Original Article

Use of Thopaz in Patients of Empyema Thoracis Undergoing Decortication

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ABSTRACT

Introduction: The management of empyema thoracis has evolved over the years. After all lung surgeries chest drain is required, however they suffer from inter observer variability and impair mobility of the patient. However, the newer digital thoracic drain system are portable and have alarms for various situations, furthermore they eliminate inter-observer variability. One such device is Thopaz™ (Medela inc, Switzerland). We wanted to compare efficacy of Thopaz™ with our conventional intercostal chest tube drain in patients undergoing decortications for empyema thoracis. **Materials and Methods:** One hundred patients were enrolled in study and were randomized into conventional and thopaz group with 50 patients in each group with help of opaque envelopes. **Results:** Both the groups were comparable in demographic parameters. Majority of the patients in our study were children and young adults. Majority of empyema thoracis involved right side with nontubercular empyema thoracis being the most common cause of decorticartion. Patients managed with Thopaz had a significantly shorter air leak duration, shorter duration of postdecortication chest tube placement and shorter postoperative hospital stay. All postoperative complications were less in Thopaz group. **Conclusions:** Patients with empyema thoracis undergoing open decortications when managed with digital chest drainage system (Thopaz) experienced faster reduction in air leak, a shorter duration of chest tube placement and in hospital stay. Thopaz usage is also associated with reduction in rate of postoperative complications. We recommend that this digital chest tube drainage system is a very useful tool in armamentarium of thoracic surgeon after lung surgeries.

KEY WORDS: Decortications, digital chest drainage system, empyema thoracis, intercostal chest tube drain, pulmonary function test, Thopaz, tubercular empyema

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INTRODUCTION

The treatment of empyema thoracis has evolved since its description by Hippocrates.[1,2] Empyema thoracis is a collection of pus in pleural space which may be free-flowing or loculated. An initial sterile exudation (simple parapneumonic effusion) in some cases may progress to complicated parapneumonic effusion and eventually empyema thoracis.[3] Several thoracic surgeons consider thoracotomy and decortication to be the best treatment for chronic empyema.[4-6]

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In 1965 Hughes advocated the use of closed tube thoracostomies with under water seal system for evaluation and treatment of haemothorax. The one-bottle system was introduced, where the bottle collected the fluid and at the same time sealed the air leaks. Gradually two-bottle and three bottle systems became available which offered advantage of draining large amounts of fluid and application of negative pressure where necessary.[7]

Historically chest tubes have been used to evacuate air and fluids following lung resections.[8] However, the timing of chest tube removal poses a difficult question as there is lot of inter user variability which at times can adversely affect the outcomes.[9] Chest tube clogging in the setting of an empyema can lead to re-accumulation of pus and infected material, a worsening clinical picture, organ failure and even death.[10] In addition, the tradional chest drainage systems do not offer accurate data regarding tube output and air leaks and they are often inconvenient to both patients and hospital staff. Another major disadvantage of the traditional systems is impaired patient mobility and comfort and the potential risk of infection when disconnecting the device to mobilize.

Furthermore, the wall suction is variable and extremely unreliable and none of these systems had the means to objectively and accurately record the amount of air leak. Traditionally, air leaks are monitored using water-based systems that allow for the subjective detection and assessment of bubbles in a water chamber. This method is prone to inter-observer variability[11] and can result in the detection of false air leaks.[12,13]

It is estimated that between 30% and 50% of thoracic surgery patients will experience an air leak either immediately or within the first postoperative day.[14] Prolonged air leaks are typically defined as an air leak lasting longer than 5 days and can increase the potential for infections; might require re-operation and can lead to prolonged hospital stays and also increase the cost of treatment.[14,15]

With advancement in technology new electronic chest drainage systems have been invented which addressed the inefficiencies and standardized the postoperative management of chest tubes and clinical decision making regarding chest tube removal.[9] All digital thoracic drain system (DTDS) are portable and powered by a rechargeable battery with a sufficiently long run time. They have alarms for various situations including tube occlusion, disconnection and suction failure. Being a completely closed system, the fluid has no contact with the outside environment and provides improved bio-safety for the health care team and patients themselves. Furthermore, these devices eliminate inter-observer variability with objective measurement of air leaks recorded in the system (mL/min) and displayed on a screen.

The Robert David Cerfolio system-1, currently relies on a static analogue measurement of "bubbles in a chamber" and still has observer variability and subjectivity.[16] There are various devices which are connected to the chest drains with some of the recent ones having digital flow meters incorporated in them.[16] In some circumstances these drains are placed on negative pressure suction to evacuate the contents of the pleural cavity as well as to help re-expand the lungs.[17]

Thopaz™ (Medela inc, Switzerland) DTDS is an example of those devices. It is a portable suction unit with a drainage canister which comes with a mains charger and can be allowed to mobilize with the patient [Figure 1]. It constantly maintains a regulated suction pressure preset by the user. In case of an air leak the device remains active and produces additional suction effect to maintain the desired negative intrapleural pressure initially preset by the user as wide variations in intraplueral pressure leads to prolonged air leaks.[18] The amount of liquid is measured directly into a graded container. Both these features allow medical personnel to take safe and confident decisions based on data and not on snapshot observations only as with the traditional systems.[9,19]

At our institution, we routinely use traditional water seal chest drainage system without external suction to facilitate lung expansion after decortications [Figure 2].

With the advent of the electronic drainage system (Thopaz), we wanted to evaluate the efficacy of this system versus our routine drainage system in patients of empyema thoracis undergoing decortication where both study groups had equal opportunity to mobilize early postoperatively. Also we wanted to study the safety and efficacy of Thopaz in Indian heath care setting. Most of the studies that have been done, have focused on use of Thopaz after lung resections with little data on its use after decortications. So it would be one of few studies done in India on use of Thopaz in decortications.

MATERIALS AND METHODS

This study included patients of empyema thoracis who underwent decortications in Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, U. P (India)

Figure 1: Thopaz with its display

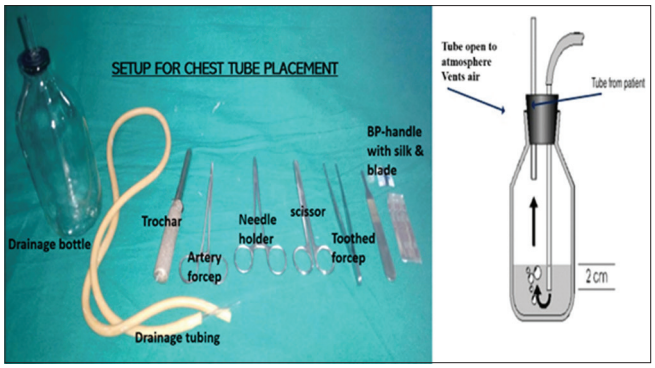


Figure 2: Conventional single-bottle system being used in our hospital

during a period of about 2 years with effect from December, 2016 to December, 2018. It was a prospective randomized single blind Study conducted at Department of Cardiothoracic Surgery. A total of 100 patients were included in our study, 50 each in conventional intercostal chest tube drain (ICTD) and Thopaz group.

Institutional ethics and advisory committee clearance

This study was approved on July 17, 2017 by the Institutional Ethics Committee of Faculty of Medicine, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, Uttar Pradesh (India).

Diagnosis of empyema was confirmed by one of the following criteria

The diagnosis of empyema thoracis requires either positive pleural fluid biochemistry (pH < 7.2, glucose <2.2 mmol/L, LDH >1000 IU/L), confirmation of loculation on imaging examination or positive culture or Gram's stain from pleural aspirate or pus aspirated from the pleural space

Computed tomography (CT) chest was done to know the loculi and anatomy of pleural space with a 16-slice Siemens® Somatom emotion® machine (if needed).

Inclusion criteria

Patients of empyema thoracis of all age groups undergoing decortication

Exclusion criteria

Patients not giving their consent, or who had previous cardiac/thoracic surgery.

Methodology

All the patients were evaluated with clinical examination, chest X-ray, routine investigations (complete blood counts, renal function test, liver function test), pulmonary function test (PFT), high resolution CT of thorax (if needed). A diagnosis of tuberculous empyema was made by microbiological and/or pathological examinations. The tubercular patients underwent decortications after at least 6–8 weeks of anti-tubercular therapy. The operative treatment was considered after relief of acute symptoms and when the patient's nutritional status had improved.

Indications for decortication

- Evidence of persistently collapsed lung (based on serial chest X-rays and/high-resolution CT of chest)
- Thick pleural peel encasing the lung
- Pleural debris >20% volume or <20% volume but symptoms (fever/tachypnea) are persistent
- Multiloculated empyema
- Cavitary lung necrosis
- Persistent broncho-pleural fistula with collapse of lung.

Patients were operated under general anaesthesia with single lumen endotracheal tube. The decortication was performed via posterolateral thoracotomy approach via 5th or 6th intercostals space. The thickened parietal pleurae were resected by detaching them from the endothoracic fascia by extrapleural dissection. The fibrinous peel constricting the visceral pleura was released carefully to avoid air leakage; the diaphragmatic pleura were also released to the extent possible in all patients. Samples taken for culture and sensitivity and histopathological examination specially to rule out tuberculosis. Lung expansion was assessed by asking the anesthetist for manual ventilation. All significant air leaks were meticulously closed using polyglactin absorbable sutures (vicryl). The thoracic cavity was thoroughly irrigated with large amounts of normal saline, betadine and hydrogen peroxide mixture until all flakes were cleared. After checking for air leaks and haemostasis and two chest tubes were inserted and connected to either conventional under-water seal drainage system or digital drainage system (Thopaz) according to our randomization chart. The digital (Thopaz) group were placed on-20 cmH20 (−2 Kpa or −15 mmHg). In the conventional group ICTD was connected to under water seal. An intercostal local anesthesia block was given and after approximating the ribs, the muscles and soft tissue was closed in layers.

Randomization was done by use of sequentially numbered, opaque, sealed envelopes. Once the surgery was complete the sealed envelope was opened and read to the surgeon. Data were collected every day until criteria for chest tube removal are fulfilled.

For the tradional chest tube group, ICTD was removed when patient had radiological (assessed by chest X-ray– posteroanterior view) and clinical expansion (good air enrty in all lung zones with normal oxygen saturation at room air) along with output of ≤50 ml serous fluid and no air leak on coughing. For Thopaz group ICTD was removed when patient had clinical and radiological expansion along with output of ≤50 ml serous fluid and air leak of <50 ml/min for 8 consecutive hours. In both groups following data was recorded: Duration of air leak (days); duration of chest tube placement (days); postoperative length of hospital stay (days); pre- and postoperative lung function (monitored by measuring vital capacity (VC) and

forced expiratory volume (FEV1) after 1 week of surgery) and postoperative complications (pleuritis, subcutaneous emphysema, empyema without fistula, pneumothorax, air leak) were noted.

Postoperative care

This included broad spectrum antibiotic, good analgesia and general care of the ICTD. In conventional group regular milking of ICTD was done to prevent clogging. A chest X-ray was taken 24 h after the surgery to confirm adequate lung expansion and correct position of the ICTD. The ICTD was removed only when the criteria for chest tube removal was fulfilled. Patients were encouraged to perform chest physiotherapy, incentive spirometry and steam inhalation.

The doctors and nursing staff were made aware of alarms that are inbuilt in Thopaz regarding blockages, high volumes of air leak and battery status.

Definitions

Air leak duration (days)

Prolonged air leaks are typically defined as an air leak lasting longer than 5 days.

Vital capacity

The maximum amount of air a person can expel from the lungs after a maximum inhalation. It is equal to the sum of inspiratory reserve volume, tidal volume, and expiratory reserve volume.

Forced expiratory volume

FEV measures how much air a person can exhale during a forced breath. The amount of air exhaled may be measured during the first (FEV1), second (FEV2), and/or third seconds (FEV3) of the forced breath. Forced VC (FVC) is the total amount of air exhaled during the FEV test.

Pleuritis

The defining symptom of pleuritis is a sudden sharp, stabbing, burning or dull pain in the right or left side of the chest during breathing, especially when one inhales and exhales. It feels worse with deep breathing, coughing, sneezing, or laughing.

Subcutaneous emphysema

Collection of air in subcutaneous tissues. Since the air generally comes from the chest cavity, subcutaneous emphysema usually occurs on the chest, neck and face where it is able to travel from the chest cavity along the fascia.

Empyema without fistula

Accumulation of pus in the pleural cavity because of infection within the lung (pneumonia) or a lung abscess spreading into the space without fistula formation. The symptoms include cough, fever, chest pain, sweating and shortness of breath.

Pneumothorax

An abnormal collection of air or gas in the pleural space that separates the lung from the chest wall. It causes a varying combination of chest pain, dyspnoea, cough, or other symptoms.

Wound infection

A wound infection is defined as surgical site infection which may be superficial or deep within 30 days of surgical operation with at least one of following sign/symptoms. Purulent discharge from the surgical site; Purulent discharge from wound or drain placed in wound; Organisms isolated from aseptically obtained wound culture and must be at least one of the signs and symptoms of infection-pain or tenderness, localized swelling, or redness/heat.

Follow up

Patients were followed in outpatient department and evaluated for lung expansion (complete/incomplete) on chest X-ray and residual pneumothorax, lung compliance (PFT) and any complication at 1 week, 1 month and 3 months interval.

Statistical tests used in the study

Statistical analyses were performed using the IBM© SPSS© Statistics version 20 (IBM© Corp., Armonk, NY, USA). Numerical variables are expressed as mean ± standard deviation. Paired variables were compared using the paired-samples *t*-test or Wilcoxon signed-ranks test while independent variables were compared using the Mann-Whitney U-test or the Student's *t*-test. The Pearson Chi-square test was used for comparing categorical variables. The results were assessed using a 95% confidence interval; a level of $P < 0.05$ was accepted as statistically significant.

OBSERVATION AND RESULTS

The mean age was 21.78 ± 15.8 (range: 2–61) years in conventional group and 19.87 ± 14.6 (1.8–58) in thopaz group [Table 1]. In other demographic features both the groups were comparable with overall with male: female ratio of 2.5:1. Majority of the patients (46%) in our study were in the young age group of 10–30 years followed by children age group of <10 years (40%) [Table 2]. Majority of empyema thoracis involved right side of lung (62%) and rest involved left side of lung (38%). Overall nontubercular empyema thoracis was most common cause of decorticartion seen in our patients [Table 3].

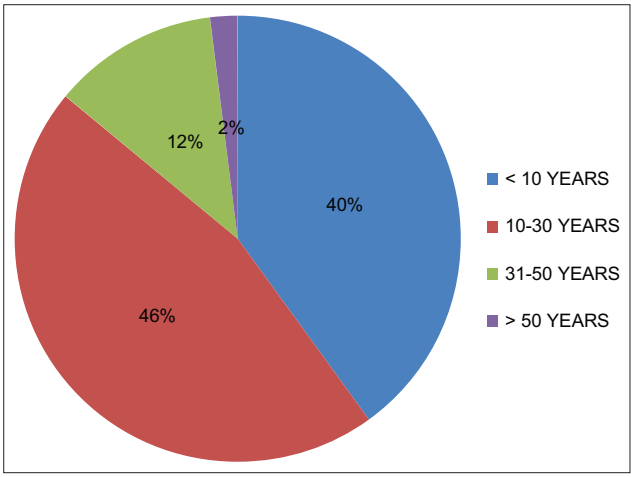
On comparing preoperative and postoperative FEV1 and FVC in both groups, it increases in both groups postoperatively which was statically significant [Table 4]. Patients with right-or left-sided empyaema thoracis and those with nontuberculous or tuberculous aetiologies benefit similarly from the decortication in terms of FEV1 and FVC in both the study groups.

The operations were performed 2–20 weeks (mean: 6.43 weeks) after the onset of the first symptoms. Patients

Table 1: Patient characteristics

	Conventional group (%)	Thopaz group (%)
Age (years)	21.78±15.8 (2-61)	19.87±14.6 (1.8-58)
Gender		
Male	72	68
Female	28	32
Laterality		
Right	64	60
Left	36	40
Aetiology		
Nontuberculosis	66 (66)	68
Tuberculous	34 (34)	32

Table 2: Pie diagram showing age distribution of patients of empyema thoracis undergoing decortication



managed with Thopaz had a significantly shorter air leak duration (5.34 days vs. 7.16 days), shorter duration of postdecortication chest tube placement (7.44 days vs. 10.44 days) and shorter postoperative hospital stay (10.16 days vs. 14.76 days) when compared to patients on conventional ICTD group [Figure 3].

In the Thopaz group none of the patients had surgical pneumothorax and subcutaneous emphysema in the postoperative period. There were statistically significant difference ($P < 0.05$) in the postoperative complications between the two groups [Table 5]. Other complication like wound infection, prolonged air leak, recurrent empyema and plueritis was less in Thopaz group as compared to conventional ICTD group.

DISCUSSION

Majority of the patients in our study were young male adults in age group of 10–30 years. However in other studies by Andrade-Alegre *et al.*,[20] Gokce *et al.*,[21] Pompili *et al.*[22] and Leo *et al.*[23] which are from developed countries patient population presented usually in 3rd decade of life and beyond with empyema thoracis for decortications. This could be attributed to lack of health facilities at community level in this part of North India, which results in delay in the diagnosis and management

Table 3: Cause of empyema thoracis in study population

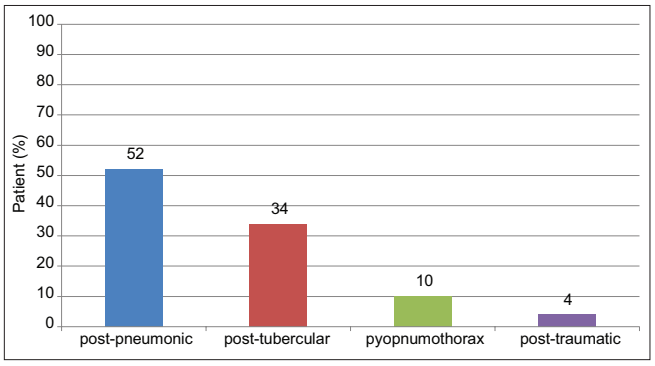


Table 4: Comparison of pulmonary functions between study groups

Study groups	FEV1 (%)		FVC (%)		*P**
	Before	After	Before	After	
Thopaz group, (n=41)	59.9±8.9	81.9±11.6	59.6±8.3	82.5±13.8	<0.05
Conventional ICTD group (n=39)	63.5±13.1	79.8±10.1	65.3±12.7	80.2±11.2	<0.05

N=41 in thopaz group and *n*=39 in ICTD group as PFT was not possible in noncooperative patients. Expressed as mean of standard deviation Student's *t*-test. FEV_1: Forced expiratory volume in the first second, FVC: Forced vital capacity, ICTD: Intercostal chest tube drain, PFT: Pulmonary Function test

of pnuemonia. Males were commonly affected in these studies similar to our; this is due to the fact that male are more prone for infection as well as trauma due to their outdoor activities.

In our study the cause of empyema thoracis was mostly bacterial pneumonia followed by posttubercular pnuemonia. Andrade-Alegre *et al.*[20] and Gokce *et al.*[21] also reported similar findings for etiology of empyema thoracis. Similar to our study, the commonest cause of empyema was nontubercular followed by tubercular.[23] However; in our study posttubercular empyema thoracis was higher as compared to other studies because of high prevalence of pulmonary tuberculosis in India.

Gokce *et al.*[21] studied decortications in chronic empyema thoracis and concluded 56% were right-sided and 44% were left-sided, which was similar to our study. The possible reason for higher right sided empyema could be due to wider, shorter and more vertical right main bronchus than left bronchus.

In our study the overall postoperative complication in Thopaz group was lower as compared to conventional ICTD group which was statically significant ($P < 0.05$); this may be due to no contact of the Thopaz canister or tubings with external environment as it is a closed system. In addition; continuous negative suction clears blood clots and debris pleural space regularly, further decreasing chance of infection or tube blockage; thus decreasing complications. Leo *et al.*[23] studied role of external pleural suction in reducing pleural complication

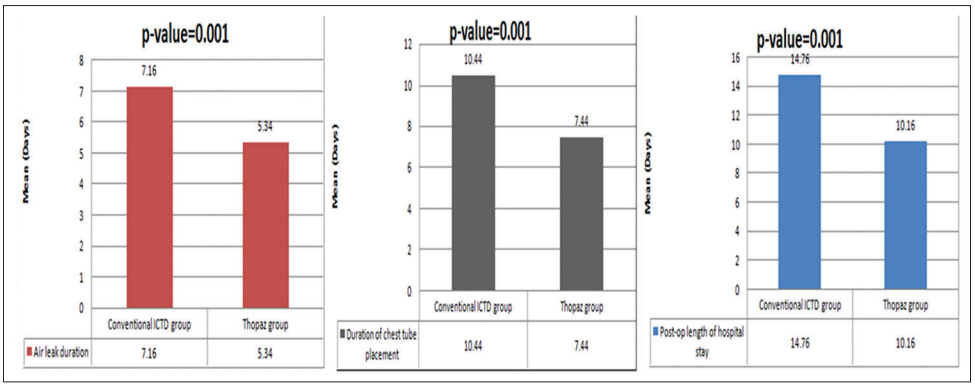
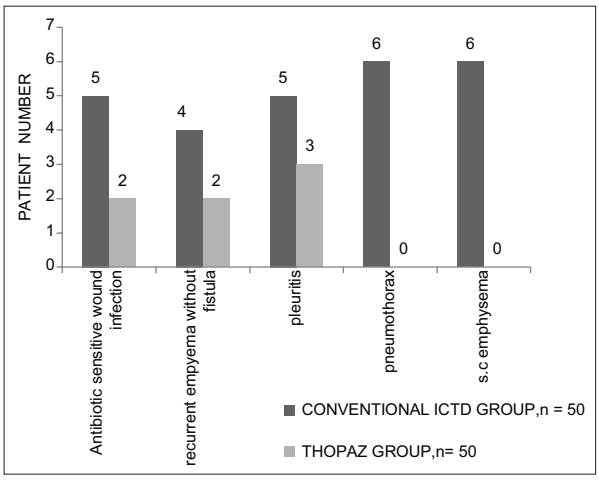


Figure 3: Mean air leak duration; mean duration of chest tube placement and mean duration of postopereative hospital stay in study groups

Table 5: Showing different post-operative complications in the study groups



after lung resection and concluded it reduced the rate of pleural complications like pleuritis ($P = 0.01$), pneumothorax ($P = 0.04$) and subcutaneous emphysema and empyema without fistula ($P > 0.05$).

Mean duration of air leak, postdecortication chest tube placement and postoperative hospital stay was less in Thopaz group as compared to conventional ICTD group and it was statistically significant too. Shintani *et al.*[24] studied role of digital chest drainage system after pulmonary resection and concluded that duration of air leak and chest tube placement in digital chest drainage system was significantly less as compared to conventional ICTD (P value < 0.0001).In another study Pompili *et al.*[23] reported average duration of chest tube placement and hospital stay in Digital chest drainage system was significantly less as compared to conventional ICTD. Similar studies by Bertolaccini *et al.*;[25] Filosso *et al.*,[26] Brunelli *et al.*,[27] and Mier *et al.*[28] concluded shorter duration of air leak, postdecortication chest tube placement and postoperative hospital stay in digital as compared to conventional ICTD with statistically significant P value. The duration of chest drainage following a pulmonary resection procedure is mainly dependent on the presence of air leakage and/or pleural effusion.[18] Digital thoracic drainage systems (DTDS) decrease air leak thus decreasing the duration of hospital stay and the cost of treatment.[29]

In our study the mean pre-ecortication FEV1 and FVC increased 1 month postoperatively ($P < 0.001$) in conventional ICTD as well as Thopaz group. We noted that improvement (%) in FEV_1 and FVC in Thopaz group was more than conventional ICTD group but it was not statically significant. Gokce *et al.*[21] studied lung decortication for chronic empyaema and its effects on pulmonary function and concluded that the mean preoperative forced expiratory volume in first second (FEV_1) and FVC increased from 61.40% and 60.89% to 78.92% and 77.48%, respectively, in the late postoperative period ($P < 0.001$).They also concluded that Patients with right-or left-sided empyema thoracis and those with tuberculous or nontuberculous etiologies benefit similarly from the decortication. Ryzman *et al.*[30] studied the pulmonary function of patients who underwent decortication for chronic pleural empyema and they found a mean increase of 15% and 20% in the FVC and the FEV1, respectively in tubercular empyema. Similarly, Choi *et al.*[31] compared the postoperative PFT improvement in 41 tuberculous and 24 nontuberculous patients with empyema and found similar results in both groups.

The present study has limitations. Most apparent is the fact that the intervention was not blinded to the patients and staff in the ward. Also, the intervention in the Thopaz group did in fact consist of two simultaneous interventions compared with the control group with a traditional drainage system, namely that it was digital thoracic drainage and at the same time applied suction. Another limitation of our study was its small sample size.

CONCLUSIONS

Patients with empyema thoracis undergoing open decortications when managed with digital chest drainage system (Thopaz) experienced faster reduction in air leak, a shorter duration of chest tube placement and in hospital stay when compared with those managed with

conventional ICTD. Thopaz usage is also associated with reduction in rate of postoperative complications. Additional clinical benefits include objective decision making on when to remove the chest tube, improved patient mobilisation and therefore chest physiotherapy, a reduction in use of X-rays, and improved infection control due to reduced risk of spillages.

We recommend that this digital chest tube drainage system is a boon to patient and a very useful tool in the armamentarium of thoracic surgeon.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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