AMMF's response to the NICE Interventional Procedures Guidance Group re their draft recommendations for the use of SIRT (selective radiation therapy) in the treatment of patients with intrahepatic cholangiocarcinoma (ICC).

IP1081/2 Selective internal radiation therapy for unresectable primary intrahepatic cholangiocarcinoma
https://www.nice.org.uk/guidance/indevelopment/gid-ipg10074/consultation/html-content

We at AMMF – The Cholangiocarcinoma Charity have serious concerns on the recommendations made, and find it difficult to understand how the conclusions were reached. We believe this is an injustice to this group of inoperable patients who, following standard chemotherapies, have no further clinically proven treatment options available to them. We believe that SIRT can provide these patients with additional months of life, which are free from debilitating treatment-related adverse events.

The recommendations made contradict two current national guidelines:

- The European Society of Medical Oncology (ESMO) Biliary Cancer Guidelines were published in September 2016. They were based on the study by Al-Adra (2014) which was included in the IPG review. This was a pooled analysis of 12 studies (298 patients), which reported median overall survival of 15.5 months, and treatment response rate of 28% in patients treated with SIRT. Furthermore, within this study 10% of patients were converted to resectable disease. https://academic.oup.com/annonc/article-pdf/27/suppl_5/v28/6678340/mdw324.pdf

- The National Comprehensive Cancer Network (NCCN) Clinical practice guidelines in oncology, for hepatobiliary cancers, also recommend the use of "Locoregional therapy" including "Arterially directed therapies" for the treatment of ICC. These were published very recently, in February of this year. https://www.nccn.org/professionals/physician_gls/default.aspx

We ask how this recommendation can go against both of these clinical guidelines? Were these guidelines, which are developed with strong clinical support from international experts, also reviewed within the NICE process? This IPG also seems to contradict the recommendations from the previous review completed in 2013, when there has been no change in the safety of the procedure, and contradicts recommendations made for the use of SIRT by NICE IPG in other liver indications, i.e. hepatocellular carcinoma (HCC), and liver dominant metastatic colorectal cancer (mCRC). How is this anomaly justified?

We would also like to stress that ICC is a rare disease, and so the evidence should be reviewed appropriately. Although most of the clinical studies are retrospective and non-comparative, they still provide invaluable evidence on the safety and efficacy of SIRT, and include substantial patient numbers. This information should not be discarded as inadequate due to the research methods used.

We feel that the current lack of funding for SIRT in England is inexcusable because, as mentioned, this is the only treatment option open to these patients following standard chemotherapies, and because clinical studies have shown it to increase median overall survival. Although we acknowledge that the IPG process only considers efficacy and safety, and not cost-effectiveness, we feel that these recommendations will only serve to further deny NHS patient access to this important procedure.

Based on these points, we strongly ask that you re-consider your draft recommendations.

Noel Corrigan
Chair of Trustees – AMMF
noel@ammf.org.uk

Helen Morement
CEO - AMMF
helen@ammf.org.uk