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A New Approach for Effective Reliability Management of Biomedical Equipment

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Abstract:

Within the modern hospitals, an increasingly common problem is the efficient management of the maintenance of biomedical equipment. If effective management of medical equipment maintenance is applied, quality health services could be provided by reducing the downtime of medical equipment as well as by decreasing the recovery time for treatment of patients. Risk based maintenance strategy helps in designing an alternative methodology to minimize the risk by identifying the breakdown pattern and then increasing the reliability. The probability of failures that obstruct the reliability can be influenced by some technical, administrative or management actions. The proposed study is based on the analysis of reliability and availability for maintenance planning on the basis of risk index and fault tree analysis. Maintenance of equipment is prioritized based on the risk which helps in reducing the overall risk of the hospital. Fault tree diagram is also developed to understand the actual scenario where highest priority or risk events are sequentially arranged. Failure probability for different biomedical equipment has been established by applying statistical method. It has been observed that Magnetic Resonance Imaging has the lowest risk index while X-Ray has the highest risk index. Also, maintenance planning has been suggested based on the reduction of risk factor to meet the acceptable criteria and reduce the probability of failure. This approach depicts that reliability of equipment is increased after implementation of maintenance planning proposed which contributes to the availability of the equipment as well as its safe operation.

Keywords: *Reliability, Availability, Risk index, Maintainability, Fault tree analysis.*

Introduction

Maintenance plays a vital role in the life cycle management of medical equipment. The diagnostic equipment of the hospital will not remain effective or reliable if proper maintenance is not done. The aim of the maintenance of medical equipment is to reduce its breakdown and to enhance performance with lowest possible cost. In the present investigation, high risk biomedical equipments are first identified by using the risk based maintenance (RBM) strategy and then statistical approaches have been utilized to reduce the actual failure rate of the machines. This helps us to minimize any unexpected loss of health quality services due to downtime and breakdown of equipments. The present investigation is conducted on the basis of data collected from the government hospital for continuous 60 days. These data are analysed for further processing of reliability so that better performance of the machines can be achieved which in turn provide quality health services.

Some works in the domain of risk based maintenance management on biomedical equipment has been done by various researchers. In the healthcare industry, a methodology (Taghipur 2011) has been proposed to implement a novel maintenance strategy on biomedical equipment. A model for the prioritization of medical equipment had been used here for maintenance decisions. With a growing proportion of advanced biomedical equipment, the economic life cycle operations and patient outcome priorities had been studied (Mkalaf 2015) by adopting Reliability Centred Maintenance (RCM) type philosophy. The contribution (Masmoudi et al. 2016) of the medical equipment maintenance management by using decision support procedure was also noteworthy. A case study for a large hospital in a developing country had been investigated (Vala et al. 2018) by using risk based maintenance approach for some medical devices of a referral hospital in a developing country. A quantitative approach for a risk based preventive maintenance program has been studied (Silva and Oineda 2000) for medical equipment where weighted classifications considering four variable like risks, design, operation and economic were critically examined. Therefore, the domain of risk based maintenance management of biomedical equipment might be a significant improvement of survival of patients.

In the current study, parametric analysis on failure probability, reliability, distribution of Probability Density Function (PDF) and Cumulative Density Function (CDF) by statistical approach and availability analysis has been conducted to identify the critical component based on risk index. Furthermore, maintenance planning has been suggested to increase the reliability of the equipment.

Materials and Methods

Maintenance Strategy

Risk-based approach for the maintenance of machine is generally used to identify, characterize, quantify, and evaluate the loss of an event. Risk can be assessed quantitatively by using failure probability and consequence analysis at different stages (Khan and Haddara 2003) which can be written by the following Equation (1).

$$\textit{Actual risk} = \text{Failure probability} \times \text{Failure Consequence} \qquad (1)$$

The goal of the proposed RBM strategy is to reduce the unexpected failure and the overall risk of the biomedical equipments under study. The RBM methodology generally involves risk identification and estimation, risk re-evaluation and maintenance planning.

Failure Model

Failure is an event that refers to a loss in production continuity. Lack of proper maintenance leads to breakdown which results into failures. On a given system the failures change non- linearly with the change of time (Dhillon 2008) as shown in Figure.1. The non-linear distribution comprises of three regions namely infant mortality period, useful life period and wear out period.

The Weibull distribution is extensively used in reliability engineering and life data analysis because of its ability to adapt to different versatile situations. Neglecting location parameter the Weibull distribution consists of two parameters, namely ‘η’ (scale parameter) and ‘β’(shape parameter). At the early stage of the machine (when $\beta < 1$), the rate of failure will decrease and at the accelerated wear-out conditions of machine components (when $\beta > 1$), the failure rate will increase. However, for β

= 1 the distribution follows constant linear failure rate. For non linear failure model, it follows Weibull distribution whereas for linear constant failure model it follows exponential probability law.

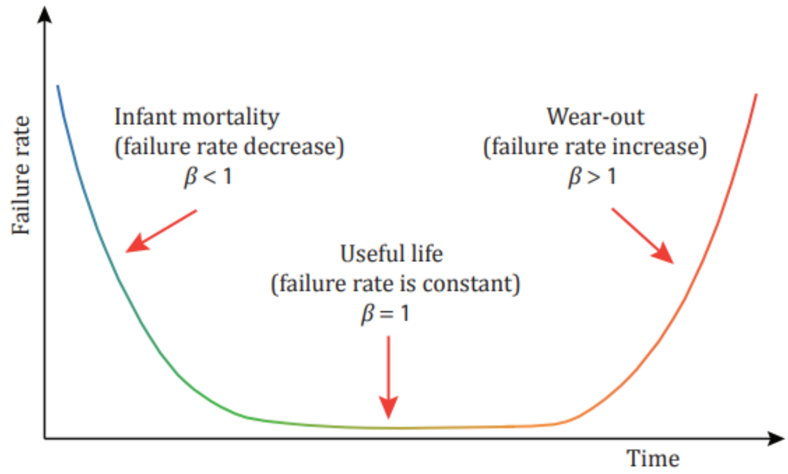

Figure 1. Bath-tub curve of an equipment describing failure rates at different periods

Anderson-Darling (AD) test (Anderson and Darling 1952) is a statistical test of how a given sample of data fits well a specific distribution with great ease by the use of Weibull analysis. For Weibull probability distribution, the lowest value of AD test possesses best fitted distribution in comparison with normal and exponential distribution (Murthy et al. 2004).

Reliability

Reliability is defined as the probability that an equipment or process performs its intended function adequately for a specified period of in a defined environment without failure. The reliability function of a machine, 'R(t)' is known as the probability of failure free operation at time 't' and can be explained by Equation (2).

$$R(t) = 1 - F(t) \quad (2)$$

The following equations (3), (4) and (5) represent the probability density functions (PDF) for normal, exponential and Weibull distributions respectively.

$$f(t) = \frac{1}{\sigma\sqrt{2\pi}} e^{-\frac{1}{2}\left(\frac{x-\mu}{\sigma}\right)^2} \quad (3)$$

$$f(t) = \eta e^{-\eta t} \quad (4)$$

$$f(t) = \left(\frac{\beta}{\eta}\right).\left(\frac{t}{\eta}\right)^{\beta-1} . e^{-\left(\frac{t}{\eta}\right)^{\beta}} \quad (5)$$

where $'\mu'$ is mean of time between failure (MTBF), 'σ' is standard deviation of MTBF and 'x' is breakdown time. Linear correlation analysis has been carried out to determine failure probability by using Equation (6) (Chowdhuri and Pal 2022).

$$F_{x,f(x)} = \frac{p}{q} \quad (6)$$

where,

$$p = n\left(\Sigma x f(x)\right) - (\Sigma x)(\Sigma f(x)) \quad (7)$$

$$q = \sqrt{[n\sum x^2 - (\sum x)^2][n\sum (f(x))^2 - (\sum f(x))^2} \quad (8)$$

'$F_{x,f(x)}$' is the correlation coefficient or failure probability , the value of which lies between +1.0 and -1.0, 'x' is breakdown time (in hours), 'f(x)' is cumulative percentage of failure (calculated from number of failures per day and sum of number of failures for 60 days), 'n' is sum of operating time for 60 days (in hours), Rate of failure will increase for positive values of correlation coefficient and in this case Weibull distribution is applicable for reliability analysis.

Availability

Availability represents the probability that a device is capable of conducting its required function when it is not failed or undergoing a repair action and plays an important role for reliability analysis. Availability or inherent availability 'A_{in}' is depended on preventive or scheduled maintenance and is expressed (Leitch 1995) by Equation (9).

$$A_{in} = MTBF / (MTBF + MTTR) \quad (9)$$

MTTR is mean time to repair and MTBF is mean time between failures. Considering administration and logistic delay time in real operation, 'A_{op}' (operational availability) can be defined as the probability that a system in stated conditions will function properly and it is expressed by Equation (10).

$$A_{op} = MTBF / (MTBF + MDT) \quad (10)$$

MDT (Mean down time) is the average time that a system is non-functional. This includes all delay time associated with repair, restoration, make ready and logistics or administrative delays.

Estimation of Consequence and Risk Index

The present investigation also includes the estimation of consequence and risk indices of equipments which are essential for effective reliability management. Expressions for consequence and risk index (Khan and Haddara 2003) are given by Equations (11) and (12).

$$\text{Consequence} = MC + PLC \quad (11)$$

MC (Machine Cost), PLC (Production Loss Cost) and price of maximum risk of the different diagnostic equipments are generally available for the purchase and accounts section of the organisation.

$$Risk\ index = \frac{Actual\ risk}{Acceptable\ risk} \quad (12)$$

Fault Tree Analysis

Fault Tree Analysis (FTA) is the detailed examination of failure events graphically which is used to detect causes of undesired failures. Boolean logic is used to analyze the system and pathways for the causes of failures. FTA is basically top-down approach to identify the basic events (i.e. component level failure) which cause the top event (i.e. system level failures) to occur. Events and logic gates are the two elements of FTA which connect the events to identify the cause of top undesired failure. Main event is generally at the top and it draws branches representing the causes of the event. Each branch is further divided into sub-branches represent their immediate causes. Until the logic reaches the lowest level of a system, it goes on and on.

Health Care Unit and Its Equipment

The present study is conducted at a government hospital located in Kolkata, West Bengal, India. Hospital has various departments which include Radiology, Biochemistry, Pathology, Microbiology etc. The radiology department plays essential role on treatment of patients as well as on research and diagnosis of diseases.

The department comprises of various biomedical instruments such as Magnetic Resonance Imaging, Ultrasonography, X-Ray, Electrocardiogram and CT-Scan. All these devices have been taken into consideration for the study are summarized in Table 1 which are generally used for emergency diagnosis of patients.

Table 1. Different Equipment of the Diagnostic Centre

Serial No.	Name of machine	Name of the company	Year of manufacture	Output
1	Magnetic Resonance Imaging (MRI)	Midnapore Diagnostic Pvt. Ltd., India	2014	It produces diagnostic images of soft tissues.
2	Ultrasonography (USG)	SynerMED Technologies LLP, India	2004	It produces high frequency sound waves to scan the internal organs of the body.
3	X-Ray	M.E.X'RAY (I)PVT. LTD, India.	2001	Images of tissues and bones inside the body are produced.
4	Electrocardiogram (ECG)	Clarity Medical Pvt. Ltd , India.	2019	It produces three wave signals for the diagnosis of heart diseases.
5	Computerized Tomography (CT) Scan	Liasio Medical Services, India.	2006	Tomographic images of internal parts of body are produced.

Results

Operating time, breakdown time and number of failures are the basic data which has been collected from the hospital for consecutive 60 days from 1st December, 2021 to 31st Jan 2022. During this period the average temperature inside the radiology department was 18-24°C and average relative humidity was 40-50%. Here, breakdown time also includes machine downtime because of unavailability of patients at regular interval of times. Collected data for five biomedical equipment under study for 60 days is given in Table 2.

Table 2. Collective Data of Five Biomedical Equipment for 60 Consecutive Days

Machine Name	Sum of operating time (in hours)	Sum of breakdown time (in hours)	Sum of Number of failures	Sum of Cumulative failures
Magnetic Resonance Imaging (MRI)	83	243	577	2581.37
Ultrasonography (USG)	1255	229	386	5220.09
X-Ray	296	850	115	3566.08
Electrocardiogram (ECG)	1388	104	208	3013.46
Computerized Tomography (CT - Scan)	1361	128	238	3781.33

Using Table 2, correlation coefficients of the above equipment have been determined by using Equations (6), (7) and (8) and positive values are obtained for all the equipment. Table 3 shows the corresponding results of the failure probability and reliability function for different biomedical equipment of the hospital which are determined from Equations (6) and (2) respectively.

Figure. 2 shows overview distribution for operating hours by using statistical regression analysis of X-Ray with the help of software **Minitab17.**

This overview plot shows the distribution of PDF that describes the failure characteristics of the X-Ray machine. Here, it also shows the values of shape and scale factors, (i.e. β = 2.02587 and η = 9.38423) with total number of failures 115 (as also shown in the Table 2), which were estimated by Minitab17.This indicates that the X-Ray machine in deteriorated condition. From survival and hazard analysis it could be predicted that survival function with respect to operating time is decreasing whereas hazard function is increasing.

Table 3. Reliability and Failure Probability of Different Biomedical Equipment

Serial Number	Name of the equipment	Failure Probability	Reliability (in %)
1	Magnetic Resonance Imaging (MRI)	0.4342	56.58
2	Ultrasonography (USG)	0.7523	24.77
3	X-Ray	0.8027	19.73
4	Electrocardiogram (ECG)	0.5224	47.76
5	Computerized Tomography (CT- Scan)	0.5358	46.42

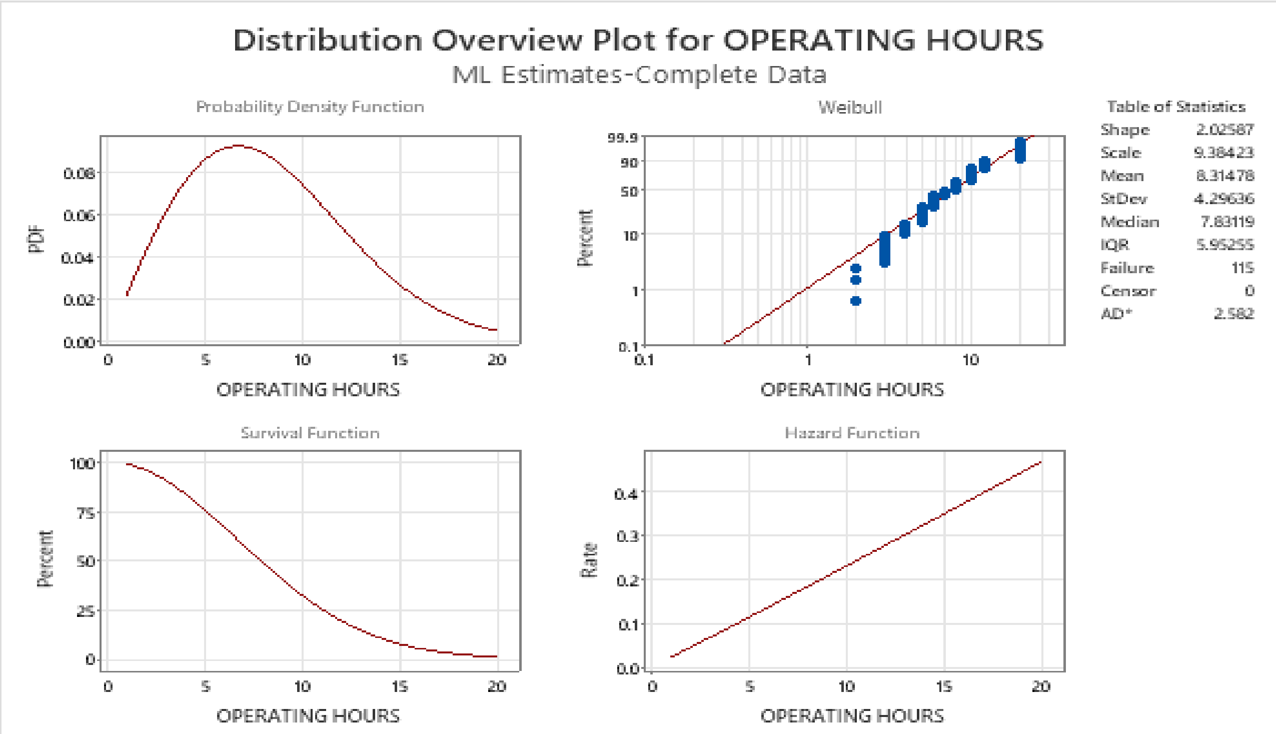

Figure 2. Overview Distribution plot of X-Ray machine obtained from Minitab17

As the failure probability of X-Ray machine is found to be the highest value in comparison with other machines (as shown in Table 3). Probability plot of it has been developed by using statistical software Minitab17 for Weibull, exponential and normal distribution and shown in Figure 3. It has been found that Weibull distribution is best fitted to having the lowest (i.e. 7.472) Anderson-Darling (AD) value.

Availability of X-Ray machine is estimated from equations (9) and (10) where MTBF is calculated from operation time and failure number, MTTR is calculated from repair time and number of repairs and MDT is calculated from down time and failure number. Figure 4 shows the corresponding availability plot of X-Ray machine.

Availability of all equipments of the hospital is represented by bar chart as shown in Figure 5 where it shows that X-Ray machine possess low availability. This is due to the excessive make ready time and downtime which have been considered as failure. Whereas Magnetic

Resonance Imaging (MRI) posses high availability during two months under study.

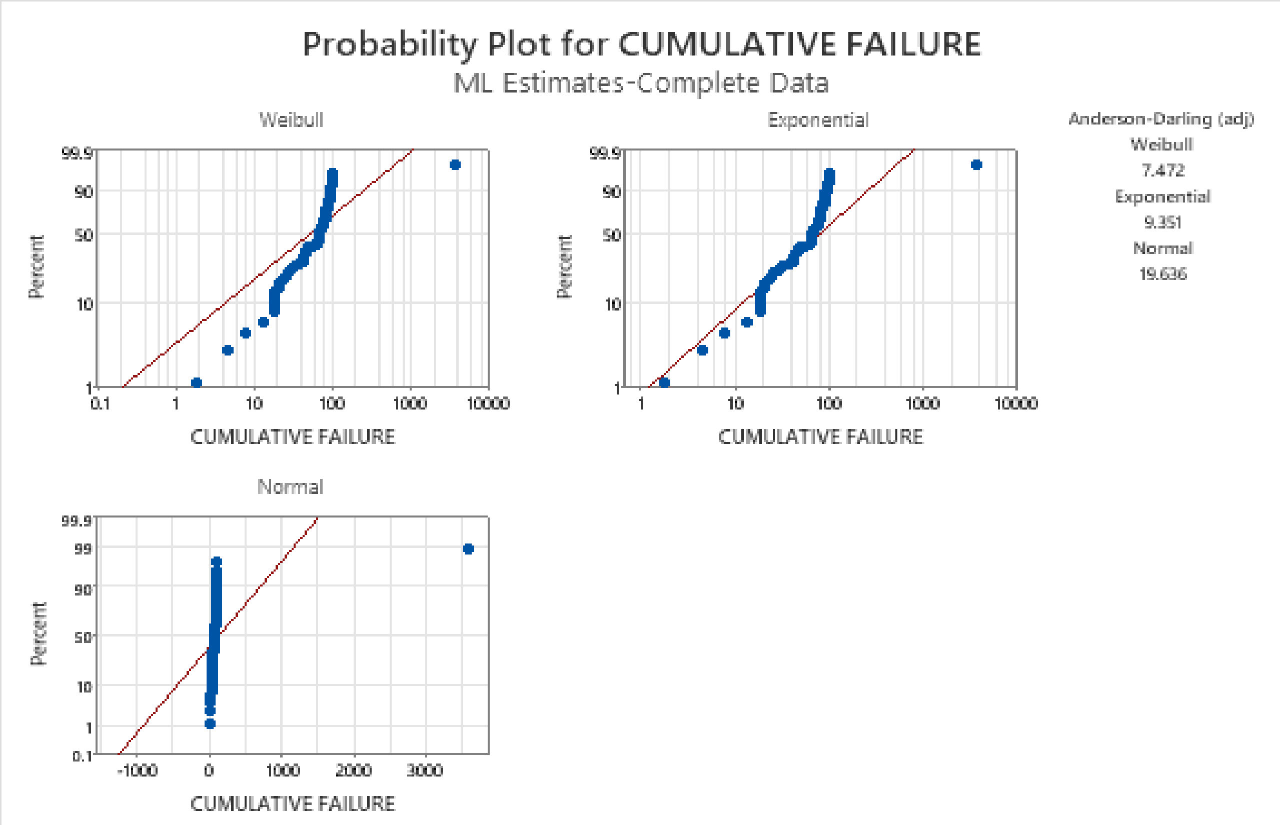

Figure 3. Probability plot of X-Ray machine

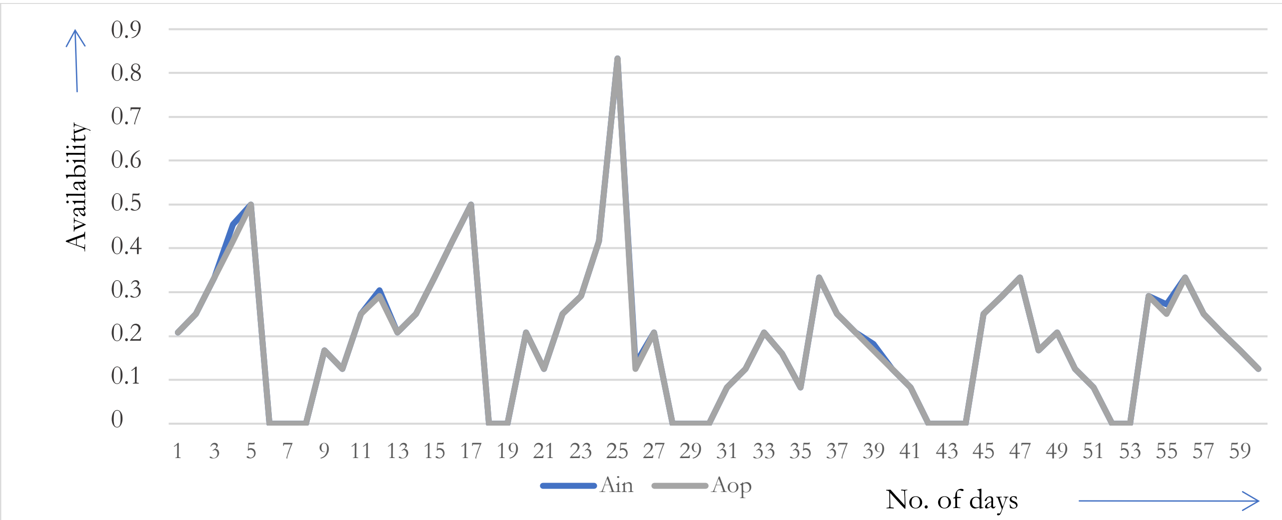

Figure 4. Availability of X-Ray Machine for Consecutive 60 Days

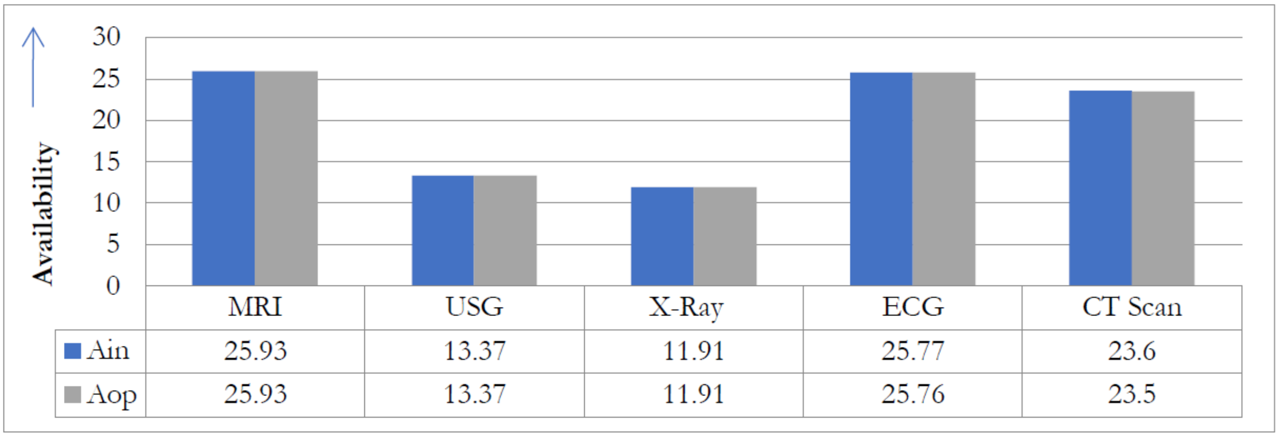

Figure 5. Bar Diagram of Various Availability of Five Biomedical Equipment

Considering acceptable risk criteria of Indian Rupees (INR) 180000 and the consequences of all the machines which are collected from administration section of the hospital, risk indices of different equipments are shown in Table 4 to understand the actual scenario. Here, the actual risk of the machines and their corresponding risk indices are calculated from Equations (1) and (12) respectively. In order to develop maintenance planning, the root cause of failure for the reduction of risk of the diagnostic centre should be analysed. It is also pertinent to mention that it is seen that X-Ray machine is having the highest failure rate and Magnetic Resonance Imaging machine is facing the lowest failure rate.

Table 4. Consequence, Failure Probability, Actual Risk and Risk Index of Different Biomedical Equipment

Serial No.	Name of the equipment	Consequence (in INR)	Failure Probability	Actual Risk (in INR)	Risk Index
E1	MRI	99195	0.4342	43070.46	0.2392
E2	USG	277519	0.7523	208777.54	1.1598
E3	X-RAY	487735	0.8027	391504.88	2.1750
E4	ECG	203143	0.5224	106121.90	0.5895
E5	CT-SCAN	238074	0.5358	127560.04	0.7086

Pareto chart of all biomedical equipments under study is generated by using software Minitab17and shown in Figure 6. From this analysis which equipment is needed to be chosen for maintenance planning can be decided.

Fault Tree Analysis of Biomedical Equipment

Fault Tree analysis (FTA) is widely used in reliability analysis and risk-based maintenance approaches. Here, different symbols are used to characterize the failure events. For example, rectangle symbol represents the resultant event that gives outcome from the failure events through the input of logic gate. OR gate denotes that the output fault event occurs if one or more of the input failure events take place; circular symbol represents the basic fault or breakdown event etc.

The notations used for all types of selected equipments are described separately in Table 5, which are used in FTA analysis. From the above concept FTA diagram is developed to understand the actual failure scenario where highest priority or high risk events are arranged from left side of the circuit as shown in Figure 7.

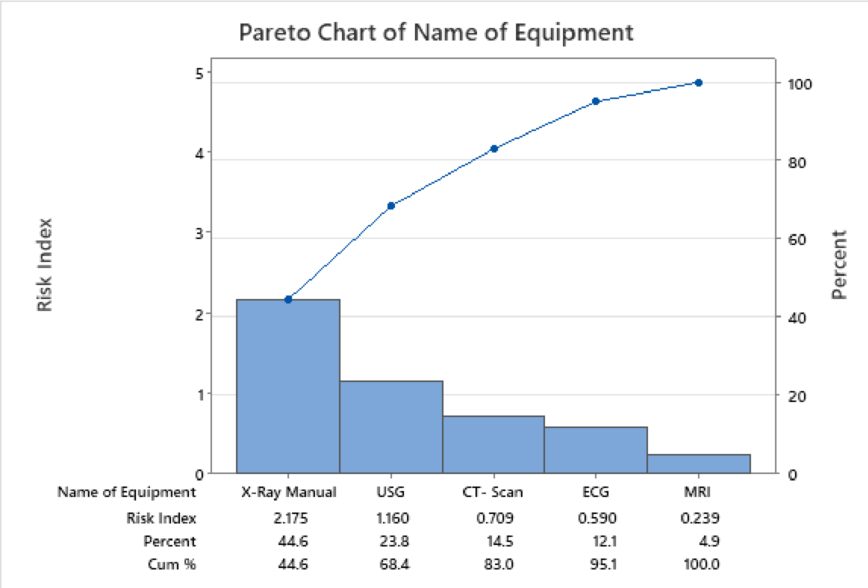

Figure 6. Overall Pareto Analysis of different Biomedical Equipment

Table 5 Failure scenario of biomedical equipment

	Failure name	Failure no.	Risk Index	Grade of Risk with respect to R.I.	Notation of equipment	Notation for all types of failures of equipment
Magnetic Resonance Imaging (MRI)	Power issues	120	0.2392	Lowest	E1	E1(1)
	Image artifacts	130				E1(2)
	Intense Vibration	250				E1(3)
	Poor cooling	80				E1(4)
Ultrasonography (USG)	Software corruption	29	1.1598	Second highest	E2	E2 (1)
	Hardware failures	40				E2(2)
	Defects in ultrasound probes	30				E3(3)
X-Ray Manual	Transformer breakdown	19	2.1750	Highest	E3	E3(1)
	Tube leakage	45				E3(2)
	IC Circuit fault	30				E3(3)
	Physical breakdown	21				E3(4)
Electrocardiogram (ECG)	Circuit fault	105	0.5895	Low	E4	E4(1)
	Malfunction of machine	103				E4(2)

Computerized Tomography Scan (CT- Scan)	Malfunction of machine	103	0.7086	Low	E5	E5(1)
	Tube failure	56				E5(2)
	Circuit fault	50				E5(3)

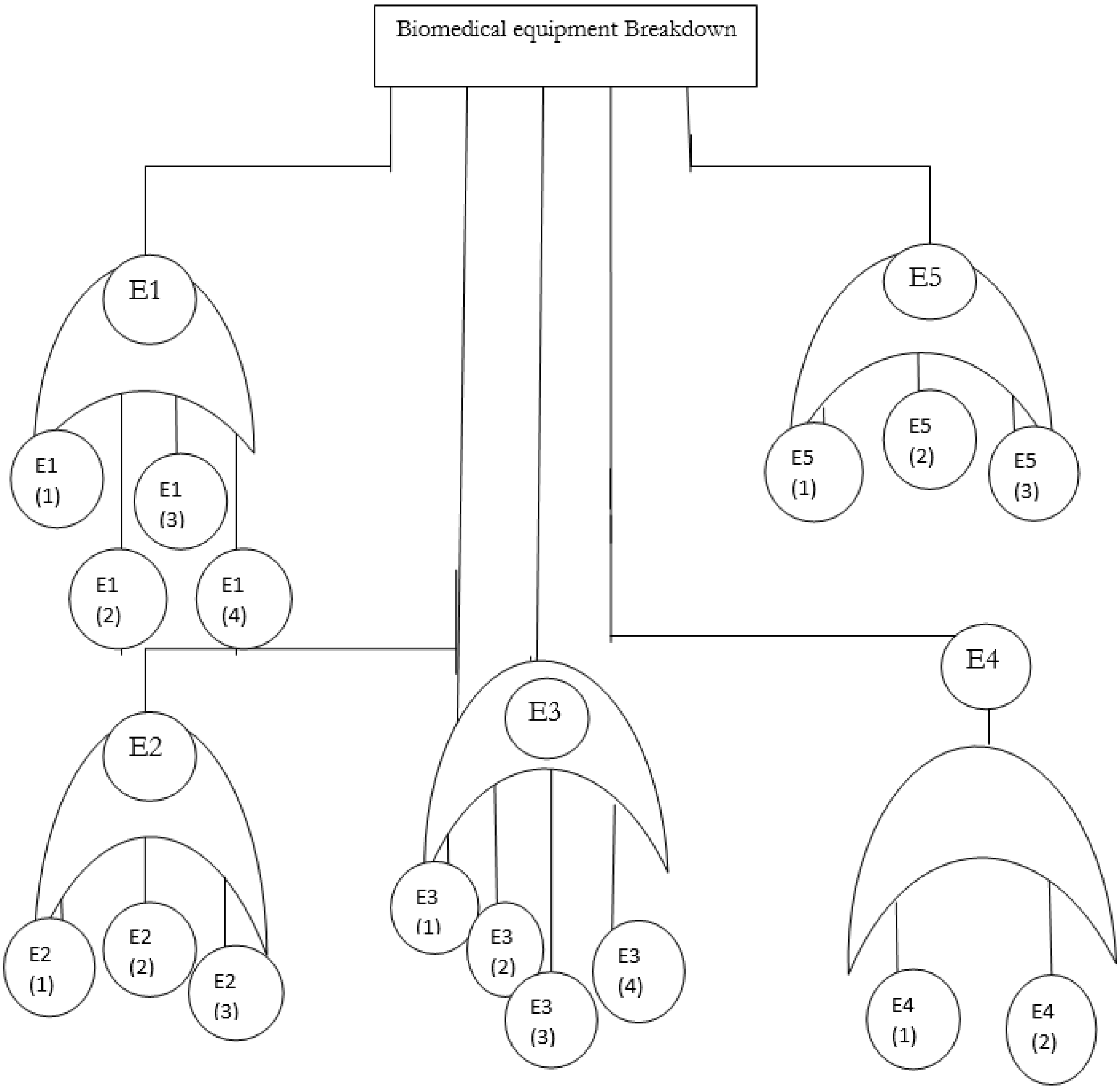

Figure 7. FTA Diagram of the Biomedical Equipment

Maintenance Planning

In order to lower the risk, to reduce the failure probability and to meet the acceptable criteria, further maintenance planning should be adapted. This will help to decrease the number of failures which in turn will support the effective management by increasing reliability of the machines.

Table 6 represents the risk reduction results of X-Ray machine after implementing further maintenance planning. The risk (in INR) has decreased to 272643.86 from 391504.88 and its corresponding probability of failure is also decreased from 0.8027 to 0.5590. Target or modified probability of failure has been determined by considering the fact that breakdown time and/or downtime can be reduced by decreasing the number of failures with the help of modern technology and management system. It has been observed that even decreasing the number of failures by 10% can lead to significant increase in percentage reliability. Therefore, the modified probability of failure for X-Ray machine is 0.5590. Consequently, reliability will increase from 0.1973 to 0.441. Considering this, the suitable interval of preventive maintenance can be predicted. So, it can be postulated that reliability of the medical equipments can be subsequently increased by applying this methodology which may be useful for the improvement of overall performance of radiology department of the hospital.

Table 6. Risk Reduction Results for X-Ray Machine

Parameter	Value
Actual risk (in INR)	391504.88
Target (modified) probability of failure	0.5590
Risk reduction (in INR)	272643.86
Modified reliability	0.441

Discussion

Effect of Failure Probability

From the present study, X-Ray is a device which has the highest failure probability, therefore, less reliability. On the other hand, MRI has the lowest failure probability with high reliability (as shown in Table 3). Overview Distribution Plot (as shown in Fig 2) also indicates that X-Ray machine is in deteriorated conditions due to shape factor of 2.02587. From survival and hazard analysis it could be predicted that survival function with respect to operating time is decreasing whereas hazard function is increasing.

Effect of Anderson Darling Test

Anderson Darling (AD) test has been performed for the X-Ray machine to obtain how dataset fits best among Weibull, exponential and normal distribution. From Fig 3 it is clear that Weibull analysis is suitable for being best fitted and lowest AD value of 7.472. It can be predicted that X-ray machine is in the process of functioning poorly since it is having a high value of shape factor following Weibull distribution.

Effect of Availability

Equipment availability is a metric to measure the percentage of time a device can be used. Availability distribution of X-Ray machine with time duration of 60 days always shows the availability value less than one. Over this duration this machine shows the maximum availability of around 0.83 and minimum 0.20. The inherent availability and operational availability of X-ray machine are also less compared to other four machines as shown in Fig 5. This may be due to excessive make ready time and breakdown time of this machine which has been considered as failure. However, MRI has high availability for two months under study due to its less amount of downtime.

Effect of Risk Factor

The risk indices of the biomedical equipment under study give a clear understanding of the actual scenario of the machine. It is also pertinent to mention the X-Ray machine is having the highest risk index due to maximum failures, whereas MRI is facing the lowest risk index because of minimum failure rate (as shown in Table 2). Based on the estimated risk factors of the mentioned equipments, future maintenance planning can be developed by analyzing the root causes of failures for the reduction of risk of the equipments of the hospital. For this, Pareto analysis has been done to understand the prioritization of the equipments for maintenance planning. This Pareto chart gives the idea of choosing the machine for it. Fault Tree Analysis (FTA) also helps to understand the clear picture of the failure events of the equipments. After modifying the probability of failure for the high risk machine, the suitable preventive maintenance time interval can be re-estimated for improving reliability of the equipments.

This type of approach for improving reliability of machines is very useful for the efficient management of the maintenance of medical equipment to provide its optimal operation.

Conclusion

The proposed technique for reliability and risk analysis predicts the failure frequency and availability pattern of all the equipments in the hospital. These predictions are used to evaluate the maintenance program based on reducing the risk factor of the machines. This methodology confirms that reliability of equipments can be enhanced by implementing further maintenance planning. This will contribute to the effective management of hospital along with satisfactory performances of the machines.

The present investigation also helps to identify the critical biomedical equipments and involves the need for robust data collection for consecutive 60 days and if the duration of data collection is extended, more accurate results can be achieved. Such data invariably generates risk factor of the equipments. It is concluded that by adapting the proposed technique for improving the reliability of the machines with the help of consequences failures and risk assessment, proper maintenance management can be implemented. The present investigation undoubtedly ensures that this approach for effective reliability management works accurately well in a hospital.

From this study it is evident that hospital management has a scope of mechanism to adjust the risk factor of the equipments after analyzing the failure probability as a function of interval period between preventive maintenance. Moreover, the proposed methodology seems to be novel as it supports not only risk management of the equipment but also maintenance management due to quantitative estimation of failure probability and associated costs of the machines. Finally, this approach may support top hospital management in complying with the requirements of quality

Conflict of interests

No conflict of interest.

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