

## National Institute for Health and Care Excellence

### IP1031/2 Endoscopic bipolar radiofrequency ablation for treating biliary obstruction caused by cancer

IPAC date: 8 March 2018

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Company APR Medtech Ltd	<b>General</b>	<p>"Efficacy and safety of endoscopic radiofrequency ablation for unresectable extrahepatic cholangiocarcinoma: a randomized trial' Jianfeng Yang et. al. was published online on 17th January 2018 in Endoscopy DOI: 10.1055/s-0043-124870.</p> <p>Please could the evidence presented in this prospectively randomised and controlled study be considered by the committee prior to making their final guidance on this procedure?</p> <p>Yours,  <div style="background-color: black; width: 40px; height: 15px; display: inline-block;"></div></p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The cited study was discussed by the committee, and will be added to table 2 of the overview.</p>

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
2	Consultee 2 NHS Professional Institute for Liver and Digestive Health	General	<p>"First RCT just published; Efficacy and safety of endoscopic radiofrequency ablation for unresectable extrahepatic cholangiocarcinoma: a randomized trial  <a href="https://www.ncbi.nlm.nih.gov/labs/articles/29342492/">https://www.ncbi.nlm.nih.gov/labs/articles/29342492/</a>.</p> <p>~The overall mean survival time was also significantly longer in the RFA+ stent group than the stent-only group (13.2 <math>\pm</math> 0.6 months [95%CI 11.8 – 14.2] vs. 8.3 <math>\pm</math> 0.5 months [95%CI 7.3 – 9.3]; P &lt; 0.001). Multivariable Cox regression analysis showed that RFA was the main protective factor affecting the survival of patients (hazard ratio 0.182, 95%CI 0.08 – 0.322; P&lt;0.001).™</p> <p>Should be included in the review but a few reservations: (i) small numbers, single centre, non-UK setting (ii) only extrahepatic and a few Bismuth I/II patients - not Bismuth III/IV patients which probably make up the bulk of unresectable patients referred for ERCP (iii) 8.5F stents used rather than standard of care metal stents - especially for extrahepatic disease, (iv) no GemCis chemotherapy or equivalent as per our NEJM paper - in my view the last two make it less relevant to UK/international practice. Also it looks like they did three-monthly ERCPs for intraductal ultrasound and stent change, which again would not be standard. "</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The cited study was discussed by the committee, and will be added to table 2 of the overview.</p>

*"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*

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