ORIGINAL PAPER

Electronic On-line Incident Reporting System (IRS) as a Tool for Risk Assessment in Radiation Therapy

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ABSTRACT

Background: Radiotherapy is one of the primary treatment options in cancer management, together with surgery and chemotherapy. Radiation therapy is technologically complex discipline involving professionals with various specialties, and using high energy radiation in treatment of wide range of different cancer types. Technical complexity, increasing number of patients, large workload, and delivery of radiation therapy treatment with lack of human, technical and financial resources in low and middle income countries creates environment with great potential to develop incidents. Emerging need of modern radiation therapy is to develop preventive approach to risk management i to improve the patient safety. **Objective:** The objective of this research is to identify and assess risk associated with radiation therapy practice in Bosnia and Herzegovina. **Methods:** An anonymous, voluntary electronic on-line radiation therapy incident reporting system (IRS) was created. IRS consists of four sections containing questions about working environment, incident occurrence, root causes and contributing factors, and incident severity assessment. Data collected using IRS were used to create taxonomy of incidents in radiation therapy. Risk assessment was made using Risk Matrix method. Research was made using the data collected from first 60 incidents reported to IRS. **Results:** Based on probability and frequency of incident occurrence and severity of consequences, it was assessed that 41.7% of incidents had low risk level (L), 50% of incidents had moderate risk level (M), and 8.3% of incidents had high risk level (H). Radiation therapy risk profile based on risk assessment results clearly shows that incidents with low frequency, low occurrence probability, but high consequences severity level have highest level of risk. **Conclusion:** The results of this research confirm that the electronic on-line radiation therapy IRS allows the identification and classification of the most significant risk factors in radiotherapy and prevention of serious incidents occurrence.

Keywords: Radiation Therapy, Incident, Risk Assessment, Risk Matrix, Safety.

1. BACKGROUND

Radiotherapy is one of the primary treatment options in cancer management, together with surgery and chemotherapy. Over 65% of all cancer patients receive radiation therapy at least once during cancer treatment. Radiation therapy contributes in 40% patients cured of cancer, and over 25% of patients have a relief of symptoms after palliative radiotherapy treatment (1).

Radiation therapy is technologically complex discipline involving professionals with various specialties, and using high energy radiation in treatment of wide range of different cancer types.

The main goal of radiation therapy treatment is irradiate target volume with maximum of prescribed therapeutic dose to achieve the control of disease (TCP - Tumor Control Probability), and keep minimum dose of radiation to organs at risk to avoid adverse effects (NTCP – Normal Tissue Complication Probability). All technological improvements in radiotherapy have been developed to achieve this goal, but it can be significantly compromised with the development of incidents.

Technical complexity, increasing number of patients, large workload, and delivery of radiation therapy treatment with lack of human, technical and fi-

nancial resources in low and middle income countries creates environment with great potential to develop incidents.

The discipline of radiation therapy has long history of quality management. Quality assurance measures are implemented in all stages of radiation therapy process with the goal to reduce occurrence of errors, as well as increase possibility to detect and correct errors in a timely manner. These measures should encompass all organizational and technological aspects of radiation therapy, not only treatment of patients, but also commissioning and service of radiation therapy equipment, and staff certification (2).

Incidents are an inevitable part of radiation therapy treatment. Serious incidents in radiation therapy are extremely rare, but when they occur, their consequences may lead to significant health damage or even death. Considering the fact that incidents can significantly jeopardize patients' safety and degrade the success of radiotherapy treatment, implementation of the risk assessment system in radiotherapy that detects and prevents incident is a crucial security issue (3). The incidents are not a result of random flow of events, or a coincidence that will be difficult to repeat. The occurrence of incidents is a consequence of systematic settings, conditions and processes. Therefore, reporting and analyzing of incidents can be used as a significant tool to improve safety in radiation therapy (4).

2. OBJECTIVE

The objective of this research is to identify and assess risk associated with radiation therapy practice in Bosnia and Herzegovina.

3. MATERIA AND METHODS

In the first phase of research, an anonymous, voluntary electronic on-line radiation therapy incident reporting system (IRS) was created. The system is available in a form of web application at https://www.irsistem.ba. IRS is based on ROSEIS (Radiation Oncology Safety Education and Information System) incident reporting form partially adapted to radiation therapy practice in Bosnia & Herzegovina.

IRS is developed using HTML, CSS and PHP, and database is structured using My SQL. During the development of the system, special attention is paid to its interaction with, functionality and simplicity.

System consists of four sections containing questions about working environment, incident occurrence, root causes and contributing factors, and incident severity assessment, and it's content is designed to meet characteristics of radiation therapy methods, techniques and workflow in Bosnia & Herzegovina.

In the second phase of research data collected using IRS were used to create taxonomy of incidents in radiation therapy. Incidents were classified according to number, type, method of detection, way of occurrence, place of origin, causes, contributing factors, clinical significance, and other generic data.

On the basis of incidents categorization, in the third phase risk assessment was made using Risk Matrix method according to recommendations of International Atomic Energy Agency (IAEA) for use of risk matrix method in radiation therapy (5).

Research was made using the data collected from first 60 incidents reported to IRS.

4. RESULTS

The risk was assessed for each reported incident separately using a Risk Matrix method based on probability of incident occurrence, frequency of incident occurrence and assessment of severity of consequences.

Analysis of incident occurrence frequency show that 13.3% of incidents had very low frequency (VL), 16.7% of incidents had low frequency (L), 60% of incidents had very low frequency (M), and 10% of incidents had high frequency (H).

The results of incident occurrence probability analysis show that 66.7% of incidents had moderate probability of occurrence (M), 25.0% of incidents had low probability of occurrence (L), and 8.3% of incidents had very low probability of occurrence (VL).

Assessment of incident consequences severity shows that 76.7% of incidents had low severity level (L), 11.7% of incidents had moderate severity level (M), 8.3 % of incidents had high severity level (H), and 3.3% of incidents had very high severity level (VH).

Based on the parameters shown in Table 1., it was assessed that 41.7% of incidents had low risk level (L), 50% of incidents had moderate risk level (M), and 8.3% of incidents had high risk level (H).

Incident occurrence frequency			
Description	N	%	Frequency
Very often	6	10.0	High frequency (H)
Often	36	60.0	Moderate frequency (M)
Rare	10	16.7	Low frequency (L)
Very Rare	8	13.3	Very Low frequency (VL)
Incident occurrence probability			
Description	N	%	Probability
Moderate	40	66.7	Moderate probability (M)
Low	15	25.0	Low probability (L)
Very Low	5	8.3	Very low probability (VL)
Severity of consequences			
Description	N	%	Severity
Very high severity	2	3.3	Very high severity level (VH)
High severity	8	8.3	High severity level (H)
Moderate severity	7	11.7	Moderate severity level (M)
Low severity	46	76.6	Low severity level (L)

Table 1. Assessment of incident occurrence frequency, probability and severity of consequences
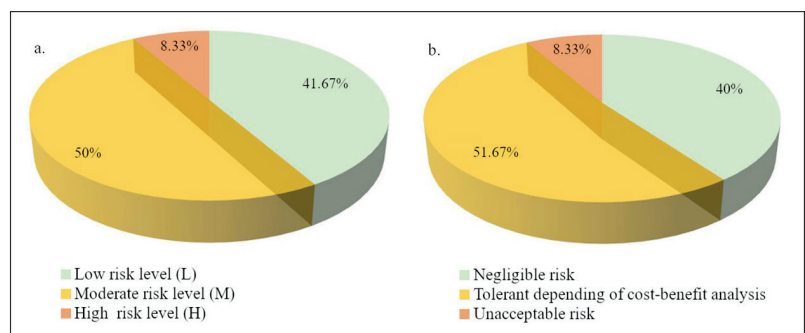
Graph 1. Distribution of radiation therapy incidents related to risk level (a) and risk acceptability (b)

Results of risk acceptability analysis show that 40% of incidents have a negligible risk, for 51.7% of incidents it is assessed that risk may be tolerated depending on the Cost - Benefit analysis, and 8.3% of incidents had unacceptable risk, especially for events with high or very high consequences severity level (Graph 1.).

Radiation therapy risk profile based on risk assessment results clearly shows that incidents with low frequency, low occurrence probability, but high consequences severity level have highest level of risk (Graph 2.).

5. DISCUSSION

Progress in radiation therapy technology in a past three decades led to significant changes in methods of radiation therapy planning and delivery. Increasing complexity and fast adoption of novel radiation therapy techniques in conditions of heavy workload has great potential for development of incidents, especially in low and medium income countries with older radiation therapy equipment with poor compatibility and lack of radiation therapy staff, especially those dedicated to quality assurance (QA) and risk management tasks.

Modern radiation therapy technologies have a great potential for errors reduction due to automation of process and integration of security barriers (6).

With implementation of 3D conformal radiation therapy techniques errors typical for conventional radiation therapy were significantly reduced, but there are some procedures that cannot be automated, as patient positioning and immobilization or commissioning of treatment planning system. These procedures are still subject of same risk regardless to technique complexity.

Conformal radiation therapy techniques were introduced to increase reliability of radiation therapy treatment and they significantly contributed to error reduction. But, thanks to progressive increasing of complexity, they become source of new type of more complex and serious errors.

That is the reason why modern radiation therapy has undergone numerous changes related to QA and risk management. Development of incident reporting systems should also evolve with changing needs of modern radiation therapy practice (7).

Design of IRS is key factor in its application. IRS should be user friendly, designed to enable quick and easy submission. Users should not be asked for long answers, the time required to report should be as short as possible. System should meet characteristics of local radiation therapy methods, techniques and workflow to avoid collection of the data with poor application value (8).

Numerous studies confirm that implementation of electronic on-line IRS increases incident reporting probability and incident reporting rate, because reporting is fast and simple and the interruption in the workflow is minimal (9,
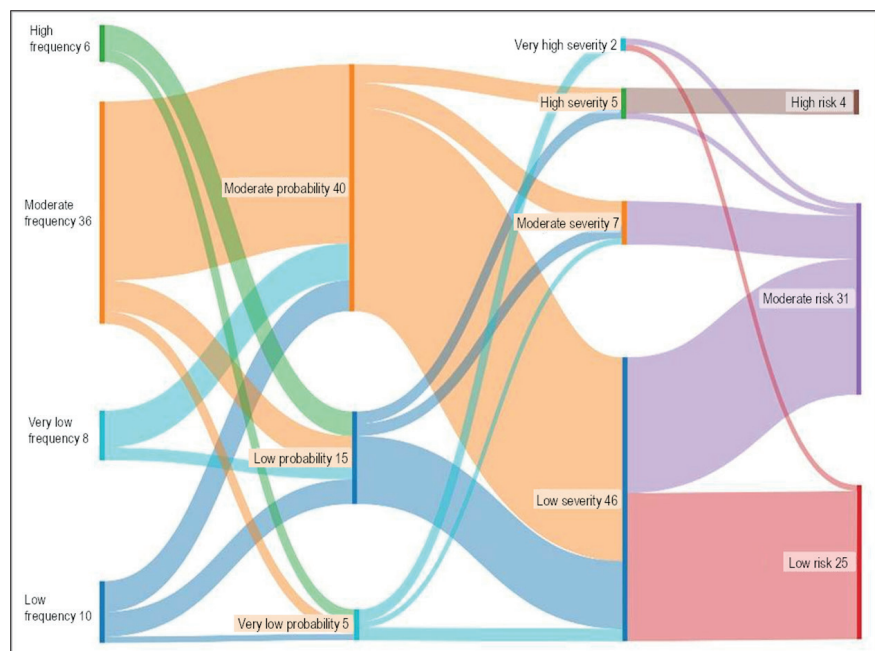
Graph 2. Radiation therapy risk profile

10). It is also confirmed that long term implementation of electronic on-line IRS reduces number of serious incidents and enables identification of numerous unknown risk factors (11).

Software solution is essential factor in improving IRS functionality. In addition to incident reporting IRS should enable access to incident taxonomy and risk analysis results, graphic data visualization and interaction with users. Voluntary IRS designed this way can significantly contribute to improvement of safety in radiation therapy environment (12, 13).

Another important feature of IRS is effective analysis of incidents and regular reporting about safety issues to system users. Feedback of useful safety related data motivates radiation therapy professionals to participate in IRS (14).

The impression that their incident report is seriously analyzed and resulted in useful security measures increases confidence in IRS among radiation therapy professionals, and it should be understood that is a long-term process. Parallel to IRS development, it is necessary to put maximum efforts to establish safety culture and create environment that allows reporting of errors without fear of punishment (15).

Key factors in IRS functioning are: efficient data collection, focus to process improvement, developing of safety culture, an expert group for analyzing reported incidents and giving quality feedback to IRS users (16).

Majority of European countries have taken som activities to implement European Commission directive for implementation of risk management as a part of quality assurance program. An overview of national and international IRSs shows that most of the incidents reporting systems are developed in high income countries, but there are no detailed reports about radiation therapy incidents and adverse events in low income countries. There are, also, significant differences in taxonomy and incident evaluation and risk assessment methodology in different countries (17).

Results of IRS implementation projects show that Risk Matrix method, together with functional software solution, is powerful tool in risk assessment, incident prevention and

improvement of radiation therapy safety. A solution that integrates modern approach in risk matrix application with previous user experience and give users possibility to use according to their professional needs can significantly improve radiation therapy safety (18, 19).

Application of Risk Matrix method in risk assessment is widely adopted in industry. In the last few decades, the Risk Matrix method found its application in health care system, especially in radiotherapy.

The Risk Matrix method allows identification and analysis of errors related to radiotherapy equipment, as well as organizational and human resources that can cause incidents with serious consequences. The risk assessment methodology in the Risk Matrix method is relatively simple and easy to implement regardless to fact that it does not use numeric risk quantification scale.

Efficient combination of IRS and Risk Matrix method provides a set of high quality data needed for efficient risk assessment and early prevention of serious incidents. Another advantage of this method is that it enables assessment security barriers robustness and their significance in risk reduction (20).

6. CONCLUSIION

The results of this research confirm that the electronic on-line radiation therapy IRS allows the identification and classification of the most significant risk factors in radiotherapy and prevention of serious incidents occurrence.

IRS provides high quality data that can be used in design of optimal risk management system and improving radiation therapy safety.

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