A randomized controlled study compares lung ultrasonography to fiberoptic bronchoscopy confirming double lumen tube positioning for thoracic surgery

Study Protocol
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Sawita Kanavitoon, MD[a],
[a]Department of Anesthesiology, Faculty of Medicine Siriraj hospital, Mahidol university, Bangkok, Thailand
Kasana Raksamani, MD[a],
[a]Department of Anesthesiology, Faculty of Medicine Siriraj hospital, Mahidol university, Bangkok, Thailand
Aphichat Suphathamwit, MD[a],
[a]Department of Anesthesiology, Faculty of Medicine Siriraj hospital, Mahidol university, Bangkok, Thailand
Punnarerk Thongchareon, MD[b] ,
[b]Department of Surgery, Faculty of Medicine Siriraj hospital, Mahidol University, Bangkok, Thailand
Sirilak Suksompong, MD[a]
[a]Department of Anesthesiology, Faculty of Medicine Siriraj hospital, Mahidol university, Bangkok, Thailand

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Background

Double-lumen endobronchial tubes is one of well-known technique for one-lung ventilation due to simplicity and high success rate of lung separation compare with bronchial blocker(1). The Blind technique is a current popular method for lung separation compare with the fiberoptic-guided method due to simplicity and a shorter period time to apply(2). Because blind intubation for double lumen tube is still more popular, evaluation for tube position is an essential part of the practice. The sensitivity of clinical guided for good lung collapse was 84.5% and specificity 41.1%(3) and even lower in an older study(4, 5), which was unreliable and vary due to subjective skills. Recently, evidence nowadays recommended the use of clinical and fiberoptic-guided check for the proper position(6).

Currently, fiberoptic bronchoscopy for evaluation for the position of DLT was considered as the gold standard. Not only evaluation for positioning, but also an adjustment for tube position(7). Though, proper tube positioning is not equal lung collapse. And in some patients with abnormal anatomy or secretion or bleeding in the airway, fiberoptic bronchoscopy is difficult or even impossible.

Instead, lung ultrasonography is a novel, safe and easy way to detect lung collapse, which has high sensitivity and specificity(5). There is also a study report 88% of accuracy of lung ultrasound in the diagnosis of anesthesia-induced atelectasis in children(8,9). The recent study also reports superior lung ultrasonography over clinical methods. Meanwhile, the misplacement of DLT in both groups could not be ensured(3). Therefore, this method might be useful for caring for thoracic patients. However, due to its new method, lung ultrasonography needs some practice and learning curve(10).

Objectives: This study aimed to demonstrate that using lung ultrasonography to confirm lung collapse resulted from proper positioning of the double lumen tube (DLT) is a comparable method to using fiberoptic bronchoscopy to confirm the DLT position.

Design: a non-inferiority randomized controlled study

Setting: A tertiary care university hospital, single institution

Participants: Two-hundreds patients with ASA classification 1-3 scheduled for elective thoracic surgery who require a left-side double lumen tube were enrolled and randomized into 2 groups. Five patients were dropped out from the protocol deviation.

Interventions:

In group FOB (n=98), standard fiberoptic bronchoscope was used to confirm the position of the DLT and adjusted the tube to proper position, while in group US (n=97), lung ultrasound was scanned in 4 zones including upper and lower lobe at flank and back of patient at the side of surgery to confirm the lung collapse resulted from proper positioning of the DLT and used to aid repositioning of the DLT if required.

Outcome Measurements: The degree of lung collapse was determined by visual grading by surgeon. Time used to adjust the DLT position was recorded.

Statistical Analysis

Sample size calculation was performed by *Mario de Bellis et al* (11)report that fiberoptic bronchoscopy provided a sensitivity of 95% for optimal LDLT position. Moreover, *Parab et al(5)* and *Chou et al(12)* report the sensitivity of lung ultrasonography to confirm lung collapse at 88-100%. As a result, we hypothesized that lung ultrasonography is not inferior to fiberoptic bronchoscopy (non-inferiority study). Non-inferiority margin equal 10% with significant *p*-value as 0.05, power 90%, the sample size each group equal 82 cases. Furthermore, concerning drop out about 15%, sample size of each group was 100. Sample size calculation was demonstrated from n4Studies as

$$n_2 = \frac{(z_{1-\alpha} + z_{1-\beta})^2}{(\epsilon - \delta)^2}\left[\frac{p_1(1-p_1)}{k} + p_2(1-p_2)\right]$$

$$\epsilon = p_1 - p_2, \quad k = \frac{n_1}{n_2}, \quad n_1 = kn_2$$

For a non-inferiority or superiority trial for binary data

Proportion in group1 (p1) = 0.950

Proportion in group2 (p2) = 0.950

Non-inferiority or superiority margin (δ) = 0.100

Ratio between 2 groups (k) = 1.0

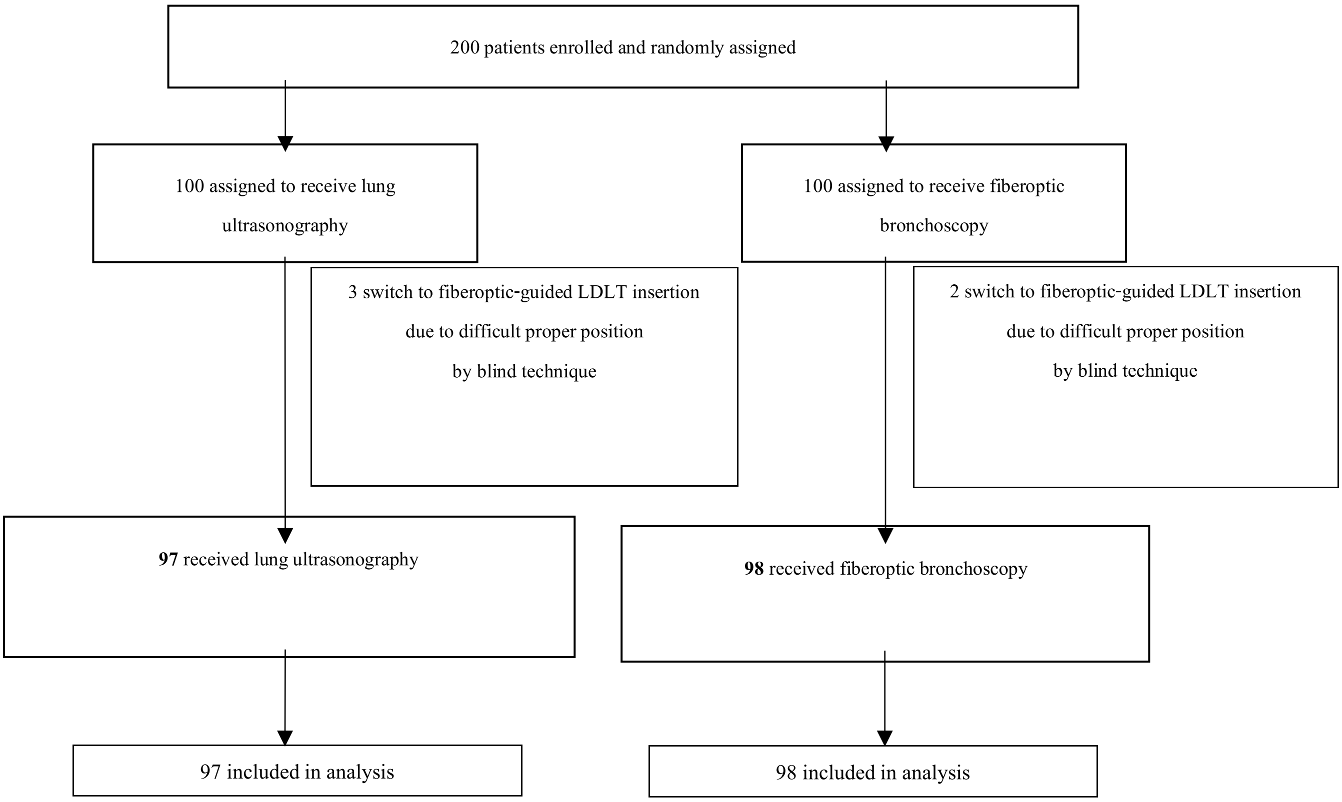
Alpha (α) = 0.05, Z (0.950) = 1.644854

Beta (β) = 0.10, Z (0.900) = 1.281552

Sample size: n1 = 82, n2 = 82

Statistical analysis was performed using SPSS version 18 for Windows (Chicago, USA). Continuous data were presented as the means and SD and statistical significance was considered when $p<0.05$. The positive predictive value was calculated to determine the effectiveness of lung ultrasound compared to fiberoptic bronchoscopy and defined as follow:
Positive predictive value (%) = TP/(TP+FP) x100

Figure 1: Trial profile



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