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Fuzzy logic assessment of X-ray tube risks in robotic C-arm angiography: a failure mode and effect analysis study

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ABSTRACT

This research examines the integration of robotic C-arm technology in angiography, a critical tool for treating cardiac conditions. The robotic C-arm, which includes an X-ray tube, is essential for scanning patients during procedures. The study also investigates the associated risks, specifically in Indonesian hospitals with cardiac facilities. Angiography is used to diagnose and treat heart disease by visualizing blood vessels and facilitating catheterization procedures. However, its mobility poses hazards and can impact the process. To address potential risks, failure mode and effect analysis (FMEA) is utilized. Traditionally, risk assessment using risk priority numbers (RPN) is conducted, but these may not accurately reflect failures due to complex evaluating processes. To overcome this limitation, fuzzy logic is employed, enhancing risk assessment accuracy. Through this approach, twenty-seven failure modes are identified across two brands, with ten major ones prioritized using fuzzy logic. These findings facilitate the development of preventive measures to mitigate future failures and enhance patient safety during angiography in hospitals. In conclusion, the study underscores the importance of robust risk management in medical equipment, particularly in dynamic environments. By integrating fuzzy logic into risk assessment, the study improves prioritization accuracy, enabling effective allocation of resources for preventive actions.

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1. INTRODUCTION

In 2022, data on the number of medical imaging devices in all Indonesian hospitals increased with 236 angiography equipment, according to the data made public by the Indonesian Ministry of Health through the medical equipment facilities and infrastructure application, or what is commonly called ASPAK in Indonesia [1]. According to information from the Ministry of Health, Indonesia has 68,945 medical equipment distribution permits [2]. This growth in the medical device industry is in line with the government's efforts to accelerate the development of the domestic pharmaceutical and medical device industry, demonstrating the rapid pace of medical device development after the pandemic era. In 2018, the Association of Indonesian Hospitals (PERSI) also released data on the top 10 largest number of inpatient cases throughout Indonesia which are heart attack and cardiac diseases having the greatest number of patients in the hospital with 1,356 cases on the patient [3].

However, damage to the equipment often occurs during use, leading to the need for immediate repairs. This can cause delays in patient care, including surgical procedures which require careful preparation and scheduling. Given the high cost of maintenance for high-tech medical equipment, such as angiography equipment, research is needed to analyze and mitigate any risks associated with damage to the equipment [4]. This will help ensure that medical professionals can use the equipment safely and optimally, and minimize the risk of accidents to patients, which must always be a top priority [5]. On the other hand, catheterization is a medical procedure that is used to diagnose and treat different types of heart and blood vessel diseases. This procedure is typically performed in a specialized area of the hospital called a catheterization laboratory, or Cath Lab, using Angiography equipment with a C-arm robotic that has an X-ray tube [6]. The angiography equipment uses X-rays and contrast media to visualize the inside of the human blood vessels, allowing doctors to identify any abnormalities or blockages [7]. Table 1 illustrates the overall percentage of angiography-related problems detected in each year from 2017 to 2021 where the data was obtained from a hospital in Jakarta. Table 1 shows the data on Angiography equipment damage in a hospital, including the number of damages and the specific parts affected each year. This is because, in general, medical equipment is also included in the risk of patient accidents occurring, which must be avoided [5]. Not just the equipment, but also several kinds of other radiology-related supporting modalities, such as the usage of PACS as a tool to complete the process of creating films from scanned images and also much research on medical equipment [8]–[10].

Table 1. Angiography damage data

Part	2017	2018	2019	2020	2021
C arm	1	1			
Chiller					
Workstation			1		
Hymodinamic	1	2			
Image Quality				1	
Monitor		1	1		
Tube X-ray	1		1	3	1
Total	**3**	**4**	**3**	**4**	**1**
Total in percent	**20%**	**27%**	**20%**	**27%**	**6%**

This study focuses on the implementation of robotic C-arm systems in angiography, with a specific focus on hospitals equipped with cardiac facilities in Indonesia. Through an in-depth analysis of associated risks and failure modes, the aim is to develop strategies for optimizing the use of this technology, ultimately improving patient outcomes in cardiac imaging and intervention. The robotic C-arm, a component of the angiography tool, utilizes a C-shaped arm with autonomous or semi-autonomous movement [11]. This technology enables real-time fluoroscopy or X-ray imaging during medical procedures such as angiography, orthopedic surgery, and spine surgery [12]. A robotic arm functions similarly to a human arm, with links connected by joints allowing rotational or translational motion [13]. These links form a kinematic chain, with the end effector resembling a human hand. The end effector can be designed for various tasks such as welding or gripping, depending on the application. In modern angiography systems, C-arm cone beam computed tomography (CBCT) technology is integrated as shown in Figure 1 [14] and Figure 2 [24].

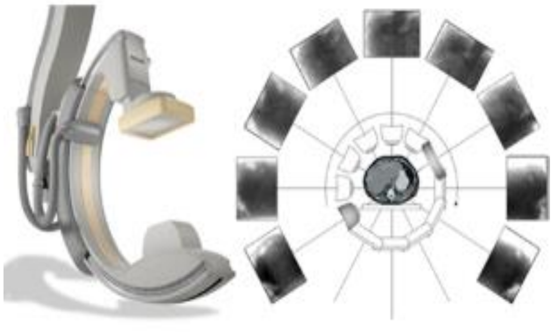

Figure 1. CBCT imaging is based on the rotation of a C-arm equipped with a flat panel detector [14]

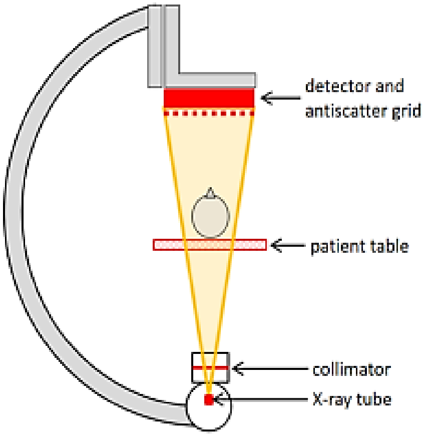

Figure 2. X-ray imaging geometry for a conventional [24]

This research is an advancement of earlier research, which used medical instruments in fuzzy failure mode and effect analysis (FMEA) and also prototype modeling in X-ray stationery [15]. The medical equipment that is utilized makes the most difference. While ventilators [16], sterilizers [17], and also brachytherapy [18] in medical imaging equipment were utilized in previous research, Angiography was the equipment used in this study. Additionally, research has been done on anesthesia equipment that only uses FMEA without using fuzzy logic [19]. Based on earlier research, showed that fuzzy FMEA is a commonly used method for identifying failure modes in a variety of contexts, including product design, quality control, and software on medical devices [20]. This researcher attempted to use fuzzy FMEA in his research while taking into account the findings and examining them from a number of angles. Previous research also has used fuzzy logic behavior using particle swarm, demonstrating its potential as a controller and as a means of enhancing mobile robots [21], [22]. By integrating fuzzy logic into the decision-making process, the system can handle uncertainty and imprecision inherent in construction delays, allowing for more flexible and adaptive solutions. Research on the utilization of autonomous robots for medical facility cleaning has been conducted in conjunction with studies on robots in medical equipment [23].

This paper contributes to the field by providing a comprehensive analysis of potential equipment damage in angiography procedures utilizing C-arm robotics. It aims to identify and analyze any damage that may occur to the equipment involved in angiography, particularly focusing on the robotic C-arm component. By examining potential causes of equipment failure leading to damage, the study sheds light on crucial factors impacting the reliability and safety of angiography systems. Additionally, the paper presents the results of a fuzzy-FMEA analysis tailored specifically for angiography procedures. This analysis offers insights into the most critical failure modes and associated risks, considering the complex and dynamic nature of angiography operations. By integrating fuzzy logic into risk assessment, the study enhances the accuracy of identifying and prioritizing potential failures, thereby facilitating the development of effective preventive measures to mitigate equipment damage and enhance patient safety during angiography procedures. Overall, this paper contributes to advancing the understanding and management of equipment-related risks in angiography, ultimately improving patient outcomes and healthcare quality in this critical medical domain.

2. METHODOLOGY

2.1. Failure mode and effect analysis (FMEA)

Traditionally, the risk of a failure mode is determined through the risk priority number (RPN) score, which combines severity, occurrence, and detection ratings. FMEA is an engineering tool used to anticipate and prevent potential failures, developed by the Defense Department of the United States. FMEA systematically examines system components to identify failure modes and their effects, offering recommendations to mitigate risks and improve reliability. Its primary aim is to assess risks based on severity, frequency, and detectability, generating an RPN for prioritizing preventive actions. This formal yet subjective analysis estimates risks and suggests improvements by targeting high RPN values, emphasizing areas needing immediate attention.

$$\text{RPN}_k = Sev_k \text{ x } Occ_k \text{ x } Det_k \quad (1)$$

2.2. Fuzzy FMEA

The difference between traditional FMEA and fuzzy-FMEA lies in how they calculate risk values. In traditional FMEA, risk is determined by multiplying the impact, occurrence, and detection of failure. However, fuzzy-FMEA divides severity, occurrence, and detection into fuzzy sets to accommodate uncertainty. This allows for more subjective evaluation using linguistic variables like “high,” “medium,” and “low.” These are then converted into fuzzy sets, offering a more flexible approach to risk assessment. Fuzzy logic is used to calculate the fuzzy risk priority number (FRPN), providing a more nuanced evaluation of risk. This method addresses uncertainties and ambiguities in data, resulting in a more comprehensive risk assessment compared to traditional FMEA.

$$\mathrm{FIS_{RPN}}(\mathrm{sev},\mathrm{occ},\mathrm{det}) = \frac{\sum_{n_{Sev}}^{m_{Sev}}=1\ \sum_{n_{Occ}}^{m_{Occ}}=1 \sum_{n_{Det}}^{m_{Det}}=1\left(\mu_{Sev}^{n_{Sev}}(\mathrm{sev})\ \mathrm{x}\ \mu_{Occ}^{n_{Occ}}(\mathrm{occ})\ \mathrm{x}\ \mu_{Det}^{n_{Det}}(\mathrm{det})\ \mathrm{x}\ b^{n_{Sev,Occ,Det}}\right)}{\sum_{n_{Sev}}^{m_{Sev}}=1\ \sum_{n_{Occ}}^{m_{Occ}}=1 \sum_{n_{Det}}^{m_{Det}}=1\left(\mu_{Sev}^{n_{Sev}}(\mathrm{sev})\ \mathrm{x}\ \mu_{Occ}^{n_{Occ}}(\mathrm{occ})\ \mathrm{x}\ \mu_{Det}^{n_{Det}}(\mathrm{det})\right)} \quad (2)$$

3. IMPLEMENTATION STEP

The fuzzy FMEA approach utilizes fuzzy string matching for reasoning from the processed knowledge base. String matching gives a similarity index with which the required failure mode gets mapped into the correct class of failure modes, thus helping to make a decision [25]. Hence risk prioritization can be done to the identified nine failure modes of an Angiography. Based on data from earlier studies, it was discovered that the FMEA method had flaws where the RPN data still had numerical uncertainty [26]. Fuzzy logic, a mathematical technique for identifying the area of uncertainty, was then applied, necessitating a fuzzification process using the fuzzy interference system, which subsequently included variables S, O, and D and was calculated as an FRPN.

4. RESULT AND ANALYSIS

The severity variable’s membership with the following possibilities high (H), very high (VH), hazard with warning (HWW), and hazard without warning (HDWW). The severity value, which was derived from the FMEA and RPN calculation results, is fed into each of these variables. The membership function for the Occurrence variable with moderate (M) and high (VH) options. The Occurrence values obtained from the FMEA and RPN computation results are put into each of these variables. The membership function for the Detection variable where there are moderate (M), low (L), and very low (VL). The severity rankings obtained from this method are referred to as F rank. Table 2 shows failure mode including robotic C-arm.

Table 2. Failure mode in robotic C-arm angiography

Linguistic variable	Code	Rank assigned	S	O	D	RPN	FRPN	Category	Rank RPN	Rank FRPN
FM1	A	C-arm stopped	7.9	4.9	4.1	158.711	236	L-M	21	18
FM2	A	Chiller cooling failure	7.9	5.7	4.2	189.126	247	L-M	16	17
FM3	A	ECG does not signal	7.5	5.4	5	222.528	278	M	12	12
FM4	A	Hymodinamic blank monitor	8	5.5	4.9	215.6	279	M	13	11
FM5	A	Hymodinamic blue screen	7.6	4.8	6.1	202.5	288	M	14	10
FM6	A	Hymodinamic blur image	7.2	5.1	4.4	161.568	274	L-M	18	13
FM7	A	Blink monitor	6.5	5.1	4.8	159.12	261	L-M	20	15
FM8	A	Red line monitor	6.1	4.5	4.7	129.25	260	L	25	16
FM9	A	Tube X-ray spitt	9.3	5.4	6.5	326.43	400	M-H	1	1
FM10	A	Tube X-ray collimator power failure	9.1	5.9	6	322.14	310	M-H	2	3
FM11	A	Tube X-ray error on heater board	9	5.7	5.7	293.7	309	M	4	4
FM12	A	Tube X-ray FRU Inggrid problem	8.7	6	5.6	292.41	308	M	5	5
FM13	A	Tube X-ray HV tank problem	8.9	6	5.5	292,32	300	M	6	8
FM14	A	Workstation bluescreen	7.1	5.5	6.2	242.11	216	M	10	20
FM15	B	Footswitch cannot function	7.67	5.2	6.1	243.1867	300	M	9	7
FM16	B	Hymodinamic NIBP not detection	7.2	5.4	5.2	202.176	234	M	15	19
FM17	B	Hymodinamic P1-P2 cable IBP problem	7.7	6	3,8	175.56	192	L-M	17	21
FM18	B	Hymodinamic display error	7.7	4.9	3.7	139.601	192	L-M	24	23
FM19	B	Image quality system Hang	8.6	5.4	5.7	264.708	300	M	7	6
FM20	B	Operating table cannot move	7.7	5.4	5.5	228.69	270	M	11	14
FM21	B	Operating table sound noise	6.2	5.5	4.3	146.63	185	L-M	23	24
FM22	B	Moving module control problem	8.1	5.5	5.5	245.025	288	M	8	9
FM23	B	Moving module push button X-ray problem	8.2	5.3	3.7	160.802	192	L-M	19	22
FM24	B	Tube X-ray error 10LL frontal generator	8.6	5.5	6.4	302.72	342	M-H	3	2
FM25	B	Workstation cannot expose	8.1	6.4	2.9	150.336	152	L-M	22	25
FM26	B	Workstation bad hard disk	7.3	5.8	2.9	122.786	136	L	26	27
FM27	B	Workstation transfer PACS problem	6.11	5	3.4	103.8889	137	L	27	26

Table 3 provides a detailed comparison of the risk rankings for 27 major failure modes in robotic C-arm angiography systems from two different manufacturers, GE (A) and Philips (B), using both traditional FMEA and fuzzy FMEA methodologies. The table includes the linguistic variable describing each failure mode, the assigned rank based on traditional FMEA (T rank) and fuzzy FMEA (F rank), and the manufacturer code. FM9 (tube X-ray Spitt) consistently ranks as the highest risk in both FMEA methods (T rank: 1, F rank: 1), indicating it is the most critical failure mode for GE. FM10 (tube X-ray collimator power failure) and FM11 (tube X-ray error on heater board) also show high-risk ranks in both methods (T rank: 2 and 4; F rank: 3 and 4, respectively), emphasizing their critical nature. The table highlights the importance of using both traditional and fuzzy FMEA approaches to capture a comprehensive risk profile.

Table 3. Traditional and fuzzy FMEA rank

Linguistic variable	Rank assigned	FMEA Ranking		Code
FM1	C-arm stopped	T Rank	21	A
		F Rank	18	
FM2	Chiller cooling failure	T Rank	16	A
		F Rank	17	
FM3	ECG does not signal	T Rank	12	A
		F Rank	12	
FM4	Hymodinamic Blank Monitor	T Rank	13	A
		F Rank	11	
FM5	Hymodinamic blue screen	T Rank	14	A
		F Rank	10	
FM6	Hymodinamic blur image	T Rank	18	A
		F Rank	13	
FM7	Blink monitor	T Rank	20	A
		F Rank	15	
FM8	Red line monitor	T Rank	25	A
		F Rank	16	
FM9	Tube X-ray spitt	T Rank	1	A
		F Rank	1	
FM10	Tube X-ray collimator power failure	T Rank	2	A
		F Rank	3	
FM11	Tube X-ray error on heater board	T Rank	4	A
		F Rank	4	
FM12	Tube X-ray FRU Inggrid problem	T Rank	5	A
		F Rank	5	
FM13	Tube X-ray HV Tank problem	T Rank	6	A
		F Rank	8	
FM14	Workstation bluescreen	T Rank	10	A
		F Rank	20	
FM15	Footswitch cannot function	T Rank	9	B
		F Rank	7	
FM16	Hymodinamic NIBP not detection	T Rank	15	B
		F Rank	19	
FM17	Hymodinamic P1-P2 cable IBP problem	T Rank	17	B
		F Rank	21	
FM18	Hymodinamic display error	T Rank	24	B
		F Rank	23	
FM19	Image quality system Hang	T Rank	7	B
		F Rank	6	
FM20	Operating table cannot move	T Rank	11	B
		F Rank	14	
FM21	Operating table sound noise	T Rank	23	B
		F Rank	24	
FM22	Moving module control problem	T Rank	8	B
		F Rank	9	
FM23	Moving module push button X-ray problem	T Rank	19	B
		F Rank	22	
FM24	Tube X-ray error 10LL frontal generator	T Rank	3	B
		F Rank	2	
FM25	Workstation cannot expose	T Rank	22	B
		F Rank	25	
FM26	Workstation bad Hard disk	T Rank	26	B
		F Rank	27	
FM27	Workstation transfer PACS problem	T Rank	27	B
		F Rank	26	

Table 3 shows that there are 27 different types of failure modes in robotic C-arm angiography equipment. These failure modes can occur in several elements of the equipment, including the monitor, workstation, hemodynamic, C-arm, chiller, and image quality. This data illustrates a variety of issues that arise with angiography equipment and are typically faced by medical professionals such as nurses and medical doctors. The issues are compiled over the course of the device's five-year use. The results from this analysis are used for ranking the importance of failure modes of angiography in general and are shown in Table 4.

Table 4. Ranking of failure modes

Failure Code	Traditional Ranking	Fuzzy Ranking
FM1	21	18
FM2	16	17
FM3	12	12
FM4	13	11
FM5	14	10
FM6	18	13
FM7	20	15
FM8	25	16
FM9	1	1
FM10	2	3
FM11	4	4
FM12	5	5
FM13	6	8
FM14	10	20
FM15	9	7
FM16	15	19
FM17	17	21
FM18	24	23
FM19	7	6
FM20	11	14
FM21	23	24
FM22	8	9
FM23	19	22
FM24	3	2
FM25	22	25
FM26	26	27
FM27	27	26

According to Table 4, the tube X-ray spitt issue is identified as the most critical failure mode with high-risk criteria by both traditional FMEA and fuzzy-FMEA rankings, especially when the T rank and F rank values are the same. Additionally, a significant issue was found in the tube X-ray error 10LL frontal generator part, where a fuzzy-based analysis revealed a problem with the generator that the traditional method rated lower in importance. This highlights the effectiveness of fuzzy logic in accurately prioritizing critical failures. Table 5 lists 10 failure modes that greatly impact the performance of robotic C-arm angiography equipment, with five of these related to the X-ray tube, the most vulnerable area. The image quality, which can hang, freeze, or malfunction during use, is also a significant concern, as it directly affects the device's performance during patient procedures.

Table 5. Failures codes assigned to failures modes

Code	Failure mode	Rank
FM9	Tube spitt	1
FM24	Error 10LL frontal generator	2
FM10	Collimator power failure	3
FM11	Error on heater board	4
FM12	Tube X-ray FRU Inggrid problem	5
FM19	Image quality system Hang	6
FM15	Footswitch cannot function	7
FM13	Tube X-ray HV tank problem	8
FM22	Moving module control problem	9
FM5	Hymodinamic blue screen	10

5. CONCLUSION

To assess damage in robotic C-arm angiography equipment, a comprehensive review of historical failures is conducted using service reports and repair data from the manufacturer. This data informs the identification and analysis of potential failure modes in the angiography system, applying both FMEA and fuzzy FMEA methodologies. These methodologies evaluate and rank failure modes based on their severity, likelihood, and detectability, prioritizing the most critical issues. By focusing on high-risk areas, particularly the X-ray tube, which is vital to the system's operation, the study aims to prevent future failures, extend equipment lifespan, reduce downtime, maximize operational hours, and minimize maintenance costs. The findings support the development of a risk management strategy, and future research should explore maintenance approaches that address these critical failure modes to ensure the system's reliability.

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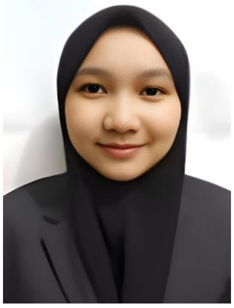

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