



RESEARCH TOPIC CLI33

Separation Surgery with adjuvant Stereotactic Radiosurgery/Stereotactic Body Radiation Therapy (SRS/ SBRT) versus Proton Beam Therapy (PBT) in the treatment of high grade Spine Metastatic Epidural Compression: a phase 2 study

Research Area

Surgical Area

Clinical Unit name

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Abstract

During the last decade, in concomitance with the rising overall incidence of spine metastases due to the improvement and spread of technologies and target therapies, the concept of radio-resistance in spine oncology has been overcome with the advent of new radiation strategies. The real novelty is the possibility to create steep dose gradients around the neural elements, minimizing dose to the nearby structures and delivering ablative radiation Humanitas University Via Rita Levi Montalcini, 4 20072 Pieve Emanuele (MI) Italy Tel +39 0282241 - Fax +39 0282242394 info@hunimed.eu hunimed.eu CF 97692990159 strutture limitrofe e veicolando dosi lesionali dal potenziale ablativo, con un impatto virtuoso sul controllo locale e sulla sopravvivenza. L'innovativo concetto di "terapia ibrida" sposta il paradigma chirurgico per la Compressione Epidurale Metastatica (CEM) da una chirurgia estesamente citoreducente ad una efficace "Chirurgia di Separazione", anche con il supporto di tecniche mini-invasive, al fine di creare un bersaglio ideale sicuro con preservazione massima del tessuto "nobile". Sono necessari ulteriori studi clinici per sostenere la longevità di queste tecniche, integrando la letteratura relativa alle evidenze neurologiche e di sopravvivenza. Mancano dati su un confronto effettivo tra terapia con fotoni versus protoni in contesto adiuvante per le metastasi spinali. L'obiettivo primario di questo studio prospettico di fase 2 è quello di valutare il tasso di controllo locale (CL) a 6 e 12 mesi in pazienti con CEM di alto grado candidabili alla chirurgia di separazione con strumentario in fibra di carbonio, in 2 popolazioni: Stereotactic Radiosurgery/Stereotactic Body Radiation Therapy (SRS/ SBRT) adiuvante (gruppo A) e Proton Beam Therapy (PBT) adiuvante (gruppo B.). Come obiettivi secondari verranno indagati: (i) l'impatto del diverso grado di decompressione circonferenziale (estensione della resezione) sul CL, il tasso di (ii) morbilità legata al trattamento e di (iv) controllo del dolore, e (v) gli indici di Qualità della Vita. doses to the tumor, with a positive impact on local control and survival. The innovative concept of "hybrid therapy" shifts the paradigm of Metastatic Epidural Compression (MEC) surgery from extended cytoreductive surgery to an effective "Separation Surgery", also with the support of mini-invasive techniques, in order to create a safe ideal target with "noble" tissue sparing. More clinical trials are required to support the longevity of these techniques, adding

to literature concerning neurologic and survival outcomes evidence. Data about a comparison between photon versus proton beam therapy in spine metastases adjuvant setting are lacking. The primary aim of this prospective phase II study is to evaluate the local control (LC) rate at 6 and 12 months in patients with high grade MEC suitable for Separation Surgery with carbon fiber hardware, in 2 populations: adjuvant Stereotactic Radiosurgery/Stereotactic Body Radiation Therapy (SRS/ SBRT) (group A) and adjuvant Proton Beam Therapy (PBT) (group B.). As secondary endpoints, (i) the impact of different grading of circumferential decompression (extent of resection) on LC, (ii) the treatment morbidity and (iii) pain control rates and (iv) the Quality of Life parameters will be investigated.

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