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FINAL REPORT

Project Title		Randomised controlled trial comparing the diagnostic CT guided transthoracic biopsy Vs cryobiopsy (via the Radial Endobronchial ultrasound guide sheath), in parenchymal pulmonary lesions suspected of lung cancer.
Name		Dr Samantha Herath
Award Received		2017 Basser Reaserch Entry Scholarship
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Chief Investigator / Supervisor		A/Prof Alvin Ing
Administering Institution		The University of Sydney
Funding Period	Start Date:	1 January 2017
	Finish Date:	31 December 2017

PROJECT SUMMARY

Lung cancer is the leading cause of cancer death worldwide. Lung cancer causes more deaths in the population than the combined death rate of breast, prostate and colon cancers. Moreover, lung cancer also has a poor survival rate with only 14% of patients diagnosed with lung cancer surviving up to 5 years. There is emerging data showing that every centimetre growth of the size of the tumour, would reduce this 5 year survival by around 10%. Therefore, early diagnosis and definitive curative treatment commenced early gives the best chance of improving survival from this deadly disease.

To diagnose lung cancer, a sample of tissue called a "biopsy" from the abnormal lung area should be taken and analysed. This analysis not only confirms if it's cancer or not but is also used for multitude of advanced tests including molecular markers and gene mutations. Having a mutation or a favourable molecular marker would remarkably improve the chance of patients leading a much more productive symptoms free lengthier survival. Increasingly more and more molecular markers are being identified making lung cancer treatment truly personalised medicine. Therefore, once an abnormal lung area is noted, obtaining the largest tissue sample at the earliest possible opportunity with the least anticipated side effects would give the best chance of cure to the patient. This study aims at developing and establishing novel minimally invasive bronchscopic diagnostic methods that can be used to obtain a larger sized biopsy, capable of all above mentioned tests with markedly improved safety profile for the patient. Lesser side effects during a procedure invariably amounts to less patient cost and inconvenience as well as reduced healthcare costs overall. In this novel method a flexible bronchoscopy which is a thin long tube is used via the mouth whist the patient is under a general anaesthesia. Through this bronchoscope we have the ability to perform an internal ultrasound scan of the lungs called Radial EBUS. This USS is capable of locating the tumour and once the area is identified biopsies are taken. The new

addition is a biopsy called cryobiopsy or "cold biopy" Essentially this is a thin probe that is passed through the bronchoscope that freezes the lung abnormality, so that it could be extracted without damaging the tissue. There is no pain or discomfort to the patient during this freezing period. In published studies so far the side effect profile had been extremely favourable with the pneumothorax rate being less than 1%. The currently used method for obtaining a lung biopsy, that had been in use for many decades.

PROJECT AIMS / OBJECTIVES

The primary objective is to compare the diagnostic accuracy of cryobiopsy against the CTguided

biopsy for Peripheral Pulmonary Lesions Secondary study objectives

1. To compare the suitability for subtyping and molecular testing (EGFR/ALK testing) between cryobiopsy and CT-guided biopsy.

2. Assess the additional diagnostic benefit of cryobiopsy over conventional R-EBUS biopsies in the same patient.

3. Compare the safety profile between the cryobiopsy technique and CT-guided biopsy for Peripheral pulmonary lesions.

4. Compare the relative cost effectiveness between cryobiopsy and CT-guided biopsy.

SIGNIFICANCE AND OUTCOMES

Lung cancer is the leading cause of cancer death worldwide. Lung cancer causes higher death rate in comparison to the death rate of combined prostate, breast and bowel cancers. Research now clearly demonstrates that even a centimetre increment in the lung mass could cause a significant reduction in the patient survival and that earlier the diagnosis, better the survival. Hence this study is looking at a novel bronchoscopic biopsy method "cryobiopsy" or cold biopsy that can be used to perform these lung biopsies to obtain larger tissue samples with minimal side effect profile. This novel method of biopsy could be employed in a larger group of patients than the current CT gold standard for lung biopsy the CT guided biopsy as the procedure can be done in patients with lesser lung function, is performed under general anaesthesia and does not require the patient to maintain a certain body position for the procedure and does not require to do a breath holding manoeuvre. The cryobiopsies are larger tissue biopsies with well-preserved architecture, therefore, the specimen can be used as histology sample to assess for multitude of molecular and genetic markers. This project aims to introduce and standardise procedural training and dissemination of knowledge of this novel, safer technique of lung biopsy.

PUBLICATIONS / PRESENTATIONS

1. Publications in submission: Cryobiopsy used in combination with Radial EBUS gives better diagnostic yield in comparison to Radial EBUS alone. Case series. Submitted awaiting review 2017 July.

2. Abstract presentations: 1. RCore Study: Using the Novel Gen Cut Core Biopsy needle to obtain a Radial Core biopsy