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A Study on Therapeutic Efficacy of ICD Insertion Alone Versus Intrapleural Fibrinolytic Therapy with Streptokinase through Tube Thoracostomy in the Management of Loculated Effusions.

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Abstract:
Background: *Loculated effusions are one form of complicated pleural effusions that were difficult to manage in the olden times, but it has become easier now with the invention of newer techniques like intrapleural fibrinolytic therapy with drugs like streptokinase ,urokinase etc. along with tube thoracostomy (ICT insertion).Hence we have selected this study to assess and compare the management of loculated effusion in patients by insertion of Intercostal drain (ICT) alone and by intrapleural instillation of fibrinolytics like Streptokinase (STK) through ICT and also to study the residual pleural thickening by radiological follow up in the study sample.*
Materials and Methods: *This prospective interventional comparative study involved a total of 32 patients allocated into 2 groups A and B with 16 in each. Of them, group A (n=16) was treated by Intercoastal tube/drain insertion alone where as group B (n=16) received intrapleural streptokinase of (2,50,000 IU), administered via ICT into pleural cavity once a day for a duration of 3 to 6 days and there after fibrinolytic efficacy in terms of duration of pleural fluid drainage is compared in both groups.*
Results: *In both groups biochemical analysis of pleural fluid was exudates. Out of 32, 18 were tuberculous effusions, 10 were synpneumonic bacterial effusions, 4 were poly microbial empyemas. In terms of patient comfort and lesser duration of hospitalization, it was better in streptokinase instillation group (an average of 7days) when compared to group with ICT insertion alone. In terms of effectiveness of procedures, it was better in streptokinase group (85.5%)when compared to ICT alone (70%)based on post discharge and after 1 month follow up by chest x ray in both groups.*
Conclusion: *Our study showed that patients with loculated pleural effusion treated with streptokinase suffered less from residual pleural thickening, as measured after one month, than those treated by ICT alone.*
Key-words: *loculated effusions , tube thoracostomy , intra pleural streptokinase instillation*

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I. Introduction

The most common causes of loculated effusions include complicated parapneumonic effusions, complicated tubercular effusions, empyemas, hemothorax and malignant effusions etc. Loculations develop due to delayed initiation and inappropriate use of medical management with anti tubercular drugs or antibiotics and delayed initiation of pleural space drainage. Presence of loculations indicates persistence of pleural fluid despite an adequate trial of simple drainage or a drainage of a fluid volume far less than expected which is seen as septations in the fluid dividing it into multiple pockets on ultrasound or computed tomography scan. The management options in such cases consist of ultrasound guided thoracocentesis of each locule, insertion of pigtail catheters one in each locule, simple intercoastal drain with suction, use of intrapleural fibrinolytics like Streptokinase or Urokinase, thoracoscopic adhesiolysis, minimally invasive video assisted thoracic surgery (VATS) or more invasive conventional thoracotomy and decortication. Although VATS and other invasive procedures are very effective, they are not routinely practiced in India due to limited access, affordability and patient's phobia for major surgical procedures. So our current study highlights the use of intrapleural streptokinase fibrinolytic therapy as a safer, easier and cost effective option for managing loculated effusions.

II. Materials and Methods

This prospective comparative study was carried out on patients of department of Pulmonary medicine at MIMS (Maharajah's institute of medical sciences) college and hospital, Nellimarla, Vizianagaram, Andhra Pradesh from January 2021 to June 2022. A total of 32 adult subjects (both males and females) of aged ≥18 yrs were

taken for this study.

Study design: A Prospective interventional comparative study.

Study location: This was a tertiary care teaching hospital-based study done in department of Pulmonary medicine at MIMS (Maharajah's institute of medical sciences) college and hospital, Nellimarla, Vizianagaram, Andhra Pradesh.

***Study duration*:** January 2021 to June 2022

***Study population*:** All the eligible patients with loculated effusions admitted in tertiary care hospital during January 2021 to June 2022.

***Sample Size* :** 32 patients .

***Subjects and selection method*:** The study population was drawn from the patients who presented to department of Pulmonary medicine at MIMS (Maharajah's institute of medical sciences) hospital and diagnosed with loculated pleural effusions from January 2021 to June 2022. Patients were divided into 2 groups A and B (each had 16 patients).

Group A (N=16) : ICT insertion alone is done.

Group B (N=16) : Along with ICT, intrapleural streptokinase instillation is also done.

***Inclusion criteria*:**

1) Patients who had loculated effusion on chest x ray or ultrasound or computed tomography.
2) Patients who were willing for the study.
3) Patients who were hemodynamically stable and fit for intercoastal tube thoracostomy and intrapleural streptokinase fibrinolysis.

***Exclusion criteria*:**

1) Patients who do not give consent.
2) Patients with poor general condition.
3) Patients with recent myocardial infarction.
4) Patients with blood dyscrasias, abnormal bleeding and clotting times.
5) Patients with Broncho pleural fistula.
6) Patients who had H/O bleeding diathesis, stroke or significant hemorrhage in the preceding six months or who were treated with intravenous fibrinolytics for myocardial infarction or ischemic stroke by any route in the past 2 years.

Materials:

1) Routine blood investigations like complete blood picture, bleeding time, clotting time, renal and liverfunction tests.
2) Peripheral blood smear.
3) ECG
4) Chest x ray, ultrasonography (USG), plain CT chest or CECT chest i.e,Contrast Enhanced Computed Tomography (if required).
5) Diagnostic thoracocentesis of pleural fluid biochemical, pathological, microbiological analysis by pleural fluidPH, total cell count, differential count, sugar, protein, ADA (Adenosine de aminase), LDH (Lactate de hydrogenase), cell block for histopathology, gram staining, acid fast staining/ZN staining, culture and antibiotic sensitivity, gene expert.
6) Equipments for thoracocentesis and intercostal drainage of pleural fluid by tube thoracostomy and for intrapleural streptokinase instillation.

Procedure methodology:

In both groups A and B, ultrasound of chest was done and locules with pleural fluid and septations were identified. Now, under aseptic conditions 2% Lignocaine local Instillation into pleural space was done and ICT was inserted in to the safety triangle in 4^{th} or 5^{th} intercoastal space in mid axillary line or at the site marked ,where there was maximum amount of loculated pleural fluid and connected to romodrain bag in both groups .In group B, when there is no drain or less than 50ml drain in prior 24hrs but still evidence of residual pleural fluid in locules as evident by chest x ray/ USG/CT chest, Streptokinase of 2,50,000 units diluted in 50 ml normal saline was instilled through ICT into pleural space and was clamped for 3 hours where as no streptokinase instillation was done in group A. After 3hrs of the clamp removal in group B patients, the pleural fluid got drained due to fibrinolytic property of Streptokinase which breaks the locules and drains the fluid into the ICT bag. The procedure was repeated once a day for 3 to 6 days depending on the radiological resolution and till no further pleural fluid was drained. We used an average of 10,00,000 units of streptokinase for most of the patients and a maximum of 15,00,000 units was used for few patients.

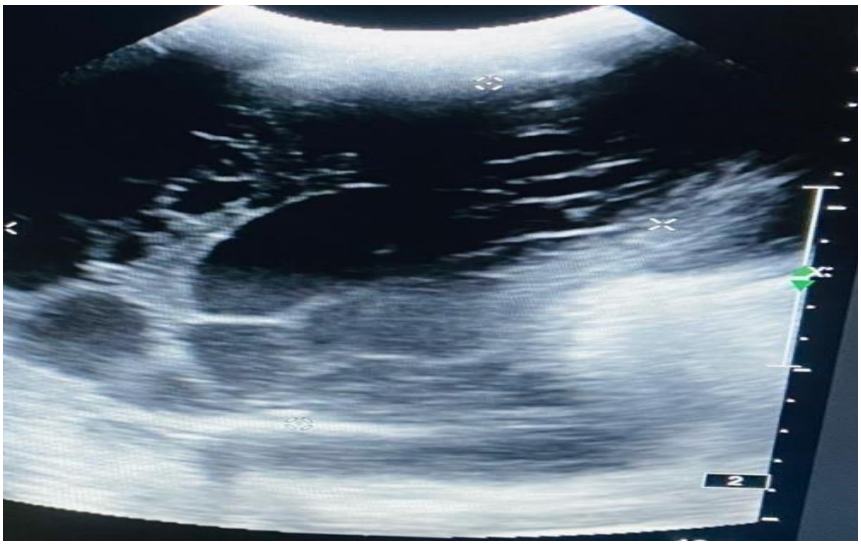


Figure 1 – Image showing pleural fluid in loculations on ultrasound Chest.

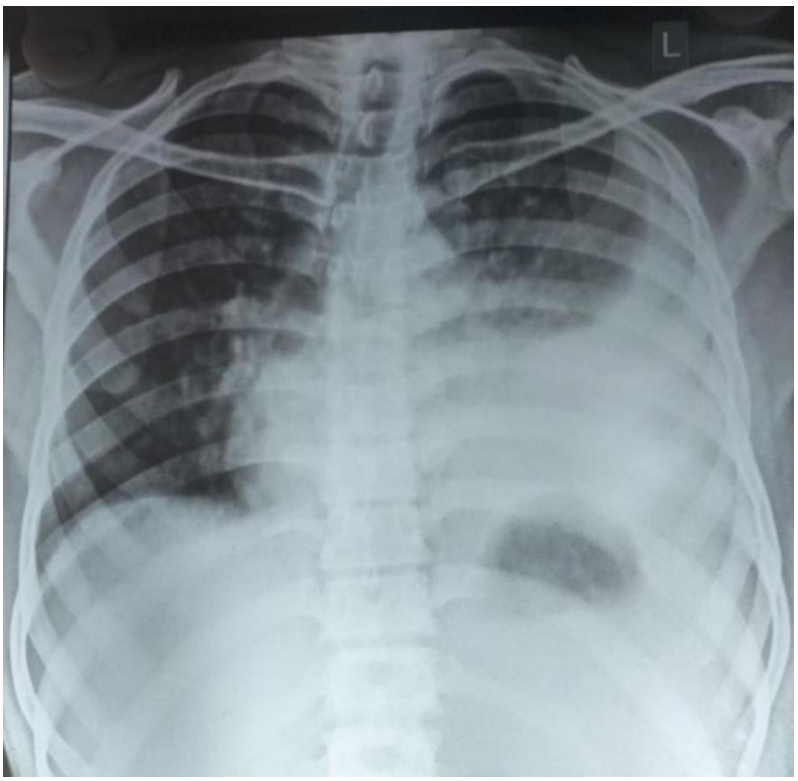


Figure.2 Chest radiograph showing left sided loculated effusion

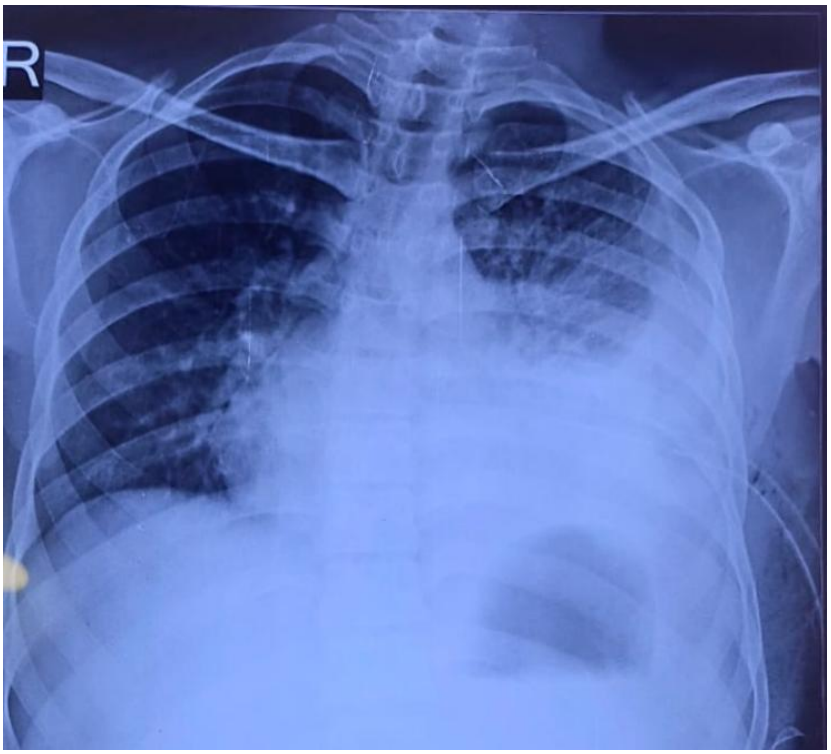


Figure 3.a Chest X ray postero-anterior view

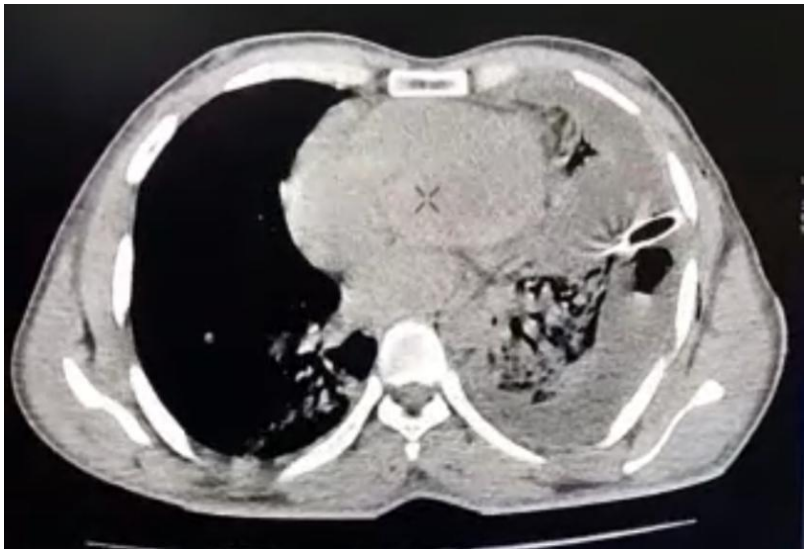


Figure 3.b Axial section of CT chest

Figure 3.a and 3.b showing left loculated parapneumonic effusion with intercostal tube in situ in the same patient

Figure :4 Image showing reddish pleural fluid with fibrotic bands in romodrain bag after intrapleural Streptokinase instillation.

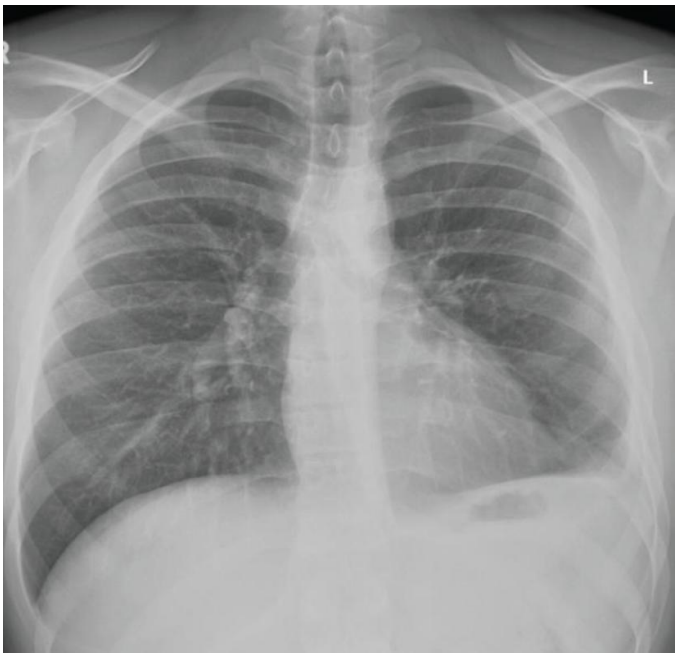
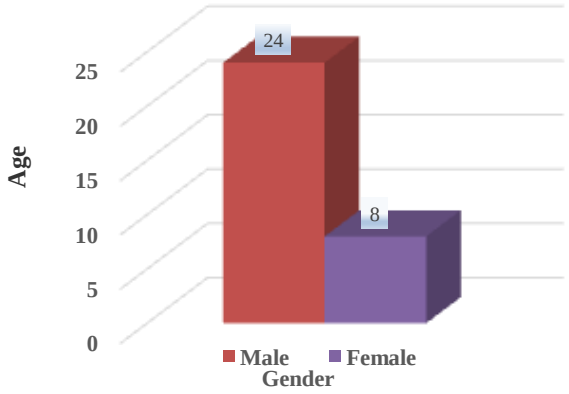


Figure:5 chest x ray showing radiological resolution after 1month in the same intrapleural streptokinase instilled patient with minimal residual pleural thickening

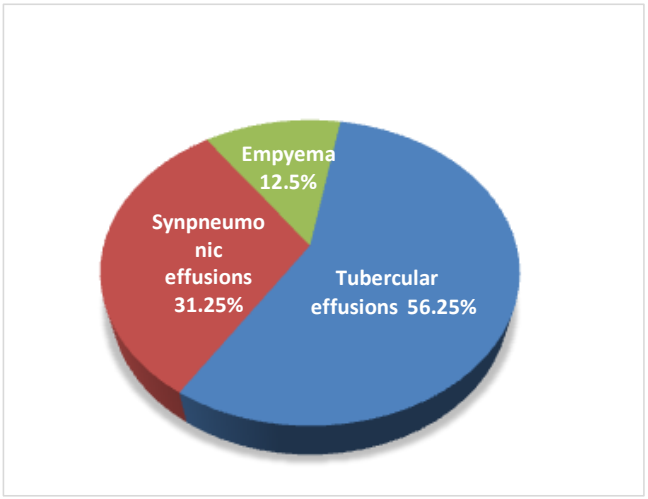
III. Results

In study sample out of 32 patients, 24(75%) were male and 8(25%) were female. Based on pleural fluid biochemical, pathological, microbiological analysis by pleural fluid PH, total cell count, differential count, sugar, protein, ADA (Adenosine de aminase), LDH (Lactate de hydrogenase), cell block for histopathology, gram staining, acid fast staining/ZN staining, culture and antibiotic sensitivity, gene expert, 18 out of 32 loculated effusions observed in the present study sample were tuberculous effusions which constitute 56.25 %, 10 were synpneumonic effusions which constitute 31.25% and 4 were polymicrobial empyemas which constitute 12.5%. Average duration of hospitalization for management of loculated effusions by ICT insertion alone was 10days, whereas by intrapleural streptokinase instillation through tube thoracostomy it was 7 days.

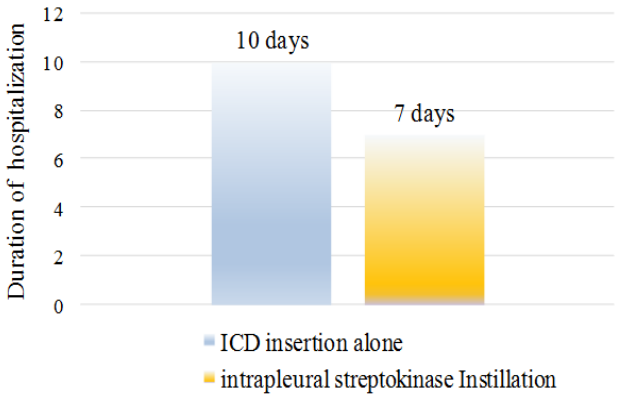
Radiological outcome measured by repeat chest x ray during follow up was 70% in group A with ICT insertion alone where as it is 85.5% in group B i.e, intrapleural Streptokinase instillation group.



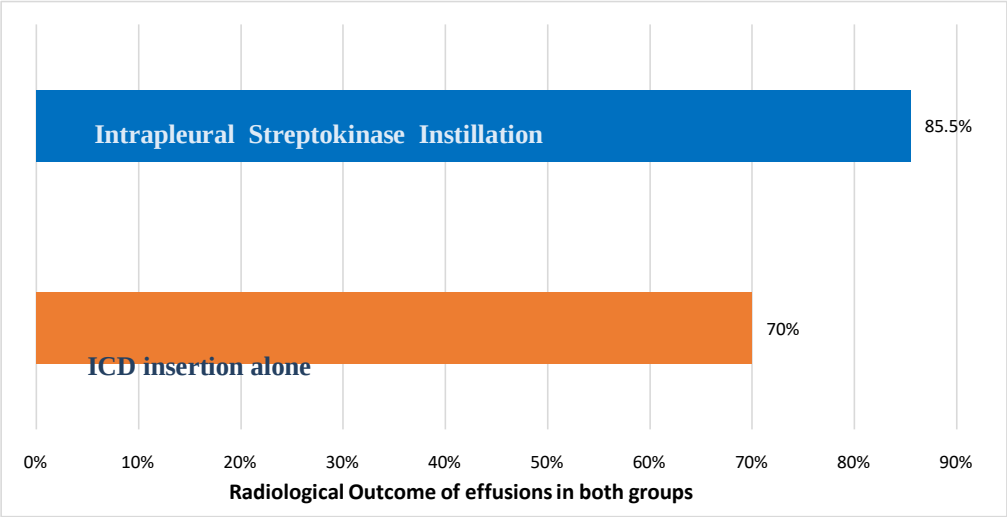
Graph.1 Bar diagram showing gender distribution in the sample.



Graph. 2 pie diagram showing etiology of various loculated effusions



Graph. 3 showing average duration of hospitalization in both study groups



Graph.4 Bar diagram showing radiological outcome in both study groups

IV. Discussion

In the present study of 32 loculated effusions, the male to female ratio was 3:1 which was comparable to Enrique Cases Viedmaa et al [14] in his study on loculated TB pleural effusions indicating a strong male predisposition in incidence of pleural infections and loculated pleural effusions.Tuberculous loculated effusions accounted for majority in our study which is due to high incidence of tuberculosis in developing countries like India. In the present study based on diagnostic pleural fluid analysis, they were diagnosed as tuberculous effusions, syn pneumonic effusions and poly microbial empyemas.

In the study by Nwagboso CI, Peter et al [12] it is shown that the factors like prolonged duration of drainage and prolonged duration of illness are predictors of poor outcome of chest tube drainage in non-purulent exudative pleural effusions. Hence in our study the duration of drainage in terms of duration of hospitalization is compared by randomizing the patients into 2 groups for interventions i.e.by ICT insertion alone and intrapleural Streptokinase instillation through ICT and they were medically managed as per diagnosis in both groups. Tuberculous effusions were treated by anti-tuberculous chemotherapy regimen for 6 months according to National Tuberculosis Elimination Programme (NTEP). Synpneumonic effusions and empyemas were treated with empirical antibiotic therapy initially and shifted to appropriate antibiotic therapy based on gram staining, culture and antibiotic sensitivity of pleural fluid for 10 to 14 days.

In the present study, the amount of pleural fluid drained was more in intrapleural streptokinase group which was reflected in average duration of hospitalization days i.e. 7 days in streptokinase group and 10 days in ICT insertion alone group. In our study, we observed the pleural fluid drain was more haemorrhagic and fibrin strands in drain on intra pleural streptokinase instillation with successive doses. This was probably due to lysis of adhesions and pleural reaction.

However systemic complications like fever, chest pain, rash, bleeding diathesis, change in bleeding time, clotting time and other blood parameters were not observed with STK dose of 2.5 lakh units/day for 3-6 days. But caution must be taken as there were rare case reports of side effects. In several case reports [3,4] ,non-randomized [8] and randomized trials[9,11], the use of intrapleural fibrinolytics had shown encouraging results. Failure of fibrinolysis is commonly used to assess effectiveness of both procedures radiologically and is defined as the need for surgical referral. [13] In the present study, failure of fibrinolysis was less in Streptokinase group indicating lower need for major thoracic surgeries like Video Assisted Thoracoscopic Surgery Adhesionolysis (VATS), Decortication or Thoracotomy.

V. Conclusion

The therapeutic efficacy for management of loculated effusions was high in terms of radiological outcome in intrapleural streptokinase instillation group (85.5%) than ICT insertion alone group (70%). Our study showed that patients with loculated effusion treated with Streptokinase suffered less from residual pleural thickening, as measured after one month, than those treated only by ICT alone. Intra pleural Streptokinase instillation reduced the need of video assisted thoracoscopic surgery adhesiolysis of locules and need for decortication surgery which had risk due to anesthesia & surgical complications and mortality risk. It can be tried in elderly who are unfit for surgery, who refuse surgery and where there were limited access to

complicated thoracoscopic procedures. It is therefore suggested that the administration of intrapleural Streptokinase through ICT is a safe, effective and simple treatment for those patients with loculated effusions.

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