Radiotherapy versus Observation following surgical resection of Atypical Meningioma (the ROAM trial)

Kaur et al.1 have produced a timely systematic review on the role of adjuvant radiotherapy for atypical meningioma (AM) and malignant meningioma. Their review highlights the paucity of good quality prospective studies and the urgent need for prospective clinical trials for AM.

Kaur et al.1 identify extent of resection (EOR) as an important prognostic factor but fail to comment on how this was defined. In 1957 Simpson2 described a classification system that is still used today. The Simpson classification predates CT and MRI and is based upon the neurosurgeon's assessment. Recently, several authors have questioned the use of Simpson grading in modern neurosurgery as a prognostic factor for risk of tumor recurrence,3 instead proposing a change that defines EOR as either gross total resection (GTR) or subtotal resection (STR). In a recent review paper, GTR was described as Simpson 1–3, that is, no residual solid tumor, while STR equated to Simpson 4–5.4 These definitions have been endorsed by both the European Organisation for Research and Treatment of Cancer (EORTC) and the Radiation Therapy Oncology Group (RTOG), and most prospective clinical trials for meningioma adopt this definition.

The latest World Health Organization classification5 has led to increased reporting of AM,6–8 and there continues to be a marked institutional variation in patient management, particularly the use of early adjuvant radiotherapy.9,10 Despite meningiomas being considered relatively radioresistant, radiotherapy remains the only available adjuvant therapy for these tumors in routine clinical practice. The role of early adjuvant radiotherapy for patients with AM who undergo a GTR, however, remains to be defined,11 leading to a lack of class I evidence.12 Of these retrospective studies, patient numbers in tumor recurrence, 3 instead proposing a change that defines evidence of local recurrence (disease-free survival), and secondary outcomes include time to second line treatment, time to death, toxicity of treatment, quality of life, neurocognitive function, and health economic analysis. Across Europe, approximately 20 centers have expressed interest in participating, of which 10 are in the UK. The study is powered to detect an absolute reduction in recurrence rate from 40% (control arm) to 20% (radiotherapy arm) and will recruit 172 patients in total. Due to the rarity of AM, it is anticipated that this trial will run for a total of 10 years. Since the patient journey starts with the resection, neurosurgeons will be critical to the success of this trial. An appreciation of genuine clinical equipoise and lack of class I evidence to support current variations in practice are paramount. Trials of intervention versus monitoring can pose a recruitment challenge, since clinicians and patients often exhibit bias.14,15 In the ROAM/EORTC 1308 trial, strategies will be employed that ensure clinicians present the trial in an unbiased way to patients in order to maximize recruitment.16 An award of £1.36 million has been made to M.D.J. by the National Institute for Health Research Health Technology Programme to fund this trial, with additional funding from Europe (to D.C.W.). The trial is scheduled to open in November 2014.

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Fig. 1. ROAM/EORTC 1308 study design.

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References