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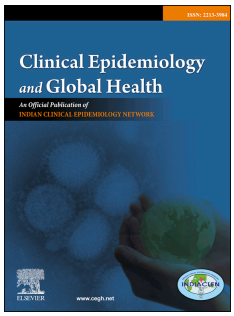

Comparison of small lumen versus large lumen inter costal catheter drainage in empyema thoracis on degree of comfort and re-expansion of lungs: An open label, quasi randomized study

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  Data collection, data analysis, manuscript writing
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  Study design, interpretation, manuscript writing
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Introduction

Community Acquired pneumonia (CAP) is the leading cause of morbidity and mortality globally in children. In 2015, India, Nigeria, Indonesia, and China contributed to more than 54% of all global pneumonia cases, with 32% of the global burden from India alone (3). Complications of CAP can be - local or distant. Local complications include pleural effusion, empyema, pneumothorax, necrotizing pneumonia, lung abscess, bronchiectasis, and pyopericardium. Distant complications of CAP are septicemia and metastatic infection like osteomyelitis, septic arthritis, meningitis, etc. (4).

ET complicates bacterialpneumonia in 5-10% of children (5). The majority of cases can be successfully managed with antibiotics and chest tube drainage alone. Thoracotomy was needed in a small proportion of cases. (6).Though the incidence of ET has declined in the west due to the effective use of broad-spectrum antibiotics, it still remains a significant health problem in developing countries due to low socioeconomic status, Malnutrition, delay in diagnosis of pneumonia, and delay in initiating treatment, misdiagnosis or inadequate/inappropriate treatment of pneumonia, non-evacuation of pus from pleural space and delayed referral to the higher centre could be the possible reasons (7). For empyema, besides antibiotics, various treatment options are available ICD or decortication by video-assisted thoracoscopic surgery (VATS) (8).

Evacuation of pus by the placement of ICDT is the initial treatment in children with ET, VATS requires anadvanced stage of ET which does not respond to ICDT(1,2&14)**.**Wide bore (>14F) tubes has been preferred for ICD placement because it is considered to improve drainage and reduce the risk of the blockade. However, the use of a wide bore ICD tube may be associated with greater discomfort for the child (1,2,12). The present study was carried out to determine the effect of small lumen ICDT versus large lumen ICDT on the degree of comfort and re-expansion of lungs in patients with ET.

Material and Methods

This study was an open-labelquasi-randomized trial conductedin the Pediatrics Department ofKing George Medical University, Lucknow from September 2018 to August 2019involving children 2 months to 12 with a diagnosis of ET. The study protocol was approved by the institute ethics committee [Ref. code: 93rd ECM II B-Thesis/P27]. ET is characterized by accumulation of frank pus in pleural space (8) The criteria for the diagnosis of ET werethe presence of pleural effusion on radiological examination and USG-guided aspiration of frank pus from pleural space. Exclusion criteria were pneumothorax, shock, malignancy, bilateral empyema, and recurrent empyema.

Patients were quasi-randomized by days of the week to undergo intercostal drainage using either a small-bore ICD catheter (Group A/12-14F) or a wide bore ICD catheter (Group B/>14F). After taking proper consent from parents (for children < 8 years) and consent from parents with assent from children (for children >8 years), in group A (12F-14F), we enrolled all the eligible patients admitted on Monday and Friday and in group B (>14F), we enrolled all the eligible patients admitted on Tuesday, Wednesday, Thursday and Saturday.

There are various techniques for ICDT insertion but in our study, the blunt dissection technique was used for ICDT insertion. Intravenous midazolam and ketamine were used to sedate all the patients and lidocaine were used for the preparation of the puncture site (usually the fifth intercostal space). After insertion of ICDT, a combination of ibuprofen & paracetamol syrup was given to all the patients for the relief of pain for 3 days. ICDT was flushed with 10 ml of sterile normal saline daily (in the morning and evening). All the patients received broad-spectrumempirical antibiotics till the culture report was awaited. When cultures were positive, the antibiotic scheme was modified accordingly.

Pain score was noted on day 4 of ICDT insertion by using the FLACC pain score (10). This is a simple scale that is independent of reporting by parents or children and has a maximum score of 10 and a minimum score of zero.USG ofthorax was done on day 1 (between 24-36 hours), betweenday 5-6, andbetween day 10-12 to assess the amount of fluid.The difference in the volume of fluid in these consecutive imaging studies was used to assess the volume of fluid drained. USG was done by a trained specialist radiologist who was blinded to the type of intervention. The catheter dwell time and duration of hospital stay were also recorded.

Sample size was calculated by assuming 2 tailed distribution of alpha-0.05 and FLACC pain score of ≥3 in 40% in children with ICDT of >14F & in 15% in children with ≤14F ICDT on day 3rd-4th of tube insertion and power of 80%. Minimum sample size required was 100. Taking into account 10% attrition due to patients leaving against medical advice (LAMA) and absconding sample size was 108.

Results were expressed as mean±SD. The Mann–Whitney U test was used for intergroup comparisons. Chi-square test was used for comparisons of group proportions with qualitative data. A value of $p < 0.05$ was considered significant.

Results

Over the one-year study period, 162 cases of pleural effusion were screened and among them, 130 fulfilled the inclusion criteria and were enrolled inthe study (66 in Group A and 64 in Group B)(Figure 1). On completion of day 5, one patient died in Group A and 5 patients died in Group B, thus there were 65 patients in Group A and 59 patients in Group B after day 5 (Figure 1).As Monday and Friday are the days of consultants which are our co-guides and also days for respiratory system specialists so most of the respiratory cases come on these two daysthat's why

we randomized two groups into group A (Monday, Friday) and group B (Tuesday, Wednesday, Thursday and Saturday) and enrolled almost equal cases in both groups during one year of the study period.

Table 1 shows baseline characteristics of ET cases in both groups. We have done pleural fluid culture of all the enrolled (130) cases of ET. Pleural fluid culture examination revealed that out of 130 cases of ET, pus culture was positive only in 42(32.30%) cases (table 1). Acinetobacter species were found in 12(9.2%), Staphylococcus Aureus in 9(6.92%), Klebsiella in 5 (3.8%) and Streptococcus pneumoniae in 2(4.5%) cases.

Clinical outcome of ET in both groups is presented in table 2. Inthe comparison of pain scores in both the groups on the 4^{th} day of ICDT insertion, mean pain score was 2.86 in group A and 7.50 in group B (p=0.034) (Table2).

Pus drained by small lumen ICDT and large lumen ICDT between day 1 & day 5 and between day 1 & day 10 of ICDT insertion was similar in both groups (Table 2).In comparison of duration of hospital stay and catheter dwell time, there was no significant difference in both groups. One patient expiredin group A due to septic shock and 5 patients expired in group B, among 5 patients 3 expired due to septic shock, and 2 patients expired due to sepsis with multiorgan dysfunction.

Discussion

Here, we are reporting the results of a prospective open-labeledquasi-randomized study conducted in a tertiary care hospital in Northern India to ascertain the effect of the size of an ICD tube on pain, drainage of pus, and durationof hospital stay in children with ET.

In our study, we found that there was no significant difference in drainage volume, catheter dwelling time, and duration of hospital stay between both the groups but smaller size (12-14F) ICD tube caused substantially less pain than large lumen (>14F) ICD tube without any impairment in the clinical outcome of the patients of ET.In coherence with our results, similar results were found by a number of authors. A prospective randomized study done by Clemensten et al (11) reported FLACC pain score of 2/10 in small lumen (≤14F) ICD tube group and 6/10 in large lumen (>14F) ICD tube group with p= 0.01in children with ET which was statistically significant. Rehman NM et al, (12) in a prospective randomized study found FLACC pain score of 4/10 versus 6/10 with p= 0.013 in small lumen (≤14F) ICD tube group and in large lumen (>14F) ICD tube group respectively which was statistically significant. Another prospective randomized study done by Rehman N M et al (13) by using visual analogue scale (VAS) for pain and found scores of 22/100 in small lumen (≤14F) ICD tube group and 26.8/100 in large lumen ICD tube group with p value of 0.04 which was statistically significant.

The available clinical data for this cohort has also allowed disquisition of the effect of size of tube on duration of hospital stay, amount of fluid drainage. In our study, on comparison of USG between day1 &day 5 and day 1&day10 the difference in the drained amount of pus in both groups was not different. Similar to our results, Clemensten et al (11) and Rehman NM et al (12,13) did not find any significant difference in drainage of pus in both groups. In many other studies, the most common organism in pus culture of patients with ET was Staph. Aureus but in our studyThe most common organism in pleural fluid culture was pseudomonas found in 14 (10.8%) cases

could be due to hospital-acquired infection, as pseudomonas and acinetobacter species are common hospital-acquiredinfections in our department.

In our study, we found that there was no significant difference in the duration of hospital stay in both groups. in group A, The mean duration of hospital stay was 21 days and in group, B mean duration of hospital stay was 25 days (p= 0.8) and these results were similar to results got by Najib M Rehman et al (2010, England), (12) 24 days in small lumen ICD tube versus 31 days in large lumen ICD tube with p=0.37, Clemensten et al (1998, France), (11) 18 days in small lumen ICD tube and 15 days in large lumen ICD tube with p= 0.32 and Megan R. Lewis et al (2017 Cardif, UK) (14). Some of these authors had assessed the effect of size of ICD tube on drainage of pus and length of hospital stay but had not evaluated its effect on pain score.Only 27 patients (16 in group A and 11 in group B) require intrapleural streptokinase, criteria for use of streptokinase wasthe presence of septations on USG thorax. none of the enrolled patients in both groups required VATS.

Strengths of our study

FLACC pain score was used for the objective assessment of pain and discomfort. This was a simple scale that was independent of reporting by parents or children.Objective ultrasound criteria were used for assessing the pleural fluid volume and the ultrasound assessor was blind to intervention type.

Weakness of our study

As this study was conducted in a tertiary care center it leads to Selection bias as a patient admitted would have taken prior antibiotics and were very sick so the patient came in a chronic condition of disease so their hospital stay could be more. The study was quasi-randomized as patients were randomized by days of the week. however, there was no significant difference in clinical and laboratory characteristics in both groups.There could have been assessment bias in pain scoring as the assessor was not blinded. This bias could not be avoided in the quasi-randomized study design.

Conclusion:

Using narrow lumen ICD tube for management of children with ET leads to significantly less discomfort to the child without compromising the drainage of empyema fluid and duration of hospital stay. As pain is of big concern in pediatric patients, therefore we concluded that the use of a small lumen ICD tube for drainage of pus in pediatric empyema should be preferred.

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Conflict of interest neither author has any conflict of interest to declare

Ethics approval: Approval of the ethics committee of our institution(King George Medical University, Lucknow) was obtained for this study (Reference code 97th ECM II B-Thesis/P117)

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Table 1: Baseline demographic and laboratory data of patients.

	Group A	**Group B**	**P value**
Patient characteristics			
Number (M/F)	66 (44/22)	64 (44/20)	0.8
Mean age, yr	4.61±2.37	4.91±3.30	0.002
Blood investigations			
Hemoglobin, gm/dl	10.52±1.24	10.08±1.05	0.33
Total leukocyte count, /cu.mm	16724.8±7731.1	16048±6792.4	0.59
Pleural fluid characteristics			
pH	6.82±0.07	6.81±0.04	0.10
Glucose, mg/dl	25.43±14.88	29.41±22.75	0.01
WBC count	577.86±907.72	567.85±774.90	0.36
Bacterial culture positive	22	20	

Table 2: Comparison of outcomes in Group A and B

	Group A (n=66)*	**Group B (n=64)***	**P value**
Pain score on 4th Day	2.86±0.839	7.50±1.272	0.034
Amount of fluid drained between Day1 and Day5, ml	159.3±125.9	179.5±167.6	0.2
Amount of fluid drained between Day1 and Day10, ml(here,n1=65and n2=59 taken)	205.6±130.2	244.5±174.7	0.7
Catheter dwell time, days (here n1=65& n2=59 taken)	16.3±8.3	20.6±10.8	0.62
Hospital stay, days (here n1=65&n2=59 taken)	21.±9.9	25.6±13.8	0.8

FIGURE 1