Radiotherapy Errors Analysis before Plan Delivery based on Probabilistic Safety Analysis Method

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ABSTRACT: The error that a wrong treatment plan be delivered was very serious. We vigorously explore effective method to analyze the factors which lead to this error, thus effectively improves radiotherapy quality. Fault tree analysis has been used for radiotherapy planning errors analysis in this study. After a fault tree was constructed from top to bottom then import the reliability data of basic events from clinical cases in a local radiotherapy center, at last the fault tree was calculated by reliability and probabilistic safety assessment program RiskA, developed by FDS Team. Results shown that the most important basic event was wrong patient and the second was diagnose errors.

Key words: radiotherapy errors, Probabilistic Safety Assessment, RiskA

INTRODUCTION

Radiotherapy was one of the major treatment options in cancer treatment [1]. Together with surgery and chemotherapy, radiotherapy plays an important role in the treatment of 40% of those patients who are cured of their cancer [2].

Within the whole process of radiotherapy, there are some regular stages such as assessment of patient, prescribing treatment protocol, positioning, simulation, imaging, planning, information transfer, patient set-up and treatment delivery. In all of these stages, the radiotherapy planning error is the most important one [3]. Radiotherapy plan itself errors sometimes due to human mistakes and inattention or transcription errors, and sometimes the plan was correct, but the patient was wrong. In either case, radiotherapy error means the patient accepted a wrong prescription plan. The event above including all errors before irradiation delivery not limited to treatment planning system (we call it top event). The factors lead to the errors was known, but the importance of every factor is difficult to determine. Even if the frequency of factors was known, the probability of total errors and the factors importance couldn't be the same turn. So a reliability analysis method was needed. This method should be used on analysis of the complex dynamic system that human and machinery factor interaction.

The probabilistic safety assessment (PSA) method which had been widely applied to nuclear power station for many years should be used for reference. As an efficient method for complex system analysis, PSA was also used on aviation and chemistry as well as nuclear field. And some radiation apparatus had used PSA in linear accelerator safety analysis [4]. The fault tree analysis (FTA) of PSA is one of the tools for system reliability and safety analysis and was considered one of the simplest, most effective and prospective tools for analyzing complicated system. Constructing a fault tree based on the logical connection of all basic events in radiotherapy and the worst case (top event) in this study was radiotherapy errors before plan delivery. The FDS team has developed a reliability and probabilistic safety assessment program RiskA which has been tested and verified [5-9]. The total probability of top event errors was obtained, and the importance of all basic events and all minimum path were arranged. These were important data to radiotherapy quality control. In clinical radiotherapy, physician and physicist could improve irradiation accuracy efficiently by pay attention on the most important events.

This study made an attempt on analyzing accurate radiotherapy planning errors by PSA method. The probability that the top event occurs and the importance of the basic events have been calculated. The research verified that PSA method should be applied on more broaden area and could provide quantitative data in engineering quality control. This work was an important part of advanced/accurate radiotherapy treatment system (ARTS) [10-12].

MATERIALS AND METHODS

Demonstrate analysis materials and study conditions

This study depends on accurate radiotherapy with Pinnical 9.0 treatment planning system (TPS). The cases of treatment planning were got from a radiotherapy center's nearly 250 patients, and 2000 times irradiation was investigated in one year. Misdiagnose date came from more cases research.

Defining the top event which needs to be analyzed

The top event means the event which you most want to avoid. The worst case of radiotherapy plan was put the wrong plan into practice. So the top event was radiotherapy plan error. According to clinical experience, the radiotherapy plan errors including two cases: one was that the plan was error and the other was that plan was correct but because of machinery or human errors the final plan which patients accepted was wrong. In one word, a wrong radiotherapy was departing from the standard of radiotherapy such as International Commission on Radiation Units and Measurement (ICRU) NO.50 and NO.62 report. Of course the plans which go against the will of doctor and accepted by wrong patient were gross errors. All cases meet the conditions above were delimited as plan errors no matter what reasons.

Form a fault tree by analyzing the accurate radiotherapy planning course

Analyze the whole process of radiotherapy plan errors occurring firstly. The sequential stages of the radiotherapy plan process were like this: assessment of patient, decision to treat and prescribing treatment protocol—stage of set plan parameters on treatment planning system and then treatment information transfer—treatment plan implement. Analyze the whole course to find a particular manipulation or equipment which causes basic event, just as leaves to roots and then list the factors. In the stages the following errors may occur:

1. Diagnose errors: some benign tumor or normal tissue may be irradiated by mistake because of misdiagnose such as disease character, positioning or tumor pathology errors. If not corrected, these errors would lead to gross mistakes in the next plan stages [13].
2. On the stage of treatment planning system, if on the premise of data select error or misunderstanding the software, or because of careless, then a wrong plan would be generated. Such as dose choice error, irradiation field error and so on [14].The worst one was dose choice error.
3. Because of the equipment performs and software quality, a proper plan may turn to a wrong plan after data transfer. Of course stuff manipulation mistakes can lead to transcription errors [15].
4. The radiotherapy plan itself was correct, but in the course of treatment the wrong plan was put into effect, this means a patient received the other's plan and not be recognized and corrected.

All errors above were listed according to the logical and a fault tree was obtained. Fig. 1 was a concise structure of fault tree. The events at the bottom were basic events. For example, diagnose errors or dose choice errors can lead to wrong plan simply. If a wrong plan was transferred, then only on the condition of physicist not realized and not corrected could lead to wrong plan.

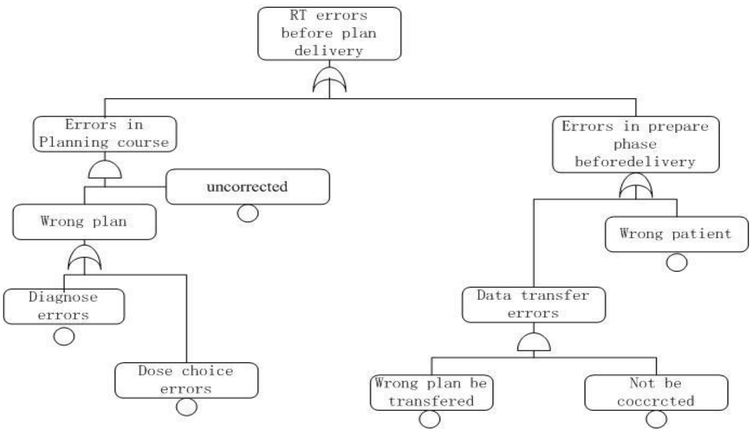

Fig.1. A concise structure of a fault tree.

Obtain the probabilities of basic events from clinical statistics and experiments.

Every basic event has its probability even if not be finding out and recorded at that time. If not be recorded, then the base reason surely could be found afterwards by summarizing investigation. The methods getting the probabilities of every basic event were listed and the probability of every basic event was shown in Table 1:

1. Diagnose errors: Most errors couldn't be recognized, the probabilities of misdiagnose could be got by reliable assumption afterwards. The sources of data not limited to the 2000 irradiation cases but from all irradiation cases in the treatment center in two years. The misdiagnose frequency divided by irradiation times in the two years, then we got the probability of diagnose errors.
2. Dose choice errors: EPID conformation could get the rates of dose errors. According to ICRU No.24 report, dose deviation must within the range of ±5%. This type errors also including prescription install errors. These errors may be checked out. The frequency of errors in 2000 times irradiation was divided by 2000, the probability of this basic event was got.
3. Incorrect: means a mistake in treatment plan system not be checked out, a wrong prescription may be sent out to physicist. In 2000 treatment plans the frequency of wrong plan was unknown now, so we simulating 1000 times errors and calculation the rates which not be corrected.
4. Wrong plan be transferred: transfer mistakes in 2000times transfer divided by 2000.
5. Incorrect by physicist: after data transfer, the physicist did not recognize the errors. The method we got the rates was the same as the method in incorrect event.
6. Wrong patient: the probability that patients taken the other's planning. The probability gathered from the error rate in 2000 times treatment.

Table 1 ： The probabilities of basic events

NO	Basic events	Definition	probability	Research cases
1	Diagnose errors	disease character, positioning or tumor pathology errors	0.0015	5000
2	Dose choice/calculation errors	on the stage of treatment plan system, dose choice error, irradiation field error and so on.	0.0020	2000
3	Uncorrected	the errors before transfer stage not be corrected	0.025	Simulated experiment
4	Wrong plan be output	a proper plan turn to a wrong plan after data transfer	0.0020	2000
5	Uncorrected by physicist	after data transfer, the physicist did not recognize the errors	0.035	Simulated experiment
6	Wrong patient	in the course of treatment the wrong plan was put into effect	0.0010	2000

The probabilities data above was from individual units, specific units have different probabilities.

Calculation in RiskA

A fault tree was built in RiskA as shown in Fig. 1, then all the basic probabilities data was put into the tree leaves (basic events) and calculated. The species analyzed were uncertainties and importance. Fussell-vesely importance, RAW importance and RRW importance were selected in importance analysis. At last the outcome has been got after calculation and analysis capabilities. We got top

event occurrence rate, minimal cut set sequence, probability importance sequence. The whole process of calculation was very convenient. Next we would analyze the happening probability of the top event and the importance of the basic events detailed.

RESULTS

In the case above, we got the top event probability 1.48×10-3. This shown that in 1000 times radiotherapy implement, there's 1.43 times wrong plan irradiated.

Minimal cut set represent the minimal path which lead to top event. As shown in Fig.2, there are several path lead to top event, percentages size was distinct. The largest path was wrong, patient, the percentages of wrong patient path was prevailing (91%), followed by transfer errors and uncorrected (4.50%), diagnose error + uncorrected (2%). The total percentage of other paths was 2.5%, including dose choice/calculation error and incorrect by physicist and so on.

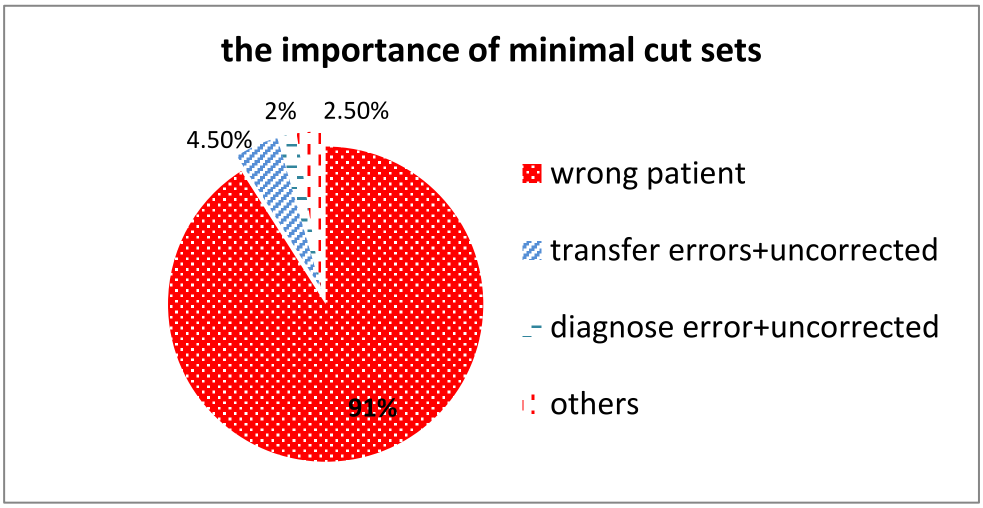

Fig.2. The importance of minimal cut sets.

As shown in Table 2, Fussel-vesely importance (FV) to the six basic events, the most important one in fault tree was wrong patient, the second one was that the physicist did not recognize the errors, and the third one was that the errors before transfer stage were not corrected. This list roughly the same with Fig.2, the difference was that this list was not basic event combined path but basic event individually. If the basic event probability reduced, the top event must be impacted, this was risk reduce worth (RRW). In the result RRW, the event wrong patient reduce has little effect to top event, but risk achievement worth (RAW) was very important, this means that the event wrong patient risen has great effect to top event.

Table 2 ： The importance of the basic events

NO	Base events	FV	RRW	RAW
1	Wrong patient	9.12e-001	1.14e+001	7.02e+002
2	Incorrect	4.39e-002	1.05e+000	2.71e+000
3	Diagnose errors	2.28e-002	1.02e+002	1.85e+001
4	Dose choice/calculation errors	2.11e-002	1.02e+002	1.85e+001
5	Wrong plan be transferred	2.42e-002	1.02e+002	2.55e+001
6	Incorrect by physicist	4.42e-002	1.02e+002	2.22e+000

DISCUSSION AND CONCLUSIONS

Radiotherapy planning stage was very important to radiotherapy course, and it is the foundation of correct treatment implementation. To accurate radiotherapy, the treatment plan software was more complex and manipulation must be more meticulous. In this study, the top event probability was 1.48×10-3, in 1000 times radiotherapy implement, there's 1.43 times wrong plan irradiated. Because of the errors often lead to fatal outcome, so this probability must be pay attention to. Shafiq's study indicated that the errors in whole radiotherapy course was 1.5×10^{-3}[3]. Someone said that this probability was much lower than the hospital admission rates for adverse drug reaction in Canada and US (about 65000 per million admissions) [16]. But before plan delivery the probability of 1.48×10^{-3} was very heavy in 2000 times irradiation. We put forward some suggestion on improving treatment plan safety according to the result analysis.

As shown in Fig.2, the most important basic event was wrong patient (91%). The event wrong patient reduce has little effect to top event, but the factor raised has great effect to top event. This mistake was very serious because of the fatal consequence possibly, so in clinical must prevent the errors of wrong patient raised. The effected measures to guarantee the patient information correct were enforcing checking rules before irradiation. The patient name and treatment number should be eye-catching on patient body (for example: wrist band). Before irradiation physicist checking the information carefully except for parole checking patient name. Some study indicated that plenty of errors because of the stuff’s intensity labor [14], and this radiotherapy center were very busy in treatment. Reduce labor intensity may be work to improve quality. This radiotherapy center wasn’t a standard organization and doesn’t represent the general level in nationwide.

The treatment plan system used in this center was imported with original packager from foreign country, and the setting display was all English and some terminology were irregular [15]. The skillful operation of a treatment plan system was hard to learn. Arrangement of the stuff and shift should be done rationally. Manages must persist in the principle of safety first and ensure the treatment time not be too tight. The stuff should be strict with themselves and manipulated according with standard.

The important factors were all human factors or closely related with human factor. For example, the most important one in fault tree structure was wrong patient, the second one was the physicist did not recognize the errors, and the third one was he errors before transfer stage not be corrected. This means most errors attributed to human mistake or inattention [17].The United States Nuclear Regulatory Commission estimated that more than 60%radiotherapy accidents contributed to human errors [18].

This study fully proved that enhancing the technology and sense of responsibility was the common concern to any dangerous work.

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