ISSN: 2230-9926

Available online at http://www.journalijdr.com

IJDR

International Journal of Development Research
Vol. 09, Issue, 11, pp. 31183-31189, November, 2019

RESEARCH ARTICLE OPEN ACCESS

APPLICATION OF A RISK ANALYSIS METHOD IN CONFORMATIONAL 3D TELETHERAPY FOR BREAST CANCER TREATMENT

[*1]Francile Cardoso de Vargas, [2]Laurete Medeiros Borges, [3]Patrícia Fernanda Dorow, [4]Andrea Huhn, [2]Gerusa Ribeiro, [5]Charlene da Silva and [6]Ernani Lange de S. Thiago

[1]Master in Radiological Protection, Corb Radiologist Technologist, Blumenau, Brazil
[2]PhD in Nursing, Professor at the Federal Institute of Santa Catarina - IFSC, Florianópolis, Brazil
[3]PhD in Engineering and Knowledge Management, Professor at the Federal Institute of Santa Catarina - IFSC, Florianópolis, Brazil
[4]PhD student in Nursing, professor at the Federal Institute of Santa Catarina - IFSC, Florianópolis, Brazil
[5]Master in Radiological Protection, professor at the Federal Institute of Santa Catarina - IFSC, Florianópolis, Brazil
[6]Doctor-oncologist, technical director of the Casa de Saúde and Radiotherapy Clinic São Sebastião, Florianópolis, Brazil

ARTICLE INFO

Article History:
Received 09th August, 2019
Received in revised form
21st September, 2019
Accepted 03rd October, 2019
Published online 20th November, 2019

Key Words:

Teletherapy; Risk analysis; FMEA; Radiological protection.

Corresponding author:
Francile Cardoso de Vargas

ABSTRACT

The objective of this research was to analyze the risks in 3D conformational teletherapy for breast cancer treatment by applying a risk analysis methodology. Treatment processes for breast cancer with 3D conformational teletherapy, image-guided radiotherapy and boost were included in the research. The stages that presented the highest risk percentages were the printing of the technical file (20%), other days of treatment (10.4%) and electron boost (13.3%). Failure modes with Severity parameter scored equal to or greater than 7 resulted in the following percentages: data sheet printing (80%), first day of treatment (79.9%), electron boost (81.8%), export planning (58.8%), other days of treatment (70.9%), boost planning (69%) and photon boost (75.8%). The stages that presented the highest percentage of failure modes with Severity parameter scored 10 were the export of the planning (58.8%), printing of the technical file (80%), first day of treatment (65.9%), other days of treatment (56.7%), photon boost (70.5%) and electron boost (75.1%). The causes of the most significant potential failure modes stem from human failures.

Citation: Francile Cardoso de Vargas, Laurete Medeiros Borges, Patrícia Fernanda Dorow, Andrea Huhn, Gerusa Ribeiro, Charlene da Silva and Ernani Lange de S. Thiago. 2019. "Application of a risk analysis method in conformational 3d teletherapy for breast cancer treatment", *International Journal of Development Research*, 09, (11), 31183-31189.

INTRODUCTION

Teletherapy is a local treatment modality for breast cancer and may be indicated at all stages of the disease. Breast cancer is the most common cancer in women in most parts of the world, and the estimate for 2019 in Brazil alone is 59,700 new cases of breast cancer (INCA, 2019). Treatment consists of the use of ionizing radiation for therapeutic purposes, with the objective of eliminating or reducing the tumor (RADICCHI, 2017). Despite the known risks of exposure to high-dose ionizing radiation, teletherapy is considered to be one of the safest areas of modern medicine (Malicki *et al*., 2018).

The safety of radiotherapy treatment is the delivery of the correct dose in the correct region of the correct patient. Error rates in this type of process are considered low, however, there is a strong incentive to reduce these rates given the potentially catastrophic nature of a patient error (FORD *et al*., 2009). The procedures performed in this sector are quite complex and are constantly prone to human and / or technical failures. In view of this, reporting errors made in radiotherapy treatments stimulated the creation of new treatment systems focused on reducing the probability of errors (CHAN *et al*., 2010). Allied to these new technologies, the implementation of risk analysis programs in radiotherapy is increasingly common to eliminate or detect any errors before they have any effect on the patient (MALICKI *et al*., 2018). The American Association of Medical Physics (AAPM) suggests the application of a prospective risk analysis methodology, seeking to identify fallible steps in the teletherapy process before an adverse event occurs, enabling new measures to be taken to reduce the likelihood of occurrence. potential failures or to increase the likelihood of these failures being detected (HUQ *et al*., 2016). From the above, the research objective was to analyze the risks in 3D conformational teletherapy for breast cancer treatment with the application of a risk analysis methodology.

MATERIAL AND METHODS

The place of the research was a private radiotherapy service located in the coastal region of Santa Catarina State - Brazil. The methodological framework for conducting this research was the methodology proposed by AAPM Task Group (TG) 100 in its Report No. 283. The Process Mapping, Failure Mode and Effects Analysis (FMEA) and Tree Analysis tools were used. Failure (FTA). The process analyzed was the 3D Conformational Teletherapy for the treatment of breast cancer patients, and this therapeutic modality presents two prescription variations, either alone or with the indication of boost. In addition, there is also the possibility of the patient choosing to perform the treatment using the IGRT imaging modality. Thus, all three of these processes were analyzed in this research. One radio-oncologist, one physicist, one dosimetrist and one radiologist technologist participated in the research, totaling 4 participants. The choice of such professionals was based on their interest in performing this work. The research participants were selected according to the following inclusion criteria: to act directly in the planning and / or administration of teletherapy for breast cancer and to participate freely and spontaneously. The first stage was carried out in January 2019, using the non-participant observation technique, which took place on 1 day, for a period of 8 hours, in the afternoon and morning shifts of the service. This stage aimed to detect all the steps involved in the process for the construction of the Process Map. It is noteworthy that the treatment protocol analyzed corresponds to approximately 60% of the protocols performed daily by the service, thus, it was considered appropriate this observation time.

The second step, called risk analysis, was performed by applying the FMEA and FTA tools. The risk analysis stage took place in two stages from February to July 2019: the first stage was held through meetings between a member (leader) of the expert group with the researcher, the purpose of this stage was to identify potential failure modes of each step, as well as the weightings of the Severity (S), Occurrence (O) and Detectability (D) parameters, from which the Risk Priority Number (NPR) of each potential failure. It took 20 weekly meetings, lasting one hour each, totaling 20 hours of discussion. In the second step, which was completed after the application of the tool, each group member received a copy of the spreadsheet for analysis and consideration. In cases where there were differences of opinion on the score of the parameters, the group chose to reach a consensus, finally reaching the results obtained. The last phase of the methodology, after calculating the NPR, is to rank the failure modes according to the obtained NPR values. To make the ranking we used as a reference the work done by Teixeira (2015) who was pioneer in Brazil regarding the risk analysis in radiotherapy services. For this, the failure modes were organized in descending order (from highest to lowest NPR value) and a cutoff value for NPR was defined by averaging 20% of the highest NPR's. Thus, we find the following NPR cutoff values:

3D conformational teletherapy for breast cancer__________535

Image Guided Radiotherapy (IGRT)__________________471

Boost____628

Thus, failure modes that presented NPR ≥ 535 in the 3D conformational teletherapy process were considered as a priority for the creation and possible implementation of new safety strategies by the researched service, as well as failure modes with NPR ≥ 471 in the process. IGRT and NPR ≥ 628 on boost. In addition, it is recommended that not only the higher value NPRs disposed by the NPR ranking be worked on, but also the failure modes with parameter S ≥ 7 be taken into account when creating new safety measures (TEIXEIRA, 2015). For data analysis and interpretation we worked with the combination of qualitative data from risk identification and quantitative data resulting from the score of parameters O, S and D, as well as the calculated NPR for each potential failure mode. The strategy used to shape the research procedures was the sequential exploratory, defined by Creswell (2010) as one that involves a first phase of qualitative data collection, followed by quantitative data collection, which is developed on qualitative results. The research was analyzed by the Ethics Committee on Research with Human Beings (CEP) and was approved under Opinion No. 3,100,847.

RESULTS

Process involved in the researched treatment: The 3D Conformational Teletherapy process is divided into two macroprocesses, ie pre-treatment and treatment. In the pre-treatment the patient goes through a medical and nursing consultation and undergoes the treatment simulation and CT imaging steps for treatment planning. The treatment is divided into the first day and the other days of treatment, since on the first day some specific procedures are performed, such as checking the fields and treatment parameters, the displacement to the isocenter and the acquisition of cone beam computed tomography images (CBCT). Finally, the treatment process involves positioning the patient on the linear accelerator and delivering the prescribed daily dose.

Pretreatment

Pretreatment comprises all the macro and micro steps necessary for the preparation of the radiotherapy treatment prescribed by the radiologist. The prescription is in the form of treatment site, dose delivery method, dose per fraction (in cGy), number of fractions, and total radiation dose required for cancer elimination or control. The first consultation of the patient occurs by referral by an oncologist and confirmation of the diagnosis of cancer through pathological examination (biopsy). The radiologistconsiderstheindication, ornot, ofradiotherapytreatment, andifconfirmed, thefirststepisto schedule a date for thesimulation. Simulation is the stage of radiotherapy treatment where the positioning of the patient is defined throughout the treatment, as well as the immobilization accessories that will be used. It is performed in the treatment room with the presence of radiologist, medical physicist, dosimetrist and radiologic technicians (PTRs). The patient is positioned as comfortably as possible on the linear accelerator treatment table, and the positioning is carefully analyzed, since it should be noted that it should allow the entry of radiation fields towards the location of the and the patient should reproduce it during all radiotherapy applications. The most common positioning protocol for the treatment of breast cancer requires the patient to be supine on a ramp surface with an angle ranging from 5º to 10º (variations available in the service), with arms raised and supported by the immobilization attachment structure; The patient is asked to keep her face away from the treatment side. It is noteworthy that there may be variations in positioning according to the patient's needs and / or limitations, for example, the arm opposite the treatment arm may be lowered or a thermoplastic mask may be worn on the patient's chest. In addition to this positioning, there is a protocol where the patient is positioned prone over a specific immobilization accessory. This positioning is ideal for use by patients who have larger breasts in order to protect risk organs such as lungs and heart (CAETANO, 2014). This protocol is not used by the researched service, as it does not have the said immobilization accessory.

For positioning to be reproducible daily, three (3) reference marks are made directly on your skin or immobilization accessory (when using the thermoplastic mask); These are 2 (two) lateral marks, on the right and left sides of the patient, and 1 (one) mark on the anterior region (thorax). Such marks are made from room positioning lasers; fuchsin dye is used for skin demarcation and tegaderm dressings to protect these markings so that they do not disappear in the bath or with perspiration itself. After the simulation, the patient goes through a nursing consultation, where all the guidance related to radiotherapy treatment is provided, such as care that should be taken by the patient, as well as their caregivers, and about the possible side effects of the treatment. It is during this consultation that the patient signs the Informed Consent (IC), authorizing the treatment. After the simulation, the next step is the computed tomography (CT) for radiotherapy planning. The acquisition of three-dimensional (3D) images - to plan the conformed technique - aims to allow the delineation of treatment targets and organs of risk present in the region to be treated, allowing the best distribution of the prescribed dose in a given target volume since the dose distribution is calculated throughout the volume to be irradiated (SBRT, 2014). In the CT step, the patient is positioned in the same way as defined in the simulation, that is, using the same immobilization accessories. CT scan lasers are used for correct patient positioning so that they must match the reference marks previously made on the patient's skin.

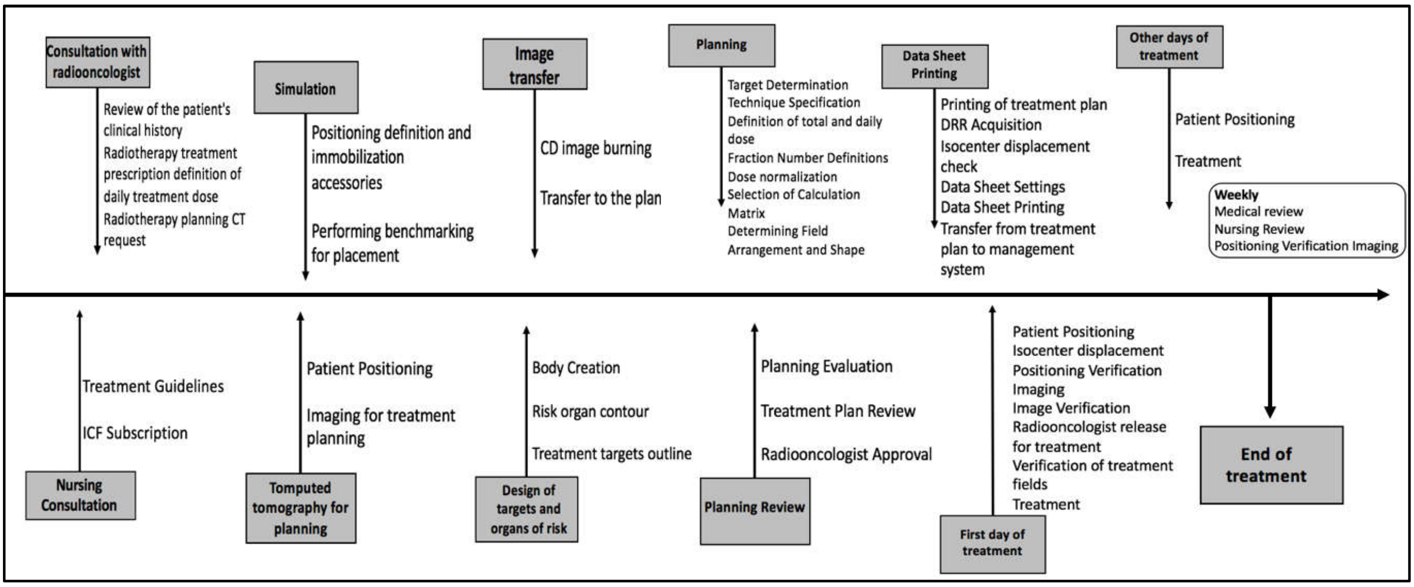
Immediately above such marks are radiopaque markers, which will appear on the axial CT section corresponding to the demarcated region; It is from these markers that the CT isocenter is defined, which will serve as a starting point for the displacement to the treatment isocenter, which will be performed on the first day of treatment. It is noteworthy that radiopaque markers are also inserted in the markings that demonstrate the limits of the treatment field, which are also made in the simulation stage by the radiologist. The planning CT is performed in a partner service of the researched place and the professionals responsible for this stage are the dosimetry of the radiotherapy team together with the radiological techniques professional of the imaging service.

The next stages of pretreatment are the delineation of treatment targets and organs of risk, ie, margins to be irradiated (GTV - Gross Tumor Volume, CTV - Clinical Target Volume, and PTV - Planning Target Volume) and the organs of risk located near these margins, with which care should be taken with respect to the radiation dose to which they will be exposed during treatment. The design is performed in the Monaco® design system by the radio-oncologist with the help of the dosimetrist. After this step, the dosimetric treatment planning is performed, which is performed by a physiotherapist specializing in radiotherapy or by a dosimetrist under the supervision of the physicist. The planning consists of several steps that involve the definition of the Hounsfield Scale (HU) versus the electronic density of the tomograph used to acquire the images for the planning; determination of treatment target; definition of tomography and treatment isocenters; specification of the treatment technique defined by the physician as well as the total radiation dose prescribed for the calculations; definition of the dose normalization point; choosing the most appropriate calculation matrix for the case; and determining the arrangement and shape of the fields and the distribution of the beam weights. The system used for planning is XiO®, and during this research the service was in the process of changing to the Monaco® planning system.

Upon completion of the treatment plan, the radio-oncologist should review it, observing compliance with the initial prescription and dose limits for radiation-exposed organs. If all measures are considered to have been respected, the plan is approved and released for further treatment. Thus, the next steps to be performed are the insertion of treatment in the management system used by the service, in this case MOSAIQ®, and the assembly of the treatment technical file. All two steps mentioned are performed by dosimetrists or medical physicists. After completion of the above steps, the pre-treatment phase is over and the treatment phase begins, where the patient effectively begins to receive the radiation dose prescribed by the physician at the initial consultation.

Treatment

The professionals responsible for applying the treatment are the PTR's, which may be technologists (higher level professionals) or technicians (mid level professionals) in radiology. Prior to initiating patient care, these professionals should conduct a conference of treatment fields directly at the LA, which is performed with the treatment map resting directly on the treatment table. In the event of any divergence, it should be checked with the help of the medical physicist before starting treatment. The displacement of the isocenter is made from the reference marks made in the simulation. This step is performed with the participation of professionals of radiological techniques, dosimetrist and medical physicist. At this time positioning verification images are acquired, which may be cone beam computed tomography (CBCT) images or digital radiographs, depending on each patient's treatment plan; These images are compared with those acquired by planning tomography or digitally reconstructed radiographs (DRR's). The purpose of this step is to verify that the location of the defined isocenter coincides with the isocenter determined during planning. The professional responsible for releasing the initiation of treatment is the radiologist. The doctor may request adjustments in the displacement performed.



Source: Researcher Authorship (2019)

Figure 1. Scheme of the teletherapy process

After release to start treatment, the planned daily dose is delivered. This step is the responsibility of the PTRs, and should be performed after checking the treatment parameters available in the management system with the patient's datasheet. Such parameters include: gantry, collimator and table angles; radiation energy; field sizes; and monitoring unit of each treatment field. In addition, it is the protocol of the service to perform the time out process, where the responsible professionals check the full name and medical record number of the patient in question. On other days of treatment the patient is directly referred to the treatment room, where he is positioned according to the simulation and receives the daily radiation dose. This same process is repeated until the last day of application. Some specific days are distinguished from the others in that, weekly, the patient undergoes medical, nursing review and new positioning verification images are acquired to monitor the reproducibility of treatment. These specifics are scheduled in the case of revisions or added to the management system in case of acquisition of weekly images. At the end, the patient goes through a medical and nursing consultation to receive the post-treatment care guidelines, as well as the necessary follow-up, besides the discharge of the radiotherapy treatment.

Teletherapy Process Map: According to Huq *et al*. (2016) The work process map is a fairly complete visual illustration of the physical and temporal relationships between the different steps of a work process, so it demonstrates the flow and interrelationship of these steps from the beginning to the end of the process. The map of the teleotherapy process of the researched service is represented by the scheme of Figure 1. The 3D conformational teletherapy process for breast cancer treatment in the researched service involves 11 steps, and 9 steps were inserted in this research. The included steps were subdivided into 62 substeps, adding 7 and 12 substeps of the other processes analyzed by the survey, IGRT and boost, respectively. All stages included in the research involve the participation of professionals from the administrative, medicine, medical physics (physicists and dosimetrists) and radiological techniques (radiology technicians and technologists).

Riskanalysis: From the application of the FMEA tool we obtained the potential failure mode numbers for each step of the analyzed processes. In this sense, Chart 1 was constructed in order to present the data obtained in the risk analysis stage of the research.

Ranking by Risk Priority Number and Severity parameter: As described in the methodology of this paper, an NPR cutoff value has been defined to select the failure modes that should be considered priority in risk management. As three different FMEA spreadsheets (3D Conformational Teletherapy, IGRT and Boost) were used, cutoff numbers were defined for each of them and, besides the failure modes that presented NPR greater than the cutoff number, those in that parameter S (severity) has been weighted at or above 7, which represents at least potentially serious toxicity or underdose in the tumor. NPR ranking results are in Appendix D of this research and Table 1 summarizes this data.

Table 1. Process data analyzed

Procedure	Number of steps	Number of Potential Failure Modes	Times the causes were pointed
Simulation	8	18	160
TC	10	21	183
Outline	6	13	108
Planning	14	32	247
Planning Review	2	5	40
Planning Export	1	2	17
Data SheetPrinting	3	5	35
Firstdayoftreatment	12	33	264
Otherdaysoftreatment	6	18	134
IGRT	7	14	122
Boost Planning	1	3	29
Boostwithphotons	8	26	207
Boostwithelectrons	3	16	165
Total	81	206	1.711

Source: Researcher authorship (2019).

It can be seen from Table 1 that 84 (eighty-four) potential failure modes of the 3D conformational teletherapy process, 11 (eleven) failure modes of the IGRT process, and 36 (thirty-six) failure modes were considered. From boost to risk management.

Table 1. NPR ranking data and parameter S ≥ 7

Stage	Number of Potential Failure Modes	Number of Failure Modes after Ranking	Percentage(%)	Number of Failure Modes with S ≥7	Percentage (%)
Simulation	160	8	5	50	31,3
TC	183	12	6,6	62	33,9
Outline	108	10	9,3	54	50
Planning	247	13	5,3	95	38,5
Planning Review	40	3	7,5	9	22,5
Planning Export	17	1	5,9	10	58,8
Data SheetPrinting	35	7	20	28	80
Firstdayoftreatment	264	16	6	211	79,9
Otherdaysoftreatment	134	14	10,4	95	70,9
IGRT	122	11	9	53	43,4
Boost Planning	29	-	-	20	69
Boostwithphotons	207	14	6,8	157	75,8
Boostwithelectrons	165	22	13,3	135	81,8

Source: Researcher authorship (2019).

Table 2. Ranking data by S ≥ 7

Stage	Failure Modes(%)				Total
	Severity				
	7	8	9	10	
Simulation	-	6,9	4,4	20	31,3
TC	-	6,6	-	27,3	33,9
Outline	-	7,4	16,7	25,9	50
Planning	-	6	9,7	25,9	41,6
Planning Review	-	-	-	22,5	22,5
Planning Export	-	-	-	58,8	58,8
Data SheetPrinting	-	-	-	80	80
Firstdayoftreatment	6,4	7,6	-	65,9	79,6
Otherdaysoftreatment	5,9	8,2	-	56,7	70,8
IGRT	-	-	7,4	36	43,4
Boost Planning	-	-	31	37,9	68,9
Boostwithphotons	-	5	-	70,5	75,5
Boostwithelectrons	-	6,7	-	75,1	81,8

Source: Researcher authorship (2019).

In addition, a total of 979 (nine hundred and seventy-nine) potential failure modes with parameter S equal to or greater than 7 were obtained for the analysis of the need for implementation of new safety measures. The stages of printing of the technical sheet, other days of treatment and boost with electrons were the ones that presented the highest percentage if considering only the ranking by NPR, being 20%, 10.4% and 13.3% respectively. Regarding the parameter S ≥ 7, the steps that presented the highest percentage were the printing of the technical file, with 80%, the first day of treatment, with 79.9% and electron boost, with 81.8%.

In addition to these, the planning export stages (58.8%), other treatment days (70.9%), boost planning (69%) and photon boost (75.8%) also presented very important percentages of failure modes with parameter S ≥ 7. Considering only the failure modes that presented the parameter S ≥ 7, we obtained the results presented in Table 2. It was verified that all stages analyzed presented failure mode percentages with the severity parameter equal to 10 (catastrophic), and the steps that presented more than 50% failure mode percentage with S = 10 were the planning export. (58.8%), technical data sheet printing (80%), first day of treatment (65.9%), other days of treatment (56.7%), photon boost (70.5%) and boost with electrons (75.1%). Among these, the electron boost treatment was the stage with the highest percentage of failure modes with S ≥ 7, with 81.8%, with 75.1% corresponding to failure modes with S = 10 and 6.7% with S = 8 (potentially severe toxicity or tumor underdose). On the other hand, the stage with the lowest number of failure modes with S ≥ 7 was the planning review, with a 22.5% percentage of failure modes with S = 10.

DISCUSSION

The stages with the highest NPR numbers of 3D conformational teletherapy started from simulation, CT planning and treatment planning. It should be noted that treatment planning in this research includes delineating the targets and organs of risk, planning, reviewing and exporting the treatment plan, and printing the data sheet. The professionals involved in these steps are PTR's (simulation), dosimetrician (simulation, CT planning, treatment design and planning), medical physicist (treatment simulation and planning) and radio-oncologist (design of targets and risk organs). The above result is quite consistent with reality, since the service has a risk management system for the treatment application, so that during the course of treatment the highest risk probability would be the wrong positioning of the patient, which includes the use of immobilization accessories erroneously. In addition, according to the Clarity Patient Safety Organization (2018) the treatment planning process is comprised of a series of complex tasks performed by various individuals (usually physician, physical and dosimetrician) who have distinct assignments that interact with each other. until the end of the step. In this sense, it is necessary to maintain an adequate level of communication between such professionals. This same publication points out that treatment planning errors account for approximately one third of all events reported in the Radiation Oncology Incident Learning System (RO-ILS) database, and that many of them were categorized into moderate to severe severity (CLARITY PSO, 2018). The research conducted by Teixeira (2015) found results that reinforce the possibility of high NPR failure modes occurring in the treatment planning process, as the referred researcher applied the same methodology used by this research in three different services. Radiotherapy and, in all services, the planning stage presented the highest percentage of failure modes. However, it is noteworthy that the procedure analyzed by Teixeira (2015) (intracranial radiosurgery) is different from the one analyzed in this research. The research by Agarwal *et al*. (2019) considered errors in radiotherapy treatment in low-income countries. From a total of 1005 patients, equivalent to 25,430 fractions, 67 errors were identified. Errors were classified as near miss or near miss and the results showed that 25 near misses involved 19 patients and 42 incidents occurred among 41 patients.

The largest number of errors originated in treatment planning, and the most critical step was the transfer of the treatment plan to the management system. Verification of the pretreatment data and the treatment itself were the following steps with the largest number of errors. Chan *et al*. (2010) conducted a survey at a radiotherapy service located in Ontario, Canada, which uses the same dose delivery and management system used by the site of this survey. The objective of the research was to identify the interaction of professionals with the system in question. It was noted that the verification process performed by the technicians prior to delivery of the treatment was considered particularly important as these professionals are required to perform many verifications such as approval of the treatment plan, verification of the treatment isocenter according to the images. as well as the verification of the linear accelerator treatment parameters with the management system. In addition, another punctuated problem was the lack of communication between the main user interface in the management system and the system used by physicians to verify image positioning, requiring the use of many screens to complete a single image. process. From the results obtained in the research by Chan *et al*. (2010), improvements were made in the user interface, aiming to solve the detected problems.

About the exclusive analysis of the Severity parameter Younge *et al*. (2015) state that it can be considered that almost any failure mode could lead to a catastrophic effect on the patient, which means that most severity scores would be weighted to 10. Therefore, care should be taken not to use scores in this way so as not to limit the usefulness of the severity parameter in classifying failure modes. In the IGRT stage, the highest NPR found after the failure mode ranking refers to the fusion of the images. This result is very important, since the use of CBCT images ensures the maximization of accuracy and precision throughout the patient's treatment process, since the verification of the images happens at the moment of treatment delivery (ACR-ASTRO, 2014). At the research site this step is performed exclusively by the doctor and requires the full attention of this professional. On the other hand, the highest NPR's achieved in boost beyond planning (as in the 3D conformational teletherapy process) was the wrong patient positioning.

Regarding this particular failure mode, a recent report from the RO-ILS database found a case in which the wrong patient was almost treated, given the fact that there were two patients with the same surname who needed treatment. to the right breast (CLARITY PSO, 2019). In this particular case, the technician who met the patient who should be treated identified the error, as he had already performed the correct patient treatment, but this event proves that this type of error can occur and should therefore be taken into consideration. Risk management programs. RASH *et al*. (2019) conducted a study using the FMEA tool to evaluate the intraoperative radiotherapy process for breast cancer patients treated with electronic brachytherapy. This type of treatment is totally different from the one analyzed by this research, however, it was the only research found conducted only on the treatment of breast cancer with radiotherapy using the methodology proposed by AAPM TG 100. Regarding the analysis of the potential causes for the failure modes found in this research, we found support in the research by Agarwal *et al*. (2019), who analyzed the root causes of errors committed in radiotherapy treatments, and presented results similar to those found in the researched service, and the most common and recurring contributing factors to errors committed in radiotherapy were the non-use of POPs, patient care documentation, miscommunication between staff and lack of knowledge and training of professionals. In our case we also highlight the lack of attention and lack of double checking among professionals.

Conclusions

The results obtained with this research showed that the steps of printing the technical data sheet, other days of treatment and electron boosting presented a higher percentage of possibility of errors considering the NPR. On the other hand, analyzing the parameter $S \geq 7$, we verified that the steps that presented the highest percentage were the printing of the technical sheet, first day of treatment and electron boost. The similarity of the results found using these two criteria reinforces the criticality involved in the printing process and electron boost treatment. After NPR failure mode ranking there was a predominance of failure modes with parameter S with values between 9 and 10, that is, representative of serious complications for the patient. In this sense, we should always draw attention to the verification of parameter D, in order to correctly visualize the real problematization presented by each potential failure mode. The possibility of process failures is often caused by human factors, such as negligence of standard operating procedures, inattention, communication failure (both oral and written, when placing position information on the data sheet, for example), as well as lack of collaboration by the patient himself. Nevertheless, one cannot disregard the possibility of failures arising from the equipment used in these sectors, hence the importance of correct maintenance and quality control. We emphasize that AAPM recommends that to perform the risk analysis using the TG 100 methodology, the existing barriers in the service are disregarded. Such barriers can be taken into consideration when considering the implementation of safety measures after the assessment of existing risks in the process. Several publications mention the methodology proposed by AAPM TG 100, noting the great acceptability of the method by professionals in the area. However, it was found that the general opinion of the researchers who used the tools proposed by the group was that the application of the methodology is tiring and needs the full support of the team involved.

REFERENCES

ACR-ASTRO. American College of Radiology – American Society for Radiation Oncology. ACR-ASTRO Practice parameter for Image-Guided Radiation Therapy (IGRT). Disponível em: <https://www.astro.org/Patient-Care-and-Research/Clinical-Practice-Statements/Consensus-Documents>. Acessoem: 09 ago 2019.

AGARWAL, J. P. *et al.* An audit for radiotherapy planning and treatment errors from a Low-Middle-Income Country Centre. *ClinicalOncology,* v. 31, n. 1, p. e67-e74, 2019.

CAETANO, Marco Alexandre Amador. Study of three immobilization systems used in radiotherapy - current and future perspective. Master Thesis (Master in Radiotherapy). *Polytechnic Institute of Lisbon*, 2014. 68p.

CHAN, Alvita J. *et al.* The use of human factors methods to identify and mitigate safety issues in radiation therapy. *Radiotherapy and Oncology,* v. 97, n. 3, p. 596-600, 2010.

CLARITY PSO. Aggregate report: Q3 – Q4 2018. Chicago: Division of Clarity Group, 2019.

CRESWELL, John W. Research project: qualitative, quantitative and mixed methods. 3 ed. Porto Alegre: Artmed, 2010.

FORD, Eric C. *et al.* Evaluation of safety in a radiation oncology setting using Failure Mode and Effects Analysis. *International Journal of Radiation Oncology** Biology* Physics, v. 74, n. 3, p. 852-858, 2009.

HUQ *et al.* The report of Task Group 100 of the AAPM: application of risk analysis methods to radiation therapy quality management. *Medical Physics*, v. 43, n. 7, p. 4209-4262. 2016.

INCA José Alencar Gomes da Silva NationalCancerInstitute. The situation of breast cancer in Brazil: synthesis of data from information systems. Rio de Janeiro: INCA, 2019. Available at: <https://www.inca.gov.br/publicacoes/livros/situacao-do-cancer-de-mama-no-brasil-sintese-de-dados-dos- information systems>. Access on: 10 Aug 2019.

MALICKI, Julian *et al.* Patient safety in external beam radiotherapy, results of the ACCIRAD project: recommendations for radiotherapy institutions and national authorities on assessing risks and analysing adverse error-events and near misses. *Radiotherapy and Oncology*, v. 127, n. 2, p. 164-170, 2018.

RADICCHI, Lucas Augusto. Incident learning system: development and implementation in a radiotherapy service. Master Thesis (Master in Production Engineering). *Federal University of São Carlos,* 2017. 139p.

RASH, Dominique *et. al.* Risk analysis of electronic intraoperative radiation therapy for breast cancer. Brachytherapy, v. 18, n. 3, p. 271-276. 2019.

SBRT. Brazilian Society of Radiotherapy. Breast cancer treatment with intensity modulated radiotherapy. 2014. Available at: <http://sbradioterapia.com.br/wp-content/uploads/2016/01/ma-cancer-de-mama-treatment-with-modulated- intensity- therapy.pdf>. Accessed on: 06 Aug. 2019.

TEIXEIRA, Flávia Crista da Silva. Study and development of a risk analysis model for intracranial radiosurgery. Doctoral Thesis (Doctorate in Biosciences). Rio de Janeiro State University, 2015. 295p.

YOUNGE, Kelly Cooper *et al*. Practical implementation of Failure Mode and Effects Analysis for safety and efficiency in stereotactic radiosurgery. *International Journal of Radiation Oncology,* v. 91, n. 5, p. 1003-1008. 2015.

****