Applicazione dell'analisi FMEA in trattamenti SBRT con CyberKnife.

Application of Failure Mode and Effects Analysis (FMEA) to CyberKnife Stereotactic Body Radiation Therapy (SBRT).

M.C. Cantone[1], E. De Martin[2], M.L. Fumagalli[2], T. Malatesta[3], P. Mancosu[4], A.S. Martinotti[5], I. Redaelli[5], I. Veronese[1], C. Vite[5]

(1) Università degli Studi di Milano, Dipartimento di Fisica, Milano (2) UO Direzione Sanitaria- Fondazione IRCCS Istituto Neurologico Carlo Besta, Milano (3) UOC Fisica Sanitaria, AFAR, Ospedale San Giovanni Calibita Fatebenefratelli, Isola Tiberina, Roma (4) Reparto di Radioterapia Oncologica, Istituto Clinico Humanitas, Milano (5) reparto Cyberknife Centro Diagnostico Italiano, Milano.

Purpose: The aim of this work was the application of the FMEA approach to assess the risks for patients undergoing SBRT treatments performed with Cyberknife. Indeed, FMEA was recognised as a powerful tool for proactive risk analysis in modern radiation oncology [1] and only few data about its use in SBRT are currently available in literature [2].

Methods and materials: This study, performed in the frame of the AIFM Working Group on SBRT, was carried out by a multidisciplinary team composed by experts in the SBRT process and in risk management.

The FMEA analysis was focused on SBRT treatments for lesions in two different anatomical regions: spine and liver. The specific processes implemented at the Carlo Besta Neurological Institute Foundation IRCCS, Milan, and at CyberKnife Center CDI Milan, were considered for the analysis respectively.

Results: The various sub-processes characterising the SBRT treatment were identified in order to generate the overall process tree. The differences between the two types of treatments were mainly observed during the stage of delivery, as a consequence of the different image-guided systems: fiducial markers coupled with Synchrony respiratory tracking system in case of SBRT for liver tumours, and vertebral tracking in case of SBRT for spine lesions. The potential failure modes occurring during the stages of planning and delivery were identified together with their causes end effects. The ranking of these failures by using the risk probability number (RPN) scoring system, based on the product of three semi-quantitative parameters standing for severity, frequency of occurrence and detectability, led to the identification of the main weaknesses of the SBRT process and to the proposal of possible additional safety measures for process quality and safety improvement.

Conclusion: FMEA proved itself to be a useful and simple tool for prospective evaluation of patient safety in modern radiotherapy. Although this study was carried out considering the processes implemented at two specific centres, the proposed methodology, as well as likely most of the findings, can be generalized thus to be useful to other centres equipped with CyberKnife.

References:
[1] Accidental Exposures from New External Beam Radiation Therapy Technologies. Annals of the ICRP 39 (4), Elsevier, 2009
[2] J.R. Perks et al., Failure Mode and Effect Analysis for Delivery of Lung Stereotactic Body Radiation Therapy, Int J Radiat Oncol Biol Phys (2012) 83, 1324-1329