Radiotherapy reliability analysis based on PSA method*

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The reliability of radiotherapy was evaluated and effective approaches were obtained in order to improve radiotherapy quality by using the Probabilistic Safety Assessment (PSA) method. This study investigated the feasibility of the PSA method being applied to radiotherapy through Image-guided Radiotherapy (IGRT) and chest tumor irradiation. A fault tree has been constructed after analyzing causal relationship of the events. After calculating RiskA, a total inaccuracy radiotherapy probability and the importance of all base events were obtained. The probability of inaccurate radiotherapy was 2.87%. Under the condition that the target delineation was perfectly right, the accuracy of radiotherapy significantly improved. With the calculation without Cone-beam Computed Tomography (CBCT) being corrected before irradiation, the accuracy significantly decreased. The most important events were connected with the human factor. Improving human technical level could enhance radiotherapy quality control efficiently.

Keywords: Probability safety analysis, Accurate radiotherapy, Reliability, Quality control, RiskA

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I. INTRODUCTION

Accurate radiotherapy focuses on more reliablility and safety. The ideal accuracy means an accurate planning target volume, which also requires planning actual dose delivery accurately and dose distribution accurately [1]. People have made many efforts to improve the reliability of radiotherapy, but in clinical trails some cases of irradiation have still not been accurate because of unskillful staffs or machinery reasons. What is accurate radiotherapy? There is no quantization definition, just describing words. Accurate analysis must rely on a reasonable definition of accurate. The standards of accuracy depend on the location of the tumor. However, the same location of the tumor has the same standard of accuracy. In addition, an effective method which could analyze the whole radiotherapy course was needed. This method should be used when analyzing the complex dynamic system of interaction between human and machinery factors. The Probabilistic Safety Assessment (PSA) method had been widely applied on nuclear power stations for many years. As an efficient method for complex system analysis, PSA was used in aerospace/aviation and chemical engineering, as well as the nuclear field. PSA method had been applied to radiotherapy by the author to assess the reliability and safety [2]. The advanced nuclear energy research team, FDS (Fusion Design and Study), deeply researched nuclear safety [3–7] and has developed a Reliability and Probabilistic Safety Assessment Program named RiskA [8–10]. This software was the first probabilistic safety assessment program applied to real-world nuclear power plants in China. This paper analyzes radiotherapy reliability based on the preliminary study of an accurate radiotherapy physics problem and technology [11–15]. The total probability of inaccuracy and the importance of all base events were obtained after being calculated in RiskA. In addition, all minimum paths have been arranged. The data for radiotherapy quality control is very important. In a clinical setting, doctors and physicists could improve irradiation accuracy efficiently by putting stress on the most important events.

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II. METHODS

A. Experiment conditions

This study is based on chest tumor cases and an Image-guided Radiotherapy (IGRT) system with Cone-beam Computed Tomography (CBCT) corrected on-line. The cases was obtained from a static hospital radiotherapy center. The conditions were: before the mid-tumor, together with chemotherapy; Elekta linear accelerator (precise) with KV magnitude CBCT; Electron portal imaging device (EPID) radiation field validation once a week; in the same simulation machine; with the same treatment planning system and treatment team.

B. Definition of the top event

In this paper, the top event is inaccurate. According to the clinical experience and various synthesized documents of radiotherapy quality demand, the IGRT inaccuracy of chest tumor is defined as follows.

1. *Irradiation targets stray from planned target more than* 1 cm

Deviation limited size is not determined nowadays though millimeter magnitude and accurate radiotherapy was widely recognized. In ordinary radiotherapy, human movement up to 2–3 cm in the cranio-caudal direction was common [16]. Without respiratory gating technique or other approaches to compromise breathing, a total deviation within 1 cm is acceptable. The dose distribution of Gross Tumor Volume (GTV) and organs at risk (OAR) would be seriously affected if the position were to stray more than 1 cm [17]. Baler *et al.* [18] noted that the target would loss 6 cm if the set-up errors were more than 1 cm.

2. *Deviation of dose delivery to a planned target is more than* $\pm 5\%$ *and dose distribution is not satisfied with plan assessment*

Radiation Units and Measurements (ICRU) Report No. 24 points out: If deviation of dose delivery to a planned target is more than $\pm 5\%$, the primary tumor lesion would be out of control and complications would increase. The target dose to OAR limitation was provided in the Radiation Therapy Oncology Group's (RTOG) 0225 and 0615 documents. The demand for dose plan assessment and the prescription dose demand were listed in RTOG No. 0418 protocols [19].

C. Building fault tree

Firstly analyze the process of all the selected radiotherapy cases. The general stages of IGRT radiotherapy in this study are shown in Fig. 1:

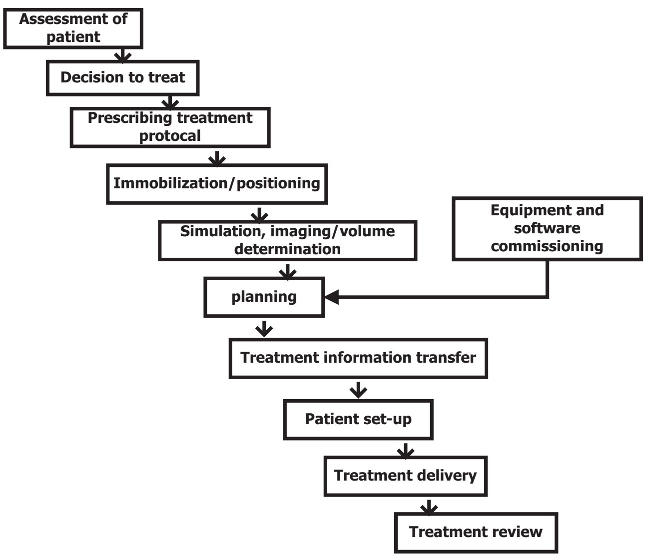

Fig. 1. Radiotherapy process.

A fault tree was built retrospectively starting from the analysis of the whole process to a certain procedure or a specific function of the device which is also known as a basic event. At last a fault tree was obtained (Fig. 2).

D. The probabilities of base events

Every base event has a probability, even if we pay no attention to it or if it was not recorded at that time. The probabilities of every event were shown in Table 1.

The methods through which the probabilities were obtained all as follows:

(1) Empirical data: Most of the probabilities of the base events could be obtained by clinical experience. For example, the frequency of misdiagnosis divided by irradiation times in the past years yield the probability of misdiagnosis.

(2) Maintenance data: Some machinery data was obtained from examination and the repair record. The probability was the frequency of fault.

(3) Hindsight: Some mistakes were not realized at that time, so analysis afterwards was the only method.

(4) Analog Statistics: The simulation statistics method means there was a multi-user outline for the same tumor. For example ICRU reported that the World Health Organization (WHO) organized 12 clinical experts to sketch the same tumor. The difference of the volumes they sketched out nearly double [20].

(5) Literature: Summarize the result by consulting the related literature and data.

E. Calculation using RiskA

We constructed a fault tree in RiskA and the configuration was the same as Fig. 1. Next, all the basic data was put into the tree leaves (base events) and calculated. The analyzed objects were *uncertainties* and *importance*. Importance analysis included : Fussell-vesely importance (cut-set importance); RAW (Risk Achievement Worth) importance; RRW (Risk Reduce Worth) importance. Lastly, the outcome was obtained after clicking calculation and analysis capabilities. The whole process of calculation was very convenient.

III. RESULTS

A. The probability of top event

According to the data in Fig. 1 and Table 1, the probability of a top event was 2.87%, as shown in Table 2. If the probability of target delineation errors is "0", that means that assuming target delineation was completely true, the probability of a top event would change to 1.18% and the total probability drops significantly. If there is no CBCT correction online, the

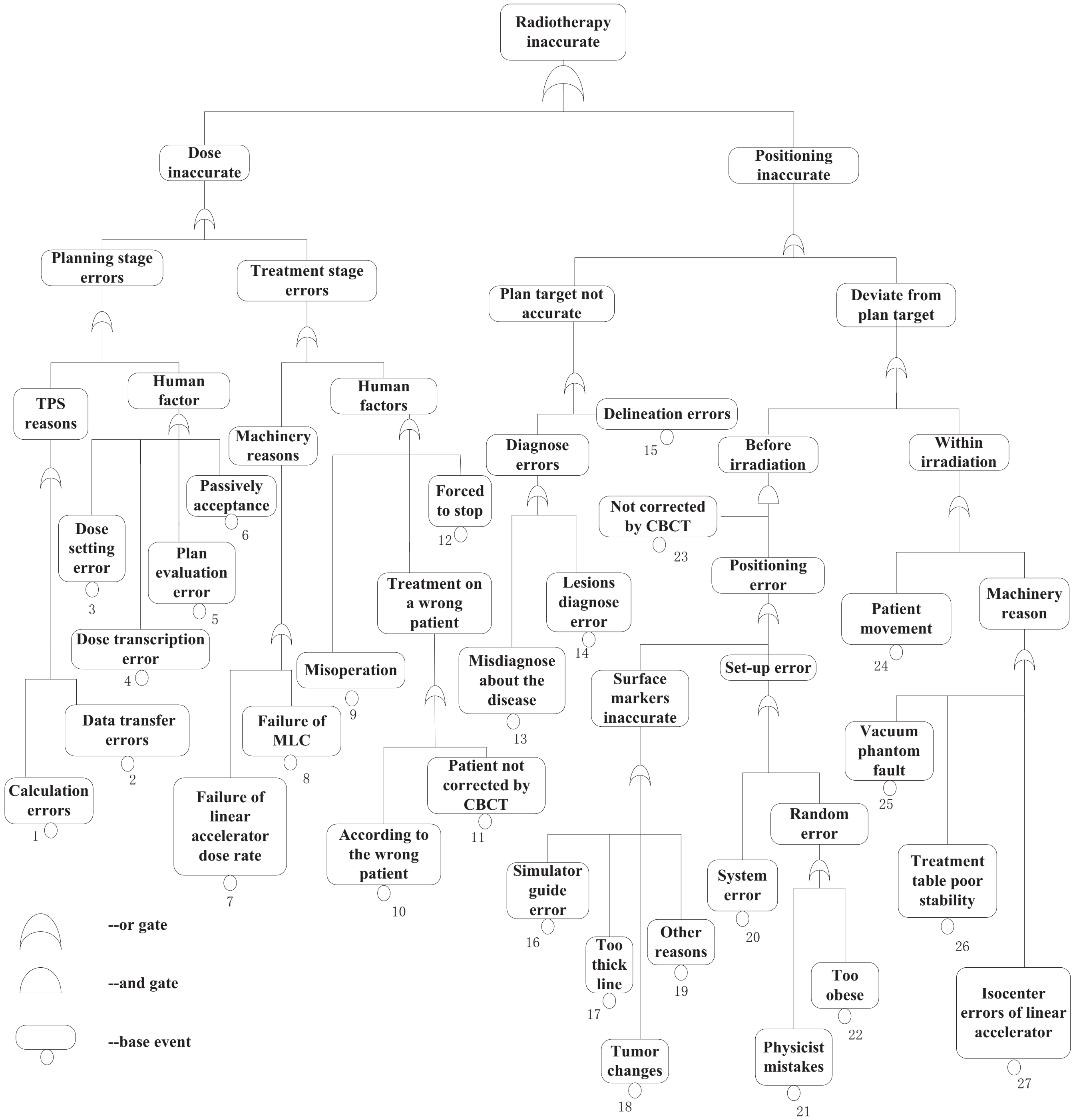

Fig. 2. A concise structure of a fault tree.

probability of a top event would change to 5.09%, the cases of inaccuracy significantly increased.

B. The importance of minimal cut sets

The minimal cut sets demanstrated the minimal combination of base events which lead to a top event. Every key path and its importance rate are listed in Table 3.

C. RRW importance of base events

The top event will be reduced correspondingly if one base event is reduced. This effect is called RRW. Contribution rates of main base event reduction has been shown by the

TABLE 1. The probabilities of base events

No.	Base events	Definition	The method of getting probabilities	Probabilities
1	Calculation errors	TPS Algorithms reasons, dose deviation more than 5%	Empirical data	0.0001
2	Data transfer errors	Plan transfer errors	Hindsight	0.0001
3	Dose setting errors	The doctors setting a wrong plan dose	Hindsight	0.0002
4	Plan transcription errors	Human errors	Hindsight	0.0002
5	Plan evaluation errors	Errors in plan evaluation	Hindsight	0.0001
6	Passively accept the dose deviation	Adjust failure or tolerate	Empirical data	0.0020
7	Linear accelerator dose rate errors	Output inaccurate doses	Maintenance data	0.0020
8	MLC reasons	Blade motion fault or leaking rays	Analog Statistics / Maintenance data	0.0012
9	Misoperation in dose delivery	Physicist errors in operating equipment	Empirical data	0.0015
10	According to the wrong patient	Confuse patients	Hindsight	0.0001
11	Patient not be corrected by CBCT	The wrong patient not be found by CBCT imaging	Hindsight	0.0015
12	Forced to stop	treatment was forced to suspend because of the machinery or patient special reasons	Empirical data	0.0001
13	Misdiagnoses about disease	Benign mass which did not suitable for radiotherapy was irradiated incorrectly	Empirical data	0.0001
14	Lesions diagnose error	Location of the tumor diagnostic error more than 1 cm	Empirical data	0.0010
15	Inaccurate delineation	PTV sketch errors more than 1 cm	Analog Statistics / Empirical data	0.0020
16	Simulator guide error	Parameters inaccuracy	Maintenance data	0.0020
17	Too thick line	Surface marker too thick	Empirical data	0.0025
18	Changes of tumor	Tumor changed more than 1 cm compared with plan	Image contrast	0.0030
19	Other reasons	Other reasons lead to surface marker inaccuracy	Empirical data	0.0001
20	System errors	Equipment errors in set-up	Literature [21, 22]	0.0025
21	physicists errors in set-up	Positioning offset greater than 1 cm	Empirical data	0.0002
22	Too obese	More than standard weight 50%	Empirical data	0.0015
23	Not corrected by CBCT	More than 1 cm deviation after CBCT corrected	Maintenance data /Empirical data	0.0015
24	Patient movement	Patient movement more than 1 cm during treatment	Empirical data	0.0020
25	Vacuum phantom fault	Leak gas between treatment	Maintenance data	0.0002
26	Treatment table poor stability	Does not meet the quality assurance requirements	Maintenance data	0.0015
27	Isocenter errors of linear accelerator	Does not meet the quality assurance requirements	Maintenance data	0.0002

TABLE 2. The probabilities of top events in three cases

Calculation conditions	Probability of a top event (inaccuracy)
Fault tree as shown in Fig. 1 and base events as listed in Table 1.	2.87%
Assumed target delineation was completely true	1.18%
Assuming no corrective CBCT online	5.09%

TABLE 3. The importance of minimal cut sets

Constitute of base events	Importance percentage
Base event 15 (Inaccurate delineation)	14.68%
Base event 14 (Lesions diagnose error)	14.00%
Base event 3 (Lesions diagnose error)	7.23%
Base event 6 (Passively accept the dose deviation)	7.03%
Base event 13 (Misdiagnoses about disease)	0.49%
Base event 24 (Patient movement)	0.26%

importance calculation function of RiskA. Base event reduction means reducing deviation and improving skills in order to reduce the probability of a top event. As shown in Table 4, the most important event was inaccurate delineation, the second was lesion diagnosis error, and the third one was misoperation in dose delivery. The foremost important events were connected with human behavior. In the calculation results the Risk Achievement Worth of base events were almost the same, so the RAW data is not listed in the paper.

IV. DISCUSSION AND CONCLUSION

A. Assessment of accurate radiotherapy

Accurate radiotherapy needs expensive equipment and complex operations, so accuracy is of great importance to cancer patients and doctors. The probability 2.87% should be paid high attention on. Total probability obtained found that the PSA method should be applied in the radiotherapy field in order to assess the reliability.

B. The important reasons leading to inaccuracy

TABLE 4. Base events reduce contribution sequence to the top event

Base event	Contribution ratio
15. Inaccurate delineation	11.90%
14. Lesions diagnose error	11.00%
9. Misoperation in dose delivery	7.40%
13. Misdiagnoses about disease	2.04%
3. Dose setting errors	1.09%
6. Passively accept the dose deviation	0.44%
27. Isocenter errors of linear accelerator	0.02%

Table 3 shows that the most important event was inaccurate delineation and the importance percentage of this minimal cut sets was 14.68%. Assumming target delineation was completely right, the probability of a top event would reduce by half. Table 4 shows that improved delineation technical level was the most efficient method to develop radiotherapy accuracy. But on a particular delineation technical level, the quality would be developed if closed to a biological target [23]. In the future, look forward the biological target recognition technology, irradiation accuracy would be improved [24].

To conclude, almost all the important factors are closely related to the human factor. For example, the most important event in fault tree structure was inaccurate delineation and the second was diagnostic error. As reported in the literature, most errors were attributed to human mistake or inattention in radiotherapy [25].

C. The importance of CBCT to positioning accuracy

Some literature demonstrated the importance of CBCT to positioning accuracy [26, 27]. As shown in Table 2, if there is no CBCT correction, the probability of inaccuracy increases to 5.69%, nearly doubled. CBCT can correct the majority of deviations by regarding it to human organs before the actual treatment. CBCT may correct positional errors for the target and critical structures immediately prior to or during treatment. Sometimes, it can correct the wrong patient leading to a safe treatment [28]. As shown in Table 1, the probability was only 0.8/1000 based on clinical experience which the deviation error greater than 1 cm after CBCT correction.

D. Guidance to clinical radiotherapy and quality assurance

The research verified that the PSA method could be used on a broader area and provide quantitative data in engineering quality control. As a credible software in application [29], RiskA should be an assessment platform of radiotherapy reliability. Focus on safety and reliability is the important feature of ARTS [30, 31]. The quality control function could be improved by integrating quantitative data in this paper. Hospital and administration management should use this method on a different level, using different combinations to analyze the reliability of the radiotherapy and to assess the quality of accuracy radiotherapy. It is emphasized that based on the result calculated by RiskA, weak links could be found and increased radiotherapy quality could be developed by improving weak links. For example, people develop dose reliability by improving the dose calculation method [32]. Of course by analyzing the reliability of the human factor, methods to improve operational reliability could be found. By verifying the reliability of multiple radiotherapy units, the whole radiotherapy reliability level could be assessed. This data could then be combined with clinical opinions, so that the expectative radiotherapy standard pattern used to guide radiotherapy could be set. In conclusion, analysis of radiotherapy reliability based on the PSA method is of great significance to formulate objective standards and quality assurance.

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