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Clinical implementation and failure mode and effects analysis of HDR skin brachytherapy using Valencia and Leipzig surface applicators

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ABSTRACT

PURPOSE: The planning procedure for Valencia and Leipzig surface applicators (VLSAs) (Nucletron, Veenendaal, The Netherlands) differs substantially from CT-based planning; the unfamiliarity could lead to significant errors. This study applies failure modes and effects analysis (FMEA) to high-dose-rate (HDR) skin brachytherapy using VLSAs to ensure safety and quality.

METHOD: A multidisciplinary team created a protocol for HDR VLSA skin treatments and applied FMEA. Failure modes were identified and scored by severity, occurrence, and detectability. The clinical procedure was then revised to address high-scoring process nodes.

RESULTS: Several key components were added to the protocol to minimize risk probability numbers. (*1*) Diagnosis, prescription, applicator selection, and setup are reviewed at weekly quality assurance rounds. Peer review reduces the likelihood of an inappropriate treatment regime. (*2*) A template for HDR skin treatments was established in the clinic's electronic medical record system to standardize treatment instructions. This reduces the chances of miscommunication between the physician and planner as well as increases the detectability of an error. (*3*) A screen check was implemented during the second check to increase detectability of an error. (*4*) To reduce error probability, the treatment plan worksheet was designed to display plan parameters in a format visually similar to the treatment console display, facilitating data entry and verification. (*5*) VLSAs are color coded and labeled to match the electronic medical record prescriptions, simplifying in-room selection and verification.

CONCLUSIONS: Multidisciplinary planning and FMEA increased detectability and reduced error probability during VLSA HDR brachytherapy. This clinical model may be useful to institutions implementing similar procedures.

Keywords: Leipzig; Valencia; FMEA; HDR; Skin; Brachytherapy; Surface applicator; Failure modes and effects analysis; Safety; Quality

Introduction

In this study, failure modes and effects analysis (FMEA) is applied to the clinical procedure for high-dose-rate (HDR) skin treatments using Valencia and Leipzig surface applicators (VLSAs). VLSAs are single-channel tungsten alloy brachytherapy surface applicators used to treat basal cell carcinoma, squamous cell carcinoma, and Kaposi sarcoma (1, 2). The applicators use a single dwell position to treat lesions up to 2 cm in diameter. They are available in several sizes (1, 2, and 3 cm), with (Valencia) and without (Leipzig) a flattening filter. Treatment involves securing the skin applicator to the patient surface and delivering radiation using an iridium-192 HDR remote afterloader. Iridium-192 undergoes beta decay to produce a complex energy spectrum, with a mean energy of 0.38 MeV. Radiation is frequently prescribed to a depth of 3 mm, thus delivering 137% of the prescription dose to the skin surface, and 80% to a depth of 5 mm (3). Despite using familiar equipment, this specific surface applicator process varies substantially from standard HDR treatment therapies.

In a modern radiation oncology clinic, physicists plan HDR brachytherapy treatments using a CT-based treatment planning system (TPS). However, a CT-based planning system is not well suited for planning skin treatments that use VLSAs for several reasons. Clinically, most superficial skin lesions are not well visualized using CT. Instead, the treatment volume and prescription depth are defined using a physical examination or high-frequency ultrasound study

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(4, 5). Additionally, not all commercially available TPSs support shielded applicators. Our clinic uses Oncentra Brachy (Elekta, Stockholm, Sweeden), which, like many systems, calculate dose using the Task Group-43 (TG-43) protocol (6, 7). TG-43 assumes an unbounded water media where low- and high-density materials are not present (8–10). The VLSAs meet neither of these criteria, as they are made of a high-density tungsten alloy, and are applied on a prominent tissue–air interface (Fig. 1). The surface applicators shield the source in most directions, creating a dose distribution that does not maintain either radial symmetry or transverse symmetry, depending on the applicator model. Thus, a TPS that uses TG-43 formalism is not appropriate for modeling VLSAs. The applicator vendor recommends clinical implementation of published dose rate distributions, which were calculated using Monte Carlo (5, 11, 12). The vendor also recommends clinical implementation of published output factors after verification (3). Some TPSs support library plans for VLSAs, which allow the user to calculate dwell time based on the manufacturer-published dose rate in the TPS, and maintain a standard HDR clinical workflow. However, this feature is not available for VLSAs in our clinic's TPS. Therefore, for each patient treatment, the source dwell time is determined using a simple hand calculation. With a hand calculation, plan parameters are entered manually, as opposed to being exported from the TPS to the treatment console. This introduces a planning procedure substantially different from what most clinics currently have in place for brachytherapy. The unfamiliarity of the clinical procedure provides opportunity for significant errors that could impact patient outcome.

Because HDR delivers a high dose of radiation to a patient in a small number of fractions, errors in any stage of the simulation, planning, and treatment could result in a significant deviation from the intended treatment. The need for a robust HDR brachytherapy quality assurance (QA) program is well established (13, 14). Recently, the QA paradigm has shifted to include the proactive approach of anticipating potential errors and evaluating associated risks (15). One effective tool for a proactive QA program is FMEA. FMEA strengthens a clinical procedure by identifying the points in a process that are most error-prone and have the most severe consequences (16, 17). This QA tool has been used in radiation oncology for the simulation and treatment planning process for CT-based external beam radiation therapy and CT-based brachytherapy (17, 18). FMEA is particularly applicable for HDR brachytherapy surface treatments; although the delivery equipment and personnel for HDR skin treatment are unchanged, the clinical procedure is quite different. Because the planning process for VLSAs is not CT based, the existing simulation, planning, and plan check workflow is not observed. Therefore, the standing QA programs may not appropriately interrogate the procedure.

The first step in FMEA is to create a detailed step-by-step illustration, called a process map, of a clinical procedure. For each step of the process, the multidisciplinary team identifies all the possible failure modes. Each failure mode is then assessed for its risk potential in three categories: *Severity* evaluates the consequences of a failure; *occurrence* estimates the probability of a failure at a given step; and *detectability* evaluates the likelihood that an error is discovered before reaching the patient. For each failure mode, a number value between 1 and 10 is assigned in each of the three categories. The product of these three values, called the risk priority number (RPN), is calculated and used for analysis of the process (17, 18). The scoring system used for this study is detailed in Table 1. It has been adapted from the scoring system proposed by Ford *et al.* (17) for FMEA in radiation oncology and Wilkinson and Kora (18) for FMEA in HDR brachytherapy. This article applies FMEA to examine the entire clinical process of simulating, planning, and treating patients using the Valencia and Leipzig HDR brachytherapy surface applicators and reports improvements made to address processes with high RPN scores.

Methods and materials

As part of the implementation of the brachytherapy skin program at our institution, physicists created a dose calculation worksheet and a proposed process map. A multidisciplinary team consisting of nurses, therapists, physics and medical residents, physicists, and two radiation oncologists reviewed the process map and offered suggestions and corrections. Each failure point was evaluated for its severity, occurrence, and detectability using the scoring system outlined in Table 1.

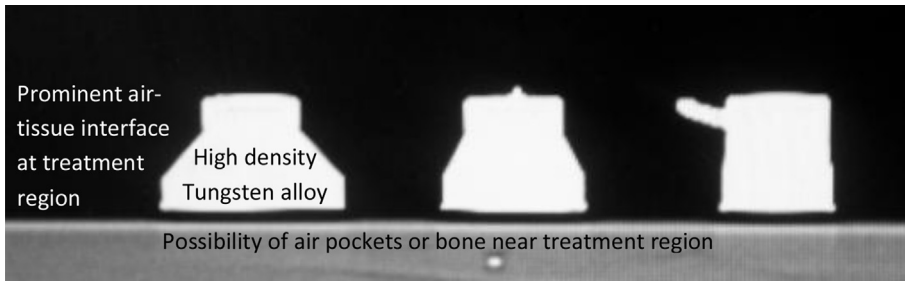

Fig. 1. CT scout film of Valencia and Leipzig surface applicators.