ELSEVIER

Brachytherapy ■ (2017) ■

BRACHYTHERAPY

Failure modes and effects analysis for ocular brachytherapy

Yongsook C. Lee, Yongbok Kim*, Jason Wei-Yeong Huynh, Russell J. Hamilton

Department of Radiation Oncology, The University of Arizona, Tucson, AZ

ABSTRACT

PURPOSE: The aim of the study was to identify potential failure modes (FMs) having a high risk and to improve our current quality management (QM) program in Collaborative Ocular Melanoma Study (COMS) ocular brachytherapy by undertaking a failure modes and effects analysis (FMEA) and a fault tree analysis (FTA).

METHODS AND MATERIALS: Process mapping and FMEA were performed for COMS ocular brachytherapy. For all FMs identified in FMEA, risk priority numbers (RPNs) were determined by assigning and multiplying occurrence, severity, and lack of detectability values, each ranging from 1 to 10. FTA was performed for the major process that had the highest ranked FM.

RESULTS: Twelve major processes, 121 sub-process steps, 188 potential FMs, and 209 possible causes were identified. For 188 FMs, RPN scores ranged from 1.0 to 236.1. The plaque assembly process had the highest ranked FM. The majority of FMs were attributable to human failure (85.6%), and medical physicist−related failures were the most numerous (58.9% of all causes). After FMEA, additional QM methods were included for the top 10 FMs and 6 FMs with severity values $>$ 9.0. As a result, for these 16 FMs and the 5 major processes involved, quality control steps were increased from 8 (50%) to 15 (93.8%), and major processes having quality assurance steps were increased from 2 to 4.

CONCLUSIONS: To reduce high risk in current clinical practice, we proposed QM methods. They mainly include a check or verification of procedures/steps and the use of checklists for both ophthalmology and radiation oncology staff, and intraoperative ultrasound-guided plaque positioning for ophthalmology staff.

Keywords: Quality management; Ocular brachytherapy; Failure modes and effects analysis; Fault tree analysis; Quality control; Quality assurance

Introduction

One of the treatment options for intraocular tumors (e.g., ocular melanoma, retinoblastoma, or choroidal hemangioma) is ocular brachytherapy using radionuclides emitting low-energy photons (^{125}I, ^{103}Pd, or ^{131}Cs) or beta rays (^{106}Ru/^{106}Rh or ^{90}Sr) (1−3). Since the Collaborative Ocular Melanoma Study (COMS) standardized methods for plaque brachytherapy, COMS plaques have been widely used in clinics. However, ocular brachytherapy is a complex and lengthy procedure which usually takes several weeks from diagnosis to plaque removal (4). In addition, medical staff members in a multidisciplinary team such as a retina specialist, a radiation oncologist, a medical physicist, an anesthesiologist and a nurse are involved in the procedure. Although there was only one medical incident (correct administration but incorrect written directive) reported to the United States Nuclear Regulatory Commission between January 2015 and April 2017 (5), due to the complexity of the procedure, radionuclide involvement, and high prescribed dose, safety is a concern.

There are several published clinical guidelines for brachytherapy, ocular brachytherapy, and eye plaques. The American Association of Physicists in Medicine (AAPM) Task Group (TG)-40 provides guidance for comprehensive quality assurance (QA) and procedures in radiation oncology including brachytherapy (6). TG-56 describes code of practice for brachytherapy, and TG-138 discusses dosimetric uncertainty for photon-emitting brachytherapy sources (7, 8). TG-129 presents dosimetry,

Received 21 March 2017; received in revised form 29 June 2017; accepted 11 July 2017.

Conflict of interest: The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

* Corresponding author. Department of Radiation Oncology, The University of Arizona, 1501 N. Campbell Avenue, P.O. Box 245081, Tucson, AZ 85724-5081. Tel.: 520-694-7427; fax: 520-694-0228.

E-mail address: yongbokkim@email.arizona.edu (Y. Kim).

1538-4721/$ - see front matter
http://dx.doi.org/10.1016/j.brachy.2017.07.005

clinical aspects, and quality management (QM) program recommendations for ^{125}I and ^{103}Pd COMS eye plaques (2), and the American Brachytherapy Society provides consensus guidelines for clinical practice of ocular brachytherapy (3). In addition, recent guidelines of TG-167 on the use of innovative brachytherapy devices and applications briefly discuss dosimetric considerations for COMS and non-COMS eye plaques (9). Nonetheless, there still exist clinical practice and QA challenges in modern low-dose-rate brachytherapy sources and dosimetry (10). In 2008, Williamson (11) stated in his publication ''Published brachytherapy guidance has largely emphasized commissioning and periodic testing of devices. QA of individual patient treatments has been given less emphasis.'' and he stressed process-specific QA guidance.

Failure modes and effects analysis (FMEA) is a risk-based process analysis tool recently adopted by the AAPM to radiation therapy treatment (12−14), and a recent publication of AAPM TG-100 provides information and guidance to application of FMEA in clinical practice (14). FMEA allows for assessing potential failure modes (FMs), identifying the weakness of process and improving a QM program in clinical procedures (15). Thus, the TG-100 report has encouraged each clinic to examine its own process and practice. To our knowledge, there were only two FMEA studies performed for ocular brachytherapy and both were in an abstract format (16, 17). In the studies, Huynh and Kim (16) performed only process mapping identifying 71 FMs for 8 major processes, and Tseng *et al.* (17) undertook FMEA identifying 21 FMs for 3 major processes and possible causes. However, neither of the studies evaluated their QM programs. In this study, FMEA and fault tree analysis (FTA) for COMS ocular brachytherapy were undertaken based on our institutional practice, and our current in-house QM program was evaluated.

Methods and materials

Process mapping

Process mapping for ocular brachytherapy was performed. A QM team consisting of 7 staff members including a retina specialist, a radiation oncologist, 3 medical physicists, an anesthesiologist, and a nurse was formed, and the entire treatment process of ocular brachytherapy performed at our institution was comprehensively reviewed. Then, a process map which includes a major process tree and sub-process steps was generated based on the guidance in AAPM TG-100 and by Ford *et al.* (14, 18).

Failure modes and effects analysis

Following process mapping, FMEA was performed by the QM team. First, potential FMs for each sub-process step were identified. Second, possible causes and the impact of each potential FM on the outcome of the process were assessed. Third, current QM (QA and quality control [QC]) methods were identified for each major process and each potential FM, respectively. Fourth, for each potential FM, each QM team member assigned numerical values to the 3 parameters, occurrence (O), severity (S), and lack of detectability (D), each ranging from 1 to 10. There are several FMEA scoring systems available from the literature, and the definitions for the 3 parameters vary among these publications (12, 15, 19). In this study, the definition and quantitative descriptions of the 3 parameters and consensus nomenclature for severity were based on Tables I and II in the AAPM TG-100 (14). Finally, risk priority numbers (RPNs) were calculated by multiplying values for the 3 parameters. Average values of O, S, D, and RPN scores were taken for FMs evaluated by 3 medical physicists or all staff. RPN scores ranged from 1 (O = S = D = 1) to 1000 (O = S = D = 10). Several sub-processes that were purely QM steps such as pre-treatment physics chart checks were omitted from the FMEA (but counted as sub-process steps) as our goal was to identify steps that could not be predicted or checked by current routine QA procedures.

Fault tree analysis

FTA was performed for the major process having the highest ranked FM (i.e., highest RPN score) identified in FMEA. FMEA and FTA determined what could go wrong in each step and what steps in current practice were not covered by our current QM program.

Suggested QM methods and risk-reduction interventions

Based on the findings in FMEA and FTA, QM (QA and QC) methods which had not existed in our current QM program were suggested and added. To reduce potential high risk and to develop an efficient QM program, in this study, the suggested QM methods were prioritized for (*1*) the 10 highest ranked FMs, (*2*) FMs with S values > 9.0, and (*3*) the major process that had the highest ranked FM. The definitions of QC and QA mentioned above are as follows. QC as error prevention covers all inputs in a process to make sure that they are correct, and therefore, errors caught by QC are relatively easy to correct (14, 20). On the other hand, QA as error interception assesses the overall results of the process and, thus, requires fewer resources to find an error, but a failure found by QA necessitates more time and effort to fix (14, 20). Therefore, QC is effective in reducing occurrence, whereas QA is effectual in increasing detectability.

Results

Process mapping

From process mapping, 12 major processes and 121 sub-process steps were identified. Figure 1 shows the major processes, and Table 1 summarizes the number of sub-process