

Lung Nodules and Cancer Waiting Time Monitoring

Background

Pulmonary nodules are well or poorly circumscribed, approximately rounded structures that appear on imaging as focal rounded opacities and by traditional definition are ≤ 3 cm in diameter and surrounded by aerated lung. They may be single or multiple and do not have associated abnormalities in the thorax such as lymphadenopathy or pleural disease. This definition is now commonly extended to include nodules in contact with the pleura. The now widespread use of helical multi-detector row CT has made it commonplace to detect, incidentally, nodules < 1 cm in diameter as well as sub-solid nodules (SSNs) that are partly or wholly ground glass opacities. Pulmonary nodules are most commonly small and benign. Between 15 and 20% of CTs of the thorax will detect pulmonary nodules. They are increasingly, but variably, entered onto the cancer waiting times pathway. The relevance to the cancer pathway relates to the chance that they are malignant. Those with a high chance of malignancy should be managed on the cancer pathway and only removed if the chance of malignancy is lowered by further investigations, or on confirmation of benignity. In contrast those with a low chance of malignancy should not be entered onto the cancer pathway unless initial nodule management suggests they have a higher chance of malignancy. The precise management of pulmonary nodules has long been debated but in July 2015, the British Thoracic Society (BTS) published NHS evidence accredited guidelines on their management[1]. These have been widely implemented in the UK. Thus, management of nodules should be according to these. A Quality Standard is to be published in the next few months.

The BTS guidelines used the available research evidence to enable accurate classification on nodules according to their risk of malignancy. Low risk is defined as $< 10\%$, intermediate as 10 to 70% and high as $> 70\%$. Although 10% may at first sight seem high, the evidence supports an even higher threshold for low risk. This is because very few patients have the diagnosis delayed significantly enough to influence prognosis but many more may be harmed by over aggressive investigation. There is also some evidence that the threshold for high risk could be higher, although evidence from British practice in the United Kingdom Lung Cancer Screening Trial suggests a low rate of invasive surgery for benign nodules[2].

The BTS guidelines recommend discharge for nodules that confer no extra risk of malignancy over baseline cancer risk (see recommendations below). Otherwise surveillance imaging is recommended for smaller nodules and those with a probability of malignancy of

<10%, as measured by a validated risk prediction model[3]. These nodules will all have 3 month interval CT. It is clearly not appropriate for these to be on the cancer waiting time pathway unless surveillance imaging suggests malignancy; this is detected by measuring growth over 3 months or 12 months.

For nodules that have a chance of malignancy of 10% or more, a PET-CT is recommended with subsequent assessment of malignancy using a further validated model[4]. Patients who have a risk of 10 to 70% are preferably biopsied although resection for those at the higher end or surveillance imaging for those at the lower end of the range is also allowed according to the patient's fitness and preferences. Where the risk is greater than 70% treatment is the preferred option, with fully informed consent; biopsy may also be done to provide confirmation. It can be appreciated that where the risk of malignancy, after PET-CT is 10% or more the patient is best managed by cancer physicians and should be on the cancer pathway, to avoid delays and ensure the correct sequence of investigations is offered. Where probability is <10%, the patient should not be on the cancer pathways so as to avoid unnecessary tests that may be harmful e.g. biopsies and high radiation imaging.

Recommendations

1. Patients with lung nodules with the following features should not be entered onto the Cancer Wait time pathway:
 - a. Those that can be discharged:
 - i. Nodules <5mm maximum diameter or <80mm³ volume.
 - ii. New nodules, not seen on a previous CT that are <3mm maximum diameter or 30mm³ volume.
 - iii. Nodules with benign features, including calcified nodules and perifissural nodules.
 - iv. Nodules that on previous imaging for at least 2 years show no growth.
 - b. Those that should have interval imaging;
 - i. Those 5 to 8mm maximum diameter or 80 to 300mm³
 - ii. Those ≥8mm maximum diameter that have a Brock model risk of <10% chance of cancer
2. Patients with lung nodules should start on the CWT pathway when:
 - a. They are referred on the two week wait system (they may be removed at first review as in 3 below).
 - b. They have a Brock risk of ≥10% (in practice, this will include all nodules >20mm diameter).
3. Patients should be upgraded onto the CWT pathway when:
 - a. They undergo PET-CT as part of risk assessment or general work-up (see below for criteria for removal).
 - b. Significant growth is confirmed on surveillance imaging (it is recognised that this may, for smaller nodules, require more than one interval image).
4. Patients with lung nodules should be taken off the Cancer wait time pathway when:
 - a. After PET-CT, they have a risk of malignancy of <10% following re-assessment of risk with the Herder risk prediction model; they then enter imaging surveillance.
 - b. They have a pathologically confirmed benign diagnosis.
5. All patients with pulmonary nodules under follow up must be actively tracked through a pulmonary nodule service to avoid missing the few that are cancers.

References

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