

National Institute for Health and Care Excellence
IP1019 Irreversible electroporation for primary liver cancer

IPAC 08/08/19

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Consultant Radiologist King's College Hospital	1.1	<p>IRE is safe and effective technique for treating primary and secondary liver tumours. Most of the patients that were treated in the literature had tumours that were unsuitable for conventional thermal ablative techniques (MWA and RFA) and not suitable for surgery. Most of the published evidence suggests complete treatment rates and recurrence rates which are comparable to RFA and MWA.</p> <p>The statement that IRE is associated with serious but recognised complications is misleading. Majority of the complications that are associated with IRE are minor. Serious complications like tumour seeding are quoted in only one paper. This is not a major issue as tumours are bracketed with 4-5 needles and are not penetrated (like MWA). Other serious complication rates such as mortality and serious haemorrhage are extremely rare and are comparable to thermal ablation.</p> <p>Given the fact that IRE offers a minimally invasive treatment option for those patients who suffer from tumours that are unsuitable for conventional ablative methods or surgery, NICE should recommend its use in centres that have the experience and expertise.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>Section 1.1 of the guidance has been changed, to include the word 'infrequent'.</p> <p>The committee noted your opinion about the safety and efficacy of the technique and reviewed additional evidence (added to Table 2) but decided not to change its recommendation.</p>
2	Consultee 2 Specialist societies BASL/BSG	General	<p>Overview: Current ablation techniques utilize thermal energy and destroy malignant cells by necrosis. The thermal energy applied can give rise to injury to</p>	Thank you for your comment.

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		<p>adjacent structure, blood vessels, gall bladder, bile duct, intestine, diaphragm etc. This means that some lesions that would be theoretically amenable to ablation are not treated in this way due to the potential complications. Ablation techniques have a higher objective response rate than other techniques that would otherwise be employed in this situation e.g. transarterial arterial embolization (TAE) /transarterial chemoembolization where objective response is lower (complete response rates ~25%).</p> <p>IRE kills malignant cells through apoptosis and a non-thermal mechanism which obviates the potential damage to adjacent anatomical structure. This means that lesions/cancers can be treated more effectively i.e. greater chance of complete and objective response to treatment.</p> <p>IRE is a useful tool to add to the list of treatments available for use in HCC and BASL would welcome its use in defined populations (eg small lesions in challenging anatomical locations for thermal ablation) and prospective studies performed against the current standard of care for non-thermal ablatable lesions</p> <p>Specific points raised via expert advice from HCC-UK:</p> <p>â€¢ There appears to be some heating element according to the following publication. Could this explain some of its associated complications? Cardiovasc Intervent Radiol. 2018 Aug;41(8):1257-1266. doi: 10.1007/s00270-018-1971-7. Epub 2018 Apr 23. Conductivity Rise During Irreversible Electroporation: True Permeabilization or Heat? Ruarus AH1, Vroomen LGPH2, Puijk RS2, Scheffer HJ2, Faes TJC2, Meijerink MR2.</p> <p>â€¢ Outcomes in terms of combination therapy should be considered.</p>	<p>Ruarus AH et al. (2018) is not within the remit of this guidance because it does not include patients with primary liver cancer.</p> <p>Yang et al. (2019) is included in the appendix of the overview.</p> <p>Distelmaier M et al. (2017) is included in table 2 of the overview. Needle track seeding is described under 'Recurrence or progression' in the efficacy section of the overview.</p>
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		<p>Cardiovasc Intervent Radiol. 2019 Jan;42(1):48-59. doi: 10.1007/s00270-018-2069-y. Epub 2018 Aug 27.</p> <p>Safety and Short-Term Efficacy of Irreversible Electroporation and Allogenic Natural Killer Cell Immunotherapy Combination in the Treatment of Patients with Unresectable Primary LiverCancer.</p> <p>Yang Y1, Qin Z2, Du D3, Wu Y1, Qiu S1, Mu F4, Xu K5, Chen J6,7.</p> <p>“ Needle track seeding not mentioned in the draft document” up to 26% treated tumour. See reference below.</p> <p>Radiology. 2017 Dec;285(3):1023-1031. doi: 10.1148/radiol.2017161561. Epub 2017 Aug 11.</p> <p>Midterm Safety and Efficacy of Irreversible Electroporation of Malignant Liver Tumors Located Close to Major Portal or Hepatic Veins.</p> <p>Distelmaier M1, Barabasch A1, Heil P1, Kraemer NA1, Isfort P1, Keil S1, Kuhl CK1, Bruners P1. “</p>	
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"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."

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