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Original Article

Comparison of the Therapeutic Effects of a Pigtail Catheter and Chest Tube in the Treatment of Spontaneous Pneumothorax: A Randomized Clinical Trial Study

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Abstract

OBJECTIVE: The purpose of this study was to compare the therapeutic effects of a pigtail catheter with a chest tube in the management of patients with spontaneous pneumothorax (SP).

MATERIAL AND METHODS: A randomized controlled trial study was performed on patients with SP from August 2016 to December 2017 at Imam Reza Hospital, Tabriz, Iran. Forty-four patients were randomly assigned into 2 groups: group A with a 14-Fr pigtail catheter and group B using a 28-Fr chest tube. Two patients were excluded from the study.

RESULTS: Forty-two patients participated in the study with 21 patients in each group. There were no significant differences between the groups in the patients' baseline data. The success rate was higher in patients with pigtail catheters (85.7%) than in patients with chest tubes (76.2%). However, the difference was not significant ($P = .43$). The procedure time was significantly shorter in the pigtail group compared to the chest tube group ($P < .01$). According to the visual analog scale (VAS), patients with pigtail catheters experienced milder pain during tube insertion than patients with chest tubes ($P = .02$). However, the pain score at the insertion site was not significantly different between the 2 groups for the first 2 days after the procedure. Patients with pigtail catheters experienced significantly less pain than patients with chest tubes during removal of the tube ($P < .01$). Also, there was no significant difference between the pain experienced by the 2 groups at the time of hospital discharge ($P = .19$). Analgesic drug usage was lower in patients with pigtail catheters compared to patients with chest tubes ($P < .01$). There was a trend toward lower median hospital stays demonstrated by patients with pigtail catheters compared to patients with chest tubes ($P = .2$).

CONCLUSION: Pigtail catheters might be as effective as chest tubes for treating patients with SP in terms of lung re-expansion.

KEYWORDS: Spontaneous pneumothorax, chest tube, pigtail catheter, pain
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INTRODUCTION

Spontaneous pneumothorax (SP) is the presence of air in the pleural cavity without any traumatic injury and includes primary SP (PSP) and secondary SP (SSP).[1-3] PSP occurs in patients who have no history of pulmonary disease, whereas SSP usually occurs in patients who have an underlying parenchymal lung disease.[4-8]

Several techniques have been introduced for the management of SP.[9] Although a small SP is a self-limiting condition that does not require treatment, particularly in asymptomatic patients, patients with large SPs should be treated using simple needle aspiration or a tube thoracostomy.[1] The British Thoracic Society (BTS) 2010 guidelines recommend simple needle aspiration as the first-line treatment for patients with a large PSP, which is defined as ≥ 3 cm from the lung apex to the ipsilateral thoracic cupola.[10] According to the American College of Chest Physicians (ACCP) 2001 guidelines, a small-bore thoracic catheter or a chest tube should be used for the management of a large PSP.[11] In addition, the ACCP guidelines recommend using a conventional chest tube to treat patients with SSP, while the BTS advocates the use of a small-bore pigtail pleural catheter.[10,11] Most surgeons prefer to use a large chest tube to treat patients with SP, although the decision may depend on the preferences of the institution and the discretion of the surgeon.[12]

Some studies have shown that using pigtail catheters and large-bore chest tubes obtain similar results in the management of patients with SP.[1,12] However, there is no consensus about the superiority of one technique over the other in treating patients with SP.[1] In the current study, we compared the efficacy of a small-bore 14-Fr pigtail catheter with a 28-Fr chest tube in treating patients with SP.

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MATERIAL AND METHODS

A single-center randomized controlled trial was conducted on patients with SP from August 2016 to December 2017 at Imam Reza Hospital, Tabriz, Iran. The study protocol was approved by the Research Ethics Committee of the Tabriz University of Medical Sciences and registered in the Iranian Registry of Clinical Trials (registration number: IRCT2016100216077N7). Written informed consent was obtained from all patients before enrollment in the study.

Patients were included in the present study if they were > 18 years old with a symptomatic SP that was > 20% in size, as determined according to the BTS guidelines.[10] Patients who met the following criteria were excluded from the study: had a tension pneumothorax, had severe comorbidity, were pregnant, had a traumatic pneumothorax, did not cooperate, required assisted ventilation, or had a bilateral pneumothorax. Patients with a history of ipsilateral pneumothorax were also excluded from the study.

Initially, all patients were evaluated by emergency physicians and pulmonologists. Laboratory investigations were performed and chest X-rays (CXR) were taken in 2 views for each patient. After a radiologist confirmed the radiological diagnosis of SP, participants were enrolled in the study by a thoracic surgeon. Patients were then randomly allocated into 2 groups using the sealed envelope method. The patients in group A were treated with a 14-Fr pigtail catheter (Cook Medical, Bloomington, IN, USA), while the patients in group B were treated with a 28-Fr chest tube.

Technical Procedures

All procedures were performed in an operating theater by a surgical resident under the supervision of a thoracic surgeon. The initial management included oxygen saturation and cardiac monitoring if the patient's oxygen saturation (SpO_2) was < 92% while breathing room air. The patients were placed in a semi-supine position with the head of the bed elevated to 30-45°. After patients in both groups were administered a local anesthetic of 10-15 mL of 2% lidocaine, a 14-Fr pigtail catheter was inserted at the top of the fourth rib in the midaxillary line using the modified Seldinger technique. The catheter was connected to a 1 way (Heimlich) valve drainage bag. Patients in group B received a 28-Fr chest tube that was inserted laterally in the fourth or fifth intercostal space using the non-trocar technique and blunt dissection with a digital exploration of the pleural space prior to chest tube insertion proposed by the BTS guidelines.[11] The chest tubes were connected to an underwater seal to allow for the slow drainage of air.

A CXR was taken after 8, 24, and 48 hours to assess the position of the tubes and to confirm lung expansion. If lung expansion was not obtained, suction was applied to the collecting system. Once the CXR showed that the lung had reached full expansion, the catheter or chest tube was removed at the surgeon's discretion. The patient was discharged 24 hours after removal of the tube.

All patients received the same oral analgesic for pain relief: 5 mg oxycodone and 500 mg acetaminophen every 12 hours. Patients were also given 30 mg of intramuscular ketorolac every 12 hours on demand (30 mg = 1 unit).

Data Collection

The following demographic and clinical characteristics were collected for each patient: age, gender, size of the pneumothorax, etiology of the SP, treatment method, and length of hospital stay. The size of the pneumothorax was calculated using the Light equation: pneumothorax percentage = $)1 - L^3/H^3) \times 100\%$, where L is the diameter of the collapsed lung and H is the involved hemithorax diameter.[13] The visual analog scale (VAS) was used as a subjective measure to assess pain intensity: 0 indicated no pain and 10 indicated the worst pain.[14] The pain intensity at the insertion site was evaluated by the patient's nurse using the VAS at the time of the tube insertion, 2 hours after insertion to reduce the effect of the local anesthesia and 24 and 48 hours after tube insertion; the nurse was blinded to the outcomes of the treatment and administration of the analgesics.

The length of hospital stay was defined as the primary endpoint. Success was indicated by complete lung expansion during hospitalization. Secondary endpoints included the procedure time, the severity of the pain at the insertion site, the total dose of analgesic used, the rate of success in lung expansion, and the rate of tube-related complications.

Statistical Analysis

The sample size for the study with a 90% power and a 95% confidence coefficient was calculated according to the Cochrane equation to include 40 patients, which was increased to 44 patients to obtain a continuity correction rate of 10%. Therefore, 44 patients were enrolled in the study with a distribution of 22 patients in each group.

All data were collected and analyzed using the Statistical Package for the Social Sciences version 23.0 (IBM SPSS Corp.; Armonk, NY, USA) program. The demographic and descriptive data were expressed as a frequency (%) for the qualitative variables and as the mean ± standard deviation for the quantitative variables. The Student's *t*-test was used to compare quantitative variables between groups, while the chi-square test was used to compare 2 qualitative variables at a particular time and between times. In this study, a *P*-value of < .05 was considered to be statistically significant.

MAIN POINTS

- Patients with pigtail catheters experience less pain during implantation and removal.
- The pigtail catheter placement may be useful for the treatment of spontaneous pneumothorax.
- Patients received a pigtail catheter experience a shorter procedure time.

RESULTS

A total of 55 consecutive patients with SP were screened over 2 years. Eleven patients were excluded from the study because they refused to participate (n = 4), had a bilateral pneumothorax (n = 2), had a previous history of pneumothorax (n = 2), was pregnant (n = 1), had hydropneumothorax (n = 1), or was < 18 years old (n = 1). The 44 patients

recruited into the study were divided into 2 groups: group A consisted of 22 patients (50%) who were treated with a pigtail catheter, while group B had 22 patients (50%) who were treated with a chest tube. During follow-up, 1 patient in group A was transferred to a private center and 1 patient in group B refused further cooperation and, thus, were excluded from the study. Therefore, a total of 42 patients with SP were analyzed (Figure 1).

Table 1 presents the clinical characteristics of the patients. In group A, 17 patients (81%) had PSP, while 18 patients (85.7%) in group B had PSP. Four patients (19%) in group A had SSP, while 3 patients in group B had SSP (14.3%). There were no statistically significant differences between the study groups in the rate of PSP ($P = .68$) and SSP ($P = .67$).

As indicated in Table 2, patients who received a pigtail catheter had a shorter procedure time (6.95 ± 1.62 minutes) than patients who had a chest tube (10.29 ± 2.49 minutes), which was a statistically significant difference ($P < .01$). The need for analgesics was also significantly lower in patients with pigtail catheters compared to patients with chest tubes ($P < .01$).

Table 2 also lists the complications that occurred after each intervention. In our study, there were no major complications that required surgery. Although the occurrence of minor complications was slightly higher in patients with a chest tube, the prevalence of tube-related complications was not significantly different between the 2 groups ($P = .7$). When accidental kinking occurred in the tube or the tube was dislodged, the pigtail catheter or chest tube was replaced or repositioned to increase chest drainage if the CXR showed that the pneumothorax was significant.

An assessment of pain during tube insertion using the VAS indicated that patients in group A experienced significantly milder pain compared with patients in group B ($P = .02$). The

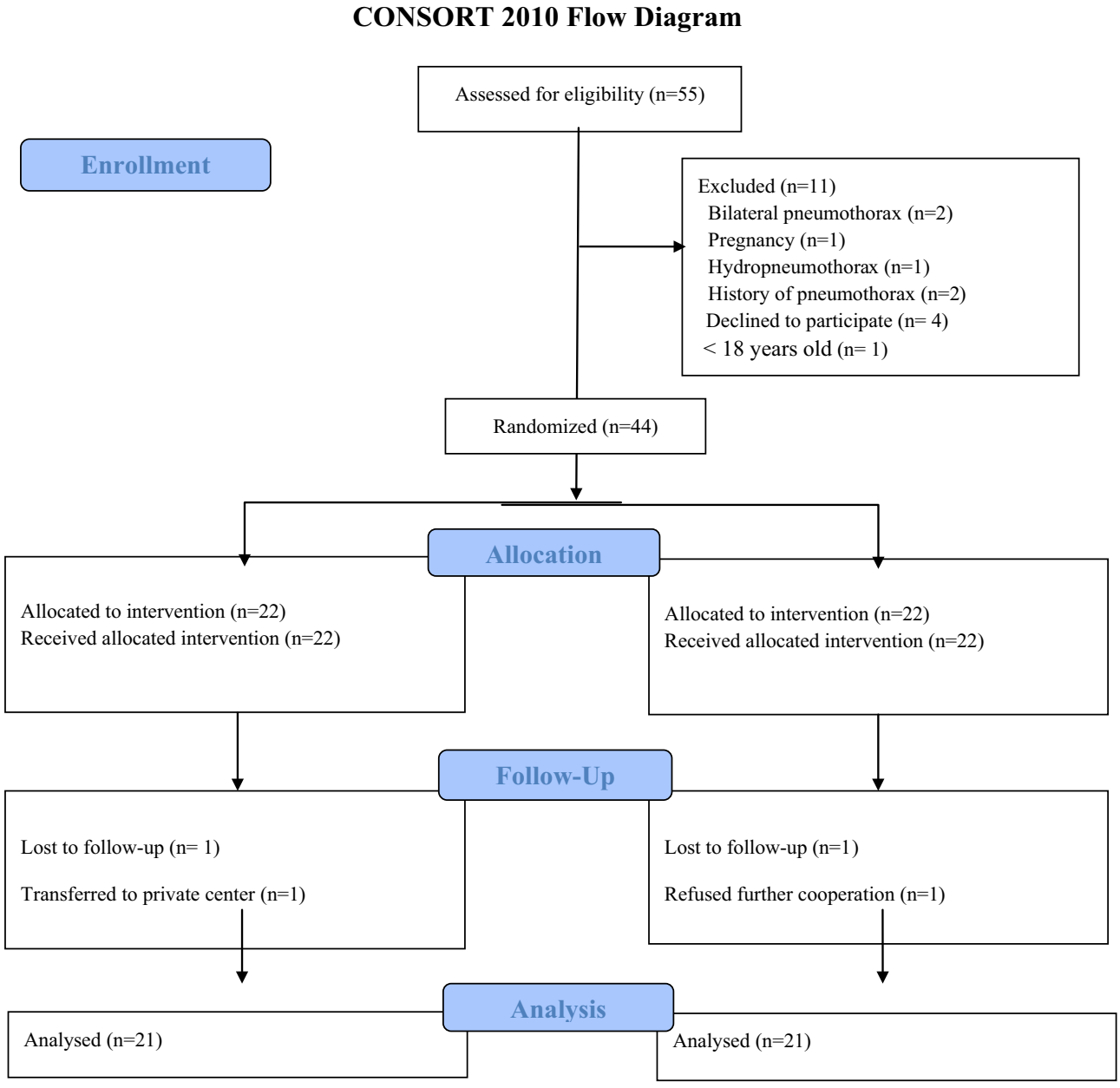

Figure 1. The CONSORT flow diagram.

Table 1. Patients' Demographic Data

	Pigtail (*n* = 21)	Chest tube (*n* =21)	*P*
Age (year)	41.05 ± 15.13	40.81 ± 14.35	.96
Gender			
Male	16	15	.72
Female	5	6	
Pneumothorax			
Primary	17 (81%)	18 (85.7%)	.68
Secondary	4 (19%)	3 (14.3%)	
Smoking	10 (47.6%)	13 (63.3%)	.35
Side of PTX			
Right	8 (38.9%)	11 (52.7%)	.35
Left	13 (61.1%)	10 (47.3%)	
Size of PTX (%)	59 ± 20	60 ± 18	.17

Table 2. Comparison of Outcomes of Pigtail versus Chest Tube Insertion in Patients with SP

	Pigtail	Chest tube	*P*
Procedure time (minute)	6.95 ± 1.62	10.29 ± 2.49	<.01
Lung re-expansion (day)	6.52 ± 2.23	7.35 ± 1.11	.21
Hospital stay (day)	7.71 ± 2.17	8.48 ± 1.16	.2
Complication (ratio)	4/21	5/21	.7
Pain medication usage (unit)	4.8 ± 0.5	6.1 ± 0.4	<.01
Success rate (ratio)	18/21	16/21	.43

pain at the insertion site was also evaluated and compared between the 2 groups for the first 2 days after the procedure. There was no significant difference between the pain at the insertion site of the pigtail catheter or the chest tube on day 1 and day 2; 5.33 ± 0.88 for group A and 5.38 ± 1.07 for group B (P = .87) and 3.76 ± 0.88 for group A and 4.29 ± 1.1 for group B (P = .1), respectively. The pain was also assessed at the time of tube removal. Patients with pigtail catheters had significantly less pain than patients with chest tubes (P < .01).

Figure 2 shows there was no trend toward a significant difference between the 2 groups in terms of pain at the time of hospital discharge (P = .19).

The rate of success was slightly higher in patients with pigtail catheters (85.7%) than in patients with chest tubes (76.2%). However, the difference was not significant (P = .43). Three patients in group A and 5 patients in group B had unsuccessful drainage and underwent a thoracoscopic bullectomy and mechanical pleurodesis. The median hospital stays were lower for patients in group A than for patients in group B, although there was no significant difference between the 2 groups (P = .2) (Table 2).

DISCUSSION

SP is a relatively common clinical presentation. Despite several improvements in the management of patients with SP, recommendations for treating SP vary according to published guidelines.[10,11,15] Common treatment options include observation with oxygen supplementation, simple needle aspiration, the use of a pigtail catheter, and placement of a chest tube.[16]

There are debates about the efficacy and postoperative benefits of treating patients with SP with a pigtail catheter and a chest tube.[1] In addition, a recent well-designed randomized controlled trial on 316 patients with SP showed that there was no advantage in treating patients with interventional management over conservative observational management. However, the study indicated that 15.4% of patients in the conservative management group required interventions to treat the SP.[2]

The current study was a randomized clinical trial of 42 patients with a large SP. The results showed that there was a significant reduction in the procedure time for patients who were treated with pigtail catheters compared to patients who received chest tubes. To our knowledge, this is the first study that compared the duration of the pigtail catheter procedure with that of the chest tube procedure in adults. However, 1 study compared the procedures in 66 premature infants and found that pigtail catheter insertion involved a shorter procedure time than chest tube insertion, which was consistent with our findings in adult patients.[17]

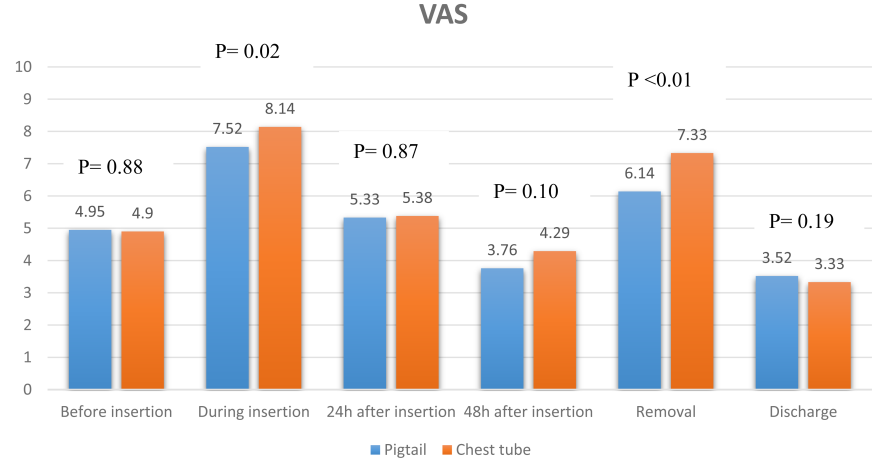

Figure 2. Mean visual analog scale tube-site pain.

In the present study, patients with pigtail catheters had significantly less pain at the time of insertion and tube removal than patients with chest tubes. Our results were similar to other studies. For example, Cafarotti et al.[18] conducted a retrospective study on 1092 patients and showed that the average pain experience of patients at the time of insertion of a small-bore wire-guided chest drain was mild with a VAS score of 4.6 mm.[18] Rahman et al.[19] studied the pain score of 128 patients who received different sizes of chest tubes and found that patients who received small wire-guided chest tubes (<10-Fr) had lower median pain scores than patients who received large chest tubes (>20-Fr).[19]

A review of the literature indicated that the duration of analgesic usage was significantly shorter in patients who received pigtail catheters than in patients who received chest tubes. For example, Hantera et al.[20] studied 60 patients with empyema and reported that the duration of analgesic use was significantly shorter in patients with pigtail catheters (mean of 2.57 days ± 0.77 days) than in patients with chest tubes (mean of 4.93 ±1.51 days); it was thought that pigtail catheters caused less pain because they did not compress the neurovascular bundle.[20] Furthermore, a study that assessed the intercostal nerve function in 16 patients using a series of 2000 Hz (Aβ fiber), 250 Hz (Aδ fiber), and 5 Hz (C fiber) stimuli and current perception threshold testing (Neurometer CPT/C®) revealed that chest tube insertion had detrimental effects on intercostal nerve function, which was associated with neuropathic pain after the procedure.[21]

In a randomized clinical study, Kulvatunyou et al.[22] compared the pain scores and use of analgesics in 40 patients with traumatic pneumothorax treated with 14-Fr pigtail catheters and 28-Fr chest tubes. The researchers reported that the use of analgesic drugs and the pain scores at the site of the tube and after 2 days were lower in patients who had a pigtail catheter compared with patients who had a chest tube respectively ($P = .040$).[22] Surprisingly, the results of the current study did not trend toward a significant reduction in pain at the insertion site after 2 days in patients who received a pigtail catheter compared with patients who had a chest tube. It can be hypothesized that careful pre-procedure preparation by experienced medical personnel preserved the intercostal nerves, which resulted in a decrease in the intensity of acute pain in patients who received a pigtail catheter and a chest tube. In addition, because of its small size, the pigtail catheter is less invasive and, thus, may have caused patients to experience milder pain during its insertion and removal than patients with a chest tube. The increased pain that patients felt at the site of the large-bore chest tube may have been associated with increased tissue trauma that occurred during insertion of the tube. The inflexibility and straight structure of a chest tube with a stiff tip may have also contributed to the pain felt at the insertion site.

Several studies have reported that the length of hospital stay was significantly shorter in patients who received pigtail catheters to treat SP than in patients who had a chest tube inserted.[23,24] For example, a retrospective study by Contou et al.[25] indicated that the duration of hospital stay was significantly shorter in the 112 patients who received small catheters compared to the 100 patients who had a chest tube: 4.5± 3.2 days and 5.5 ± 3.0 days, respectively ($P = .02$). Chang et al.[1] reported that patients treated with pigtail catheters had significantly shorter hospital stays than patients with chest tubes ($P < .001$). Conversely, in the present study, the hospital stays were not significantly longer in patients with a chest tube. Other studies have shown that there was no significant difference in the length of hospitalization between patients with a chest tube and patients with a pigtail catheter.[12,26] We believe that the heterogeneous data and few studies about the length of hospital stays included in the analysis by Chang et al.[1] influenced the findings. Therefore, there is a need for further studies to investigate how the treatment method affects the length of hospitalization stay in patients with SP.

Some studies indicated that there was no significant difference in terms of the prevalence of complications between patients who received a pigtail catheter and patients who had a chest tube.[1,27] Similarly, our results showed that there were no significant complications in either study group. However, a clinical trial conducted by Hussein et al.[28] on 22 patients reported a lower prevalence of complications in patients who had a small-bore tube compared with patients who received a large-bore chest tube. A retrospective study of 73 patients by Benton and Benfield[29] revealed that patients with a large-bore drain had a higher complication rate (32%) than patients with a small-bore drain (5%; $P < .02$). Studies on the treatment of traumatic pneumothorax showed that the complication rate was similar in patients treated with a pigtail catheter and a large-bore chest tube.[22,30] Other studies indicated that patients with SP who were treated with a pigtail catheter had a significantly lower complication rate than those treated with a large-bore chest tube.[12,28,31]

Our study demonstrated that pigtail catheters had a slightly higher efficacy than chest tubes; the success rate was 85.7% for pigtail catheters and 76.2% for chest tubes. We found that the pigtail catheter was useful for the management of both PSP and SSP. Our results agreed with several studies. For example, a retrospective study of 168 patients by Chen et al.[32] showed that the pigtail catheter is appropriate as an initial treatment for patients with SP associated with obstructive lung diseases and malignancies. Similarly, the results of a retrospective comparative study showed that small-bore catheters were as effective as chest tubes for treating patients with SP[25] In a prospective study of 41 patients, Kuo et al.[31] found that pigtail catheters and chest tubes had a similar efficacy; the study also found that patients treated with pigtail catheters had lower rates of recurrence than patients with chest tubes. In a meta-analysis of 11 investigations involving 875 patients, the success rate was found to be similar between patients treated with a pigtail catheter and those treated with a large-bore chest tube.[1] In addition, an analysis of the subgroups according to the type of pneumothorax (i.e., traumatic, spontaneous, or iatrogenic) showed that there were no significant differences in the success rate between patients treated with a pigtail catheter and patients treated with a large-bore chest tube.[1]

The current study had some limitations. First, the small patient population did not allow us to make an accurate assessment of the performance of the pigtail catheter. Future large

randomized clinical trials could be performed to confirm our results. Second, although the CXR is a widely used modality for diagnosing SP, it was difficult to accurately measure the volume of the pneumothorax due to the 2-dimensional images. Another limitation was that the follow-up period was restricted to the length of stay in hospital; studies with long follow-up periods would achieve more valuable results. This study was also limited by the fact that the procedures were performed by surgical residents who may have influenced some of the study outcomes because of their experience and skills. Finally, because pigtail catheters are expensive, they were not available in all medical centers.

In conclusion, the results obtained from our study suggested that the use of pigtail catheters to treat patients with SP might decrease the procedure time, reduce the pain score during insertion of the tube, and reduce analgesic drug usage when compared with the use of a chest tube. However, those might not be effective in terms of the outcome, such as the success rate and the hospital stays. We determined that the placement of a pigtail catheter is safe to perform and could be considered as a first-line treatment in patients with SP.

Ethics Committee Approval: Protocol was approved by the Regional Ethics Committee headed by the Vice-Chancellor of Research and Development at Tabriz University of Medical Sciences and registered in the Iranian Registry of Clinical Trials: IRCT registration number: IRCT2016100216077N7. Registration date: 2016-10-20, 1395/07/29

Informed Consent: Written informed consent was obtained from all patients before enrollment in the study.

Peer Review: Externally peer-reviewed.

Author Contributions: Concept - SZ.R.; Design - SZ.R., A.R.; Supervision - SZ.R.; Resources - SZ.R. A.R.; Materials - SZ.R. H.A.; Data Collection and/or Processing - A.R., H.A.; Analysis and/or Interpretation - A.R., H.A.; Literature Search - SZ.R. A.R., H.A. ; Writing Manuscript - SZ.R., A.R. H.A. ; Critical Review - SZ.R., H.A.

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