Contemporary Clinical Trials Communications 9 (2018) 60–63

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

LOGIS (LOcalization of Ground-glass-opacity and pulmonary lesions for mInimal Surgery) registry: Design and Rationale

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ARTICLE INFO

Keywords:
Ground-glass opacity (GGO)
Localization
Lipiodol
Hook-wire
Video-assisted thoracic surgery (VATS)

ABSTRACT

Background and purpose: An optimal pulmonary localization technique for video-assisted thoracic surgery (VATS) of small lung nodules has not yet been established. The LOcalization of Ground-glass-opacity and pulmonary lesions for mInimal Surgery (LOGIS) registry aims to establish a multicenter database and investigate the usefulness and safety of localization techniques for small pulmonary lesions in individuals undergoing VATS.
Methods/Design: The LOGIS registry is a large-scale, multicenter cohort study, aiming to enroll 825 patients at 10 institutions. Based on the inclusion and exclusion criteria, all study participants with pulmonary lesions indicated for VATS will be screened and enrolled at each site. All study participants will undergo preoperative lesion localization by the hook-wire or lipiodol localization methods according to site-specific methods. Within a few hours of marking, thoracoscopic surgery will be done under general anesthesia by experienced thoracoscopic surgeons. The primary endpoints are the success and complication rates of the two localization techniques. Secondary endpoints include procedure duration, recurrence rate, and all-cause mortality. Study participant enrollment will be completed within 2 years. Procedure success rates and incidence of complications will be analyzed based on computed tomography findings. Procedure duration, recurrence rate, and all-cause mortality will be compared between the two techniques. The study will require 5 years for completion, including 6 months of preparation, 3.5 years for recruitment, and 1 year of follow-up endpoint assessment.
Discussion: The LOGIS registry, once complete, will provide objective comparative results regarding the usefulness and safety of the lipiodol and hook-wire localization techniques.

1. Introduction

The diagnosis rate of small pulmonary lung nodules has been increasing with the increasing use of computed tomography (CT) in lung cancer screening and daily practice [1–3]. While malignancy rates of small pulmonary lesions depend on nodule size and characteristics, they are not negligible upon with subsolid nodules as well as solid nodules [4,5]. Therefore, proper management of small pulmonary nodules is an important issue [6]. Because of its safety and minimal invasiveness, video-assisted thoracoscopic surgery (VATS) is widely used for diagnosis and treatment of small pulmonary nodules [7]. However, if the targeted pulmonary lesion is too small or too deeply located to be

Abbreviations: CT, computed tomography; eCRF, electronic case report form; GGO, ground-glass opacity; LOGIS, LOcalization for Ground-glass opacity and pulmonary lesions for mInimal Surgery; NAB, needle aspiration biopsy; VATS, video-assisted thoracic surgery

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https://doi.org/10.1016/j.conctc.2017.12.001
Received 9 July 2017; Received in revised form 5 December 2017; Accepted 6 December 2017
Available online 07 December 2017

visible or palpable, pre-VATS localization is mandatory for successful minimally invasive surgery without open thoracotomy conversion [8–10].

Pulmonary localization techniques for small lung nodules vary greatly and employ various materials or methods [11–14]. However, an optimal pulmonary lesion localization method that is effective and safe for VATS has not yet been established. Currently, CT-guided hook-wire localization is the most widely used method for pre-VATS localization [15]. However, a previous meta-analysis reported that CT-guided hook-wire localization exhibited a lower success rate and higher complication rate than microcoil and lipiodol localization [16]. Lipiodol localization for small lung nodules prior to VATS has been reported to be accurate and safe, with high success rates and low complication rates [13,17,18]. Pulmonary lesion localization using lipiodol has been consistently reported as exhibiting a success rate of over 90% [16]. The ongoing LOcalization of Ground-glass-opacity for mInimal Surgery (LOGIS) trial involves comparison of effectiveness and post-procedural complications between the hook-wire and lipiodol localization methods for VATS resection of ground-glass opacity (GGO) lesions [15]. However, depending on nodule characteristics and operator experience, there could be variations in results. Therefore, it is necessary that multi-institutional cohorts of a larger scale be established to comparatively evaluate the safety and effectiveness of various pulmonary lesion localization techniques.

2. Materials and methods

2.1. Overall study design

The LOcalization of Ground-glass-opacity and pulmonary lesions for mInimal Surgery (LOGIS) registry is a retrospective and prospective multicenter registry of patients who have undergone or will undergo pulmonary lesion localization by the hook-wire or lipiodol method prior to pulmonary VATS (Fig. 1).

2.2. Study objectives

This study aims to establish a multicenter registry of pulmonary-lesion localization techniques and investigate the usefulness and safety of two different localization methods for small pulmonary lesions in individuals undergoing VATS.

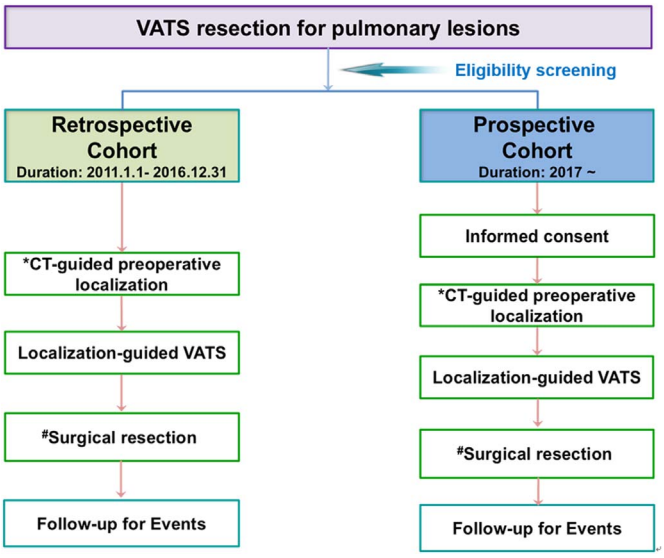

Fig. 1. Overall study design of the LOGIS registry.

2.3. Ethical considerations

The institutional review board of each participating institution reviewed and approved the study protocol. Informed patient consent will be obtained for the prospective cohort, and its requirement will be waived for the retrospective cohort. Patient records and data will be anonymized and de-identified prior to analysis.

2.4. Funding

The LOGIS registry is a physician-initiated registry, sponsored by Guerbet. Therefore, the authors are solely responsible for the design and conduct of this study, analysis of all study data, and drafting and editing of the manuscript, as well as its final contents.

2.5. Targeted population

Based on the inclusion and exclusion criteria, all subjects with pulmonary lesions indicated for VATS, including solid and GGO nodules, will be screened and enrolled at each site.

The inclusion criteria are as follows: consenting adults who is equal or older than 19 years of age; pulmonary lesions (solid nodules or GGO nodules) indicated for VATS; no contraindications for surgery; and willingness to sign the informed consent form.

The exclusion criteria are: contraindication for surgery; uncooperative behavior; severe neurologic or physiologic problems; unwillingness or inability to provide informed consent; and pregnancy.

2.6. Study endpoints

The primary endpoints of the LOGIS registry are the procedure success rates and complication rates of the lipiodol and hook-wire localization methods. Secondary endpoints include procedure duration, recurrence rate, and all-cause mortality. Procedure duration is defined as the period from the start of pre-localization CT to the end of pulmonary-lesion localization. The end of localization is defined as the time at which the needle leaves the lungs after lipiodol administration or the time at which the hook-wire is anchored onto the lesion. Recurrence is defined by the discovery and diagnosis of new lesions through histological examination or medical imaging during the follow-up period. All-cause mortality includes death from any reason.

2.7. Participating sites and eligibility criteria for participation

The requirements for participating sites to contribute to the LOGIS registry are same as those stipulated for the LOGIS trial [15].

Minimum requirements for participating sites include:

(1) Experienced radiologists who have at least 1 year of experience with at least 30 cases of lipiodol or hook-wire localization for pulmonary nodules
(2) Experienced thoracic surgeon who has at least 3 years of experience with at least 100 cases of VATS
(3) Multi-detector CT scanner (≥16-slice) for localization

Overall ten university hospitals are participating in this multicenter registry. The lipiodol-guided localization group is consisted of five hospitals and the hook-wire-guided localization group is composed of the remaining five hospitals, based on their routine localization practices at each site.

2.8. Patient recruitment and evaluation

The LOGIS registry includes patients who have undergone or will undergo VATS for lung lesions after localization by the lipiodol or hook-wire methods. Following surgery, patient demographic characteristics,