

National Institute for Health and Care Excellence

IP1953 Radiofrequency ablation as an adjunct to balloon kyphoplasty or percutaneous vertebroplasty for palliation of painful spinal metastases

IPAC date: 12th January 2023

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Merit Medical (company)	General	<p>Dear NICE interventional procedures Committee, On behalf of Merit Medical, Thank you for the opportunity to provide comments in response to the NICE draft recommendation GID-IPG10244 entitled “Radiofrequency ablation as an adjunct to balloon kyphoplasty or percutaneous vertebroplasty for palliation of painful spinal metastases”</p> <p>In addition to the relevant evidence published in the “Overview” document we would like to bring to your attention the Cardiovascular and Interventional Radiological Society of Europe guidelines “CIRSE Standards of Practice on Thermal Ablation of Bone Tumours” (https://pubmed.ncbi.nlm.nih.gov/35348870/), highlighting that radiofrequency ablation “has an established role in the successful management of bone lesions, with both curative and palliative intent”, providing Standards of Practice document and up-to-date recommendations for the safe performance of thermal ablation of bone tumours.”</p> <p>Additional references on the key roles of radiofrequency ablation prior to vertebral augmentation: -Vertebroplasty/kyphoplasty treatment alone of spinal</p>	<p>Please respond to all comments</p> <p>Thank you for comments. The CIRSE guidelines have been considered by IPAC and included in the Overview document. The additional references on vertebroplasty/kyphoplasty alone will not be included in the overview as it is out of the remit of this guidance.</p>

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			<p>metastases is not effective: Polymethylmethacrylate alone and the exothermic reaction generated during its polymerization is not sufficient to destroy tumor cells. Anselmetti GC et. al. Cardiovasc Intervent Radiol. 2009 https://pubmed.ncbi.nlm.nih.gov/19280257/ Cement augmentation via kyphoplasty or vertebroplasty increases the intrametastatic pressure and hypothetically forces tumours cells into the surrounding blood vessels. Mohme M et. al. Sci Rep. 2017 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5543076/ The most common serious complications related to BKP include cement extravasation and "tumor extravasation". Avoiding SREs. Cruz JP et.al. J Neurosurg Spine 2014 https://pubmed.ncbi.nlm.nih.gov/24905395/</p> <p>-Radiofrequency ablation of spinal metastases for avoiding the displacement of the tumor into the venous system with vertebral augmentation. Avoiding SREs. "Oncology intervention is actively moving beyond simple bone cement injection. Archimedes taught us that a volume displaces its volume. Where does the tumor we displace with our cement injection go? It is no longer acceptable that we displace tumor into the venous system with our cement injections. We must kill the tumor first." Munk PL Semin Musculoskelet Radiol. 2011 https://pubmed.ncbi.nlm.nih.gov/21500132/</p>	

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			<p>-Aims of performing RFA is to address the biological pain palliation:</p> <ul style="list-style-type: none"> · Rybak et al. Radiol Clin N Am 2009 https://pubmed.ncbi.nlm.nih.gov/19361670/ · Callstrom et. al. Skeletal Radiol 2006 https://pubmed.ncbi.nlm.nih.gov/16205922/ <p>Thanks for your attention, Fabio PULLANO Sales & Marketing Director EMEA</p>	
2	Consultee 2 Medtronic (Company)	1	We agree with the draft recommendations and thank the Committee for their careful consideration of the evidence.	Thank you for your comments.

"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."