Fiabilité de l'appareil d'hémodialyse via la distribution de Weibull en présence des incertitudes

Reliability of the hemodialysis machine through Weibull distribution in the presence of uncertainties

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RÉSUMÉ. Les appareils d'hémodialyse, utilisés pour traiter l'insuffisance rénale, sont des équipements médicaux vitaux directement responsables de la vie du patient. Dans cet article, la fiabilité de la machine d'hémodialyse dans un environnement stochastique a été analysée via la distribution de Weibull. À partir de l'historique des pannes, les paramètres d'échelle et de forme de la distribution de Weibull ont été estimés à l'aide des méthodes analytiques et graphiques. L'effet des facteurs d'influence externes sur la fiabilité de la machine est étudié. Ces facteurs ont un effet aléatoire qui dépend de l'environnement stochastique externe du système. La méthodologie adoptée consiste à introduire une perturbation gaussienne sur les paramètres de Weibull et étudier son effet sur les indicateurs de la fiabilité. Les moyennes et les écarts types des paramètres de Weibull sont calculés et utilisés pour extraire les moyennes et les écarts types des indicateurs de fiabilité en utilisant un développement en série de Taylor de premier ordre. Les simulations numériques permettent de visualiser la moyenne et l'écart type de la fiabilité de l'appareil d'hémodialyse.

ABSTRACT. Hemodialysis devices are vital medical equipment which are directly responsible for the patient's life, used to treat kidney failure. In this paper, the reliability of the Hemodialysis machine in stochastic environment was analyzed using a Weibull distribution approach. From the failure history, the scale and the shape parameters of the Weibull distribution were estimated using analytical and graphical methods. The effect of the external influencing factors on the machine reliability is treated. These factors have a random effect which depends on the external stochastic environment of the system. The adopted methodology consists in introducing a Gaussian perturbation on the Weibull parameters and studying its effect on the reliability indicators. The means and standard deviations of the Weibull parameters are calculated and used to extract the mean and standard deviation of the reliability indicators through the first-order Taylor series expansion. The numerical simulations lead to visualize the mean and the standard deviation of the reliability of the hemodialysis machine.

MOTS-CLÉS. Fiabilité, loi de Weibull, environnement stochastique, Variable gaussienne.

KEYWORDS. Reliability, Weibull distribution, stochastic environment, Gaussian variable.

1. Introduction

Failure of medical equipment may affect the healthcare services effectiveness and cause severe injury to the patients and harm the environment [ZAM 21]. Failure is a partial or total loss of the properties of an element which significantly decrease and leads to the total loss of its operating capacity. This failure may be due to its design, manufacture, installation, or even maintenance [ARU 07] [BRI 10]. Any production systems are subject to aging and wear [CIR 89], these physical phenomena cause the failure, which has a significant impact on the cost of operating the system or on security. In the literature, several authors have presented numerous classifications of failures and show the impact of the aging mechanical systems on the reliability [ALF 99]. Influence factors are either internal or external factors that affect the reliability of the system. A classification of these factors, based on the life stages of the system under consideration, was proposed by [BRI 07]: design factors, manufacturing factors, system installation factors, factors which influence system usage and maintenance factors. We can add to this list human and organizational factors that generally have a broader impact on the system [AVE 06]. There are many procedures and methods used to improve medical equipment reliability through a mathematical maintenance [KHA 13]. The objective of model that analyses the effect of maintenance on the survival probability of medical equipment based on maintenance history and age of that equipment. The aim of the study, presented by [BAH 18], leads to extract the factors affecting the medical equipment maintenance management.

In engineering studies, the distribution that best characterizes a set of data should be chosen [O'CO 12]. In industry area, the Weibull distribution is one of the most used probability density functions. According to [LYO 91], the Weibull model is the best appropriate when carrying out reliability analysis for mechanical components. The main advantage of this distribution is its ability to account for small samples of failure data. The flexibility in fitting different failure modes and in simulating many other statistical distributions is one of the important attractions of the mentioned distribution [LIH 88]. The Weibull probability analysis is widely employed for studying the life data and can be applied to several situations.

In the literature, the reliability analysis is based on a deterministic approach. Indeed, all reliability parameters, which are uncertain, are described by unfavorable characteristic values. Uncertainties are related to the used methods, the considered approximations, the modeling and the influencing variables [TEB 08]. The main contribution of this work is the study of the effect of uncertain Weibull parameters on the reliability. The uncertainties were introduced in the shape and scale parameters as a Gaussian variables. The formulation of the mean and the standard deviation of the reliability indicators using the first-order Taylor series expansion is among the originalities of this article. The proposed formulation was implemented by hemodialysis case study and the question of the reliability statistics is treated.

This paper presents a study of the reliability of the hemodialysis machine in stochastic environment through the two-parameter Weibull distribution. The estimation of the Weibull parameters is offered through graphical and analytical methods. The uncertainties were introduced in the Weibull parameters; and their effect on the device reliability was studied. Our methodology consists in introducing uncertainties on the shape and scale parameter in the form of a Gaussian distribution. The means and standard deviations of the Weibull parameters are calculated and used to extract the mean and standard deviation of the reliability indicators through the first-order Taylor series expansion. The numerical simulations show the effect of the random environment on the reliability of the hemodialysis machine. The next section studies the reliability in presence of uncertainties. The random Weibull parameters are estimated as a mean and a standard deviation using different methods. Then, the random reliability indicators are formulated through the first-order Taylor series expansion. In the third section, the numerical results are presented in the case of the hemodialysis machine based on the failure history.

2. Reliability analysis in presence of uncertainties

2.1. *The Weibull parameters estimation*

There are a number of methods for estimating the values of the Weibull parameters; some are graphical and others are analytical. Graphical methods (GM) are not very accurate but they are relatively fast. Analytical methods include maximum likelihood method (MLM), least square method (LSM), and method of moments (MOM) [RAZ 09]. These methods are considered more accurate and reliable compared to the graphical method. In this work, shape and scale parameters are considered random following a Gaussian distribution and can be written in the following form:

$$\tilde{\beta} = \beta + \sigma_\beta \varepsilon \ \text{ and } \tilde{\eta} = \beta + \sigma_\eta \varepsilon \qquad [1]$$

Where $\tilde{\beta}$ and $\tilde{\eta}$ are the random shape and scale parameters, respectively. β and η are its means, respectively, σ_β and σ_η are its standard deviation, respectively, ε is the reduced centered Gaussian variable. The mean is calculated by the following equation:

$$\beta = \frac{1}{N}\sum_{i=1}^{N}\beta_i \ \text{ and } \eta = \frac{1}{N}\sum_{i=1}^{N}\eta_i \qquad [2]$$

Where β_i and η_i are the shape and scale parameters, respectively, for the i^{th} draw and N is the total number of draws.

The standard deviations of the shape and scale parameters are given by:

$$\sigma_\beta = \sqrt{\frac{\sum_{i=1}^{N}(\beta_i - \beta)^2}{N}} \text{ and } \sigma_\eta = \sqrt{\frac{\sum_{i=1}^{N}(\eta_i - \eta)^2}{N}} \quad [3]$$

Hence, our study consists of estimating the effect of the uncertainties of the shape and scale parameter on the reliability through the Weibull distribution.

2.2. *The failure rate estimation*

The random failure rate is expressed as a random function following a Gaussian distribution:

$$\tilde{\lambda}(t) = \lambda(t) + \sigma_\lambda(t)\varepsilon \quad [4]$$

Where $\lambda(t)$ is the mean of the failure rate and $\sigma_\lambda(t)$ its standard deviation

According to two-parameter Weibull distribution, the random failure rate is offered, as a function of the shape and scale parameter, by the following expression:

$$\tilde{\lambda}(t) = \frac{\tilde{\beta}}{\tilde{\eta}}\left(\frac{t}{\tilde{\eta}}\right)^{\tilde{\beta}-1} \quad [5]$$

In order to formulate the mean and the standard deviation of the failure rate, the logarithmic failure rate can be used as follow:

$$ln\left(\tilde{\lambda}(t)\right) = ln\left(\tilde{\beta}\right) - \tilde{\beta}\, ln(\tilde{\eta}) + \left(\tilde{\beta} - 1\right) ln(t) \quad [6]$$

To linearize the failure rate equation, we will use the first-order Taylor series expansion of $ln\tilde{\lambda}(t)$, $ln\left(\tilde{\beta}\right)$ and $\ln(\tilde{\eta})$ in the vicinity of their mean, we obtain:

$$ln\left(\tilde{\lambda}(t)\right) = ln\left(\lambda(t)\right) + \frac{\sigma_\lambda(t)}{\lambda(t)}\varepsilon \quad [7]$$

$$ln\left(\tilde{\beta}\right) = ln(\beta) + \frac{\sigma_\beta}{\beta}\varepsilon \quad [8]$$

$$ln(\tilde{\eta}) = ln(\eta) + \frac{\sigma_\eta}{\eta}\varepsilon \quad [9]$$

Introducing equations (7), (8) and (9) in equation (6), we can write:

$$ln\left(\lambda(t)\right) + \frac{\sigma_\lambda(t)}{\lambda(t)}\varepsilon = [ln(\beta) - \beta\, ln(\eta) + (\beta - 1)\, ln(t)] + \left[\frac{\sigma_\beta}{\beta} - \frac{\beta}{\eta}\sigma_\eta + \sigma_\beta\, ln\left(\frac{t}{\eta}\right)\right]\varepsilon \quad [10]$$

The identification of the different terms in equation (10) leads to extract the mean and the standard deviation of the random failure rate as:

$$ln\left(\lambda(t)\right) = ln(\beta) - \beta\, ln(\eta) + (\beta - 1)\, ln(t) \quad [11]$$

$$\frac{\sigma_\lambda(t)}{\lambda(t)} = \frac{\sigma_\beta}{\beta} - \frac{\beta}{\eta}\sigma_\eta + \sigma_\beta\, ln\left(\frac{t}{\eta}\right) \quad [12]$$

Finally, we obtain:

$$\lambda(t) = \frac{\beta}{\eta}\left(\frac{t}{\eta}\right)^{\beta-1} \quad [13]$$

$$\sigma_\lambda(t) = \lambda(t)\left[\frac{\sigma_\beta}{\beta} - \frac{\beta}{\eta}\sigma_\eta + \sigma_\beta\, ln\left(\frac{t}{\eta}\right)\right] \qquad [14]$$

2.3. *The reliability estimation*

The random reliability is expressed as a random function following a Gaussian distribution:

$$\tilde{R}(t) = R(t) + \sigma_R(t)\varepsilon \qquad [15]$$

Where R(t) is the mean of the failure rate and $\sigma_R(t)$ its standard deviation

According to two-parameter Weibull distribution, the random reliability is offered, as a function of the shape and scale parameter, by the following expression:

$$\tilde{R}(t) = \exp\left(-\frac{t}{\tilde{\eta}}\right)^{\tilde{\beta}} \qquad [16]$$

The first-order Taylor series expansion of $\tilde{R}(t)$ leads to write:

$$\tilde{R}(t) = exp\left(-\frac{t}{\tilde{\eta}}\right)^{\tilde{\beta}} = 1 + \left(-\frac{t}{\tilde{\eta}}\right)^{\tilde{\beta}} \qquad [17]$$

The logarithmic reliability is formulated in the following equation:

$$Ln\big(\tilde{R}(t) - 1\big) = \tilde{\beta}(Ln(-t) - Ln(\tilde{\eta})) \qquad [18]$$

To linearize the random logarithmic reliability equation, we will use the first-order Taylor series expansion in the vicinity of the mean. The 2 terms left and right of equation (18) can be expanded as follows:

$$\mathrm{Ln}\big(\tilde{R}(t)\text{-}1\big) = \mathrm{Ln}\big(R(t)\text{-}1\big) + \frac{\sigma_R(t)}{R(t)}\varepsilon \qquad [19]$$

$$\tilde{\beta}\big(\mathrm{Ln}(-t) - \mathrm{Ln}(\tilde{\eta})\big) = \beta\mathrm{Ln}\left(\frac{-t}{\eta}\right) + \left(\sigma_\beta \mathrm{Ln}\left(\frac{-t}{\eta}\right) - \frac{\beta}{\eta}\sigma_\eta\right)\varepsilon \qquad [20]$$

The identification of the equations (19) and (20) leads to extract the mean and the standard deviation of the random reliability as:

$$Ln(R(t) - 1) = \beta Ln\left(\frac{-t}{\eta}\right) \qquad [21]$$

$$\frac{\sigma_R(t)}{R(t)} = \sigma_\beta Ln\left(\frac{-t}{\eta}\right) - \frac{\beta}{\eta}\sigma_\eta \qquad [22]$$

And then:

$$R(t) = exp\left(-\frac{t}{\eta}\right)^{\beta} \qquad [23]$$

$$\sigma_R(t) = R(t)\left(\sigma_\beta Ln\left(\frac{-t}{\eta}\right) - \frac{\beta}{\eta}\sigma_\eta\right) \qquad [24]$$

2.4. *The cumulative density function estimation*

The random cumulative density function is expressed as a random function following a Gaussian distribution as follow:

$$\tilde{F}(t) = 1 - \tilde{R}(t) = F(t) + \sigma_F(t)\varepsilon \qquad [25]$$

Where F(t) is the mean of the cumulative density function and $\sigma_F(t)$ its standard deviation. The mean and the standard deviation of $\tilde{F}(t)$, can be determined as follow :

$$F(t) = 1 - R(t) \quad [26]$$

$$\sigma_F(t) = \sigma_R(t) \quad [27]$$

2.5. *The probability density function estimation*

The random probability density function is expressed as a random function following a Gaussian distribution as follow:

$$\tilde{f}(t) = \tilde{\lambda}(t) \times \tilde{R}(t) = f(t) + \sigma_f(t)\varepsilon \quad [28]$$

Using the express of $\tilde{\lambda}(t)$ and $\tilde{R}(t)$ as random variables, we obtain :

$$f(t) + \sigma_f(t)\varepsilon = \lambda(t)R(t) + \left(R(t) \times \sigma_\lambda(t) + \lambda \times \sigma_R(t)\right)\varepsilon \quad [29]$$

The identification of the different terms in equation (29) leads to extract the mean and the standard deviation of the random probability density function as:

$$f(t) = \lambda(t) \times R(t) \quad [30]$$

$$\sigma_f(t) = R(t) \times \sigma_\lambda(t) + \lambda \times \sigma_R(t) \quad [31]$$

3. Numerical results and discussions

3.1. *Reliability analysis of hemodialysis machines*

The reliability of hemodialysis machines is very important for nephrologists to guarantee not only patient safety but also efficiency and continuity of treatment. Improper maintenance leads to inadequate dialysis session and high level of complications. There is a need for an effective maintenance strategy in order to improve hemodialysis machines reliability. In this paragraph, the reliability of a group of 6 hemodialysis machines (M1, M2, M3, M4, M5 and M6) will be studied. The data of the failure history of the 6 devices was collected during the period from 2013 to 2022. All machines work with an average of 3.5 hours per day and 6 days per week. These data are summarized in table 1. Time Between Failures (TBFi) were arranged in ascending order to calculate the cumulative density function F(ti). According to table 1, the total number of data for each machine is n<20. The cumulative density function is calculated using Median rank formula [CHI 97]:

$$F(t_i) = {}^{i - 0.3}\!/_{n + 0.4} \quad [32]$$

The estimation of the weibull parameters through the graphical and analytical methods is summarized in table 2. The mean and the standard deviation of the shape and scale parameters were calculated using the equations (2) and (3), respectively. In table 3, Weibull Parameters and MTBF were summarized for the 6 hemodialysis devices. The reliability indicators ($\lambda(t)$, R(t), F(t), f(t)) proved to be useful tools to assess the current situation, and to predict reliability, mainly in the short term, for upgrading the operation management of the system. These indices were extracted and discussed. The Mean Time Between Failure (MTBF) is given in the following equation:

$$\text{MTBF} = \int_0^{+\infty} R(t) = \eta.\Gamma\left(1 + \frac{1}{\beta}\right) \quad [33]$$

Where Γ is the gamma function.

Failure number	M1		M2		M4	
	Date of failure	TBF (h)	Date of failure	TBF (h)	Date of failure	TBF (h)
01	05/06/15	2450	05/06/15	2450	05/06/15	2450
02	09/11/15	427	15/05/17	1949.5	29/05/17	2040
03	20/11/17	2047	20/11/17	514.5	07/08/18	192.5
04	27/07/19	1673	06/03/20	2268	28/02/18	549.5
05	06/03/20	595	18/09/20	385	03/08/18	311.5
06	05/09/21	1372	16/09/21	990.5	06/03/20	584.5
07	01/11/21	147			03/08/20	280
Failure number	**M3**		**M5**		**M6**	
	Date of failure	**TBF (h)**	**Date of failure**	**TBF (h)**	**Date of failure**	**TBF (h)**
01	04/01/16	3034.5	13/03/15	2226	29/05/13	413
02	29/05/17	1389	04/01/16	766.5	12/07/13	101.5
03	12/06/17	42	13/01/16	28	01/09/14	1130
04	20/11/17	441	22/07/16	535.5	05/06/15	763
05	15/10/18	871.5	19/09/16	140	09/11/15	427
06	11/09/19	903	02/08/17	878.5	07/08/17	1750
07	06/03/20	486.5	08/01/18	434	31/10/18	1228
08	29/03/21	896	05/02/18	66.5	09/08/19	780.5
09	22/07/21	304.5	28/02/18	63	06/03/20	560
10			10/08/18	336	29/07/20	255.5
11			06/03/20	1575	07/01/22	1456
12			08/07/20	203		
13			24/02/21	633.5		
14			05/11/21	703.5		

Table 1. *The failure history (TBF) of hemodialysis machines*

Methods	Parameters	Machines					
		M1	M2	M3	M4	M5	M6
LSM	β	0.928	1.232	0.844	1.027	0.625	1.162
	η	1363	1642	934	904	572	887
MLM	β	1.078	1.318	0.892	1.052	0.694	1.387
	η	1504	1764	1148	1036	728	952
MOM	β	1.179	1.405	0.954	1.061	0.762	1.638
	η	1583	1802	1176	1125	791	1050
GM	β	0.963	1.161	0.862	0.908	0.607	1.105
	η	1358	1524	970	879	473	823
Mean β		1.037	1.279	0,888	1.012	0.672	1.323
Mean η		1452	1683	1057	986	641	928
σ_β		0.099	0.091	0.042	0.062	0.061	0.210
σ_η		95.684	109.18	106.23	99.992	125.55	83.913

Table 2. *Estimation of the random Weibull parameters of hemodialysis machines.*

Device	Failure number	β	η	Life Phase	MTBF (h)	R(t) (%)	F(t) (%)	λ(t) (failure/hour)	f(t) (1/hour)
M1	7	1.037	1452	useful	1394	38.34261	61.6573	0.0007131	0.000273
M2	6	1.279	1683	aging	1555	40.50366	59.4963	0.0007433	0.000301
M3	9	0.888	1057	Early	1112	35.13142	64.8685	0.0008353	0.000293
M4	7	1.012	986	useful	986	36.78794	63.2120	0.0010263	0.000377
M5	14	0.672	941	Early	876	29.12589	70.8741	0.0009462	0.000275
M6	11	1.323	928	aging	857	40.65484	59.3451	0.0013894	0.000564

Table 3. *Estimation of the reliability indicators of hemodialysis machines*

To better understand and analyze the information contained in table 3, the reliability indicators are illustrated in the form of a histogram in figure 1. Figures 2, 3 and 4 illustrate λ(t), R(t), F(t) and f(t) of the 6 hemodialysis machines. According to this study, The reliability R(t) of M2 and M6 must be revised immediately. Their failure rate λ(t) increase significantly with time. M2 and M6 are in the aging life (β>1) and must be supervised continuously. The failure rate of M1 and M4 is constant during the time, these machines are in the useful life (β=1). The machines M3 and M5, which are in the early-life (β<1), have a decreasing failure rate. To avoid the inconvenient impact of the failures on the dialysis system, it is recommended to upgrade the operation management. The maintenance strategy must initially focus on the M2 and M6, which are on aging phase.

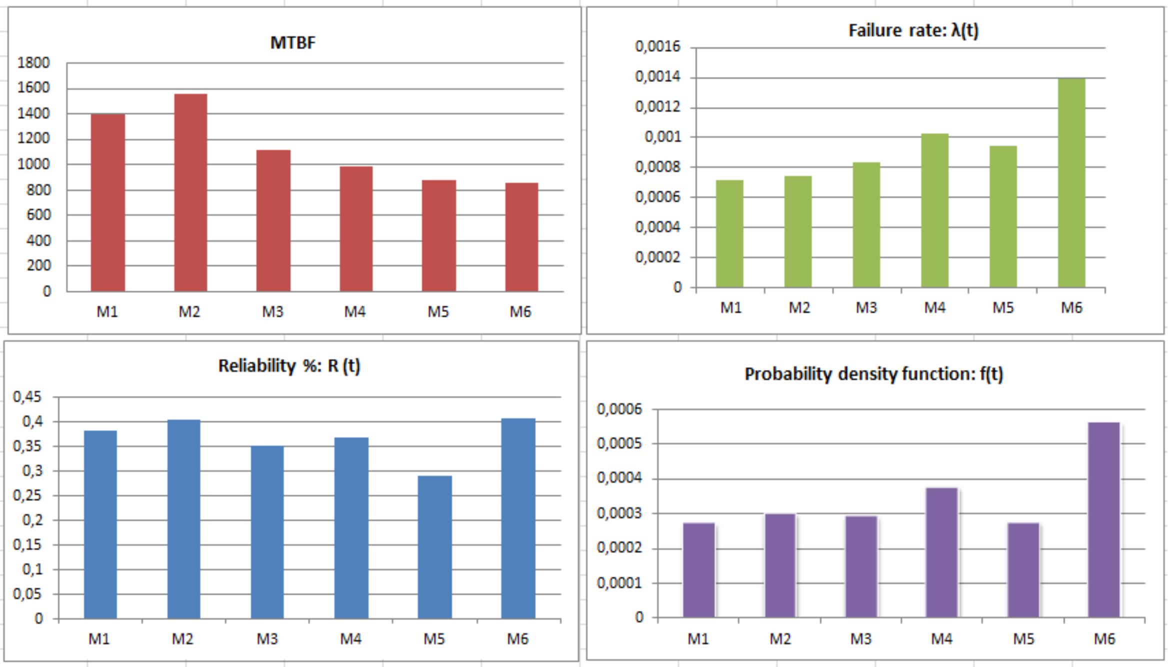

Figure 1. *Histogram of the reliability indicators of hemodialysis machines*

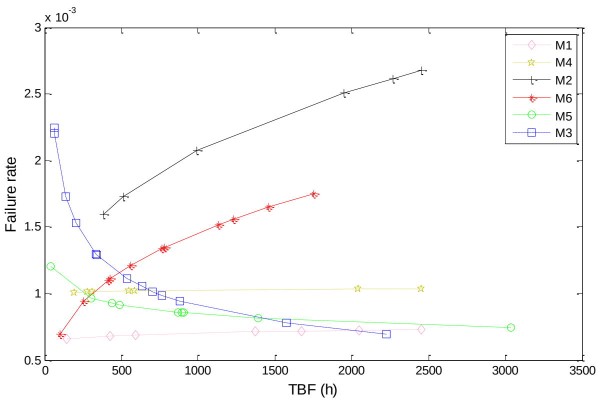

Figure 2. *Failure rate of hemodialysis machines*

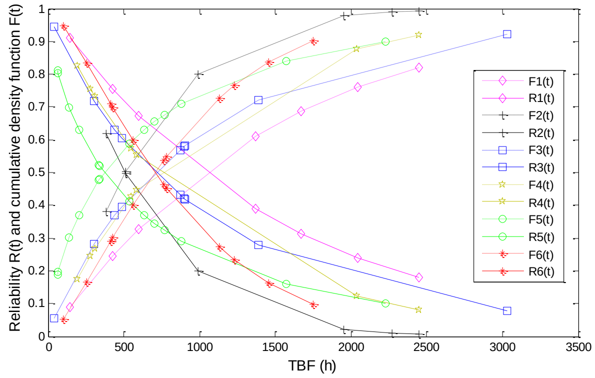

Figure 3. *Reliability and cumulative density function of hemodialysis machines.*

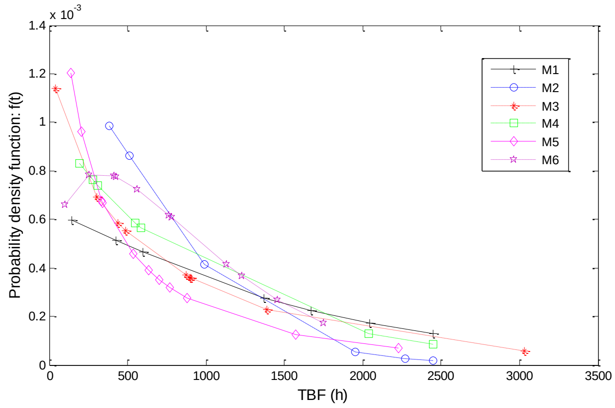

Figure 4. *Probability density functions of hemodialysis machines*

3.2. *Reliability analysis of hemodialysis machines in presence of uncertainties*

The uncertainty, introduced in the Weibull parameters, is related to the influencing factors which are ambiguous and described by unfavorable characteristic values. The random environment of the dialysis machine leads to introduce a perturbation in the shape and scale parameters. In this part, the effect of this perturbation on the behavior of the reliability indicators will be studied. The shape and scale parameters follow a Gaussian distribution as $\tilde{\beta} = \beta + \sigma_\beta \varepsilon$ and $\tilde{\eta} = \eta + \sigma_\eta \varepsilon$. The mean and the standard deviation of the shape and scale parameters were given in table 4. The standard deviation of reliability indicators will be presented for each device. Figure 5 presents the standard deviation of the failure rate for the 6 hemodialysis machines. The curves presented in figure 5 illustrate the evolution of the uncertainties in the failure rate for the different phases of the lifetime of the hemodialysis machine. The standard deviation for aging life (M2 and M6) is more significant and increases during this mature phase. In the aging phase, the effect of the perturbation introduced in the Weibull parameters is more serious and affect perilously the failure rate. Many case studies are presented in order to illustrate the behavior of the failure rate following different level of uncertainty introduced in the shape parameter. Figure 6 and 7 show the standard deviation of the reliability and the probability density function, respectively. It should be noted that the errors introduced into the Weibull parameters are amplified for all the reliability indicators and for all the machines regardless of the life phase. In conclusion, the results provide evidence of the propagation of errors that can affect a system and their significant influences on the reliability, in particular, at aging phase. To avoid the inconvenient impact of the uncertainties in the failures on the dialysis system, it is recommended to upgrade the operation management. To guarantee the functioning and availability of the machines, it is necessary to take into account the errors observed over the periods of the systematic inspection.

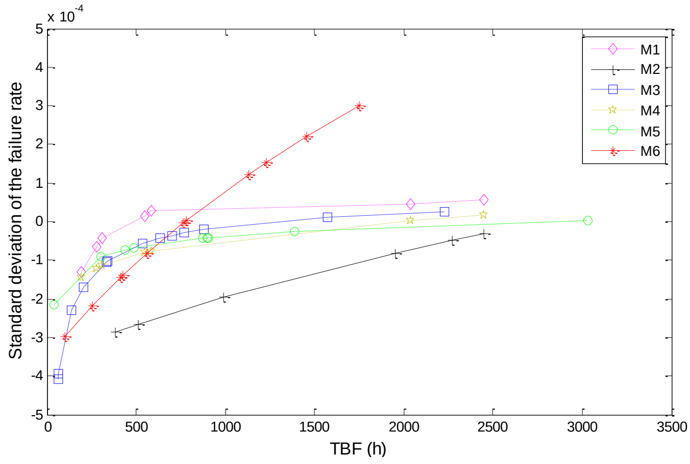

Figure 5. *Standard deviation of the failure rate of hemodialysis machines.*

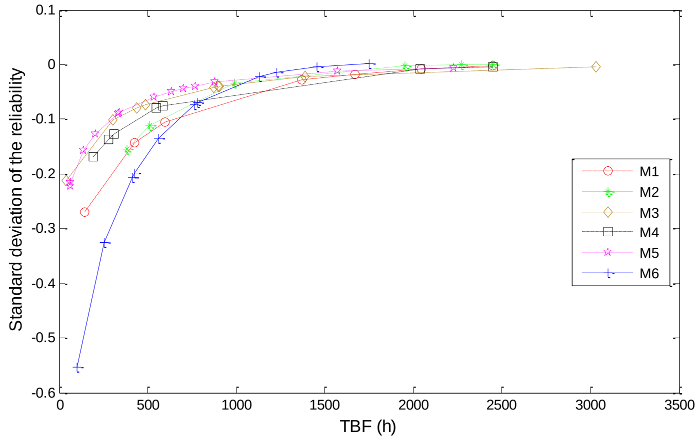

Figure 6. *Standard deviation of the reliability of hemodialysis machines.*

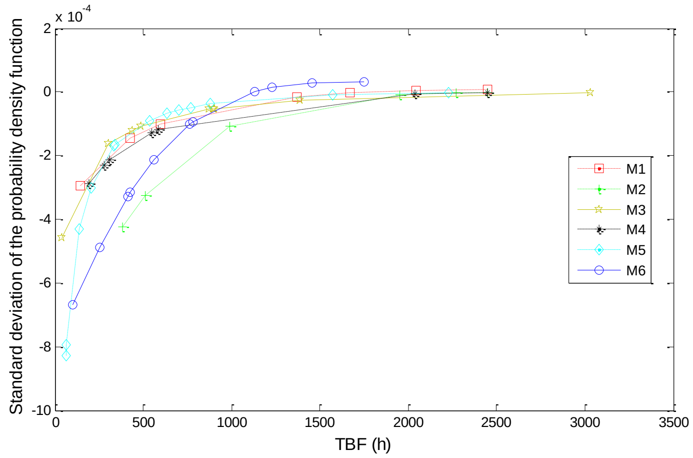

Figure 7. *Standard deviation of the probability density functions of hemodialysis*

4. Conclusion

In this paper, the reliability of the hemodialysis machine is evaluated through Weibull distribution. A statistical analysis of the failure data is adopted to harness the failure and repair data of the machine. From the failure history, the shape and scale parameters of the used distribution were estimated using analytical and graphical methods. The question of the reliability and the failure rate is treated in order to develop an inspection/maintenance optimization model. The stochastic reliability indicators were studied by introducing the effect of influencing variables. The effect of these variables is random and depends on the external environment of the system and directly affects the system reliability by accelerating (or decelerating) the degradation of the equipment. The methodology adopted consists in introducing a perturbation on the Weibull parameters and studying its effect on the reliability indicators. Weibull parameters are considered random with a Gaussian distribution. The formulation of the reliability in a stochastic environment is detailed using Weibull distribution. The simulations show the statistics of the reliability indicators for several configurations of the hemodialysis machine.

It is essential that for future research, the continuous monitoring of the failure data for the dialysis system must be ensured. The re-estimation of the reliability and the maintainability can be carried out, and the maintenance policy of the hemodialysis machines can be evaluated. This could help minimize failures and repair times, whereas the efficiency of the system can be improved.

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