National Institute for Health and Care Excellence

IP1051/2 Microwave ablation for treating primary lung cancer and metastases in the lung

IPAC date: 11 November 2021

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 The UK Clinical Expert Group for Lung Cancer and Mesothelioma	**1.1 and 1.3**	"The UK Clinical Expert Group for Lung cancer and Mesothelioma welcome this guidance from NICE. The guidance is in line with what we believe is the current evidence base. We would prefer clarification in the wording to be considered as follows; 1. In the opening paragraph the potential for serious complications is rightly included. It would be correct to include the words ""‥ similar to other direct ablation procedures for lung cancer. 2. In section 1.3 we would recommend that all alternative procedures and therapies should be discussed to facilitate informed shared decision making"	Thank you for your comment. Additional wording has been added to sections 1.1 and 3.6: *"1.1 Evidence on the safety of microwave ablation for treating primary lung cancer and metastases in the lung is adequate but shows it can cause **infrequent** serious complications…"* *"3.6 The committee was informed that evidence on the efficacy of microwave ablation for primary and metastatic lung cancer is similar to other ablation procedures in terms of tumour size reduction. **Other ablation procedures are also associated with similar complications.**"* The committee considered the comment relating to 1.3 but decided not to change the guidance
2	Consultee 2 Johnson and Johnson company	**1.1**	"Considering that we are drawing a parallel between RFA and MWA and considering that the two procedures are considered similar would you consider updating the recommendations in term of governance for RFA as well and align them with the one you are proposing for MWA. The current governance for RFA is much simpler "This procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit" https://www.nice.org.uk/guidance/ipg372/chapter/1-Guidance"	Thank you for your comment. The committee considered this comment but decided not to change the guidance. The IP programme makes recommendations based on the assessment of the efficacy and safety of individual procedures rather than comparative interventions. When making decisions, the committee was aware of, and considered, IPG372 and its recommendation.

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3	Consultee 2 Johnson and Johnson company	**1.5**	Considering the complexity of treatments and the rapid advances in oncological treatment we recommend that the standard of care for decision making is a multidisciplinary team where all the relevant specialist are present including an interventional radiologist/oncologist "The decision making about treatment options for patients with primary or metastatic lung cancer must be lead by a multidisciplinary team."	Thank you for your comment. Addition wording has been added to section 1.5: "*People with primary or metastatic lung cancer should be referred to an **appropriately constituted** multidisciplinary team*."
4	Consultee 2 Johnson and Johnson company	**2.4**	Consider including that large bore probes are not recommended for lung tissue	Thank you for your comment. Additional wording has been added to section 2.4: *"The procedure is usually done using general anaesthesia, and occasionally using local anaesthesia and sedation. Under imaging guidance, a **small** probe is advanced through the chest wall and into each targeted lesion..."*
5	Consultee 2 Johnson and Johnson company	**2.4**	Consider including that for patients with multiple lesions and or bilateral lesions a staged treatment of the lesions with multiple sessions is standard practice.	Thank you for your comment. Extra wording has been added to section 2.4 *"… Patients with larger tumours or multiple lesions may have multiple pulses of energy delivered within a treatment session **or have a staged treatment with multiple sessions**."*
6	Consultee 2 Johnson and Johnson company	**3.2**	Please consider including local recurrence as a key outcome	Thank you for your comment. 'Local recurrence' has been added as an additional key efficacy outcome.
7	Consultee 2 Johnson and Johnson company	**3.3**	Consider including bronchopleural fistula with prolonged air leak as a key safety outcome	Thank you for your comment. 'Bronchopleural fistula with prolonged air leak' has been added as an additional key safety outcome.
8	Consultee 2	**3.4**	"In the literature there is evidence supporting outcomes that have a positive impact on patient experience,	Thank you for your comment.

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	Johnson and Johnson company		consider including that microwave ablation is a minimally invasive, fast procedure with most procedures lasting 1-2 hours with only 5-10 minutes of active ablation time. Many patients leave the hospital the same or following day with only a small bandage over the probe insertion site. J. Horn, et al, Percutaneous Microwave Ablation of Renal Tumors Using a Gas-Cooled 2.4-GHz Probe: Technique and Initial Results. Journal of Vascular Interventional Radiology 2014; 25: 448 – 453. Lubner et al. Microwave Tumor Ablation: Mechanism of Action, Clinical Results and Devices. JVIR 2010 Aug: 21(8 Suppl): S192-S203."	The following wording has been added to section 2.5: "***Microwave ablation is a minimally invasive procedure with most procedures lasting 1 to 2 hours with only 5 to 10 minutes of active ablation time.***" Horn et al. (2014) – patients with renal tumours - does not meet the inclusion criteria. Lubner et al. (2010) has been added to the appendix.
9	Consultee 3 Medtronic company	**General**	Medtronic would like to thank NICE for the opportunity to comment on these draft recommendations.	Thank you for your comment.
10	Consultee 3 Medtronic company	**1.1**	"Medtronic do not agree that this procedure should be used with 'Special Arrangement' and believe that the evidence base supports that 'Normal Arrangement' should be adopted. We respectfully ask the committee to re-consider their recommendations."	Thank you for your comment. The consultee considered this comment but decided not to change the guidance. The IP programme makes recommendations based on the assessment of the efficacy and safety of individual procedures.
11	Consultee 3 Medtronic company	**3.1**	"We strongly believe that Macchi (2017) should be explicitly included in the key evidence and not as part of the Meta-Analysis undertaken by Sun (2018). Macchi (2017) was an RCT conducted in Italy, which meets the inclusion criteria for identification of relevant studies. References Macchi, M. et al. (2017) 'Radiofrequency versus microwave ablation for treatment of the lung tumours: LUMIRA (lung microwave radiofrequency) randomized	Thank you for your comment. The IP programme performs a rapid review of the literature. Sometimes evidence synthesis papers are included in the key evidence and the papers that are included in these literature reviews and meta-analyses are not always extracted separately. The selection of studies for the key evidence was in line with the IP manual (section 9.2).

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			trial', Medical Oncology 2017 34:5. Springer, 34(5), pp. 1–10. doi: 10.1007/S12032-017-0946-X."	Macchi (2017) met the inclusion criteria and was included in the appendix. Sun (2018) was included in the key evidence. When making decisions, the committee considered all the evidence included in the overview (both the key evidence and appendix).
12	Consultee 3 Medtronic company	**3.1**	"We acknowledge that Wang (2018) was a non-randomised comparative study, however we disagree that this should be excluded. Wang (2018) was combined with Yao (2018) in a subgroup analysis that was reported in the meta-analysis, Chan (2021). Further, Yao (2018) was included in the key evidence. We kindly ask the committee to include Wang (2018) alongside Yao (2018). References Y, W. et al. (2018) 'Comparison between computed tomography-guided percutaneous microwave ablation and thoracoscopic lobectomy for stage I non-small cell lung cancer', Thoracic cancer. Thorac Cancer, 9(11), pp. 1376–1382. doi: 10.1111/1759-7714.12842."	Thank you for your comment. The IP programme performs a rapid review of the literature. The selection of studies for the key evidence was in line with the IP manual (section 9.2). Chan (2021) and Wang (2018) were included in the appendix. When making decisions, the committee considered all the evidence included in the overview (both the key evidence and appendix). Yao (2018) (n=162; follow-up, 5 years) was included in the key evidence. Chan (2021) included 8 studies; of these 2 were relevant to MWA for lung cancer and the reported outcomes relevant to this procedure were limited.
13	Consultee 3 Medtronic company	**3.1**	"We acknowledge that Palussiere (2021) is a review and was not included in the summary of key evidence, however we would like the committee to consider the statement from this article, specifically about thermal ablation. "Many recent reviews and database analyses show that outcomes after TA (mainly RFA and MWA) are comparable to SBRT in terms of survival rates." Most importantly, we would like to draw the attention of the committee towards patients who are unfit for surgery in which Thermal Ablation has demonstrated both safety and overall survival.	Thank you for your comment. Additional wording has been added to section 3.6: *"The committee was informed that evidence on the efficacy of microwave ablation for primary and metastatic lung cancer is similar to other ablation procedures in terms of tumour size reduction.* ***Other ablation procedures are also associated with similar complications.****"*

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			References Palussière, J. et al. (2021) 'Is There a Role for Percutaneous Ablation for Early Stage Lung Cancer? What Is the Evidence?', Current Oncology Reports 2021 23:7. Springer, 23(7), pp. 1–10. doi: 10.1007/S11912-021-01072-4."	In terms of the role of thermal ablation for patients who are unfit for surgery, this is covered by section 3.8: *"This procedure may have a role for patients with primary or metastatic lung cancer who are unable to have surgery or whose tumour is not resectable".* Palussiere et al. (2021) has been added to the appendix.
14	Consultee 4 NHS professional	**1.1**	Statement 1.1 is possibly misleading, it states that MWA is effective but can cause serious complications. The NICE complication profile states that the complication rates in MWA are no different from RF, or surgery, there needs to be a qualifying statement to make its equivalence clear, as in its current format a reader might be lead to believe that MWA has a worse complication rate (which is largely due to grade 2/3 pneumothorax) than other invasive treatment options. The rate of serious complications based on the NICE literature summary is very low, with one reported death due to arrhythmia two days after treatment.	Thank you for your comment. Sections 1.1 and 3.6 have been changed: *"1.1 Evidence on the safety of microwave ablation for treating primary lung cancer and metastases in the lung is adequate but shows it can cause* ***infrequent*** *serious complications…"* *"3.6 The committee was informed that evidence on the efficacy of microwave ablation for primary and metastatic lung cancer is similar to other ablation procedures in terms of tumour size reduction.* ***Other ablation procedures are also associated with similar complications.****"*
15	Consultee 4 NHS professional	**General**	This is a comprehensive document and the recommendations are based on what evidence is available. We hope that PPI input can be sought at the consultation stage.	Thank you for your comment.