Lung cancer investigation, treatment and survival

P194 | **ONCE-DAILY QVA149 PROVIDES SUPERIOR BRONCHODILATION AND IMPROVES LUNG FUNCTION VERSUS TWICE-DAILY FLUTICASONE/SALMETEROL IN COPD PATIENTS: THE ILLUMINATE STUDY**

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Introduction QVA149 is a novel inhaled once-daily dual bronchodilator containing a fixed-dose combination of the long-acting β_2-agonist (LABA) indacaterol and the long-acting muscarinic antagonist (LAMA) glycopyrronium, in development for the maintenance treatment of COPD. This study evaluated the superiority of QVA149 once daily in terms of efficacy over fluticasone/salmeterol twice daily in patients with COPD.

Methods In this 26 week, multicentre, double-blind, double-dummy, parallel-group study patients aged ≥40 years with moderate-to-severe COPD (post-bronchodilator $FEV_1/FVC < 0.7$ and FEV_1 ≥40% to <80% predicted), no history of exacerbations in the previous year and smoking history ≥10 pack-years, were randomised (1:1) to receive QVA149 110/50µg (via the Breezhaler® device) or fluticasone/salmeterol 500/50µg (via the Accuhaler® device). The primary efficacy end point was standardised FEV_1 area under the curve (FEV_1 AUC_{0-12h}) at Week 26. The pre-dose trough FEV_1 on Week 12 and 26 and peak FEV_1 on Day 1, Week 12 and Week 26 were also measured.

Results A total of 523 patients (35.1% on inhaled corticosteroids use) were randomised [QVA149, n=259; fluticasone/salmeterol, n=264; male (70.9%); mean age: 63.3 years; mean post-bronchodilator FEV_1: 60.2% predicted], 82.6% completed. FEV_1 AUC_{0-12h} was found clinically meaningful and statistically significant in favour of QVA149 compared to fluticasone/salmeterol on Day 1, Week 12 and Week 26 (Least squares mean [LSM] treatment difference=70mL, 120mL, 140mL, respectively; all p<0.001). Pre-dose trough FEV_1 was significantly (p<0.001) higher for QVA149 compared with fluticasone/salmeterol at Week 12 and 26 (LSM treatment difference=90mL and 100mL, respectively; p<0.001). The LSM treatment difference for peak FEV_1 was also statistically significant for QVA149 compared with fluticasone/salmeterol on Day 1 (70mL), Week 12 (150mL) and Week 26 (150mL), all p<0.001.

Conclusion QVA149 once daily provided superior bronchodilation at all time-points compared to fluticasone/salmeterol twice daily and showed clinically meaningful improvements in lung function for a sustained period of 26 weeks. In moderate-to-severe COPD patients without a history of exacerbations in the previous year, LABA/LAMA dual bronchodilation with once-daily QVA149 proves a superior alternative to twice-daily fluticasone/salmeterol.

P195 | **CASE SERIES: HOW USEFUL ARE FLEISCHNER GUIDELINES FOR NODULE SURVEILLANCE IN A DISTRICT GENERAL HOSPITAL?**

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Background Surveillance of pulmonary nodules aims to identify early-stage lung cancers where radical therapy can offer cure. Interval CT scans track nodule characteristics with Fleischner criteria commonly used in an attempt to standardise care. There remains debate regarding the applicability of Fleischner guidance in populations of UK patients that can differ substantially from those included in existing studies that define the Fleischner recommendations.

Objectives

- Audit compliance of pulmonary nodule follow up with Fleischner Guidelines.
- Compare local outcomes with those used to create Fleischner guidelines.
- Compare local compliance with published compliance.

Methods Patients referred to a specialist respiratory nurse service for pulmonary nodule surveillance since 2008 (including patients already under surveillance) with opportunity for 2 years of completed follow-up were included with retrospective review of the nodule database/electronic records and imaging. Patients were risk stratified according to nodule size and Fleischner risk category (e.g. smoking).

Results 111 patients under surveillance were identified of whom 56 were Male and 55 Female with median age 67 (34–91) years. 67 were solitary and 44 were multiple. Patients were stratified to Low- and High-risk groups according to main nodule size: (L1–4 or H1–4 respectively). Each group included; High-risk: H1 (<=4mm)10, H_2 (>4–6mm) 25, H3 (>6–8mm) 19 and H4 (>8mm) 36 cases and Low-risk: L1 (<=4mm) 0, L2 (>4–6mm) 5, L3 (>6–8mm) 4 and L4 (>8mm) 3 cases.

89 patients completed standard follow-up and were discharged. Positive scans included Lung tumours (3) - (two underwent lobectomy); Aspergilloma (1); Rectal carcinoma (1)- discovered by non-Fleischner abdominal CT. Surveillance was discontinued for: Patient choice/co-morbidity (8); Nodule resolution (3); Not documented/lost (6).

Conclusion Fleischner guidelines were well adhered to and were also utilised where their application is less well defined e.g. development of a new nodule during follow-up prompted either re-initiation or more commonly continued/modified trajectory of Fleischner - an area notably not well covered in current guidance. Furthermore principals of Fleischner recommendations were applied to multiple nodules but management of such patients is often not as easily followed as solitary nodules.

MacMahon et al, University of Chicago, Radiology 2005; 237:295–400.
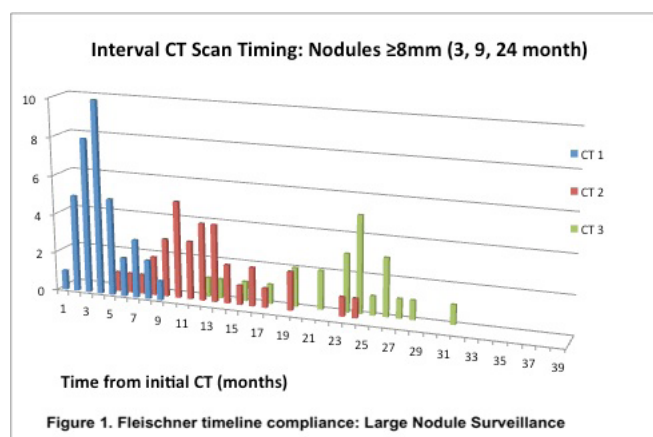
Abstract P195 Figure 1

PERCUTANEOUS ULTRASOUND-GUIDED BIOPSY OF INTRATHORACIC PARIETAL MASSES – A SAFE ALTERNATIVE TO CT-GUIDED BIOPSY?

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Background The current gold standard method for sampling intrathoracic lesions is via a CT-guided approach. However, most parietal-attached intrathoracic lesions can be visualised with ultrasound and sampled.

Aims A prospective audit of consecutive patients with CT-identified intrathoracic parietal-attached lesions, sampled percutaneously by an ultrasound-guided approach, was carried out to assess efficacy and safety. The lung MDT was instrumental in selecting patients.

Materials and Methods Seventeen consecutive patients were audited over a span of 8 months. This cohort included 12 males and 5 females with an age range from 42 to 84 years (median 63 years). The biopsies were performed by 4 skilled investigators assisted by a specialist nurse, using an 18 gauge single-trochar puncture under standard aseptic conditions. A Toshiba Applio ultrasound unit, with Doppler-flow map capabilities was used to avoid vessel puncture. Patients recovered in the radiology department observation ward.

Results Interpretable specimens were obtained in 16 patients. A single patient needed a repeat, successful, US-guided procedure. The median duration for the procedure was 26 minutes, with a median observation time before discharge of a further 40 minutes. Two patients developed small pneumothoraces and one patient suffered minor haemoptysis, none of which required admission.

Conclusion Where applicable, this technique is safe, fast, avoids radiation and may result in fewer complications compared to the CT-guided approach. Fewer personnel are required and CT scanner time is freed for other uses. Moreover, in the hands of an ultrasound-skilled respiratory physician, this method correctly applied would provide an earlier route to diagnosis for the Lung MDT.

OBTAINING A TISSUE DIAGNOSIS IN LUNG CANCER PATIENTS WITH POOR PERFORMANCE STATUS MAY NOT INFLUENCE TREATMENT OR CONFER SURVIVAL BENEFIT

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Introduction Further investigation and treatment following a radiological diagnosis of lung cancer is influenced by the fitness of a patient. A pragmatic approach to investigative procedures is often adopted based on the risks and benefits. Another consideration is whether tissue diagnosis is necessary for anticipated future treatment. Tissue diagnosis is usually deemed essential prior to administration of radical radiotherapy and chemotherapy, but less so for palliative radiotherapy.

Methods All patients with lung cancer diagnosed in North Glasgow in 2009 and 2010 were prospectively recorded in a registry. We subsequently investigated the relationships between WHO performance status (PS) and tissue diagnosis, treatment and survival. Patients were followed up for at least 18 months after entry into the registry.

Results 1190 patients were diagnosed with lung cancer during the study period and clinical details were recorded at a multidisciplinary meeting. PS was recorded in 91%.

Overall, tissue diagnosis was achieved in 76% of patients. Tissue diagnosis was achieved in 98% of patients with PS 0 following diagnostic procedure or surgery (table 1). Nearly 90% of these patients underwent chemotherapy, surgery or radical radiotherapy.

Tissue diagnosis was attempted in 71% and 46% of PS 3 and 4 respectively. Of these patients, treatment was influenced by tissue diagnosis in 15% and 0%. Survival was compared in these patients and there was no difference between patients with a PS of 3 or 4 that had tissue diagnosis attempted and those that did not (median days (interquartile range); PS3: tissue 53 (19–138) vs no tissue 59 (17–156); PS4: 18 (8–36) vs 16 (6–32)).

Conclusions A significant percentage of patients with performance status 3 and 4 undergo diagnostic tests to establish a tissue diagnosis. However, treatment is only influenced by this in a minority of cases. Considering likely future treatment is important when pursuing a tissue diagnosis in these patients. In addition, attempting tissue diagnosis in these patients did not confer any survival benefit.

TEN YEAR FOLLOW UP OF MESOTHELIOMA IN NORTH YORKSHIRE

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All 123 malignant mesothelioma patients in York and North Yorkshire between 2002–2011 were analysed from Cancer Registry and

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	0	1	2	3	4	Not recorded
n	132	381	336	186	48	107
Tissue diagnosis attempted, n (%)	126 (96)	355 (93)	300 (89)	132 (71)	22 (46)	59 (55)
Tissue diagnosis achieved*, n (%)	129 (98)	358 (94)	278 (83)	118 (63)	17 (35)	55 (51)
Treatment, n (%)						
Best supportive care	4 (3)	29 (8)	68 (25)	65 (55)	14 (82)	22 (40)
Palliative XRT	11 (9)	82 (23)	91 (33)	36 (31)	3 (18)	17 (31)
Chemotherapy	66 (51)	133 (37)	86 (31)	15 (13)	0 (0)	9 (16)
Surgery or radical XRT	48 (37)	114 (32)	33 (12)	2 (2)	0 (0)	7 (13)

*Some patients had tissue diagnosis following a surgical procedure.