Risk Analysis of Transesophageal Echocardiography Telemanipulator in Catheterization Laboratory

Indhika F. Warsito, Christina Pahl, Eko Supriyanto, A. Soesanto

Abstract— The use of conventional Transesophageal Echocardiography (TEE) machine in Catheterization Laboratory (Cath Lab) remain few safety issues related to radiation and ergonomics. In order to solve these, TEE telemanipulator has been proposed. This has however other risks which may arise during the use of the machine including electrical, mechanical, and electromagnetic risks. In this paper, the risk analysis of TEE Telemanipulator in Cath Lab is discussed. This includes the hazard identification and risk level estimation. Electrical, mechanical, electromagnetic, radiation and operational hazards are identified. Failure Mode and Effect Analysis (FMEA) is used to estimate the level of risk. Test result shows that the risk of TEE manipulator type II is lower compare to conventional TEE Machine and TEE manipulator type I.

Keywords—Catheterization laboratory, failure mode and effect analysis, telemanipulator, transesophageal echocardiography, risk analysis, x-ray radiation

I. Introduction

Transesophageal Echocardiography or TEE is well-known used for monitoring and diagnosing of perioperative management cardiac surgical [1]. Full TEE system consists from three main parts. First one is TEE Probe which is used to collect ultrasound image from the patient, second one is ultrasound machine that is used to display acquired image and
control the image mode, and the last one is probe handle which is operated and hold by hand to control the movement of end-probe for getting desired angle [1].

Due to high trend of cardiovascular disease, interventional cardiology procedure demands have increased in the last decades [2]. As a result, Transesophageal Echocardiography's number of use have also increased since it is usually used during this procedures. Inside catheterization laboratory, interventional cardiology is usually performed. However, there is main drawbacks for TEE usage in the cath lab.

Inside cath lab, equipment other than TEE, there is one medical device called angiography which is used for guidance during operation. Angiography uses X-ray to generate image. Typically, x-ray will not be very dangerous if only use under recommended dose. But unfortunately, due to its high resolution generated image demand and lengthy duration of procedure, it produce quite high radiation dose. Typical effective dose around natural background is 3 mSv. But inside catheterization laboratory that is used for coronary angiography, its radiation can be measured around 7.0 mSv that is more than 2 times then natural background. Furthermore, during percutaneous coronary intervention the dose was calculated around 15.0 mSv, that is 5 times more than natural dose [3], [4]. Moreover, during several procedures such as coronary stenting or valve implantation which can take up to 6 hours,

Moreover, during several procedures such as coronary stenting or valve implantation which can take up to 6 hours, other than high dose of radiation exposure, by using TEE, the operator face serious ergonomic problem. During operation, TEE operator should hold the probe during this period in non-relax condition. This situation gives a toll to body of the operator and there are reports of musculoskeletal disorder on unusual high incident rates such as carpal tunnel syndrome [5], [6].

Due to these problem, transesophageal echocardiography telemanipulator system is proposed. This system will mitigate the radiation risk exposed on the user, and reduce ergonomic problem by development of human interface device for this system. First version of TEE telemanipulator has been developed in IJN-UTM Cardiovascular Engineering Center which consist of TEE Mechanical Holder and user interface by using computer program. Second version of TEE telemanipulator is currently being developed in IJN-UTM Cardiovascular center to improve compatibility with clinical demands and to improve human-machine interaction. This new system

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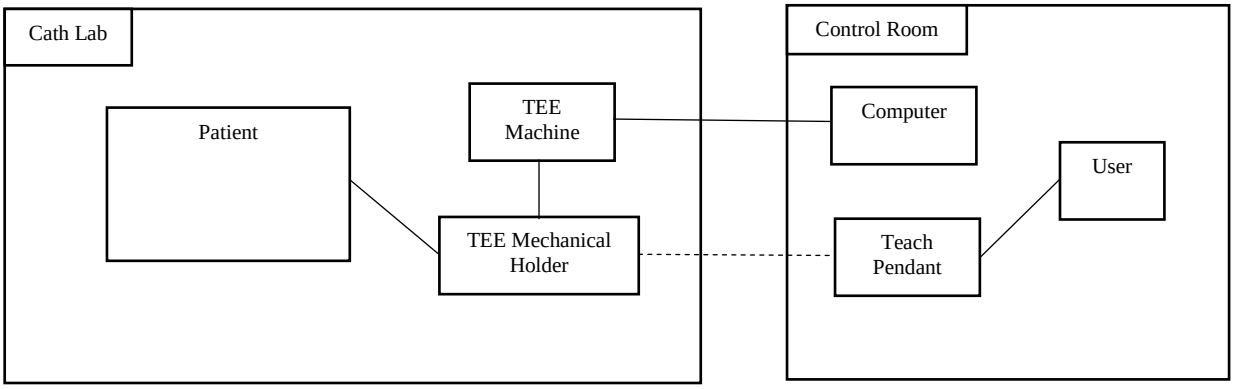

Fig 1. Arrangement of TEE telemanipulator system

will consist of 2 part, which are called TEE Mechanical Holder that is used as substitute of hand in conventional TEE, and Teach pendant that is used by user input to control the movement of probe. This new system placement diagram is shown in figure 1.

In European Union, risk management is required for medical device to get their approval for selling it in their region. It has been demanded since 1993 in the form of Medical Device Directive 93/42/EEC[7], and since then the directive has been modified several times but still require developer to include risk management files. In order to follow this directive, designers should refer to several available international standard and need to comply it within their products. Main guideline in risk management for medical device is EN ISO 14971:2012 [8]. The standards describe and explain in general, how to organize risk management file and which method should be used.

As part of risk management (fig. 2), risk analysis give introduction to the process, by identifying intended use of device, identifying known or foreseeable hazards, and estimate the risk of each hazards. After risks have been estimated, they will enter risk evaluation step. In this step, hazard will be judged whether its risk is acceptable or not and whether risk reduction is necessary or not.

New TEE telemanipulator system that is proposed to reduce radiation and ergonomic risk from current conventional TEE system, cause another risk which need to be identified and analyzed. In this study, risk analysis and risk evaluation will be performed for this system. Furthermore, specification recommendation will be given based on this risk analysis and evaluation to reduce the risk produced by this new system.

In this study, our objective is to risk analysis and risk evaluation and give specification recommendation for development of this new system.

For identification of hazard, this study will focus on electrical, electromagnetic, mechanical, radiation, and ergonomic hazards. Other type of hazards such as biological, chemical, and software are not included.

II. Material and Methods

1. Block Diagram of Conventional TEE Machine (Figure 3)
2. Block Diagram of TEE Manipulator Version I (Figure 4), (Using Cable Connection, AC Power Supply for probe holder controller, Plastic Casing and Motor Outside, Mouse and Touch Screen User Interface)
3. Block Diagram of TEE Manipulator Version II (Figure 5), (Using wireless connection, rechargeable battery power supply, stainless steel casing, customized Teach Pendant)

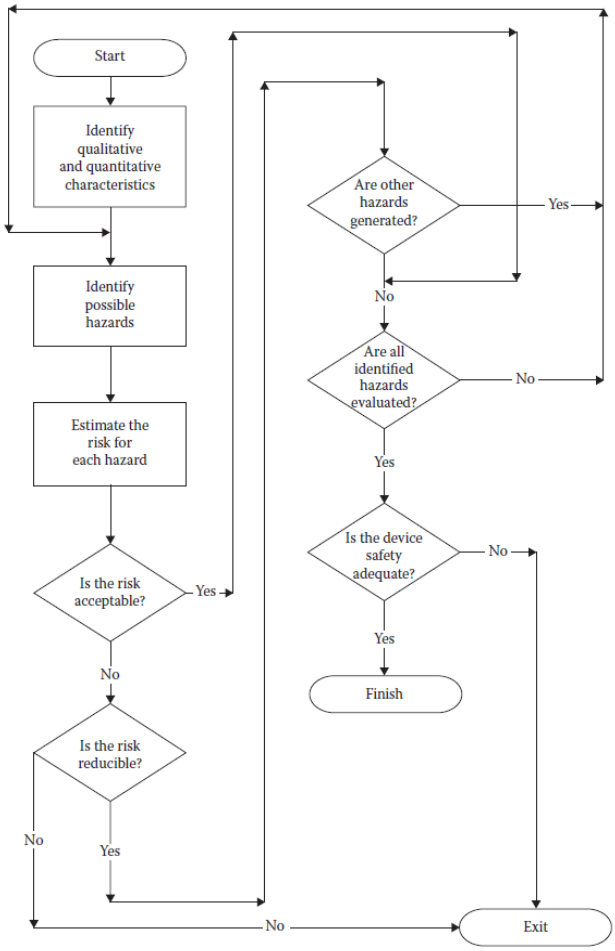

Figure 2 Risk Management Process

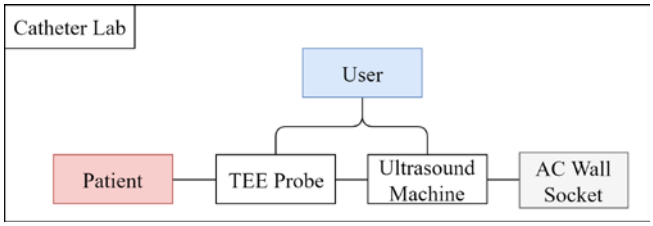

Figure 3 Block Diagram of Conventional TEE

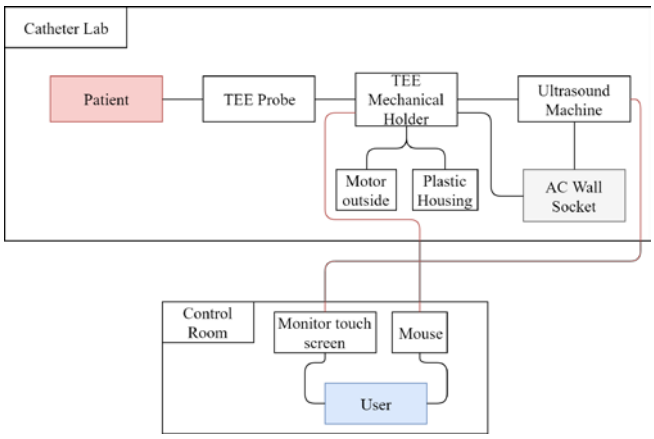

Figure 4 Block diagram of 1st TEE telemanipulator

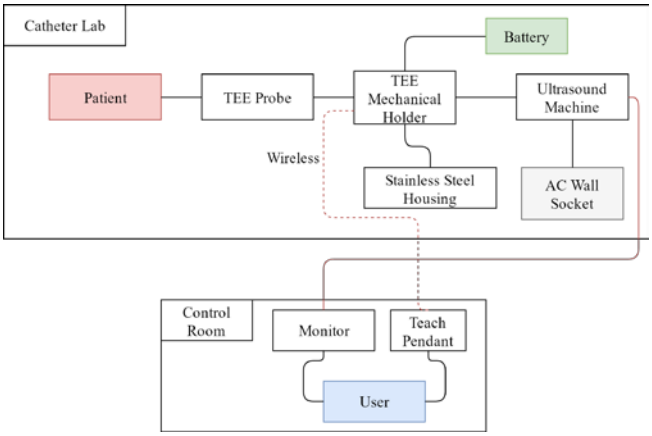

Figure 5 Block diagram of 2nd TEE telemanipulator

Risk management is continually iterative process. Risk management is needed to increase probability of discovering potential problem before become crisis. However, risk analysis will be conducted first before other steps in risk management. Risk analysis consists of three main steps [9],[10].

Methods of Risk Analysis:
1. Identify intended use and purpose of medical device
2. Identify known or foreseeable hazards
3. Estimate the risk of identified hazards

A. Identification of intended use

In this step, proposed device goal need to be discussed. TEE telemanipulator system consists of two device which are called TEE Mechanical holder and teach pendant. This

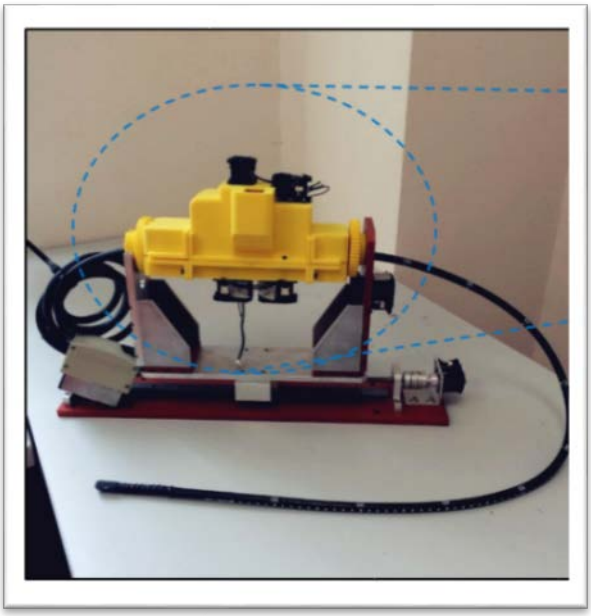

Figure 6 TEE telemanipulator version 1(TEE Mechanical Holder)

system is used for manipulating TEE probe, to obtain ultrasound image during its usage. Placement configuration

of this device is shown in figure 1. All of those system are used inside Catheterization laboratory, therefore following hazard identification will be focused on Cath Lab.

B. Identification of known or foreseeable hazards

Based on identification of intended use and characteristic of device, there are several list type of hazards which is identified.

Electrical

First, since it is powered by electrical energy, possible electrical hazard need to be identified .

- AC Leakage Current
  If the device is powered by AC type power supply, it is possible that unintended current or called as leakage current is shown. Leakage current is harmful for human at certain degree. Severity of this leakage current is shown in table 1 [11].

Table 1. Estimated effects of 60 Hz AC Current

1 mA	Barely perceptible
16 mA	Maximum current an average man can grasp and “let go”
20 mA	Paralysis of respiratory muscles
100 mA	Ventricular fibrillation threshold
2 A	Cardiac standstill and internal organ damage
15/20 A	Common fuse breaker open circuit

- DC Leakage Current
  For device powered with portable power supply such as battery, it is also possible that leakage current occurs.

- Wrong polarity connection
  If battery is put in wrong order inside the battery-powered device, it can cause device disruption and destroy other electronic component inside the device.

- Over-current
  It is possible that current flows to device is higher than expected values which able to cause malfunction of device and even destroy electronic components inside the device.

Electromagnetic (EM)

Inside catheterization laboratory, other than TEE, there are several electrical device such as angiography, ultrasound machine, defibrillator, and even smartphone or other communication device. This device potentially emits electromagnetic field which able to interfere with other electrical device such as TEE telemanipulator, and it is also possible that the device will interfere other device reversely. Hence, it is necessary to identify this type of hazards in this study.

- Radiated Emission
  Lightning, communication device, TV, or radio are several sources which able to cause interference to electrical device. This type of interference does not need any medium to be transmitted and able to disrupt performance of device.

- Conducted Emission
  In reverse with radiated interference, this type of electromagnetic interference is transmitted through cable.

- Electrostatic Discharge
  Sudden electric flow between two electrically charged objects caused by contact, dielectric breakdown, or electrical short

Mechanical

Moreover, as integration of mechanical system in Transesophageal telemanipulator, it should be mentioned that if there is something wrong with motor, gears, and end-effector then it is fail to achieve its purpose. Therefore, mechanical hazard of the device need to be identified as well.

- Unintended movement
  During usage of system, it is possible that somehow the mechanical system will move inappropriate

- Sharp edges and surface
  Any exposed sharp edges or surface will contribute to injury of user sooner or later

- Falling hazard
  Handheld device is possible to be fallen during usage of the system, i.e. for this system is teach pendant

- Vibration
  During the usage, vibration can occur and able to disrupt performance of the system. Therefore, it needs to be identified as mechanical hazard

Radiation Hazards

- X-ray radiation
  One of electromagnetic form which able to penetrate human body. High dose and long term exposure can cause significant effect to human body. This radiation is mainly caused by angiography inside cath lab [12],[13].

Ergonomic Hazards

During usage of the system, user will also take risk to its body [14].

- Repetitive movement
  Repeating same task for some duration of time can cause stress to same location of muscle.

- Uncomfortable workstation height
  Too high or too low workstation height can cause strain to human muscle.

- Poor body positioning
  Awkward or not normal body position cause strain to certain part of human body.

C. Estimation of risk hazard

Risk is combination of the probability of harm's occurrence and severity of that harm. There are several methods that can be used to estimate the risk of hazard, such as Failure Mode and Effect Analysis which is most common. In order to use this method, we need also data to be used as reference for determination cause of hazards, its probability of occurrence, and severity of hazards. Usually, this data can be obtained from published standards, scientific technical data, result of appropriate investigations, expert opinions, or by usability tests employing typical users. In this study, fault tree analysis and failure mode and effect analysis method will be explained.

Failure Mode and Effect Analysis

Failure mode and effect analysis (FMEA) is qualitative technique which consequences of component fault more are identified and evaluated systematically. This methods is using "bottom-up" approach, identifying the next higher functional system level. FMEA incorporate an investigation of the degree of severity of the consequences, probabilities of occurrence. Since it is not possible to quantify the risk of hazards, occurrence probability and its severity then estimated and categorized into several classes (Table 2 and 3).

Table 2 Categorization of severity

	S	Severity Description
5	Catastrophic	Death
4	Critical	Major injury, life threatening injury
3	Serious	Minor injury requiring treatment
2	Minor	Minor injury NOT requiring treatment
1	Negligible	Minor irritant to patient or end-user

Table 3 Categorization of occurences

	O	Occurence Description
5	Frequent	1/100 uses
4	Probable	1/1000 uses or once per week
3	Occasionally	1/10,000 uses or once per quarter
2	Remote	1/1,100,000 uses or once per year
1	Improbable	1/10,000,000 uses or once per 3-5 years

III. Result of Analysis

The risk associated with the identified hazards were estimated by using FMEA methods. FMEA tables from each identified hazards are shown in table 3-7. This FMEA table consists of failure mode, source, victim, pathways, protection, occurrence, severity, and risk priority number. Risk priority number is obtained by multiplication of severity and occurrence. These tables (Table 3-7) show risk of hazards for 2nd TEE Manipulator.

Based on this FMEA tables, we able to give several specification recommendations:

Electrical

- Using DC power supply is recommended since its leakage current severity is significantly lower than using AC power supply.
- Isolation transformer is recommended to reduce the risk of leakage current.
- To prevent accident caused by wrong polarity connection in DC, it is recommended to put diode to ensure electrical flow direction.
- By using fuse, flow current can be cutoff when input current is higher than maximal recommended current.

Electromagnetic

- It is recommended to use metal housing as protective for radiated emission
- Conduct electromagnetic compatibility testing, and follow limits of recommended value in international standards such as IEC 60601-1-2

Table 3. Failure Mode and Effect Analysis of Electrical Hazard on 2nd TEE Telemanipulator

Failure Mode	Leakage Current (AC)	Leakage Current (DC)	Wrong polarity (DC)	Over-current
Source	AC Power supply (220 or 240 V)	Battery (12 V)	Battery placement	Power supply
Victim (Effect)	User	User	Device	Self device, patient
Pathways	Conducted connection	Conducted connection	Conducted connection	Cable
Protection	Isolation transformer	Isolation transformer	Diodes, control design	Fuse
Occurrence	2	1	5	2
Severity	3	2	1	2
Risk Priority Number (O x S)	**6**	**2**	**5**	**4**

Table 4. Failure Mode and Effect Analysis of Electromagnetic Hazard on 2nd TEE Telemanipulator

Failure Mode	Radiated Emission	Conducted Emission	Electrostatic Discharge
Source	Lightning, Electrical device	Power supply	User
Victim (Effect)	Self device	Self Device	Self device, user
Pathways	Air borne	cable	Conducted contact
Protection	Shielding, Standard limitation	Shielding	Shielding
Occurrence	2	2	3
Severity	2	2	2
Risk Priority Number (O x S)	**4**	**4**	**6**

Table 5. Failure Mode and Effect Analysis of Mechanical Hazard on 2nd TEE Telemanipulator

Failure Mode	Unintended movement	Sharp edges and surface	Falling	Vibration
Source	Self device (i.e. gear movement)	Device housing edge and surface	Drop of device	Device motor, untighten mechanical lock
Victim (Effect)	User, device	User	User, device	Device
Pathways	Contact	Contact	Gravity	Physical medium
Protection	Housing	Smooth finishing, cover	Housing design, strong material	Tight, design placement
Occurrence	2	5	3	3
Severity	2	1	2	2
Risk Priority Number (O x S)	**4**	**5**	**6**	**6**

Table 6. Failure Mode and Effect Analysis of Radiation Hazard on 2nd TEE Telemanipulator

Failure Mode	X-ray radiation
Source	Angiography
Victim (Effect)	User, patient
Pathways	No medium
Protection	Place away from x-ray radiation
Occurrence	1
Severity	1
Risk Priority Number (O x S)	**1**

Table 7. Failure Mode and Effect Analysis of Ergonomic Hazard on 2nd TEE Telemanipulator

Failure Mode	Repetitive Movement	Uncomfortable workstation height	Poor body positioning
Source	Clinical task	Device placement	Interface location, chair position
Victim (Effect)	User	User	User
Pathways	Muscle	Muscle	Muscle
Protection	-	Design modification	Design modification
Occurrence	5	2	3
Severity	2	2	2
Risk Priority Number (O x S)	**10**	**4**	**6**

Mechanical

- To prevent unintended movement, inside system need to be covered for limiting the movement up to necessary movement
- Sharp edges should be chamfered or increase edge radius to reduce injury to user. Furthermore, there should be smooth finishing technique for surface
- To maintain integrity of the system, especially for handheld device, its structure and material should be designed to sustain for drop test
- Vibration can be minimized by using tight lock mechanism or the design should limit the movement of component inside safety area.

X-ray radiation

- For 2nd TEE telemanipulator, since the placement of the interface (teach pendant) is in non-radiated room, then no need for further reduction

Ergonomic

- Design need to be modified by changing human interface device and its workspace such as chair, to ensure natural position of user.

In figure 3, it is shown risk comparison between conventional TEE, 1st TEE telemanipulator, and 2nd TEE telemanipulator. This risk number is obtained from taking average of risk priority number for each hazard category.

From figure 3, it shows that by comparing with conventional TEE and 1st TEE telemanipulator, 2nd TEE telemanipulator has more advantageous and less risk than others. However, in terms of electric and mechanical, its risk higher than conventional TEE, since there are more electric and mechanical components to be handled.

IV. Conclusion

From analysis of different electrical system from our own research and the literatures. Identification of main critical hazards are possible. Identification of hazard can be achieved by separating into several categories which include electrical, electromagnetic, mechanical, radiation, and ergonomic. Risk estimation of each hazard can be calculated by using failure mode and effect analysis method which are shown on table 3-7 for 2nd TEE telemanipulator.

This should be reminded that Technical system especially robotics system can never be risk-free. However, all risks need to be reduced as far as reasonably practicable (ALARP) that is directed in ISO 14971:2012 [8]. Benefit of the system should dominate its risk. To prove this analysis, usability testing need to be made on the basis of risk analysis.

Even though, based on figure 3, electrical and mechanical risk of 2nd TEE telemanipulator are still higher than conventional TEE, it can be concluded that as overall 2nd TEE telemanipulator have less risk than conventional TEE during this analysis. However, it needs to be reminded

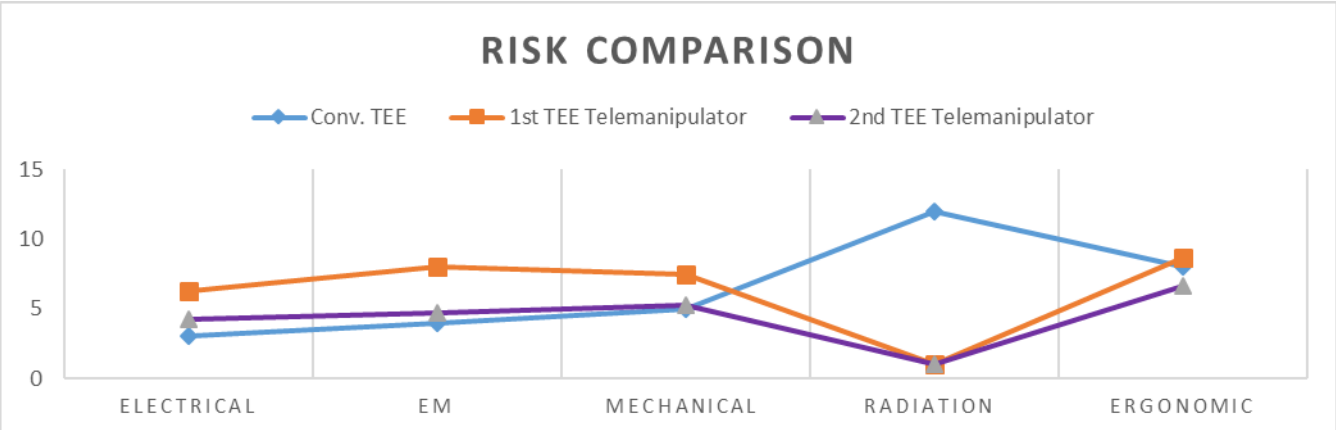

Figure 3 Risk Comparison between conventional TEE, 1st TEE telemanipulator, and 2nd TEE telemanipulator

that biological, chemical, and software risk analysis is not yet included.

Systematic and complete risk analysis is required to review robot-assisted procedure and to further improve whole system. Furthermore, it needs to be verified that the risk of system lies below beyond the benefit. However, for complex mechatronic system, this analysis is difficult, quantitative measurement of risk severity and occurrence probability in the most cases cannot be obtained. Furthermore, it is hard to get objectively safety level. Therefore, qualitative evaluation have to be used than using number to decide whether using the systems in operating sites.

Risk analysis need to be performed for investigation of hazards to support developer and user. If this has been done since the beginning of development, it can improve the safety, affects the design, and avoid several investigated hazards. However, risk analysis is only sensible, when is performed by developer and user

Identification of hazards and some of its cause have been analyzed. Furthermore, several reduction and measures to minimize the risk is described in this paper. This identified hazard can be used for future risk analysis of similar medical robot. And this may serve for usability testing of medical robotics in the future.

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