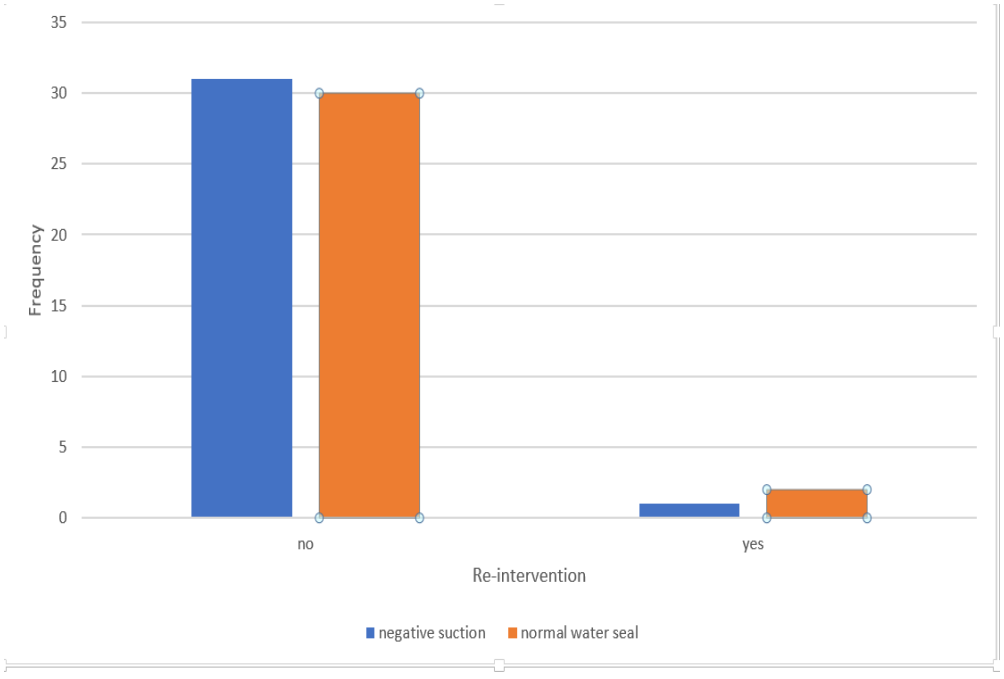
Graph 8: Simple Boxplot Showing ISS

ISS in both groups were 17, group A (IQR- 12.5-22), group B (IQR-12-21.5) which was statistically not significant (p=0.609)



Graph 9: Bar chart showing complications in both groups

Complications were more in group B (in 5 patients) as compared to group A (in 2 patients)



Graph 10: **Bar chart Showing Reintervention in both groups**

Reintervention required in 2 patients in group B as compared to 1 in group B

CONSORT DIAGRAM

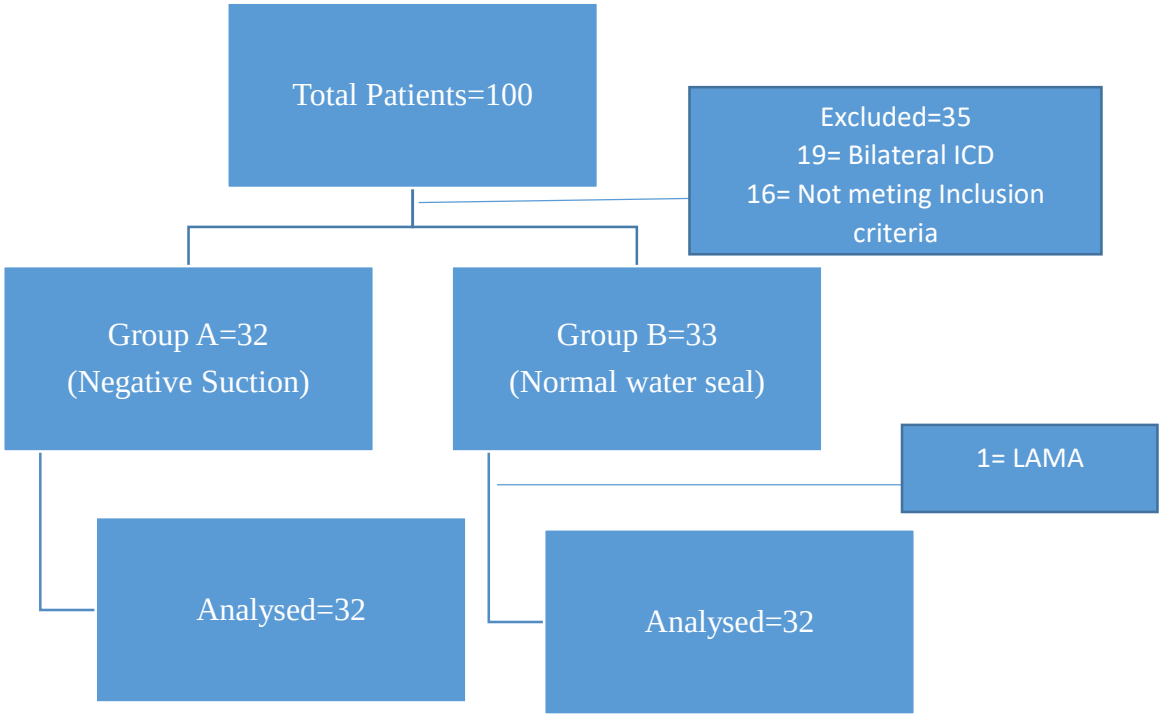


Fig 12

DISCUSSION

In this study, we assessed the outcomes of thoracic trauma patients who underwent tube thoracostomy. In our study, we found a strong association between length of ICD duration and hospital stay with slow negative pleural suction in trauma patients. Thus proposing it as a tool to assess outcomes in thoracic trauma patients.

Patient characteristics:

The majority of patients included in this study were males (87.5 %) between the age group of 42 years (IQR-23 to 61) in negative suction group as compared to 35 years (IQR- 22 to 52 years) in normal water seal group(32). Patients with chest injuries had ICDs implanted on the basis of chest X-ray, CT scan, or other clinically significant findings. Size of the chest tube was between 28 and 32 Fr, which had no impact on complications or postoperative discomfort(33). Patient was transferred to a ward following ICD insertion, where randomization-based negative suction was applied. They were encouraged to undergo Incentive spirometry and chest physiotherapy on regular basis. Analgesics were provided to all based on WHO pain management protocol and were monitored daily for ICD output.

ICD removal criteria:

- When daily ICD output < 200 ml per day.
- Lungs fully expanded on chest x ray.
- Patient saturation normal and clinically stable.
- No air leak on ICD.

Chest X ray was done after 6 hours of ICD removal(35). Patient were discharged if post ICD removal chest X-ray showed fully expanded lung with no complication. In our study, the ICD duration in the group A was 3 days (IQR- 2- 3.75); this difference was significant (p 0.001) when compared to group B it was 5 days (3-8.5 days), which was consistent with other studies.

In the group A , the duration of ICD was 2 days minimum and 11 days maximum, compared to 2 days minimum (also equivalent to the group A) and 14 days maximum

in the group B. The negative suction group experienced a considerably shorter hospital stay.

Hospital stay reduced in group A as compared to group B which was 5 days in group A vs 10 days in group B (P-0.004).

Minimum length of hospital stay in group B was 3 whereas it was 2 in group A. Maximum length of hospital stay was 22 in group A whereas it was 34 in group B.

Patients with grade 1 & 2 (Cerfolio grading) air leak were managed conservatively.

In our study total 7 patients developed complications. Out of which, 3 mortalities were recorded, 2 in normal water seal group and 1 in negative suction group.Total 3 patients were admitted in AICU among these two were from group B and one from group A. In group B, pneumonia and diffuse SDH with lung contusion were the main causes of mortality, whereas in group A, diffuse axonal damage was the cause of death.

Among 4 morbidity in our study, three patients had retained pneumothorax in group B of them two patients underwent VATS decortication for retained hemothorax. One patient had reinsertion of ICD in same sitting of hospital stay. This shows VATS decortication in same sitting lead to decreased morbidity, less duration of surgery, better and complete drainage of retained hemothorax(36).Incidence of clotted hemothorax was more in group B the lead to VATS.

One patient in group A had recurrent hemothorax for which readmission & reinsertion of ICD was done which was removed on day 3.

In our study the ISS of both groups was 17 (P-0.609) with IQR 12.5-22 in group A and IQR 12-21.5 in group B.

When we compared with studies **like Carlos H. Morales et al**(26) which showed that negative suction was not effective when compared with normal water seal group in term of ICD duration (p=0.35) and hospital stay (p=0.22).

Muhammad Muslim et al(27) showed that negative suction was effective in terms of hospital stay and ICD duration. Mean duration of chest drain removal was 8.2 +/- 3.14 days and 12.6 +/- 4.20 days, respectively ($p<0.05$) In groups I (negative suction group) and II(Normal water seal group), the hospital stays lasted 7.2 +/- 2.07 days and 12.4 +/- 3.63 days, respectively ($p<0.05$). However, this study only included patients with

penetrating chest injuries; patients with blunt trauma were not included in this review.

Majumdar MNI et al (28) showed that negative suction was effective in terms of ICD duration and hospital stay similar to our study, the average length of the chest tube was 7.13 (5- 16 days) in group I (negative suction group) as compared to 11.83 (6 - 28 days) in group II (Normal water seal group) . In group I, the average length of stay was 8.97 days (6 -18 days), compared to 13.47 days (8- 32 days) in group II. This study did not provide a definite criteria for chest tube removal and used a wide range of negative pressure (- 5 mm Hg to -20 mm Hg).

Tim Michael Feenstra et al conducted systematic review and meta-analysis of tube thoracostomy following traumatic chest injury; suction versus water seal. This study also showed same result as our study that application of negative suction decreased ICD duration (MD-3.38 days, $p<0.005$), hospital stay (MD-3.9 days, $p<0.0003$) but incidence of clotted pneumothorax and re-interventions showed no significant difference and the quality of evidence, was (very) low to moderate according to GRADE.

Mohammad Ali Hessami et al conducted RCT which showed 200 ml/day of drainage was safe to remove the chest tube and even leads to a shorter hospital stay, as opposed to 150ml/day. Length of hospital stay (LOS) was shorter on average (4.1 vs. 4.8, $p=0.04$) in 200 ml group.

In our study all thoracic trauma patients were included (blunt trauma, penetrating trauma), Continuous negative suction was defined (-20 cm of H2O) and criteria for removal was clearly defined (Output <200 ml/day, Spo2 Normal, no air leak, clinically there should be no dyspnea). Our study's strength is that our study had removal criteria, defined values for blunt and penetrating injuries, or defined values for negative suction.

Increase in length of hospital stay can be explained on basis of high ISS, other injuries like neurological, abdominal and infectious complication like pneumonia.(37)

LIMITATIONS OF OUR STUDY

- Patients with bilateral ICDs were removed from both groups (not mentioned about bilateral ICDs in study).
- Comorbidities can affect the duration of ICD and hospital stay which was not included in our study.
- Pain management was not stratified.

.

CONCLUSION

At the beginning of study, we had initially set out to study whether application of continuous slow negative suction can affect ICD duration, hospital stay, complication and re-interventions. So from our study we concluded that application of negative suction can decrease the ICD duration, hospital stay, complication and reinterventions like VATS. So we can apply the slow negative suction on all trauma patient undergoing tube thoracostomy can lead to decrease morbidity, decrease chest pain due to ICD placement, less hospital stay, and early return to work.

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Annexure I

Institutional ethics Clearance Certificate

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2021/ 3518 Date: 12/03/2021

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3353**

Project title: **"Efficacy of slow negative pleural suction in thoracic trauma patients undergoing tube thoracostomy- A randomised control trial"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**M.S. Dissertation**
Student Name:	**Dr. Deepak**
Guide:	**Dr. Ramkaran Chaudhary**
Co-Guide:	**Dr. Ashok Puranik, Dr. Naveen Sharma, Dr. Mahaveer Singh Rodha, Dr. Nishant Kumar Chauhan & Dr. Manoj Kumar Gupta**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation. If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary

Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Annexure II

Patient Performa

Efficacy of slow negative pleural suction in thoracic trauma patients undergoing tube thoracostomy – A Randomised control trial

GENERAL INFORMATION:

1. Group:

A	B

2. Signed Consent Form Yes No

3. Completed Form Yes No

PATIENT DETAILS:

Name: UHID No.

Age / Sex:

Date of Trauma: Date of tube thoracostomy insertion:

Date of tube thoracostomy removal: Date of discharge:

Total hospital stay after Surgery

GROUP A (SUCTION) GROUP B (WATER SEAL)

DURATION OF CHEST TUBE:

Date of removal- Date of insertion

COMPLICATIONS

- PNEUMONIA
- MEDIASTINITIS
- EMPYEMA

- SSI
- RESIDUAL PNEUMOTHORAX
- RESIDUAL HEMOTHORAX
- POST REMOVAL EMPYEMA
- POST REMOVAL FIBROTHORAX

POST TUBE THORACOSTOMY DETAILS:

DAY	1	2	3	4	5	6	7	8	9	10
AIR LEAK										
DRAIN										
CHEST XRAY										

Table 9

	Abbreviated injury scale
Head & neck	
Face	
Chest	
Abdomen	
Extremity	
External	
Iinjury severity score	

Annexure III

ALL INDIA INSTITUTE OF MEDICALSCIENCES,JODHPUR

DEPARTMENT OF GENERAL SURGERY

PATIENT INFORMATION SHEET

Name: Age/Gender:

Phone No: Address

I have been asked to volunteer for a study which is 'Efficacy of slow negative pleural suction in thoracic trauma patients undergoing tube thoracostomy – A Randomised control trial

For chest tube insertion in trauma patient there are two technique 1. With slow negative pleural suction, 2. With normal water seal. I will undergo either one of the technique. The consequences of both the technique have been explained to me. Because of these techniques there is no life threat to patient either intra procedure and post procedure. Data collected from patient does not share with anyone except thesis team & we do coding of patient .Data collected from patient can be share with patient.

In any case of queries you may contact:

Dr Deepak
PG General Surgery
All India Institute of Medical Sciences, Jodhpur
Mob no: 9671822408

Annexure IV

जनरल सर्जरी विभाग

मुझे मेरी स्वेच्छा से एक अध्ययन में हिस्सा लेने के लिए पूछा गया है जो कि ट्रामा मरीज चेस्ट ट्यूब डालकर नेगेटिव स्कशन कि प्रभावकारिता का मूल्यांकन करने के लिए एक कर्मरहित नियंत्रण प्रशिक्षण। चेस्ट ट्यूब डालने के दो तरीके हैं -:
वाटर सील बनाम नेगेटिव स्कशन

मुझे एक तरीके से चेस्ट ट्यूब डलवानी होगी। दोनों तरीकों के परिणाम मुझे अच्छी तरह से बता दिए गए हैं। इस तकनीकी ऑपरेशन के दौरान या बाद में मरीज की जान को कोई खतरा नहीं रहता है। मरीज से एकत्रित डाटा जांच टीम के अलावा किसी से साझा नहीं किया जाएगा और मरीज की कोडिंग की जाएगी। मरीज को एकत्रित डाटा के बारे में मरीज को जानकारी साझा करने का अधिकार होगा।

और जानकारी के लिए संपर्क करें।

डॉक्टर दीपक

जनरल सर्जरी विभाग

अखिल भारतीय आयुर्विज्ञान संस्थान,

मोबाइल नं -: 9671822408

Annexure V

All India Institute of Medical Sciences Jodhpur, Rajasthan
Informed Consent Form

Title of Thesis: Efficacy of slow negative pleural suction in thoracic trauma patients undergoing tube thoracostomy- A Randomised control trial.

Name of PG Student: Dr DEEPAK Tel. No. 9671822408

Patient/Volunteer Identification No.: _____

I_____ S/o or D/o _____
R/o _____
Give my full, free, voluntary consent to be a part of the study "_____", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from _____(Company Name) or from regulatory authorities. I give permission for these individuals to have access to my records.

Date:_____ _____

Place: _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____ _____

Place: _____ Signature of PG Student

1. Witness 1

_____

Signature

Name: _____

Address: _____

_____

2. Witness 2

_____

Signature:

Name: _____

Address: _____

_____

Annexure VI

अखिल भारतीय आयुर्विज्ञानसंस्थान, जोधपुर, राजस्थान

रोगी सूचित स्वीकृति पत्र

प्रोटोकॉल/अध्ययन नं: ट्रामा मरीज चेस्ट ट्यूब डालकर नेगेटिव स्कशन कि प्रभावकारिता का मूल्यांकन करने के लिए एक कर्मरहित नियंत्रण प्रशिक्षण।

मोबाइलनं. 9671822408

इस ट्रायल के लिए रोगी की आईडी...

इस सुचनापत्र की सामग्री दिनांक.....को प्रदान की गई थी, मैंने सावधानीपूर्वक पढ़ लिया है / मुझे मेरी भाषा में विस्तार से समझा दिया गया है जो मुझे समझ में आती है और मैंन पूरी सामग्री को अच्छी तरह समझ लिया है. मैं पुष्टि करता हु कि मुझे प्रशन पूछने का अवसर दिया गया हैं/अध्ययन का प्रकार और प्रयोजन तथा इसके संबंधित जोखिम / लाभ और अध्ययन पूरा होने की अनुमानित अवधि तथा अध्ययन के अन्य विवरण मुझे विस्तार से समझा दिये गये है. मुझे बताया गया है कि मेरी भागीदारी स्वेच्छानुसार है और में कोई कारण बताए बिना किसी भी समय अपनी सहमति वापस लेने के लिए स्वतंत्र हूं और इस पर मेरी चिकित्सा के कानूनी अधिकारों पर कोई प्रभाव नहीं पड़ेगा मुझे पता है कि इस अध्ययन मे मेरी बीमारी के बारे मे जमा की गई जानकारी और मेरे चिकित्सा नोट्स अखिल भारतीय आयुर्विज्ञानसंक्त्यान जोधपुर के जिम्मेदारव्यक्तियों द्वारा देखी जाएगी. में इन व्यक्तियों को अपने अधिलेख देखने की अनुमति देता हूँ मैं भी उपरोक्त अध्ययन में भाग लेने के लिए सहमत हु

दिनांक ..... हस्ताक्षर /अंगूठे का निशान

स्थान.....

मैं यह प्रमाणित करता हूँ कि उपरोक्त सहमति मेरी उपस्थिति में ली गई है।

दिनांक .....

स्थान.....

अनुसंधानकर्ता के हस्ताक्षर

1. गवाह
   हस्ताक्षर
   नाम:
   पता.....मोबाइलनं.....

2. गवाह
   हस्ताक्षर
   नाम:
   पता.....मोबाइलनं.....

KEY TO MASTER CHART

Gender	
M	1
F	2
Group	
A	1
B	2
Complications	
Pneumonia	1
Mediastintis	2
Empyema	3
SSI	4
Residual Pneumothorax	5
Residual hemothorax	6
Post removal empyema	7
Post removal fibrosis	8
No complication	0
Death	9

MASTER-CHART

	ID	AGE_SEX	Gender	GROUP	GROUP	DOT	DOI	DOR	ICD_Duration_in_days	Hospital_stay_in_days	ISS	COMPLICATIONS
1	2021/03/014730	36	1	A	1	24-3-2021	25-03-2021 (RT)	28-3-2021	3	6	17	0
2	2021/03/016449	55	2	B	2	29-3-2021	29-03-2021(LEFT)	2-4-2021	4	5	17	0
3	2021/04/002032	45	2	A	1	4-4-2021	04-04-2021 (RIGHT)	7-4-2021	3	4	12	0
4	2021/04/003691	62	1	B	2	6-4-2021	07-04-2021(LEFT)	10-4-2021	3	4	9	0
5	2021/04/006560	26	1	B	2	11-4-2021	11-04-2021(RT)	15-4-2021	4	16	12	9
6	2021/05/006130	25	1	B	2	16-05-2021	16-05-2021(LEFT)	24-05-2021	8	12	34	0
7	2021/05/007655	18	1	A	1	22-5-2021	23-05-2021(LT)	26-5-2021	3	5	22	0
8	2021/06/009348	21	1	A	1	21-6-2021	21-6-2021	25-06-2021(RT)	4	7	14	0
9	2021/09/016283	60	1	B	2	24-9-2021	26-09-2021 (LEFT)	3-10-2021	7	17	9	6
10	2021/09/017410	19	1	A	1	27-9-2021	28-09-2021(RIGHT SIDED)	1-10-2021	3	5	22	0
11	2021/09/018130	40	1	A	1	26-9-2021	28-09-2021 (RIGHT SIDE)	3-10-2021	5	10	17	0
12	2021/10/002566	22	1	B	2	2-10-2021	04-10-20219LEFT SIDED0	11-10-2021	7	8	17	0
13	2021/10/011926	52	1	A	1	17/10/2021 (rt)	19-10-2021	22-10-2021	3	9	9	0
14	2021/11/004233	57	1	A	1	09-11-2021	09/11/2021 (Lt)	12-11-2021	3	4	17	0
14	2021/10/015444	48	1	B	2	24/10/2021 (right)	24-10-2021	28-10-2021	4	6	12	0
16	2021/11/008350	53	1	B	2	14/11/2021- Lt	16-11-2021	30-11-2022	14	19	12	0
17	2021/11/010249	35	1	B	2	18/11/2021 (Lt)	19-11-2021	28-11-2021	9	24	35	0
18	2021/11/012557	22	1	A	1	23/11/2021 (Lt)	24-11-2021	28-11-2021	4	6	35	0
19	2021/11/013145	75	1	A	1	24/10/2021 (Lt)	24-11-2021	27-11-2021	3	5	12	0
20	2021/11/013860	30	1	A	1	23-11-2021	23/11/2021 presented to AIIMS 26/11/2021 with left ICD insitu	04-12-2021	11	22	29	0
21	2021/11/015461	30	2	A	1	29-11-2021	29/11/2021-right	02-12-2021	3	5	17	0
22	2021/12/000588	20	1	B	2	30-11-2021	30/11/2021-left outside	06/12/2021 admitted on 01/012/20521	7	7	14	0
23	2021/12/000801	40	1	A	1	01/12/2021- fall	02/12/2021- Left	4-12-2021	2	4	14	0
24	2021/12/012157	68	1	B	2	16-12-2021	21/12/2021-rt	24-12-2021	3	10	14	0
25	2021/12/012744	63	1	B	2	21-12-2021	21/12/2021-rt	24-12-2021	3	5	19	0
26	2021/12/015503	36	1	B	2	26-12-2021	27/12/2021- Right	07-01-2022	11	34	27	0
27	2021/12/015637	62	1	A	1	25-12-2021	27/12/2021-Right	30-12-2021	3	6	21	0
28	2021/12/016834	20	1	B	2	28-12-2021	28/12/2021-left side	31-12-2021	3	15	12	0
29	2021/12/017301	75	1	A	1	29/12/2021-	29/12/2021-Right	31-12-2021	2	7	22	9
30	2022/01/021919	82	1	A	1	03/01/2022- faLL from bed	05/01/2022- left	07/01/2022 and VAc on 08/01/2022	3	5	17	0
31	2022/01/022067	35	1	B	2	04-01-2022	04/01/2022- right outside	17-01-2022	13	14	17	0
32	2022/01/028067	38	2	B	2	15-01-2022	15/01/2022-Right	18-01-2022	3	4	17	0
33	2022/01/031019	25	1	A	1	20-01-2022	21/01/2022- left	23-01-2022	2	7	35	0
34	2022/01/033475	25	1	B	2	25-01-2022	29/01/2022-Left	02-02-2022	3	10	17	0
35	2022/01/034521	25	1	B	2	27-01-2022	27/01/2021- outside left	30-01-2022	3	6	17	0
36	2022/01/035426	70	2	A	1	28-01-2022	29/01/2022- right	31-01-2022	2	10	12	0
37	2022/02/006789	70	1	A	1	09/02/2022- fall from 8 feet	09/02/2022 right ICD outside, reinsert on 12/02/2022	16-02-2022	4	10	9	0
38	2022/02/010591	28	1	B	2	18-02-2022	18/02/2022-left side			4	45	9
39	2022/02/012179	75	2	A	1	21/02/2022-Lt	21-02-2022	01-03-2022	8	8	14	0
40	2022/02/015363	18	1	B	2	18-02-2022	24/02/2022-Right	05-03-2022	9	17	17	0
41	2022/02/016103	30	1	B	2	25/02/2022- fall from 100 ft height	25/02/2022-left	08-03-2022	11	12	17	0
42	2022/02/016867	48	1	B	2	26-02-2022	26/02/2022 (Right)	03/*03/2022	5	6	17	0
43	2022/03/002291	27	1	B	2	03/03/2022-Left	04-03-2022	12-03-2022	8	25	27	6
44	2022/03/010938	19	1	A	1	05-03-2022	15/03/2022-lt	16/03/2022 reinserted with negative removed on 18-03-2022	3	15	10	0
45	2022/03/014705	21	1	A	1	21-03-2022	22/03/2022-Rt	25-03-2022	3	4	29	0
46	2022/03/015963	34	1	B	2	23-03-2022	23/03/2022-right	31-03-2022	8	8	17	0
47	2022/03/016764	40	1	B	2	23-03-2022	24/03/2022-left	29-03-2022	5	7	19	0
48	2022/03/017458	50	1	B	2	22-03-2022	24/03/2022-rt	03-04-2022	10	11	10	0
49	2022/03/017912	54	1	A	1	25-03-2022	25-03-2022-right	29-03-2022	4	22	17	0
50	2022/03/019993	66	1	B	2	28-03-2022	29-03-2022-right	04-04-2022	6	7	17	0
51	2022/04/001460	60	1	A	1	03-04-2022	04/04/2022-lt	07-04-2022	3	16	24	0
52	2022/04/004404	50	2	B	2	07-04-2022	07/04/2022-lt	11-04-2022	4	19	22	0
53	2022/04/005003	54	1	A	1	08-04-2022	08/04/2022-right	10-04-2022	2	3	22	0
54	2022/04/005028	38	1	A	1	08-04-2022	08/04/2022-Lt	10-04-2022	2	3	5	0
55	2022/04/005442	18	2	B	2	09-04-2022	09/04/2022-rt	12-04-2022	3	19	22	0
56	2022/04/005896	26	1	B	2	10-04-2022	11/04/2022-right	24-04-2022	13	14	22	6
57	2022/04/006774	62	1	B	2	11-04-2022	12/04/2022-left	14-04-2022	2	3	12	0
58	2022/04/017394	59	1	A	1	26-04-2022	28/04/2022-rt	02-05-2022	4	5	22	0
59	2022/04/018231	55	1	A	1	26-04-2022	29-04-2022- RT	01-05-2022	2	4	27	0

60	2022/05/001934	62	1	A	1	04/052022	04/05/2022- right	07-05-2022	3	3	22	0
61	2022/05/003717	18	1	A	1	07-05-2022	07/05/2022-lt	10-05-2022	3	5	34	0
62	2022/05/005502	22	1	B	2	09-05-2022	10/05/2022-right	14-05-2022	4	4	12	0
63	2022/05/013052	23	1	A	1	20-05-2022	21/05/2022-left	23-05-2022	2	2	17	6
64	2022/06/004794	25	1	A	1	07-06-2022	07-06-2022-Lt	09-06-2022	2	3	9	0