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Failure modes and effects analysis in image-guided high-dose-rate brachytherapy: Quality control optimization to reduce errors in treatment volume

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ABSTRACT

PURPOSE: Analyze the inputs which cause treatment to the wrong volume in high-dose-rate brachytherapy (HDRB), with emphasis on imaging role during implant, planning, and treatment verification. The end purpose is to compare our current practice to the findings of the study and apply changes where necessary.

METHODS AND MATERIALS: Failure mode and effects analysis was used to study the failure pathways for treating the wrong volume in HDRB. The role of imaging and personnel was emphasized, and subcategories were formed. A quality assurance procedure is proposed for each high-scoring failure mode (FM).

RESULTS: Forty FMs were found that lead to treating the wrong volume. Of these, 73% were human failures, 20% were machine failures, and 7% were procedural/guideline failures. The use of imaging was found to resolve 85% of the FMs. We also noted that imaging processes were under used in current practice of HDRB especially in pretreatment verification. Twelve FMs (30%) scored the highest, and for each one of them, we propose clinical/practical solutions that could be applied to reduce the risk by increasing detectability.

CONCLUSIONS: This work resulted in two conclusions: the role of imaging in improving failure detection and the emphasized role of human-based failures. The majority of FMs are human failures, and imaging increased the ability to detect 85% of all FMs. We proposed quality assurance practices for each high-scoring FM and have implemented some of them in our own practice.

Keywords: Failure mode and effects analysis; High-dose-rate brachytherapy; Image guided; Quality assurance; Treatment volume

Introduction

High-dose-rate brachytherapy (HDRB) treatment plays a major role in the management of many radiation therapy patients especially those with cervical cancer (1–4). The Groupe Européen de Curiethérapie and the European Society for Radiotherapy and Oncology working group has emphasized the role of three-dimensional image-based treatment planning including dose-volume parameters, tumor and organ at risk (OAR) delineation, applicator reconstruction, and radiobiologic considerations (4–8). Three-dimensional planning also requires correct geometrical reconstruction of the applicators and catheters (6–18).

As processes get more complex, quality assurance (QA) becomes more involved and time consuming and a more focused QA system is needed. Failure modes and effects analysis (FMEA) is a risk-based process analysis tool that has been used recently in radiation therapy to reevaluate various radiotherapy processes and the required QA system (19–29). The use of FMEA in modern-day practice is championed by the American Association of Physicists in Medicine in their very recent task group known as TG-100 "Application of Risk Analysis Methods to Radiation Therapy Quality Management" (30).

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Conflicts of interest: None.

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In 2008, Williamson (31) challenged the current practice of QA used for image-guided brachytherapy stating that those practices are directed to non−image-based systems. He reviewed the published guidelines on brachytherapy and concluded that "none of the documents reviewed provided detailed guidance for image-guided brachytherapy procedure …" (31). Furthermore, he noted that almost 40% of brachytherapy events and misadministrations "involved implanting the wrong organ because of poor transrectal ultrasound (US) image quality, image misinterpretation, or failure to verify the needle position." The figure 40% should raise a flag and instill a sense of urgency to introduce proper image guidance and related QA. In the same year, Thomadsen (32) analyzed various quality management systems used in radiation therapy and found 108 misadministration events in brachytherapy. Most of these resulted from "inappropriate actions by a person." The human-factor emphasis in Thomadsen's article represents a deviation from the machine-focused QA mentality that is prevalent. Still the same year, Williamson *et al.* (33) reported the recommendations of the 2007 symposium conducted by the American Society for Radiation Oncology, American Association of Physicists in Medicine, and the National Cancer Institute, where it was reiterated that the current QA is not sufficient for image-based planning or image-guided treatments.

After this plethora of articles and the need to redesign the QA system using risk-based analysis, Wilkinson and Kolar (34) looked into the failures that would lead to wrong dose in HDRB delivery and identified 25 potential failure modes (FMs), which were grouped into six categories. They found that FMs associated with image sets, catheter reconstruction, indexer length, and incorrect dose points had the highest ranking. In their paper, they propose few actions to increase the detectability of certain errors.

A more recent publication (35) used FMEA to investigate the CT-guided brachytherapy process for the purpose of reducing the time of the procedure. Roles were reassigned as well as the QA process redistributed to allow for parallel tasking and thus reducing procedure time by 29%. Another recent article (36) used FMEA for the purpose of improving QA and reducing errors leading to reportable events. The authors did a comprehensive analysis and found 170 FMs, and the highest ranking FM was a communication error "failure to inform dosimetry that the simulation was completed …" This failure in communication was scored as high as applicator instability. Applicator instability populated four out of six highest ranking FMs. As a solution to detect these failures, the authors propose the use of checklists with time stamps.

In radiation therapy, there are two major objectives, delivering the correct dose to the correct treatment volume. Wilkinson and Kolar (34) already discussed the failures leading to the wrong dose, whereas our work discusses the latter, failures leading to the wrong volume. For this work, we dissect the role of imaging processes in reducing many FMs in HDRB, starting from image-guided insertions, image-based planning, and image-based delivery (treatment verification). Furthermore, we propose practical clinical QA procedures (not including checklists) to reduce the risk of the highest scoring FM.

Methods and materials

Major process tree

We have identified 14 major processes common to any HDRB procedure, as shown in Fig. 1. Process Number 5, primary image acquisition, includes the CT simulator (CT-sim) acquisition as well as the orthogonal x-ray films. For the CT acquisition, two scenarios have been studied: One where the patient is transferred to the CT-sim room, and the other where the patient is in a brachytherapy-dedicated room and a cone beam CT (CBCT) simulator is available. The difference between the two is the extra step in moving the patient to another imaging table and the potential of applicator instability.

It should be noted that the process tree we generated, Fig. 1, does not follow the recommendations of TG-100. Process mapping should not have a choice, an "or" process. It should reflect what should be done. As seen from Fig. 1, Process #5 discusses CT imaging or orthogonal planar imaging. Our practice uses either images from CT-sim or from CBCT but not orthogonal images. However, this was mentioned here to include it in a later analysis comparing FMs between processes using CT images vs. orthogonal images.

Process #13, pretreatment image-based verification, represents one of the earliest conclusions of this work. In external beam treatment, image-guided patient setup using either electronic portal imaging devices or CBCTs is routinely practiced. Pretreatment image verification is used to verify that no shift occurred in the relative position between the applicator and the OARs. If such shift was observed, then dose reassessment is done.

The dashed processes shown in Fig. 1 are image dependent and are the focus of this work.

Fault tree analysis and the risk priority number

Fault tree analysis (FTA) is shown in Figs. 2a and 2b. FTA is constructed from left to right, beginning at the end error, in this case "the wrong volume" and finding the failures that lead to it. Each failure is then analyzed for failures upstream that cause it and so on. The analysis continues until the failures are outside the control of the process, and this is the right most FM in Figs. 2a and 2b. We note three remarks regarding Figs. 2a and 2b:

a. It is understood that for each failure to occur, the event is coupled with a failure in the quality control, this is represented by an (AND) gate. For a subset of