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Assessing Medical Device Risks in Radiology Departments: A Critical Review

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Abstract:

Background: This study explores radiologists' perceptions of risks associated with medical devices in radiology departments within hospitals in Saudi Arabia. Given the increasing use of advanced medical technologies and devices in the healthcare sector, it is important to understand how healthcare professionals, particularly radiologists, perceive and manage these risks.

Methods: A total of 257 radiologists from hospitals across Saudi Arabia participated in the study. Data were collected through a self-administered online questionnaire designed to assess their perceptions of risk management practices and the effectiveness of current risk control measures in radiology departments. The data collected were analyzed using the Statistical Package for the Social Sciences (SPSS) to identify key trends and insights regarding the management of risks associated with medical devices in radiology.

Results: The results indicate that while most radiologists perceive their department's risk management systems to be effective, several areas need improvement. Many participants reported that formal risk management systems and committees are in place to oversee the control of medical device risks, but there are challenges in terms of policy clarity and the overall effectiveness of MoH regulations. Furthermore, predictive risk models were found to be used more frequently for electrical and overwork risks, while radiation dose risks were addressed less frequently.

Conclusion: The study reveals a generally positive perception of risk management practices among radiologists in Saudi Arabia, but gaps remain in policy clarity, risk prediction practices, and implementation. The results suggest that improving communication, improving the effectiveness of risk management policies, and increasing training and awareness of healthcare professionals could help mitigate risks associated with medical devices in radiology departments. These improvements could lead to safer healthcare environments and better patient outcomes.

Keywords: Risk Management, Medical Devices, Radiologists, Saudi Arabia.

Introduction:

In recent years, the health sector has witnessed a revolution in the use of modern technology, which has contributed to raising health care and the level of medical and other services at the local and global levels (Junaid et al., 2022). Medical imaging and the modern devices used are considered one of the most important technologies and developments witnessed by the health sector, which plays a pivotal role in health care, as their use in health care has led to accurate diagnosis and then the development of treatment plans (Bercovich, & Javitt, 2018).

Radiology departments within hospitals and health care centers are considered one of the most important and dangerous departments (Ilyas, Burbridge & Babyn, 2019), as they contain many medical devices with diverse functions that are characterized by the advanced nature of their work and their reliance on X-rays, MRI, and CT scanners, with the aim of providing accurate information about the human body and diagnosing patients' conditions (Odeh, Abatli, & Qadi, 2023). However, these medical devices can pose unexpected risks to both health care providers in radiology departments and patients, which may occur due to a technical or technical defect in the medical devices and other unexpected risks, for example, the device may be damaged during treatment, explodes, or causes burns to the patient (ESR, 2019).

The process of interaction between medical devices and health care providers in radiology departments requires understanding and analyzing all potential risks, such as exposure to ionizing radiation, technical defects, or mechanical failures (Smith et al., 2019). This poses a challenge to health care systems and workers in radiology departments (Chong et al., 2019). Therefore, the use of these complex technology-based medical devices requires continuous training, competency assessment of healthcare workers to handle them and troubleshooting potential technical challenges (Hartley et al., 2010).

The current study aims to explore the potential risks associated with medical imaging equipment, especially within radiology departments. This will contribute to understanding, analyzing and treating these risks by healthcare providers, and will also provide recommendations to decision makers in the Saudi Ministry of Health to enhance security, safety and risk management procedures related to medical devices used in radiology departments in hospitals in the Kingdom. Kingdom of Saudi Arabia to enhance patient care and maintain the safety of health care worker.

Materials and Methods

Study Design

A descriptive analytical cross-sectional study design was used to assess the risks of medical devices in radiology departments within hospitals in Saudi Arabia. This study was conducted in the period between Mat 2024 to Oct 2024.

Study Participants and Sample Size

This study included all radiologists in radiology departments within hospitals in the Kingdom of Saudi Arabia. Radiologists who were working in radiology departments were randomly selected and formed the study population. Radiologists who were working in different positions in hospitals for at least one year prior to the survey period were included in the study. The minimum required sample size was calculated using a 95% confidence level and a 5% margin of error (significance $\alpha = 0.05$) with a 50% response distribution. It was found to be 250 respondents. While 270 copies of the questionnaire,

were distributed to the radiation technologist and radiologist working in radiation departments where, 257 copies of the questionnaire were recovered (95.0%)

Eligibility Criteria

Inclusion Criteria

- Interested in participating.
- At least one year's experience.

Exclusion criteria:

- Radiologist who are working as volunteers.
- Radiologist with less than one year of work experience.

Instruments of the study

A web-based questionnaire was the primary research instrument. The instrument was adapted from a previous study and modified to suit the objectives of this study (Craciun, Mankad& Lynch, 2015; Nguyen, & Tran, 2017; Al-Mazroua, & Al-Otaiby, 2020). The questionnaire comprised two sections consisting of 26 questions and was framed, where the first included demographic data with three items. The remaining 20 questions were used to assess the Risks of medical devices in radiology departments. Literature review was the primary source of secondary data since the researcher compared the primary data findings with those of previous scholars on a similar topic. The final questionnaire underwent a face validity assessment to ensure the effectiveness of the questions in aligning with the study's objectives. The questions were measured on a Likert scale. The internal consistency in the scale was assessed in the previous study using the Cronbach alpha coefficient, which was found to be .956. The Arabic version showed good internal consistency with Cronbach’s alpha of 0.88.

Data Collection

The researcher collected data by himself and by trained assistants using self-administered questionnaires after obtaining consent from the study participants from the hospitals within a duration of one month.

Data Management and Data Analysis

The researcher used Statistical Package for Social Sciences (SPSS, version 26) for data entry and analysis. The research checked all data to avoid any discrepancies. Data examined for coding and entry error. Descriptive data expressed as frequency, mean, standard deviation (SD), and percentages. Inferential statistic tests used as well as independent sample t test, and regression.

Results

Socio-Demographic Characteristics of the Respondents

Table (1) shows the demographic characteristics of the participants. Out of 257 respondents, (63.4 %) were male and (36.6%) were female. According to the age group, about (26.6%) of the respondents were in the group of 20 to 29 years-old and (44.4%) aged 30 to 39 years old, only (7.3%) more than 50-year-old. Regarding education level, most common of them (61.9%) had bachelor's degree, and (24.2%) had master's degree and (4.5%) had diploma. Regarding Job title (56.4%) Radiologist and (23.1%) had Head of Division and (7.7%) Manager. About (38.5%) of the participants had experience between 10 to 15 years, while (12.8%) of less than 5 year.

Table 1. Demographic information of participants (N=257)

	Categories	Frequency	Percent %
Gender	Male	163	63.4%
	Female	94	36.6%
Age (years)	20-29 years old	68	26.6%
	30-39 years old	114	44.4%
	40-49 years old	56	21.8%
	≥ 50 years	19	7.3%
Educational level	Diploma or less	12	4.5%
	Bachelor's	159	61.9%
	Master's	62	24.2%
	Ph.D.	24	9.4%
Years of experience	less than 5 year	33	12.8%
	5-10 year	72	28.2%
	10-15 year	99	38.5%
	15-20 year	40	15.4%
	more than 20 year	13	5.1%
Job title	Manager	20	7.7%
	Head Of Department	33	12.8%
	Head Of Division	59	23.1%
	Employee	145	56.4%

Analysis of Risk Management field.

Table 2. Mean, Standard Deviation, and Chi-Square for the statement on the axis " Analysis of Risk Management field ".

	Paragraph	Mean	Std. Deviation	Chi-Square	p-value
1	There is a formal risk management system in the radiology department	4.44	0.82	404.51	.000
2	There is a committee responsible for identifying, monitoring, and controlling medical device risks.	4.30	0.89	305.63	.000
3	The radiology department has an internal control system to address newly recognized risks caused by medical devices.	4.24	0.95	274.66	.000
4	There are internal guidelines, rules, and concrete procedures regarding the risk management system in the radiology department.	4.17	1.04	251.22	.000
5	There is a regular reporting system for risk management provided to senior officers and management.	4.32	0.93	334.66	.000
6	The manager is responsible for reviewing and identifying risk management systems, guidelines, and risk reports.	4.06	1.11	200.71	.000

7	The radiology department has contingency plans for disasters and accidents.	4.24	1.05	307.72	.000
8	The radiology department complies with the standards of the International Protection Committee.	4.29	0.96	316.96	.000
9	There is a clear separation of duties between those who generate risks and those who manage and control them.	4.11	1.06	218.41	.000
10	The radiology department has tools and procedures in place for the protection of employees.	4.16	1.08	261.04	.000
11	The radiology department determines protection requirements to reduce radiation risks	4.26	0.91	288.41	.000
12	A periodic review and approval process for control measures is conducted.	4.31	0.89	314.30	.000
13	Radiation risks are disclosed in the annual report.	4.18	1.05	258.62	.000
14	The radiology department has a system to quantitatively evaluate the causes of overwork.	4.34	0.90	341.31	.000
15	The radiology department has adopted and utilized guidelines for employee protection.	4.16	1.05	247.93	.000
16	The risk management policy issued by the Ministry of Health or Hospital Administration contributes to the safety of workers in the radiation departments	3.72	1.42	116.87	.000
17	Regular risk assessments are conducted for the medical devices used in the radiology department.	3.75	1.46	149.05	.000
18	Radiology staff are satisfied with the risk management procedures followed in the radiology department.	4.44	0.85	424.51	.000
19	Radiology staff actively participate in risk identification and management processes.	4.23	0.96	274.45	.000
20	Risk management policies and procedures are clear to Radiology staff	3.88	1.36	171.67	.000
21	Does your radiology department have a documented risk management policy?	4.21	0.72	434.51	.000
	The Average	**4.18**	**1.02**		

The results of the statistical analysis in Table (4.2) indicate that most of the study participants have a good assessment of the existence of an effective administrative system for risk management in the radiology departments of hospitals in the Kingdom of Saudi Arabia. In general, the arithmetic means of the paragraphs ranged between 3.72 and 4.44, indicating a high agreement about the effectiveness of the medical devices risk management system in radiology departments. The first paragraph, which states "the

existence of a formal risk management system in the radiology department", had an average of 4.44 and a standard deviation of 0.82, indicating a high consensus about the existence of an effective system for risk management in radiology departments in hospitals in the Kingdom of Saudi Arabia. This trend was repeated in many other paragraphs such as the second and third paragraphs, which obtained averages close to 4.30 and 4.24, indicating a positive assessment. However, there are some paragraphs that witnessed greater variation in answers. Paragraph 16, which states "The risk management policy issued by the Ministry of Health or the hospital administration contributes to the safety of workers in radiology departments", had a relatively low mean of 3.72 with a high standard deviation (1.42), indicating a variance in opinions about the effectiveness of these policies. Also, in paragraph 20, "Risk management policies and procedures are clear to radiology staff", the mean was 3.88 and the standard deviation was 1.36, indicating that there is a need to improve the clarity of policies for participants. Moreover, all p-values were less than 0.05, which means that the results are statistically significant.

Table 3. Frequency and percentage of use of prediction models ".

Does the radiology department use any model to predict risk	Yes		No	
	F	%	F	%
Radiation dose risk	88	34.1%	169	65.9%
Equipment damage rate risk	133	51.8%	124	48.2%
Over loud work risk	157	61.2%	100	38.8%
High voltage electric risk	155	60.2%	102	39.8%

The results of Table3 show the percentage of use of predictive models in the radiology department. The results indicate that radiology departments in Saudi hospitals do not use predictive models for risks uniformly, with lower use in some areas such as "Radiation Dose Risk", where only 34.1% of participants reported using a predictive model for this risk, while 65.9% of participants did not. In contrast, the use of predictive models for "Equipment Damage" risks was more balanced, with 51.8% of participants using these models, while 48.2% did not. As for "Overwork" risks, the use of predictive models was very high, with 61.2% of participants reporting using them, while 38.8% did not. Finally, with regard to "High Voltage Electric Current" risks, 60.2% of participants indicated that they use a model to predict these risks, while 39.8% did not use any model.

Medical Device Risk Management in Radiology Departments and gender

Table 4. Differences between Medical Device Risk Management in Radiology Departments and gender

Topics	Gender	N	Mean	Std	T	Sig
Medical Device Risk Management in Radiology Departments	Male	163	78.62	14.69	1.653	0.122
	Female	94	80.21	15.24		

Table (4) shows that there are no statistically significant differences between gender and Medical Device Risk Management in Radiology Departments (sig. > 0.05).

Medical Device Risk Management in Radiology Departments and age

Table 5. Differences between Medical Device Risk Management in Radiology Departments and Age

Topics	Age	N	Mean	Std	T	Sig
Medical Device Risk Management in	20-29 years old	68	78.59	16.24	3.589	0.021
	30-39 years old	114	81.32	15.03		
	40-49 years old	56	73.17	12.89		

Radiology Departments	≥ 51 years	19	74.25	13.42
	total	257	77.24	14.86

Table (5) demonstrates statistically significant differences (sig. < 0.05) between the Medical Device Risk Management in Radiology Departments and age.

Medical Device Risk Management in Radiology Departments and Years of Experience.

Table 6. Medical Device Risk Management in Radiology Departments and Years of Experience.

Topics	Years of Experience.	N	Mean	Std	T	Sig
Medical Device Risk Management in Radiology Departments	≤ 5 years	133	79.48	16.40	5.13	0.003
	5-10 year	85	79.27	13.12		
	10-15 year	92	76.30	15.44		
	15-20 year	54	76.28	10.53		
	5-10 year	364	78.01	15.38		
	total	257	77.86	14.17		

According to Table (6), there are statistically significant differences (sig. < 0.05) between the Medical Device Risk Management in Radiology Departments and experience.

Medical Device Risk Management in Radiology Departments and educational level.

Table 7. Medical Device Risk Management in Radiology Departments and educational level.

Topics	educational level.	N	Mean	Std	T	Sig
Medical Device Risk Management in Radiology Departments	Diploma or less	12	73.84	15.2	2.981	0.034
	Bachelor's	159	75.77	14.78		
	Master's	62	79.38	15.87		
	Ph.D.	24	62.29	11.32		
	total	257	71.77	14.12		

Table (7) demonstrates that there are statistically significant differences (sig. <0.05) between the educational level and the Medical Device Risk Management in Radiology Departments.

Medical Device Risk Management in Radiology Departments and Job title.

Table 8. Medical Device Risk Management in Radiology Departments and Job title.

Topics	Job title	N	Mean	Std	T	Sig
Medical Device Risk Management in Radiology Departments	Manager	20	80.43	15.72	1.329	0.285
	Head Of Department	33	82.14	16.10		
	Head Of Division	59	76.23	17.58		
	Employee	145	79.71	8.67		
	total	257	79.63	14.52		

Table (8) demonstrates that there are no statistically significant differences (sig. > 0.05) between the Job title and the Medical Device Risk Management in Radiology Departments.

Discussion

The results of the study showed that the majority of participants had a positive assessment of the risk management systems in radiology departments. With a mean score of 4.32, the results indicated general agreement on the existence of formal risk management systems, with some variability in responses. This finding is consistent with similar studies, such as that conducted by Cracione et al. (2015), which emphasized the importance of risk management systems in radiology to prevent harm and infection. However, this study also found areas for improvement, particularly in the clarity of risk management policies and the effectiveness of regulations set by the Ministry of Health. These findings suggest that while systems are in place, the operation and communication of these systems could be improved. Cracione et al. (2015) found that incorporating various medical precautions in radiology departments is key to reducing risk, which is consistent with the result of the current study in which most participants agreed on the existence of formal risk management systems. However, similar to Jamshidi et al. (2014), this study suggests that there is a need to improve the clarity of procedures and policies, which would enhance the overall effectiveness of risk management in radiology departments.

The study also examined the use of predictive models in radiology departments. The results showed that the application of predictive models was not consistent across different types of hazards. For example, the use of models for radiation dose hazards was relatively low (34.1%), while the use of predictive models for overwork and high-voltage electrical hazards was higher, with 61.2% and 60.2% of participants reporting their use, respectively. This suggests that radiology departments in Saudi hospitals are more proactive in managing risks associated with overwork and electrical hazards, compared to radiation dose hazards. This finding contrasts with some of the studies reviewed, such as Smith and Johnson (2018), which focused on optimizing radiation doses in CT scans. While radiation dose hazards are recognized as critical in radiology, the lower use of predictive models for this type of hazard in the current study suggests a gap in the application of modern predictive tools to radiation safety. This finding suggests a need for more systematic implementation of predictive models for radiation exposure, especially given the technological advances in medical devices.

The results also indicated that there were no statistically significant differences between gender and medical device risk management in radiology departments, with the p-value > 0.05 (0.122), indicating that gender does not significantly affect the assessment of the effectiveness of the risk management system. However, the average assessment was higher among males than females, but this difference was not statistically significant. On the other hand, the study showed statistically significant differences between age groups and medical device risk management, with the p-value < 0.05 (0.021), indicating the influence of age on the assessment of the effectiveness of risk management. The age group 30-39 years showed the highest average assessment with an average of 81.32, followed by the age group 20-29 years with an average of 78.59, while older age groups such as 40-49 years and ≥50 years had lower assessments. These findings are consistent with previous studies, such as Johnson (2017), which found that younger people are more adaptable to new technologies, which is reflected in their evaluation of the effectiveness of technological systems such as risk management systems. In contrast, other studies, such as Lee (2016), have found that older individuals may have more difficulty adapting to technological changes, which may lead to lower evaluations of new systems.

Conclusion and Recommendations

The current study aims to identify the risks of medical devices in radiology departments in Saudi Arabian hospitals and their tools, while studying the effect of demographic factors such as gender, age, educational level, and years of experience in medical device risk management and their impact on medical device risk management in radiology departments. The results indicate that while there were no significant gender differences in the perception of risk management effectiveness, age showed a clear effect. Younger age groups, especially those aged 30–39 years, showed higher ratings of the effectiveness of medical device risk management systems, while older age groups, especially those aged 50 years and above, had lower ratings. These findings are consistent with existing literature indicating that younger individuals are more adaptable to technological innovations and systems than older age groups, who may face challenges in adopting new technologies. The results also reflect the importance of continuous training and education for all age groups in healthcare settings. With the rapid advancement of medical technologies, it is crucial for healthcare professionals to stay up to date with the latest risk management protocols. Although there are no significant gender differences, attention still needs to be paid to the comprehensiveness of training programs to ensure that all employees, regardless of gender or age, are equipped with the knowledge and skills necessary to effectively deal with potential risks associated with medical devices.

In conclusion, the current findings indicate a generally positive perception of risk management systems in radiology departments in Saudi hospitals. However, there are areas that require improvement, such as clarity of risk management policies and adoption of predictive models for radiation dose risk. In addition, demographic factors such as education and experience play an important role in shaping risk management perceptions, suggesting that ongoing training and updating of protocols are essential to maintaining an effective safety culture in radiology departments.

Direction for Further Research

This research is an important step towards understanding the effectiveness of medical device risk management systems in radiology departments, but there are several areas that need further exploration. Future research could focus on studying the long-term effects of different risk management interventions on improving radiologist and patient health and hospital performance. Longitudinal studies may provide a deeper understanding of how these systems evolve and improve over time. In addition, research needs to explore the effectiveness of emerging technologies such as artificial intelligence, machine learning, and predictive analytics in radiology work settings. How these tools contribute to early detection of risks and integrate with existing systems could be studied. The role of organizational leadership and corporate culture in shaping the success of risk management initiatives should also be investigated. Such studies may help provide practical guidance for improving risk management.

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