National Institute for Health and Care Excellence

IP342/2 – Preoperative high dose rate brachytherapy for rectal cancers
Consultation Comments table

IPAC date: Thursday 11 June 2015

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 The Royal College of Radiologists	**2**	Thank you for your email of 14 April regarding the consultation on the safety and efficacy of Preoperative high dose rate brachytherapy for rectal cancers [IP342/2]. I am writing on behalf of The Royal College of Radiologists. The RCR feel the consultation document is very reasonable but would like to mention two factual points – a) intra-operative radiotherapy (treatment during surgery) is not given in the UK and b) the management of rectal cancer is governed in the UK by NICE guideline CG131. I hope these comments will be helpful and I would be grateful if you would please acknowledge receipt. Thank you.	Thank you for your comment. The Committee was advised that there is current interest in the use of intraoperative radiotherapy in the UK. Section 2.2 of the guidance has been amended to include reference (and a hyperlink) to this NICE guideline, CG131 Colorectal cancer: The diagnosis and management of colorectal cancer.

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2	Consultee 2 Specialist Adviser	**1**	Dear Sir, I am one of the NICE specialist advisors for pre-operative brachytherapy for rectal cancer. I would like to make the following comment on your consultation document. 1. Brachytherapy for rectal cancer is not routinely used at present and its use as pre-operative treatment is not widely practice. 2. There is a group from Montreal who advocate pre-operative brachytherapy for rectal cancer as the sole treatment and they have treated large number of patients. They have published several papers but your provisional recommendations state 'Evidence on the efficacy of this procedure used without EBRT is inadequate in quantity'. I am not sure if this statement is correct. You need to rephrase it, at least, as there are over 400 patients treated in Canada using this technique with very good results (Te Vuong et al.). Randomise trial with external beam is planned jointly with the Dutch group shortly. The toxicity from this procedure is much less than with EBRT as the whole pelvis is not irradiated. 3. There is evidence that those patients who had HDR brachytherapy achieved better sphincter preservation (72% vs 42% [p,0.0001] in RCT of 230 cohort)	Thank you for your comment Two studies from Montreal are included in table 2 of the overview (Hesselager et al, 2013; Vuong T et al, 2010) and others are included in appendix A of the overview. The figures on sphincter preservation are reported in section 4.1 of the guidance.

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3	Consultee 2 Specialist Adviser	**General**	4. There is evidence of major response (44%vs 28% [p=0.04]). But response was greater in tumours less than 3.7cm(no stats). 5. I would like to draw your attention to increasing use of this procedure for elderly and medically unfit patients for surgery. Traditionally, EBCRT alone was use for this group of patients. Only 30% of patients achieved complete response. Patients who had brachytherapy boost had higher complete response and longer duration of the local control of their disease. A randomise trial is now been set up for this group of patients. 6. At ████ we use combination of HDR brachytherapy together with contact X-ray brachytherapy for patients with more advanced rectal cancer. A publication is on this cohort is due out shortly. 7. The applicators used for this procedure are different in each of these trial which makes it difficult for comparison of their results. The different doses used in these trials make it more difficult to compare their results. There are mainly two different types of applicator OncoSmart@ which uses 8 channels and rigid applicator which use only central single line source. The dose received at depths are different.	Thank you for your comment. The figures on 'major response' are included in section 4.3 of the guidance. This guidance was based on evidence for preoperative brachytherapy only. The use of HDR brachytherapy as a treatment for patients who are unfit for surgery could be considered as a separate notification. Guidance that recommends 'special arrangements for clinical governance, consent and audit or research' is routinely considered for review after 3 years. A Committee comment has been added to the guidance to acknowledge that application techniques are evolving.

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4	Consultee 2 Specialist Adviser	**General**	8. Modern brachytherapy techniques uses 3D planning techniques whereas older trials quoted in your reported use single line source with 2D old technology which is different. 9. Centres using newer methods of planning and treatment using multiple channels are planning to use MRI for planning brachytherapy which has much more accurate dose delivery 10. There is revival of interest in intra operative brachytherapy for advanced rectal tumours during operations. Radiation can be delivered directly on to the residual tumour attached to major vessels and pelvic bones during pelvic exenteration. As the number of patients in this category are small randomised trial will be difficult to set up. Patients can benefit from less extensive surgical procedures if this type of brachytherapy is regarded as acceptable nonstandard procedure. I hope my comments are helpful in production of your document on 'pre-operative brachytherapy for rectal cancer'.	Thank you for your comment. A Committee comment has been added to the guidance to acknowledge that imaging technology is evolving. The current interest in intraoperative brachytherapy was noted by the committee.

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