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Predictive Risk Assessment of Heart Failure using HAZOP and Qualitative Risk Analyses

Temitope Alaba Oshin
Department of Chemical Engineering
Landmark University
Omu-Aran, Kwara, Nigeria
oshin.temitope@lmu.edu.ng

Ayomide Josephine Tawose
Department of Chemical Engineering
Landmark University
Omu-Aran, Kwara, Nigeria
tawose.ayomide@lmu.edu.ng

***Abstract*— Hazard and Operability study (HAZOP) is an engineering tool utilized in the process industries to prevent the occurrence of industrial hazards and plan mitigation strategies. Heart failure is a cardiovascular hazard that can be avoided and averted given proper prior preventive protocols. It is a common cardiovascular disease whose prevention is a subject of high interest. The aim of this research is to predict the risk of heart failure employing, in novelty, HAZOP study coupled with conventional qualitative risk analysis. In recent times, a lot of attention has been given to HAZOP study in identifying risks and hazards in engineering systems; hence, the exploratory use of this initiative in a cross-disciplinary terrain in physiology is considered to be unique. In this work, HAZOP analysis was carried out on the heart qualitatively using guidewords such as less flow, no flow, reverse flow, more pressure, less pressure and the conditions that could cause these were considered at different nodes or parts of the heart such as the vena cava, the right and left atria, the ventricles and the tricuspid valve. In the course of the analysis, the consequences were identified and the severity of each cause were also obtained with the probability sourced from literature and employed for qualitative risk assessment using a risk matrix. Safety functions and safeguards were also proposed based on the consequences that were identified. The risks involved with different causes of heart failure were estimated with the probability and severity being known. The results from this research reveal that with the use of HAZOP it is possible to identify different scenarios that cause heart failure, quantify how severe the effects of the causes can be and how probable they are and assign numerical risk scores to the causes and effects. The method shows promise for predictive and prognostic purposes for the prevention and care of heart failures.**

Keywords*— *heart failure; risk analysis; HAZOP; blood flow; cardiovascular system; SDG 3; good health and wellbeing

I. Introduction

The heart is a muscular organ whose contraction pumps blood into the circulatory system, delivering oxygen and nutrients and allowing all the cells to perform their physiological activities. Heart failure, is a condition in which the heart cannot supply the body's tissues with enough blood. The result is a cascade of changes that lead to severe fatigue, breathlessness and, ultimately death. In the past quarter century, much progress has been made in understanding the molecular and cellular processes that contribute to heart failure, leading to the development of effective therapies. Despite this, chronic heart failure remains a major cause of illness and death. Moreover, because the condition becomes more common with increasing age, the number of affected individuals is rising with the rapidly ageing global population. New treatments that target disease mechanisms at the cellular and whole-organ level are needed to halt and reverse the devastating consequences of this disease [1]. In the light of this, mostly desired are preventive and early detection methods of the risks of heart failure in the growing world population, especially as the condition can be considered a major health hazard.

A circumstance might be considered hazardous if it has the potential to cause harm. Process hazard analysis (PHA) techniques like the Hazard and Operability (HAZOP) Analysis are used to identify risk situations for processes [2]. The HAZOP study is used to pinpoint potential dangers that have an impact on receptors including people, the environment, and property, as well as operability dangers that raise questions about how well the process will work. It developed from Work Study and Critical Examination [3]. HAZOP investigations are frequently used to spot serious operability or quality issues, and this is usually included in the study's declared objectives. HAZOP studies are arguably the most widely utilized process hazard analysis (PHA) techniques in use today, and many practitioners consider them to be the most thorough and comprehensive [2]. HAZOP analyses concentrate on examining departures or deviations from original process operability or design intents.

The usage of HAZOP is appealing for a variety of reasons. It verifies sound engineering principles, complies with legal requirements, looks into occurrences, complies with internal audit recommendations, or aids in the creation of a safety management system [4]. HAZOP is regarded as an effective method for recognizing risks, which could increase security, prevent accidents, and increase system reliability by lowering operational issues [5]. When it is combined with the use of conventional risk assessment, especially the use of a risk matrix, the outcome could be a valuable predictive and operational hazard-prevention protocol. A risk matrix gives the ability to prioritize risks and deviations, enabling a more detailed implementation plan. HAZOP also contributes with its structure, protocol, and systematic approach (namely the usage of nodes, keywords, and deviations) [6]. Additionally, it pinpoints issues that can endanger facility security as well as those that might cause a loss of continuity or product specifications [6].

HAZOP techniques are utilized in the process industries to prevent the occurrence of industrial hazards and plan mitigation strategies. Since heart failures can be conceptualized as some form of cardiovascular hazards that can be avoided and averted given proper prior preventive protocols, it is the goal of this research to adopt the step-by-step HAZOP method of analysis or risk identification technique in a cross-disciplinary application terrain to blood flow through the heart in order to predict and prevent occurrence of cardiac episodes like heart failure. So far, as at the time of writing this paper, there has not been any work which deployed the engineering tool of HAZOP analysis to the risk assessment and prognostic analysis of diseases especially heart failure. This contribution to the body of knowledge is what this paper is addressing.

II. Materials and Methods

The methodology used in this research builds on the block flow diagram of the heart, to the process flow diagram and then the HAZOP analysis in which each part of the heart was picked as a node and they were analyzed.

A. *The Heart as a Process Unit*

Fig. 1 outlines the block flow diagram of the heart with each block showing how blood flows through the heart.

In process engineering analogy, the process flow diagram of the heart can be conceptualized as using some process "equipment" such as valves which regulate blood flow in the heart and vessels which receive blood from one side of the heart to the other.

B. *HAZOP Analysis on the Right Side of the Heart*

After drawing the block flow and process flow diagram of the heart, HAZOP analysis was carried on each part of the heart considering them as a node. Specifically, HAZOP analysis was carried out on the right side of the heart picking each part of the heart as a node, using guidewords, identifying their possible causes, consequences and giving safeguards. Fig. 2 displays the step-by-step flowchart of the HAZOP analysis utilized in this work.

Table I shows the HAZOP analysis carried out on the vena cava using a guideword (less) and the deviation (less flow). Also considering things that could cause less flow in the vena cava such as superior vena cava syndrome, cancer, blood clot and what their consequences will be, what will happen if people suffer from these causes and also giving safeguards. Safeguards in this term means precautionary measures that can be taken to avoid undesirable situations.

Table II shows the HAZOP analysis carried out on the right atrium using a guideword (reverse) and the deviation (reverse flow). Also considering things that could cause reverse flow in the right atrium and what are the consequences of reverse flow in the right atrium and also giving safeguards.

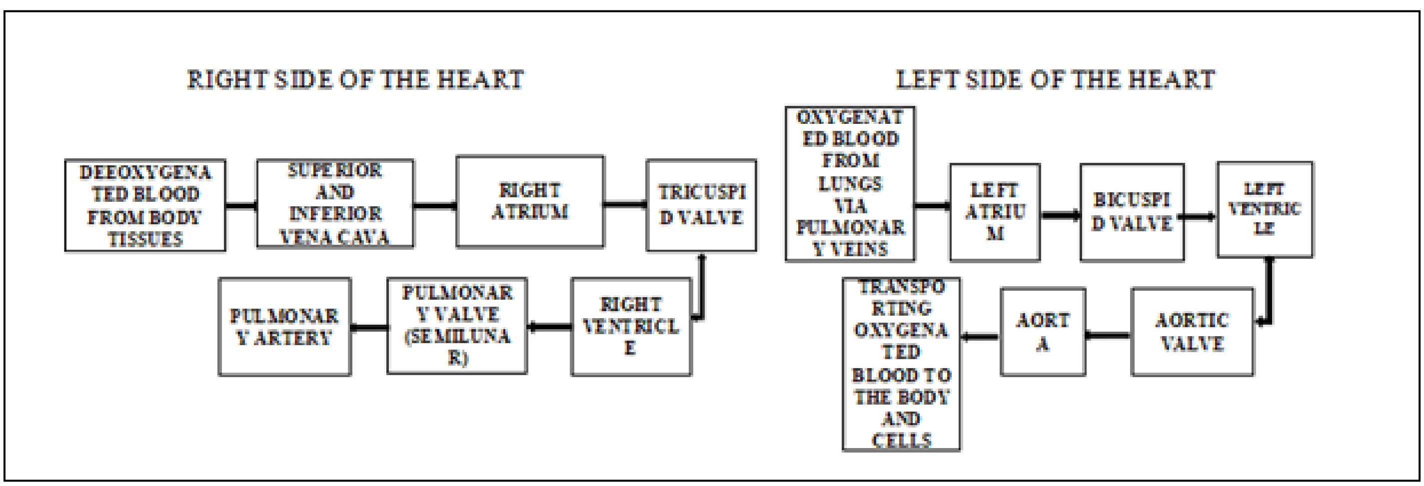

Fig. 1. Flow Diagram of the Human Heart

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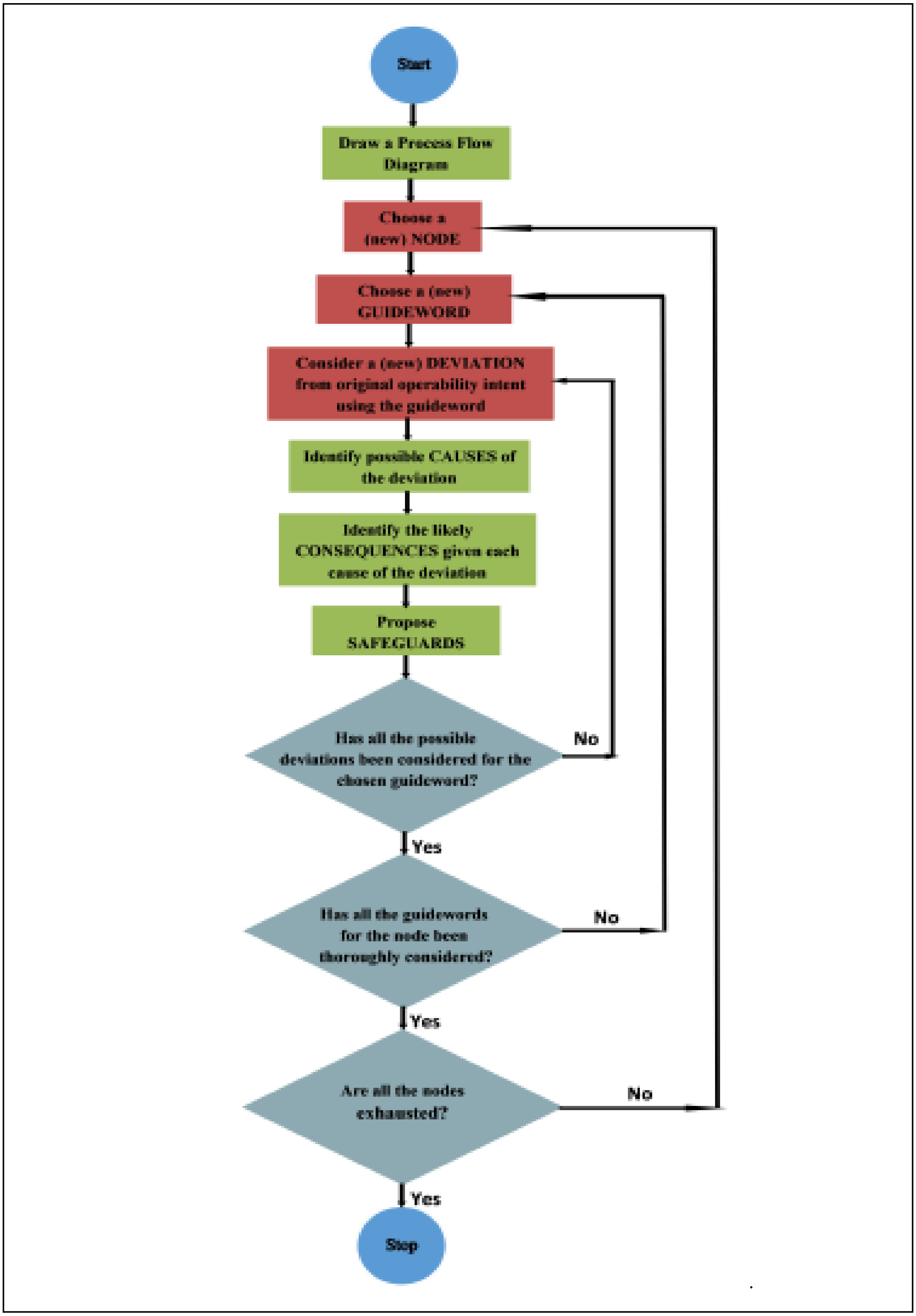

Fig. 2. HAZOP Flowchart

TABLE I. HAZOP ANALYSIS ON THE VENA CAVA

Node 1	
Node	Superior and inferior vena cava
Guideword	Less
Element	Human heart
Deviation	Less flow
Possible causes	Superior vena cava syndrome which causes flow of blood in the superior and interior vena cava vein slows. Cancer, blood clot etc. [7]
Consequences	Breathing problems, lightheadedness, swelling in the upper body, coughing etc. (Cedars Sinai, 2021) [7]
Safeguards	Radiation therapy, thrombolysis, medicines to ease symptoms [7]

TABLE II. HAZOP ANALYSIS ON THE RIGHT ATRIUM

Node 2	
Node	Right atrium
Guideword	Reverse
Element	Human heart
Deviation	Reverse flow
Possible causes	Regurgitation, which causes the valves to be leaky
Consequences	Reduces forward blood flow and can lead to volume overload in the heart. The backup causes higher blood pressure, which damages the right side of the heart
Safeguards	Quitting smoking, exercising, getting enough rest

III. RESULTS AND DISCUSSION

A. *Qualitative Risk Analysis*

The process of determining the severity and likelihood of an unwanted situation occurring, as well as deciding which actions will be taken to eliminate or restrict the risk to an acceptable level, is known as qualitative risk evaluation. The estimation of the identified extraordinary events should be accomplished by a simple double criterion pointed qualitative method. Using this method, the risks R are evaluated in two items according to the formula:

$$R = P \times S \tag{1}$$

where P is probability of occurrence and S is severity of consequences [8].

Table III shows the assignation of the probability of occurrence ranging from the lowest (very low) to the highest (very high).

TABLE III. PROBABILITY OF OCCURRENCE [8]

P	Probability of occurrence	Meaning
1	<0.0001	Very low
2	0.001-0.0001	Low
3	0.01-0.001	Middle
4	0.1-0.01	High
5	>0.1	Very high

Table IV shows the assignation of the severity of consequences ranging from not severe to fatally severe in percentage.

Table V shows the assignation of the estimated risk which is the probability of occurrence multiplied by the severity of consequence ranging from nonsignificant to significant.

B. *Modified HAZOP Analysis*

Table VI shows a comprehensive explanation on one of the nodes that was selected (the vena cava). The node chosen in Table VI is the vena cava with a keyword (less), what could go wrong with the vena cava (deviation) was also chosen to be (less flow).

The causes of the deviation were considered (what can cause less flow in the vena cava) and then the table proceeds to show the chances (probability) of the causes (how many people stand the chance of having superior vena cava syndrome). Table VI further shows the effects of the cause of the sickness which in this case is the superior vena cava syndrome and gives safety functions, things to be done in other to avoid or minimize the superior vena cava syndrome. Table VI also gives the severity of each effect, using the mortality rate of the effects to classify the severity, after getting the severity for each effect, the estimated risk was calculated using the formula (R = P x S).

TABLE IV. SEVERITY OF CONSEQUENCES [8]

S	Severity (%)	Meaning
1	<0.01	Not severe
2	0.1-0.01	Mildly severe
3	1-0.1	Seriously severe
4	10-1	Critically severe
5	>10	Fatally severe (deadly)

TABLE V. ESTIMATED RISK [8]

Risk	R =P × S
1-3	Nonsignificant
4-8	Low significant
9-25	Significant

TABLE VI. MODIFIED TABLE FOR THE HAZOP STUDY OF THE VENA CAVA

Event	Keyword	Deviation	Causes	Probability (P)	Effects	Safety Functions	Severity (S)	Estimated risk (R)
1	Less	Less flow	Superior vena cava syndrome (C1)	Very low (<0.00001) [9]	Swelling and closing of the breathing tube (epiglottis) (E1) Pericarditis (E2) Blood clots that can break loose and travel to the lungs or brain (E3)	Radiation therapy Chemotherapy	Critically severe (0.01 E1) [10] Critically severe (0.011 E2) [11] Fatally severe (0.667 E3)	Low significant (E1) Low Significant (E2) Low significant (E3)
	Less	Less flow	Breast cancer (C2)	Low (0.00086) [12]	Less efficient pumping of blood in the heart (Systolic dysfunction) (E1) Heart attack (E2)	Chemotherapy	Fatally severe (0.544 E1) [13] Fatally severe (0.3 E2) [14]	Significant (E1) Significant (E2)
	Less	Less flow	Blood clot (C3)	Middle (0.0027) ("Data and statistics on venous thromboembolism," 2020)	Heart attack (E1) Crushing chest pain (E2)	Regular exercise	Fatally severe (0.3 E1) [14] Critically severe (0.03 E2) [15]	Significant (E1) Significant (E2)

Table VII shows a comprehensive explanation on one of the nodes that was selected (right atrium). The node chosen in Table VII is the right atrium with a keyword (reverse), what could go wrong with the right atrium (deviation) was also chosen to be (reverse flow).

The cause of the deviation was considered (what can cause reverse flow in the right atrium) and then the table proceeds to show the chances (probability) of the causes (how many people stand the chance of having regurgitation). Table VII further shows the effects of the cause of the sickness which in this case is the regurgitation (leaky valves) and gives safety functions, things to be done in other to avoid or minimize regurgitation. Table VII also gives the severity of each effect, using the mortality rate of the effects to classify the severity, after getting the severity for each effect the estimated risk was calculated using the formula (R = P x S).

C. Graphical Representation of Results

Fig. 3 is a bar chart indicating the result gotten for each cause and effect after obtaining the estimated risk and classifying them into different categories for the vena cava. The y-axis shows the estimated risk and the x-axis shows the cause and effect. The estimated risk for each cause and effect in this bar chart are 4,4,5,10,12 and 15 respectively. Cause 3 and effect 1 (C3E1) with the estimated risk of 15 has the highest risk which implies that people who have heart attack stands a great chance of being at risk compared to other cause and effect on the chart.

With HAZOP analysis, the different possible causes of heart failure and their various effects were identified with the bar chart for the vena cava further showing that some people are at high risk than others with these causes and their effects. The bar chat shows that people who fall under C1E1, C1E2, C1E3 are not at high risk compared to the people who fall under C2E1, C2E2, C3E1, C3E2.

TABLE VII. MODIFIED TABLE FOR THE HAZOP STUDY OF THE RIGHT ATRIUM

Event	Keyword	Deviation	Causes	Probability (P)	Effects	Safety functions	Severity (S)	Estimated risk (R)
2	Reverse	Reverse flow	Regurgitation (Leaky valves)	Very high (0.2) ("Mitral valve prolapse," 2022)	Congestive heart failure (E1) (Clinic,2022) Pulmonary hypertension (E2) (Clinic,2022)	Maintaining a healthy weight range	Critically severe (0.005E1) [16] Fatally severe (0.68 E2) [17]	Significant (E1) Significant (E2)

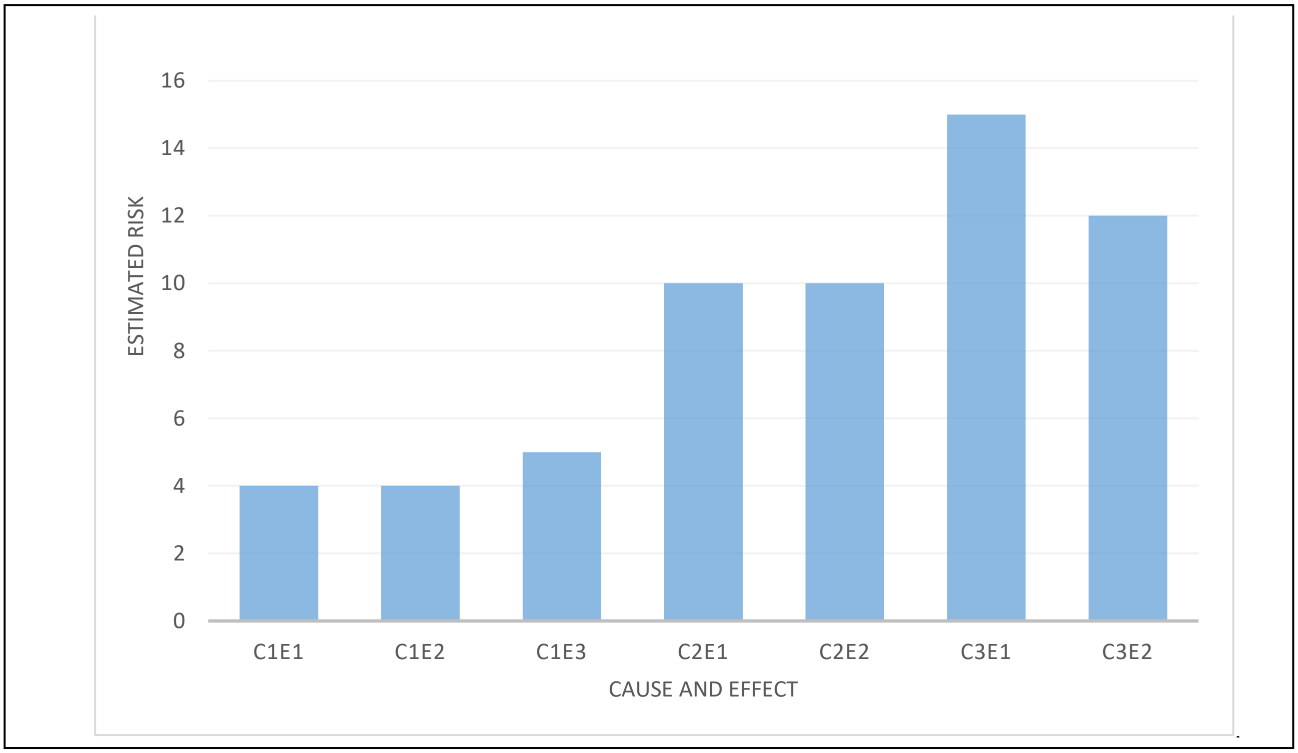

Fig. 3. Bar Chart Displaying the Estimated Risks for Various Cause and Effects for the Vena Cava

Fig. 4 is a bar chart indicating the result obtained for each cause and effect after getting the estimated risk and classifying them into different categories for the right atrium. The estimated risk for each cause and effect in this bar chart are 20 and 25 respectively. Cause 1 and effect 2 (C1E2) with the estimated risk of 25 has the highest risk which implies that people who have pulmonary hypertension stands a great chance of being at risk compared to other cause and effect on the chart. The HAZOP analysis results typified by the bar chart for the right atrium (Fig. 4) helps to further understand that some people are at high risk than others with these causes and their effects. The chart shows that people who fall under C1E1 are not at high risk compared to the people who fall under C1E2. Also, from the result shown in Fig. 4, people suffering from pulmonary hypertension due to regurgitation are at higher risk. The estimated risk scores and the results here presented can aid clinicians to propose mitigating strategies to reduce the risks.

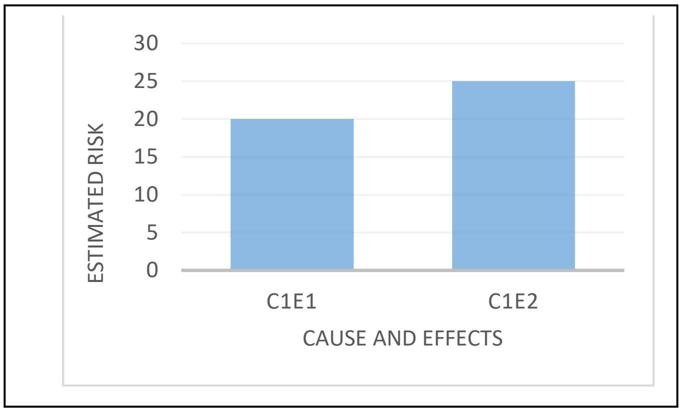

Fig. 4. Bar Chart Displaying the Estimated Risks for Various Cause and Effects for the Right Atrium

D. Evaluation and Comparison of Results

The qualitative risk assessment was carried out for each part of the heart considering them as a node and results were obtained by calculating the estimated risk which is the probability multiplied by the severity.

Table VI reports different causes of less flow in the vena cava and also showed the effects of each of them. Based on the result gotten from literature breast cancer and blood clot have higher probability than the superior vena cava syndrome. However, after estimating the risk for each cause (C3E1) in Fig. 2 had the highest estimated risk followed by C3E2. This result shows that with the already existing results and the results that were obtained are similar thereby indicating that heart failure is of great risk.

Table VII reports different causes of reverse flow in the right atrium and also showed the effects of each of them. Based on the result gotten from literature regurgitation (leaky valves) have higher probability. However, after estimating the risk for each cause C1E2 had the highest estimated risk followed by C1E1. This shows that the already existing results and the results that were obtained similar thereby indicating that heart failure is of great risk.

IV. Conclusion

HAZOP is used to carry out risk analysis mainly on engineering systems because it gives the most thorough and comprehensive result. In this paper, HAZOP analysis carried out on the heart has shown that there are various risks involved in the causality of heart failure. The objective of this study, which is to predict the risks of heart failure, has been met using HAZOP analysis. With HAZOP analysis the risks involved with heart failure were successfully predicted and the causal scenarios were also identified using a qualitative risk assessment method which quantifies how severe and likely their effects can be. The study's findings show that using HAZOP, it is possible to categorize the various situations that might lead to heart failure, determine how serious the consequences of those situations can be and how often they are, and assign numerical risk scores to those causes and consequences. The technique has potential for prognostic and predictive applications in the treatment and prevention of heart failure.

Following the result of HAZOP analysis of identification of risk scenarios, this work has focused on qualitative method of risk assessment with probabilities of occurrence of the causal events being grouped into five classes, as well as the severity of consequences. While this approach has helped to achieve a preliminary result and displayed the usefulness of the HAZOP and risk analyses for the predictive assessment of heart failure, it would be recommended to consider a more detailed quantitative risk modelling approach for better results for future work.

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