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A risk-based approach to development of ultrasound-based high-dose-rate prostate brachytherapy quality management

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ABSTRACT

PURPOSE: The purpose of this study was to apply a risk-based approach to the development of a quality management (QM) program for ultrasound-based high-dose-rate (HDR) prostate brachytherapy (pBT) treatment planning and delivery.

METHODS AND MATERIALS: A QM program was developed by a multidisciplinary team, using both an in-house risk-and-benefit balance impact template (RABBIT) tool and a failure modes and effect analysis (FMEA). FMEA scores were determined by three physicists, one radiation therapist and two radiation oncologists who were familiar with the protocol. The QM program produced by both risk-based techniques was then compared and consolidated.

RESULTS: The RABBIT tool identified 26 potential risks during the treatment planning and delivery process. During the FMEA, a total of 35 potential failure modes were identified from the seven major processes in ultrasound-based HDR pBT. For the 35 potential failure modes, risk priority number scores ranged from 14 to 267. The highest ranked failure mode was identified to be mislabeling/connection of the transfer tubes/catheters. From the risks analyses, a comprehensive QM program was developed.

CONCLUSION: Both the RABBIT tool and process mapping and FMEA were shown to be valuable tools in developing a QM program for ultrasound-based HDR pBT treatments. A considerable number of the potential failure modes identified in both tools were related to human or procedural errors, highlighting the importance of checklists and protocols in delivering a safe and effective ultrasound-based HDR pBT treatment.

Keywords: FMEA; Real-time HDR brachytherapy; Oncentra prostate; Quality management

Introduction

High-dose-rate (HDR) prostate brachytherapy (pBT) treatments are widely practiced in the radiation oncology community. When used in combination with external beam radiotherapy (EBRT) in the form of a boost, it provides a safe and effective form of treatment for intermediate- and high-risk prostate cancer (1). This is emphasized by a number of recent studies showing an improved quality of life outcome for combined EBRT and HDR brachytherapy compared with EBRT alone (1–3) and studies reporting favorable results using HDR brachytherapy as a monotherapy (4, 5).

HDR pBT treatments are typically planned using a postoperative CT scan. This workflow necessitates movement of the patient off the operating table and out of the dorsal lithotomy position. Movement of the patient in this manner has been shown to result in shifts of the catheters in the inferior direction, relative to the prostate, in the time between CT scanning and treatment (6, 7). The use of transrectal ultrasound images for treatment planning has been increasing rapidly in recent years, owing to its excellent visibility of the prostate tissue and surrounding organs at risk (8). Modern brachytherapy treatment planning systems (BTPSs) are able to use the ultrasound echoes of the implanted catheters for the definition of the catheter position within the patient, allowing for "real-time" HDR pBT treatment planning (8). The major advantage of this workflow is the removal of the requirement to correct for catheter displacements relative to the prostate in the time between imaging and treatment, as described previously

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(8). The definition of the catheter position however strongly affects the dose distribution in brachytherapy, and as this is a new technique, there is a need for more comprehensive pretreatment or *in vivo* quality assurance (QA) (9).

With the introduction of complex processes, such as ultrasound-based HDR pBT planning and delivery, a more intensive and robust QA system is needed. Prescriptive approaches to HDR brachytherapy QA are provided in the American Association of Physicists in Medicine (AAPM) task group reports 56 (10) and 59 (11). Williamson (12) reviewed published brachytherapy misadministrations in 2008 and found that almost 40% of these were related to image misinterpretation, implanting the wrong organ because of poor image quality, and failure to verify the needle position. The study concluded that the current recommendations for brachytherapy QA practice should be directed more toward image-based systems. Thomadsen (13) also reviewed published brachytherapy misadministrations and found 108 events related to human and procedural factors. It is therefore beginning to be acknowledged in the brachytherapy community that prescriptive methods of quality management (QM) may not be sufficient in HDR brachytherapy to prevent serious errors in the treatment planning and delivery process.

Despite its long-standing use in industry, the use of failure modes and effects analysis (FMEA) in radiation oncology has been comparatively recent (14). Over the past several years, the number of publications applying FMEA to radiation oncology has increased dramatically. For EBRT, FMEA has been successfully applied to intensity-modulated radiation therapy (14), intraoperative radiation therapy (15), stereotactic body radiotherapy (16), amongst many others.

FMEA has also been shown to be effective for HDR brachytherapy. Swamidas *et al.* (17) identified 20 failure modes specific to intracavitary HDR brachytherapy, including aspects of treatment planning, source strength measurement, and applicator QA. Mayadev *et al.* (18) also performed FMEA on intracavitary HDR brachytherapy and found 170 failure modes, the highest ranking of which were applicator instability and communication failures after patient simulation.

Wilkinson and Kolar (19) examined potential failure modes during the HDR brachytherapy treatment planning process leading to an incorrect delivered dose, whereas Wadi-Ramadi *et al.* (20) focused on failure modes leading to the incorrect treatment volume. Both studies identified mislabeling of catheters or errors in catheter reconstruction as high-ranking failure modes. Each of the studies then go on to provide suggestions for QM to reduce the risk related to each failure mode. A novel application of FMEA in HDR brachytherapy to reduce the time between implantation and treatment delivery was performed by Damato *et al.* (21). The authors of this study were able to successfully redesign their QA program to reduce the time between brachytherapy implantation and treatment by 29%.

The aim of this study was to apply a risk-based approach to the development of a QM checklist for ultrasound-based HDR pBT treatment planning and delivery using Oncentra pBT treatment planning system (Elekta Brachytherapy, Veenendaal, Netherlands) (8, 22). Both an in-house developed risk-and-benefit balance impact template (RABBIT) assessment tool (23) and an FMEA approach were considered. During the FMEA process, each failure mode was ranked to determine the most likely failure modes and those with the most severe source of error in the process. This ranking system was then used to create an optimized QM program specific to ultrasound-based HDR pBT. The QM programs developed using both risk-based tools were then compared and consolidated with the aim to minimize the risk at each step in the treatment planning and delivery process.

Materials and methods

Risk-and-benefit balance impact template tool

The RABBIT tool is an in-house developed risk assessment tool designed to aid the end user in project management, QM, risk management, and compliance management (23). The tool provides a four-step process in the implementation of modern technology: project scope, technology readiness level, risk-and-benefit assessment, and decision guidance. It also requires a multidisciplinary approach to risk assessment so that all objectives and processes can be considered. During commissioning of ultrasound-based HDR pBT, the RABBIT tool was used to assess the potential risks associated with each stage in the treatment planning and delivery process. From this, a comprehensive QM checklist was developed to minimize the potential occurrence and maximize the detectability of each risk.

Process map

A process map of the ultrasound-based HDR pBT planning and delivery process was developed initially by three physicists, one radiation therapist and two radiation oncologists who were familiar with the treatment. Each team member first developed their own process map and identified failure modes at each step in the process. Individual process maps and failure modes were then discussed and amalgamated at a multidisciplinary team meeting. In this analysis, all potential failure modes were considered, regardless of the current QA program.

Failure modes and effects analysis

Individual team members scored each of the failure modes identified in the process map according to likelihood of occurrence (O), severity (S), and detectability (D). Each parameter (O, S, D) was given a score from 1 (less likely to occur, less severe, easy to detect) to 10 (more likely to occur, more severe, hard to detect) using the AAPM TG 100 formalism (14), as shown in Table 1. Scoring for severity was determined using the descriptions in Table 1 of the