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A Comparative Study of Pigtail Catheter and Malecot Chest Tube Thoracostomy in the Management of Empyema Thoracis and Pyopneumothorax at a Tertiary Care Centre in North India

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Abstract:
Background: The study aimed to compare the effectiveness of pigtail catheter vs. malecot chest tube thoracostomy in the management of empyema thoracis and pyopneumothorax.
Methods: This prospective randomised interventional study was conducted in the Department of Respiratory Medicine at a tertiary care centre in north India between September 2020 and August 2021. One hundred patients, qualified as per inclusion criteria, were included in the study, and randomization was done using the random number table method. After allocation concealment and randomization, the intervention was done in the sense that Group A (51 cases) received a pigtail catheter (14F) and Group B (49 cases) received a malecot chest tube (28F) (a total of 100 cases). After the intervention, both groups were observed for 14 days. On the 14th day, the data for the primary observations (radiological clearance on day 1, day 7, day 14th, and mean duration of hospital stay) and secondary observations (postoperative pain score, post-procedure complications) were noted, and statistical analysis was done**. Results:** Radiological clearance in the malecot chest tube group (28F) is better on days 1 (0.55±0.13) and 7 (0.75±0.08) than in the pigtail catheter group on day 1 (0.52±0.18) and day 7 (0.72±0.11). But, radiological clearance on day 14 in the malecot chest tube group (0.91±0.06) and the pigtail catheter group (0.91±0.08) is comparatively equal ($p<0.05$). The mean duration of hospital stay and pain scores were better in the pigtail catheter group than in the malecot chest tube group.
Conclusions: Our study suggests pigtail catheters are a safe and effective method and should be considered in the management of empyema thoracis and pyopneumothorax.

Keywords: Empyema Thoracis, Pigtail Catheter, Malecot Chest Tube, Thoracostomy, Pleural Effusion, Hospital Stay, Pain Score

Introduction:

Empyema thoracis and pyopneumothorax carry a concerningly high mortality rate of 6-24%. Often stemming from complications of community-acquired or hospital-acquired pneumonia, this serious condition requires prompt intervention with tube thoracostomy and antibiotics (1). Tube thoracostomy is an invasive procedure done by placing a chest tube for therapeutic drainage of fluid or air from the pleural space (2). Complicated parapneumonic effusions and empyema thoracis are treated with tube thoracostomies and antibiotics. A chest tube of appropriate size and type is required for effective drainage of the empyema (3). The most commonly used tubes are malecot chest tubes, and pigtail catheters. In this study, we compared the efficacy and outcomes of pigtail catheters (14F) vs. malecot chest tubes (28F) in the management of empyema thoracis and pyopneumothorax patients.

Materials and methods:

This study has been registered with ClinicalTrials.gov (**CTRI/2020/03/024189**).

This is a randomised prospective interventional study conducted between September 2019 and August 2020 in the Department of Respiratory Medicine at a tertiary care centre in north India. The study was approved by the institute ethics committee, and written consent was obtained from all patients who were enrolled in the study.

Eligibility criteria: Patients with pleural diseases such as empyema thoracis and pyopneumothorax and patients aged more than 12 years are included in the study. Patients with an age of less than 12 years, failure to give consent, or patients with bleeding diathesis or coagulation disorders are excluded from the study.

Randomization was done using the random number table method. Total cases: 100. After allocation concealment and randomization, intervention was done in the sense that Group A (51 cases) intervened with a pigtail catheter and Group B (49 cases) intervened with a malecot chest tube. After the intervention was done, both groups were observed for 14 days for lung expansion (radiological clearance), duration of hospital stay, post-procedure complications, and pain score. On the 14th day, outcomes were measured, and statistical analysis was done.

Baseline characteristics such as age, sex, residence, occupation, socioeconomic status, and other baseline variables were considered. The primary outcome measures were radiological clearance (lung expansion) and tube site pain (pain score). Secondary outcomes are hospital length of stay and post-procedure complications.

Sample size calculation:

Sample size is 50 in each group(statistically calculated)

The calculations, in the context of radiological improvement(lung expansion) Analysis ……a priori

Input Tail(s) = 2
Effect size d = 0.57142
Alpha err prob = 0.05
Power(1-beta err prob) = 0.80
Allocation ratio N2/N1 = 1
Output Non centrality parameter (λ) = 2.8571430
Critical t value = 1.9844675
Df = 98

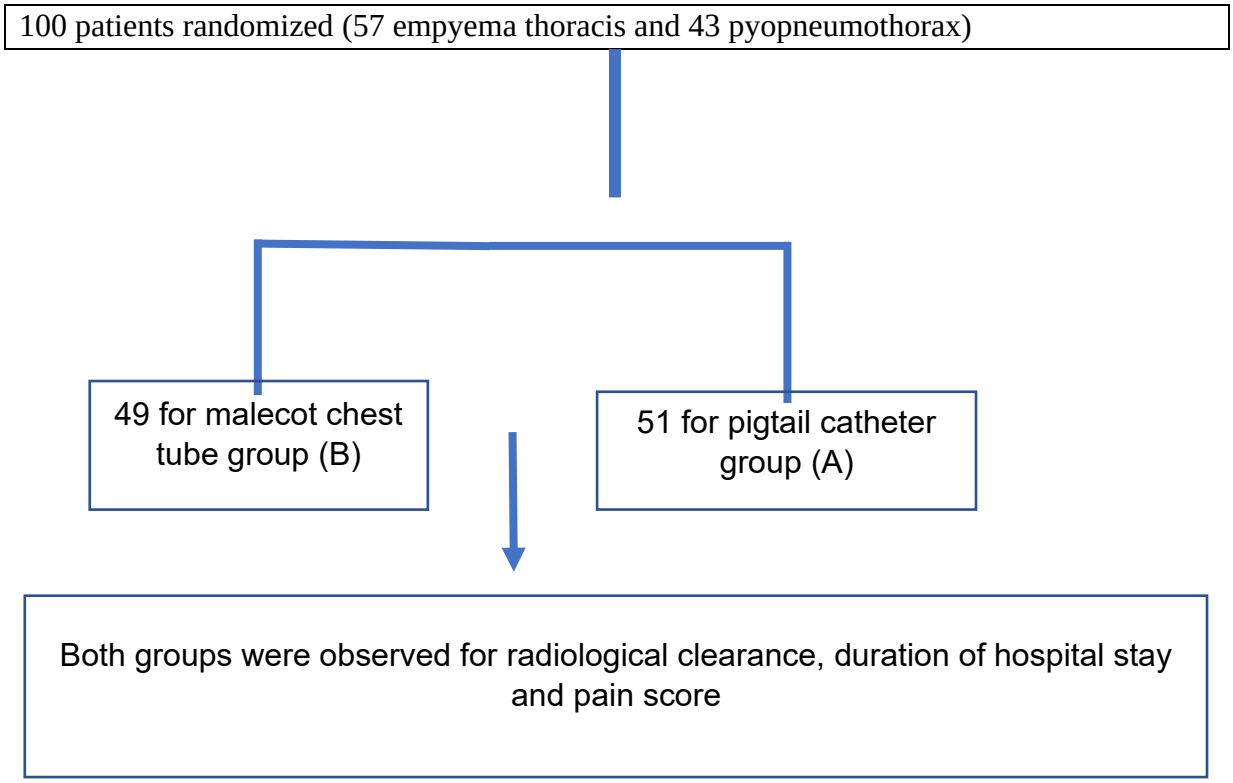
Sample size group 1 = 50
Sample size group 2 = 50
Total sample size = 100
Actual power = 0.8075976

A comprehensive clinical history and detailed clinical evaluation were taken from all patients. To detect the mean difference (days) in radiological clearance (lung expansion): Assuming the mean +/- standard deviation of the duration of radiological clearance in Group A (pig tail) and Group B (malecot chest tube thoracostomy), i.e., 8.0 +/- 3.5 days and 10 +/- 3.5 days, at 80% power of the study and a minimum two-sided 95% confidence interval, the calculated sample size for each of the two groups was 50-50. Finally, in this study, we will include at least 50 patients in group A and 50 patients in group B (total 100). The sample size was estimated using the software G Power version 3.1.9.2 (Dusseldorf University, Germany).

Study plan:

Randomization was done using the random number table method. Total cases: 100. After allocation concealment and randomization, intervention was done in the sense that Group A (51 cases) intervened with a pigtail catheter and Group B (49 cases) intervened with a malecot chest tube. After the intervention was done, both groups were observed for 14 days for lung expansion (radiological clearance), duration of hospital stay, and pain score. On the 14th day, output was measured and statistical analysis was done. Post-procedural pain assessment following tube thoracostomy placement can be effectively achieved through the Visual Analog Scale (VAS). This widely recognised tool offers a reliable and efficient means of quantifying pain intensity. The VAS utilises a 10-centimetre horizontal line, along which patients mark their perceived pain level (4).

Study design



Results:

A total of 100 patients(57 empyema thoracis and 43 pyopneumothorax) were included in our study. There were 51patients in pigtail catheter group and 49 in malecot catheter group.

Table:1 Baseline Characteristics.

	Pigtail catheters (A)	Malecot catheters (B)	p value
Age(years)	36.41± 15.68	35.41 ± 16.05	0.08
Gender			
Male	24	33	
Female	27	16	0.046
Empyema thoracis	29	28	0.067
Pyopneumothorax	21	22	0.059
Right side pathology	36%	28%	
Left side pathology	15%	21%	0.161

(Table 1) summarises baseline information about two groups: patients with pigtail catheters and those with malecot catheters. All baseline characteristics between the two groups were not statistically significant. The results revealed that the mean age of the patients in both groups was approximately 36 years old. More males than females were observed in both groups, though the difference was significant only in the malecot catheter group (p = 0.046). Empyema thoracis was slightly higher in both groups, which was not statistically significant (p-value = 0.067 for pigtail catheters and p-value = 0.059 for malecot catheters).

Table: 2 Comparison of outcomes.

	Pigtail catheter(A)	Malecot catheter(B)	p value
Radiological clearance			
Day 1	0.52 ± 0.18	0.55 ± 0.13	0.636
Day 7	0.72 ± 0.11	0.75 ± 0.08	0.38
Day 14	0.91 ± 0.08	0.91 ± 0.06	0.86
Duration of hospital stay	8.75 ± 1.98	10.02 ± 2.9	0.013
Pain score(post procedure)	6.67 ± 1.32	7.9 ±1.42	0.001

(Table 2) There is no significant difference in radiological clearance on days 1, 7, and 14. However, patients with pigtail catheters had a shorter hospital stay than those with malecot catheters (8.75 days vs. 10.02 days), and the difference was statistically significant (p-value = 0.013). In addition, malecot catheter patients reported more pain score (post procedure) than pigtail catheter users (p = 0.001).

Table: 3 Post procedure complications of Pigtail catheter(A) and Malecot catheter(B).

	Pigtail catheter(A)	Malecot catheter(B)	Z value	p value
Accidental catheter out	4	11	-2.0448	0.05136
Subcutaneous emphysema	2	7	-1.8104	0.0703
Bleeding	0	3	-1.7942	0.07346

Catheter blockage	13	0	3.789	<0.001
Nil complications	32	28	0.5717	0.56868

(Table 3) Catheter blockage was significantly more common with pigtail catheters (p-value < 0.001). There were no statistically significant differences between the two groups for the other complications (accidental dislodgement, subcutaneous emphysema, and bleeding).

Discussion:

Tube thoracostomy, the placement of a chest tube for draining air, blood, or fluid from the pleural cavity, has been the primary approach to treating various pleural disorders for four decades (5). Pigtail catheters and malecot catheters have been utilised for draining pleural collections (6). Malecot catheters were originally created and used for percutaneous nephrostomy procedures. It is made of polyurethane plastic and features a tip shaped like an umbrella, expanding when inserted into the cavity to improve anchoring (7). Pigtail catheters are commonly manufactured from flexible materials such as silicone or polyurethane, enabling easier insertion and lowering the chances of complications during placement (8). Pigtail catheters demonstrate a notably higher rate of re-intervention in comparison, less pain, and less tissue damage to large-bore chest tubes when used for managing pneumothorax, hemothorax, and pleural effusion (9). The present study compared the efficacy and outcomes of pigtail catheters (14F) vs. malecot chest tubes (28F) in the management of empyema thoracis and pyopneumothorax patients. We found that there was no statistically significant difference in baseline characteristics or radiological clearance (lung expansion) in both groups. Our findings are consistent with previous studies by Khare R. et al., who also reported similar results regarding baseline characteristics. Khare R. et al. found no statistically significant difference in age, gender, or anatomical side of pathology. The research results showed that utilising pigtail catheters was linked to a decreased length of hospital stay, less pain, and similar success in comparison to intercostal chest tubes (10). In a study done by Desai et al., out of the 85 patients (34 pleural effusions and 51 pneumothorax) included in the study, pigtail catheters had decreased hospitalisation duration and less pain when contrasted with traditional drainage methods (ICD) (11). A retrospective study by Agrawal et al. (2018) found that pigtail catheters were associated with less pain and shorter hospital stays compared to urosacs for ambulatory chest drainage (12). Similar to other studies mentioned above, our study found that pigtail catheters had a shorter hospital stay and a lower pain score than those with malecot catheters, and the difference was statistically significant. A retrospective study done by Liu et al. (2010) for 276 pleural disease patients found that the success rate for empyema drainage by ultrasound-guided pigtail catheter insertion was 72.2% and concluded that it is an effective and safe method to drain various pleural fluids (13). Jayakrishnan, B. et al. examined the use of ultrasound-guided pigtail catheter insertion to drain pleural fluid in 141 patients and found it to be safe and effective, with a success rate of over 90%. He concluded that ultrasound-guided pigtail catheter insertion is a good option for draining pleural effusions (14). The limitations of the above studies (Liu et al. (2010) and Jayakrishnan, B. et al. (2021)) are that it was a retrospective study and there was no comparison with other chest tubes. However, our study is a randomised prospective interventional study done in 100 patients, mainly focused on the comparison of the efficacy of pigtail catheters and malecot chest tubes. Our study differs from the research done by Chein-Heng Chen et al. (2011). The author retrospectively conducted a comparison study between pigtail catheters and chest tubes in the treatment of parapneumonic effusion among 32 patients, revealing that there were no significant differences in the duration of drainage or length of hospital stay between the two treatment groups (15). This difference might be due to variations in sample size and patient selection

criteria (the sample size was 32 children with a mean age of 14 years, but our study had 100 patients with a mean age of around 35 years). Bediwy and Amer (2012) found that pigtail catheters are generally effective and safe for draining pleural fluid, although they may not be as successful in cases of empyema and loculated effusions. Their study involved the evaluation of 51 pleural effusions, including 5 loculated effusions and 6 empyema cases, which indicated a decreased success rate with pigtail catheters for these specific conditions (16). This difference once again might be due to the relatively small sample size (51 pleural effusions), with only a few cases of empyema (6 cases) and loculated effusions (5 cases). Even in the case of adult thoracic trauma patients, the meta-analysis revealed that pigtail catheters demonstrate favourable outcomes compared to chest tubes. Specifically, pigtail catheters were associated with higher initial drainage volumes and a reduced need for video-assisted thoracoscopic surgical intervention, suggesting they may be a more effective treatment option in this patient population (17).

Conclusion:

Overall, the study suggests that pigtail catheters may be preferable to malecot catheters for chest drainage because they are associated with a shorter duration of hospital stay and lower pain scores.

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