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Fuzzy Inference Systems for Optimized Drug Dosing in Heart Failure Management

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Abstract: The proposed fuzzy inference system uses a number of key clinical variables (i.e. systolic blood pressure, estimated glomerular filtration rate, serum potassium, symptoms of congestive heart failure, overall symptom severity and Nt-Pro BNP burden) to provide an optimal drug dosing solution for patients suffering from heart failure in a logical manner that is understandable to the clinician. It takes various forms of input data and normalizes it; then uses fuzzy logic mapping techniques to map the input data to fuzzy set membership values and apply a Mamdani type fuzzy logic rule base with defuzzification using the centroid method to determine recommended intensity levels for administration of three types of drugs used to treat heart failure (loop diuretics, Angiotensin Receptor-Neprilysin Inhibitors and Mineralocorticoid Receptor Antagonists). Additionally, this system includes a "safety filter" which prevents the generation of potentially unsafe dose recommendations by preventing recommendations that violate certain critical thresholds associated with renal function, elevated serum potassium or hypotension. Thus, although no other studies have been identified that use fuzzy logic for determining optimal drug dosing regimens for treating heart failure, the addition of the safety filter increases the confidence in using this new approach. An example case demonstrating how the fuzzy inference model works is shown by applying it to a previously published clinical case report describing a patient in India who suffered from advanced chronic kidney disease, had experienced multiple episodes of decompensated heart failure and presented with high levels of circulating Nt-Pro BNP. The application of this fuzzy inference system resulted in recommendations to significantly increase the dosage of loop diuretics being administered, but also to begin cautiously administering an Angiotensin Receptor-Nephrilysin Inhibitor at a lower than maximum approved dose due to concerns regarding potential worsening of hyperkalemia and/or hypotension. No recommendation was made to initiate Mineralocorticoid Receptor Antagonist (MRA) therapy. The authors demonstrate that subsequent simulations using follow up data show that if there are improvements in both congestion status and the level of biomarkers (e.g., Nt-Pro BNP), this system may be able to assist clinicians in gradually increasing the dosage of medications while maintaining safety. Ultimately, these results suggest that fuzzy inference systems offer a useful tool for developing clinically meaningful and mathematically flexible approaches to personalize pharmacologic treatment options for individual patients with uncertain conditions.

Keywords: Fuzzy inference system, heart failure management, optimized drug dosing, Mamdani inference, personalized medicine, loop diuretics, ARNI, mineralocorticoid receptor antagonist, clinical decision support, renal safety, NT-proBNP, congestion assessment.

I. INTRODUCTION

Heart Failure (HF) is an extremely complex clinical syndrome in which the patient experiences multiple episodes of fluid overload, progressively declining function, repetitive hospitalizations, and significant variability in treatment as a result of large numbers of variables such as blood pressure, renal status, electrolyte status, symptom burden, and biomarker levels in HF patients. Although GDMT has resulted in improvement in the overall outcomes for HF patients, there are several challenges for clinicians in achieving optimal doses of medications for their HF patients. Clinicians have to weigh decongestation against neurohormonal blockade, preserve renal function, and avoid the potential risks associated with hyperkalemia when using incomplete or unreliable data. As opposed to traditional threshold based models which may fail to represent the incremental changes in the various clinical parameters that define typical heart failure care (especially in patients who have end-stage CKD or experience frequent decompensations), Fuzzy Systems offer a unique computational method to represent both quantifiable and non-quantifiable clinical information in terms of clinically meaningful language categories; and to use these representations via rules which mimic the decision making process used by experts. This study developed a fuzzy decision-support model to guide clinicians in recommending loop diuretic intensity, ARNI dose intensity, and MRA eligibility on a patient-by-patient basis as well as incorporate safety limits established within current clinical practices for managing heart failure patients. Through its combination of mathematical structure, clinical logic, and a case-based approach, it is hoped that the study will

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demonstrate the ability of fuzzy systems to facilitate clinician's selection of individually tailored, safe, and adaptable medication dosages for heart failure patients.

Akinyokun *et al.* (2015) proposed an early fuzzy-logic based expert system for diagnosing heart failure. The authors illustrated how rule-based reasoning enables clinical symptomatology, patient history and diagnostics indicators to be translated into a structured decision support mechanism. Akinyokun et al.'s work represents a major contribution because they demonstrated that fuzzy systems can deal better with the uncertainties inherent in cardiovascular data than rigid binary models. Symptoms of heart failure, such as fatigue, oedema, shortness of breath, and arrhythmias typically do not present themselves in completely separable ways, so using membership functions and linguistic rules provided greater flexibility and clinical relevance to the diagnostic process. Akinyokun et al's work helped provide evidence of fuzzy logic as a viable methodology for assisting clinicians in complex cardiac diagnoses. **Santhanam and Ephzibah (2015)** expanded upon Akinyokun et al's findings through the incorporation of fuzzy reasoning with genetic optimization for predicting heart diseases. Santhanam and Ephzibah's contributions represent a significant advance in their work because they have taken what may otherwise be considered a fixed-rule based system and incorporated dynamic adaptability via evolutionary search. As a result of incorporating a genetic algorithm to optimize both rule selection and parameters, Santhanam and Ephzibah were able to increase predictive performance and reduce the uncertainty associated with classifying patients at risk of developing heart disease. Furthermore, the integration of genetic algorithms with fuzzy logic represented a major methodological development as it has demonstrated that fuzzy systems can be augmented with optimization techniques to develop more robust cardiovascular risk predictions. **Yang and Garibaldi (2015)** developed a hybrid framework designed to identify heart disease risk factors automatically. What makes Yang & Garibaldi's research particularly noteworthy is that it shifted some of the focus away from directly diagnosing heart disease towards extracting and interpreting relevant risk factors. This represents an area of interest in preventative cardiology where early identification of contributing variables such as blood pressure, cholesterol levels, age, lifestyle, etc., can assist in the implementation of interventions. Yang & Garibaldi's results suggest that fuzzy and hybrid intelligent systems are capable of performing tasks other than just diagnosing disease; specifically that they can discover clinically meaningful associations amongst data related to heart health. **Alqudah (2017)** has proposed an Expert Fuzzy System for coronary heart disease diagnosis which demonstrated how fuzzy logic remains as a viable option for many clinical applications especially when dealing with specific populations. Alqudah's proposal was useful as it illustrated how fuzzy models could be adapted to various health care systems to remain interpretable. For areas with limited support for decision assistance tools or areas without access to expensive commercial decision support tools; fuzzy models represent low cost solutions to black box models. Overall, this research illustrates the potential for fuzzy systems to evaluate vague patient information and variable physician opinions regarding the presence of coronary heart disease. **Arabasadi *et al.* (2017)** have proposed a hybrid approach using both artificial neural networks and genetic algorithms to diagnose heart disease. The significance of their work lies within their demonstration of a new trend toward integrating learning techniques with optimization techniques to improve diagnostic performance. Artificial Neural Networks alone provide no rules governing decisions whereas Hybrid Systems utilizing both neural networks and optimization techniques can determine non-linear patterns contained within clinical data. Additionally, the use of Genetic Algorithms to optimize either the parameters or structure of the model provides additional robustness to the model. Therefore, they demonstrates a shift towards Intelligent Systems based on adaptive computational learning in Cardiovascular Medicine versus pure Rule-Based Intelligence. **Sharma and Saxena (2017)** used fuzzy logic combined with genetic algorithms to predict heart disease risk levels. They provided a significant contribution by focusing primarily on Risk Stratification (the classification of risk levels) rather than simply providing a yes/no diagnosis. Clinically speaking, determining the risk level or severity of a patient is very important for developing treatment plans and for continued monitoring of patients. By incorporating fuzzy inference with Evolutionary Optimization, the authors illustrate that Intelligent Systems can categorize patients into multiple risk levels that will make predictions more clinically relevant to real-world Medical Decision Making processes in which disease progression is often in stages rather than in fixed states. **Uyar and İlhan (2017)** combines three forms of AI: Recurrent Learning, Neural Networks, and Genetic Algorithms into a single paradigm. As stated above, this paradigm is called Recurrent Fuzzy Neural Network. The reason why they are able to combine these three paradigms into a single framework is due to the nature of the problems being studied. Clinical Parameters have the ability to affect one another during diagnosis. The model's recurrent structure allows it to capture sequential relationships found in health data, while its use of genetic algorithms enables the search space for optimal solutions to be expanded. **Iancu (2018)** extends the previous research on Fuzzy Based Medical Diagnosis. He does not combine his fuzzy logic based system with another form of AI. Instead, he refines the fuzzy logic mechanism itself. He uses what is known as Mediatory Fuzzy Logic, which handles Intermediate Conditions more effectively. This is important because many diseases exist along a continuum. For example, blood pressure may vary from normal to high. Therefore, there exists many possible values that fall outside of the two extremes. His methodology provides support for smooth transition between different levels of diagnosis, which is essential in capturing the complexity of clinical reality. **Nasiri and Akbarzadeh Kalat (2018)**

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extends previous research on Fuzzy Control Systems by providing evidence that Adaptive Back Stepping Design can be successfully applied to Cancer Treatment. While the application of this methodology is not directly related to Heart Failure Management, it is indirectly applicable through the application of drug therapy. In addition to diagnosing patients using AI, we can now use AI to adjust the dosage of drugs that need to be administered to achieve maximum effectiveness while minimizing side effects. **Nazari *et al.* (2018)** used fuzzy inference systems in conjunction with fuzzy AHP to develop a multi-criteria decision analysis system for the assessment of patients with heart disease. Their findings were important since they brought fuzzy analytical hierarchies to cardiovascular medicine. Clinicians regularly evaluate multiple components when diagnosing cardiac conditions such as lab tests, imaging studies, patient history, and presenting symptoms. By developing a combination of hierarchical methods of ranking and fuzzy inference methods, their work presented a systematic method for evaluating and combining uncertain clinical diagnostic variables. The authors showed that fuzzy systems could be employed to aid in the resolution of complex medical issues, and provide improved interpretation of clinical decision-making models. **Ramirez *et al.* (2019)** proposed a hybrid classification framework employing both artificial neural networks along with type-1 and type-2 fuzzy systems for the analysis of cardiac arrhythmias. They made significant contributions since they extended the application of fuzzy systems beyond general predictive diagnostics of heart disease to recognize patterns within cardiac signals. Since type-2 fuzzy systems have greater ability to represent higher degrees of uncertainty than do type-1 fuzzy systems, they are well-suited to classify and analyze cardiac signals which are commonly noisier and more variable than other types of signals. Their work illustrated that advanced fuzzy architectures may enhance the accuracy of classifications related to electrophysiological abnormalities and therefore expand the range of applications of fuzzy intelligence in cardiology. **Karar *et al.* (2020)** proposed an adaptive intuitionistic fuzzy control methodology for optimizing dosage administration of cancer drugs. Although the target disease area is oncology, the methodologies proposed in Karar's study are highly applicable to optimizing dosages of medications for treating heart failure. Intuitionistic fuzzy logic provides additional value due to its inclusion of not only membership and non-membership but also hesitation. Hesitation allows for a better representation of uncertainty in physiological responses, which is critical when considering variability in reaction and partial unknowns related to drug dosing. The authors suggested that utilizing advanced fuzzy control methodologies would enable safe and personalized therapeutic regulatory practices; a concept that is directly transferable to managing medications for heart failure. **Korzhakin and Sugiharti (2021)** utilized genetic algorithms with adaptive neuro-fuzzy inference to predict survival for heart failure patients. The significance of this study stems from its ability to bring prognostic modeling into the neuro-fuzzy area. Prognosis of patient survival is an integral part of managing heart failure; helping to determine treatment intensity, how often to monitor the patient, and what type of long term care will be needed. By using both adaptive inference, as well as optimization techniques; they demonstrated that intelligent systems have the potential to go beyond diagnosis and be able to predict outcomes. This illustrates a more mature clinical application of fuzzy based intelligence in the area of heart failure research. **Muhammad and Algehyne (2021)** created a fuzzy expert system for diagnosing coronary artery disease. They also highlighted the practical use of transparent and intelligible intelligent systems within the healthcare environment. The significance of their findings is two fold: first, the continue to provide transparent diagnostic support, but secondly, they focus upon real world applications. Clinicians find some types of medical decision making systems more appealing when they can clearly understand how input data translates to conclusions. Therefore, fuzzy rule-based models are typically considered to be more suitable for these needs than are non-interpretable machine learning methods. Thus, Muhammad and Algehyne's research indicates that fuzzy expert systems remain relevant for providing trustworthy and understandable decision-making tools in environments requiring high levels of transparency. **Khaleel and Chiad (2022)** developed an advanced neuro-fuzzy model for predicting heart failure. The work by Khaleel and Chiad represents a current development point in the progression of fuzzy modeling of the cardiovascular system. Their research is significant as it addresses the issue of heart failure prediction with a hybrid approach which integrates the learning capabilities of neural networks with the transparent reasoning abilities of fuzzy inference. In this manner their method can be applied to handle the numerous and nonlinear associations existing among the indicators of heart failure; while maintaining some level of interpretation. The research of Khaleel and Chiad, shows increasing interest in the use of predictive intelligence, personalization and hybrid models in contemporary cardiovascular clinical decision making. **Aziz et al. (2025)** proposed an intelligent fuzzy clinical decision support framework combining disease prediction with the generation of personal drug dosages based on a variety of input factors. They stated their major contention is that most clinical information collected from patients is uncertain, vague, and/or linguistically represented; therefore, Fuzzy Inference Systems (FISs) are better suited for addressing this level of complexity in diagnosis and therapy selections than rule-based systems and statistical models. The researchers reported that their proposed clinical decision support system improved the interpretability of predictions generated by the system while maintaining high levels of predictive ability -- the authors demonstrated the potential of the proposed clinical decision support system to accurately predict disease presence at rates of approximately 92%, while providing significantly reduced Root Mean Square Errors (RMSE) of 0.19 when compared to traditional machine learning techniques including Artificial Neural Networks (ANNs) and Support Vector Machines (SVM). A significant advantage of the proposed model is that the model provides both diagnostic and treatment recommendations within a single framework, thereby making the model more

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applicable for use in clinical practice rather than limited to the application of disease classification. Additionally, the researchers suggested that the use of a fuzzy rulebase enables clinicians to generate safe and transparent therapeutic recommendations since dosage recommendations may be traced back to logical medical reasoning.

II. MATHEMATICAL FRAMEWORK

2. Mathematical Framework:

2.1 Input vector: Let the patient state at time t be

$$x(t) = [x_1, x_2, x_3, x_4, x_5, x_6] \quad (1)$$

where

x_1 = SBP (mmHg), x_2 = eGFR(mL/min/1.73 m^2), x_3 = Serum potassium (mEq/L)

x_4 = Congestion index, x_5 = NYHA/symptom score, x_6 = NT − proBNP burden/trend index.

To unify scales, define normalized variables

$$z_i = \frac{x_i - x_i^{min}}{x_i^{max} - x_i^{min}}, z_i \in [0,1] \quad (2)$$

For the congestion index, use a weighted composite:

$$x_4 = 0.30E + 0.20O + 0.20W + 0.30B \quad (3)$$

where E = edema score, O= orthopnea score, W= weight-gain score, and B = biomarker congestion score, each scaled to [0,1].

Table 1: Model variables and linguistic ranges

Variable	Symbol	Example crisp range	Fuzzy labels
Systolic BP	x_1	80–160 mmHg	Low, Acceptable, High
eGFR	x_2	5–90	Severe, Moderate, Preserved
Potassium	x_3	3.0–6.0	Low-normal, Normal, Borderline, High
Congestion index	x_4	0–1	Mild, Moderate, Severe
Symptom score	x_5	1–4	Mild, Moderate, Severe
NT-proBNP index	x_6	0–1	Low, Elevated, Markedly elevated

2.2. Output vector: The system produces $y(t) = [y_1, y_2, y_3]$ (4)

where

y_1=loop diuretic dose intensity index∈[0,100],

y_2=ARNI dose intensity index∈[0,100]

y_3=MRA eligibility/intensity index∈[0,100].

2.3. Fuzzy sets: For each input, define linguistic labels such as:

(i) SBP: Low, Acceptable, High

(ii) eGFR: Severe impairment, Moderate impairment, Preserved

(iii) Potassium: Low-normal, Normal, Borderline-high, High

(iv) Congestion: Mild, Moderate, Severe

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(v) Symptoms: Mild, Moderate, Severe

(vi) NT-proBNP: Low, Elevated, Markedly elevated

Triangular membership functions may be written as

$$\mu_{tri}(x; a, b, c) = \begin{cases} 0 & x \leq a \\ \frac{x-a}{b-a} & a < x \leq b \\ \frac{c-x}{c-b} & b < x < c \\ 0 & x \geq c \end{cases} \quad (5)$$

and trapezoidal membership functions as

$$\mu_{tri}(x; a, b, c, d) = \begin{cases} 0 & x \leq a \\ \frac{x-a}{b-a} & a < x \leq b \\ 1 & b < x \leq c \\ \frac{d-x}{d-c} & c < x < d \\ 0 & x \geq c \end{cases} \quad (6)$$

Figure 1. Membership Functions for Systolic Blood Pressure (SBP)

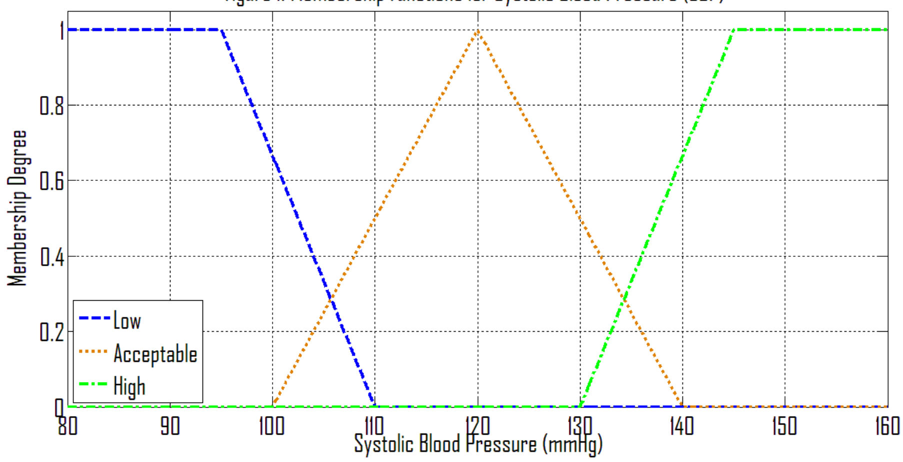

Figure 2. Membership Functions for eGFR

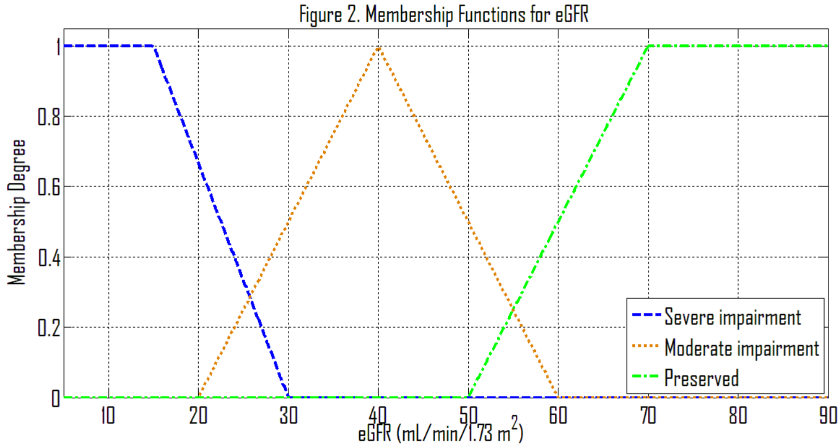

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Figure 3. Membership Functions for Serum Potassium

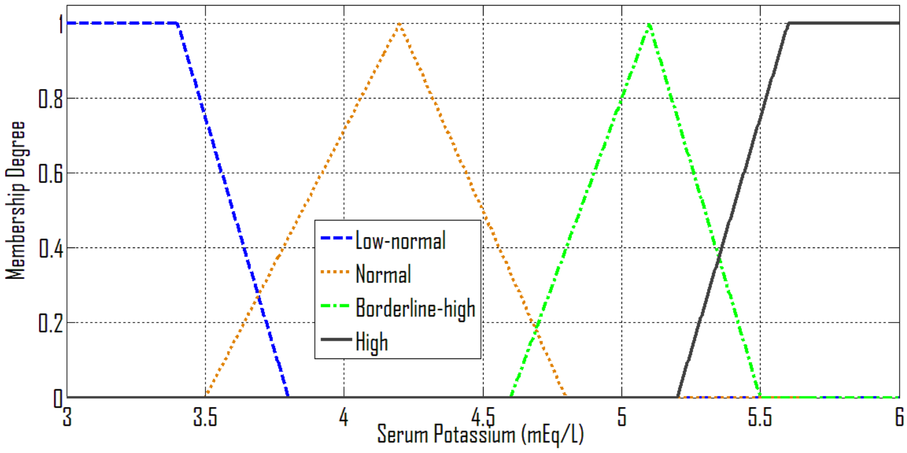

Figure 4. Membership Functions for Congestion Index

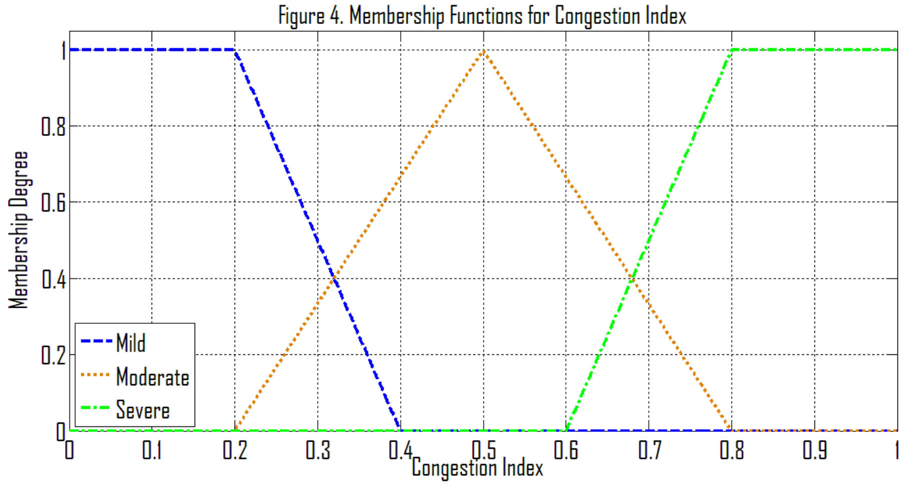

Figure 5. Membership Functions for Symptom Score

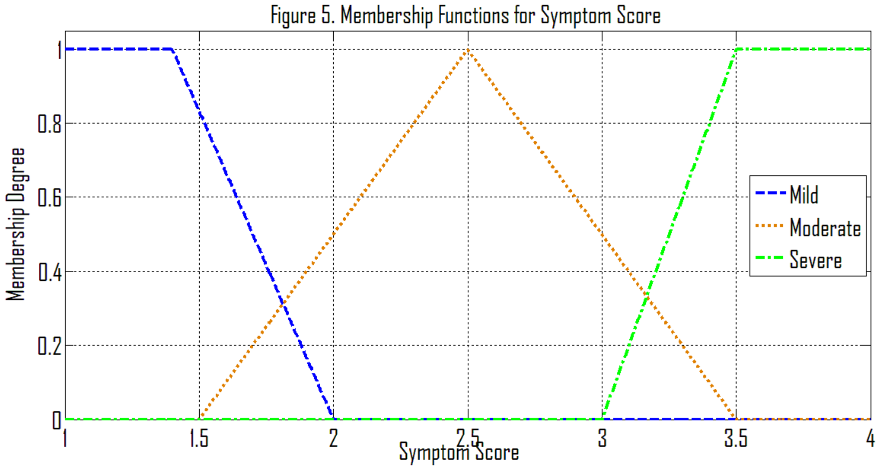

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Figure 6. Membership Functions for NT-proBNP Index

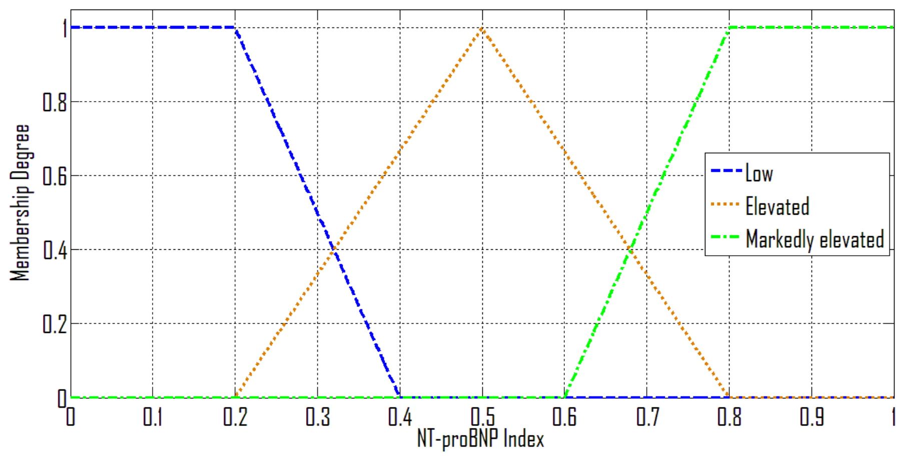

Figure 7. Output Membership Functions for Loop Diuretic Intensity

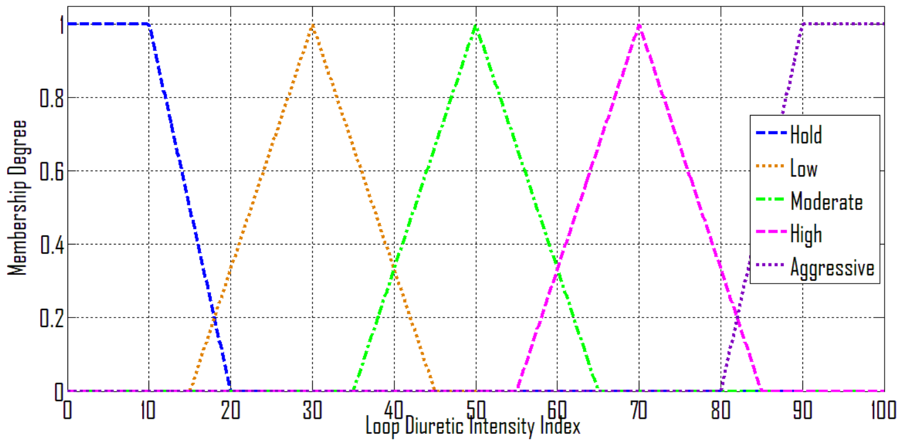

Figure 8. Output Membership Functions for ARNI Intensity

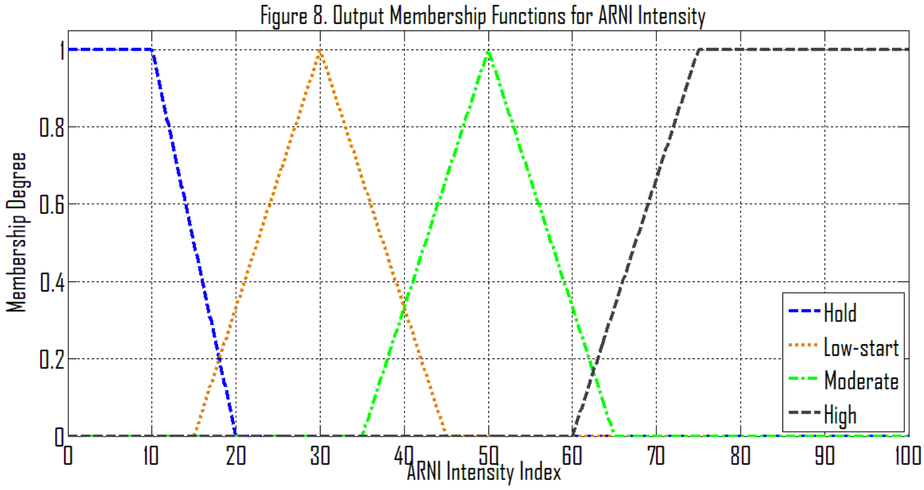

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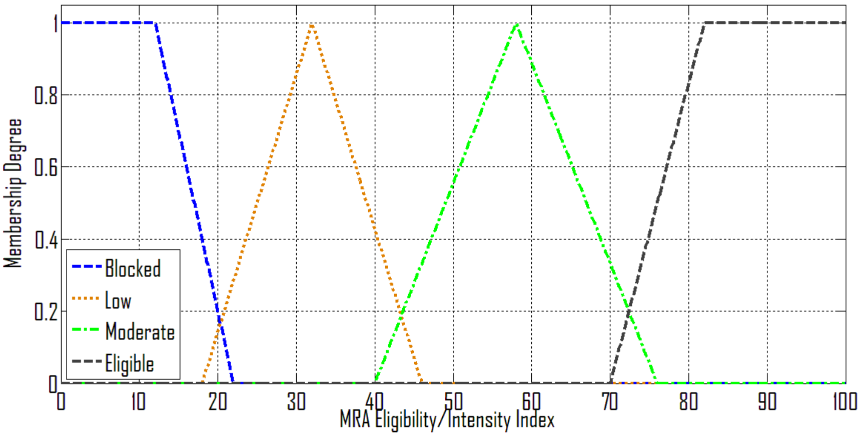
Figure 9. Output Membership Functions for MRA Eligibility/Intensity



2.4. Rule base: A typical fuzzy rule is

R_k: IF x_4 is Severe AND x_1 is Acceptable AND x_2 is Moderate AND x_3 is Normal, THEN y_1 is High and y_2 is Moderate.

Using Mamdani inference, the firing strength of rule k is

$$\alpha_k = \min\left\{\mu_{A_1^k}(x_1), \mu_{A_2^k}(x_1), \dots, \mu_{A_6^k}(x_1)\right\} \quad (7)$$

Aggregated output membership for target y_j:

$$\mu_{Y_j}(y) = \max_k \left[\min\left\{\alpha_k, \mu_{B_j^k}(y)\right\}\right]$$

Defuzzification by centroid: $y_j^* = \frac{\int y\mu_{y_j}(y)dy}{\int \mu_{y_j}(y)dy}$ (8)

Table 2: fuzzy rules		
Rule	**Antecedent**	**Consequent**
R1	IF congestion is severe AND SBP is acceptable AND eGFR is moderate	loop diuretic = high
R2	IF congestion is severe AND eGFR is severe	loop diuretic = moderate-high with renal caution
R3	IF SBP is low	ARNI = low/hold
R4	IF eGFR is severe AND K is normal	ARNI = low-start
R5	IF eGFR > 30 AND K < 5.0 AND symptoms persist	MRA = eligible
R6	IF K is high	MRA = hold
R7	IF congestion is mild AND BP is low	no diuretic escalation
R8	IF NT-proBNP is markedly elevated AND symptoms severe AND BP acceptable	favor GDMT intensification

2.5. Safety filter: After defuzzification, apply hard clinical constraints:

$$y_3^* = 0 \text{ if eGFR} \leq 30 \text{ or } K \geq 5.0 \quad (9)$$

because MRA initiation is contraindicated below these thresholds in HFrEF guidance.

For ARNI: $y_3^* \rightarrow \text{low} - \text{start bandif eGFR} < 30$

because sacubitril/valsartan labeling recommends a reduced starting dose in severe renal impairment.

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For diuretics:
if congestion is persistent and loop response is inadequate, a thiazide-type add-on may be considered, but only with electrolyte caution.

2.6. Optimization objective: The fuzzy system can be tuned by minimizing

$$J = w_1 C_{res} + w_2 H_{risk} + w_3 R_{risk} + w_4 K_{risk} + w_5 S_{underTx} \tag{10}$$

C_{res}: Residual congestion penalty
H_{risk}: Hypotension penalty
R_{risk}: Renal worsening penalty
K_{risk}: Hyperkalemia penalty
$S_{underTx}$: under-treatment penalty
with $w_i > 0$ chosen by the investigator.

III. NUMERICAL CASE DEMONSTRATION

A peer-reviewed open-access Indian case study reported on a 59-year-old male patient that suffered from chronic kidney disease (CKD) stage 5 and coronary artery disease (CAD). He also suffered from reduced left ventricular ejection fraction (LVEF) due to heart failure with preserved ejection fraction (HFrEF), leg swelling (ankle edema) and hypertension as evidenced by his blood pressure of 128/78 mmHg. Laboratory values included a serum creatinine concentration of 5.1 mg/dL, an estimated glomerular filtration rate (eGFR) of 11 mL/min, potassium of 3.5 mEq/L, elevated N-terminal pro b-type natriuretic peptide (NT-proBNP) of greater than 25,000 pg/L and a history of three hospitalizations for heart failure within the past year. The patient's sacubitril/valsartan had been discontinued one month prior to the initial evaluation of the current condition due to hyperkalemia. However, it was reinstituted after being held for four weeks at a lower-than-recommended starting dose. It was then gradually titrated up with close monitoring while maintaining doses of torsemide and metolazone based upon the previous medical treatment regimen.

3.1. Crisp input construction:

Using the case data, define the normalized state:

SBP =128 mmHg $\Rightarrow z_1 = 0.60$

eGFR =11$\Rightarrow z_2 = 0.07$

Potassium =3.5$\Rightarrow z_3 = 0.17$

Congestion index $x_4 = 0.78$ from ankle edema + recurrent HF + biomarker burden

Symptom score $x_5 = 0.85$

NT-proBNP index $x_6 = 0.95$

These last three are derived study variables and should be reported as model-engineered features.

Assume the following memberships:

$\mu_{SBP,Acceptable}(128) = 0.82, \mu_{eGFR,Severe}(11) = 0.93$

$\mu_{K,Normal}(3.5) = 0.70, \mu_{Congestion,Severe}(0.78) = 0.80$

$\mu_{Symptom,Severe}(0.85) = 0.88, \mu_{NTproBNP,Marked}(0.95) = 0.95$

3.2. Membership degrees:
3.3. Rule firing:

For ARNI-start rule:

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R_A: IF BP is Acceptable AND eGFR is Severe AND K is Normal THEN ARNI is Low-start
$\alpha_A = \min\{0.82, 0.93, 0.70\} = 0.70$

For loop-diuretic rule:

R_D: IF Congestion is Severe AND BP is Acceptable THEN loop diuretic is High

$\alpha_A = \min\{0.80, 0.82\} = 0.80$

For MRA rule:

R_M: IF eGFR >30 AND K<5.0 THEN MRA
This rule is rejected by the safety filter because eGFR =11, which is below the recommended initiation threshold.
3.4. Defuzzified outputs: Let centroid defuzzification yield:
$y_1^* = 74.2$: strong decongestive strategy
, $y_2^* = 36.8$: low-dose ARNI start
, $y_3^* = 0$: MRA not eligible at baseline
3.5.Clinical translation: The output maps to:

(i) Loop diuretic: maintain/intensify loop-based decongestion with close renal/electrolyte monitoring

(ii) ARNI: start in the low-dose band, consistent with severe renal impairment labeling and with the published case's low-dose restart followed by gradual titration

(iii) MRA: do not initiate at baseline because eGFR is too low under guideline thresholds

Table 3: Numerical case-study results

Quantity	Value	Model meaning
SBP	128 mmHg	Hemodynamically acceptable
eGFR	11 mL/min/1.73 m²	Severe renal risk
Potassium	3.5 mEq/L	Potassium acceptable
NT-proBNP	>25,000 pg/L	Marked disease burden
LVEF	30%	HFrEF phenotype
y_1^*	74.2	Strong diuretic intensity
y_2^*	36.8	Low-dose ARNI start
y_3^*	0	MRA blocked

3.6. Follow-up simulation: If, after 4–6 weeks, edema falls from severe to moderate, SBP remains >110 mmHg, potassium remains <5.0, and creatinine is stable relative to baseline trend, the model may shift to:

$$y_1^* = 58, y_2^* = 54, y_3^* = 0 \tag{11}$$

which means decongestion can be stepped down slightly while ARNI can be titrated from low to moderate intensity. This trajectory qualitatively matches the published report, where low-dose sacubitril/valsartan was titrated upward and tolerated with monitoring.

Table 4: Dose-index interpretation

Index band	Interpretation
0–20	Hold / contraindicated

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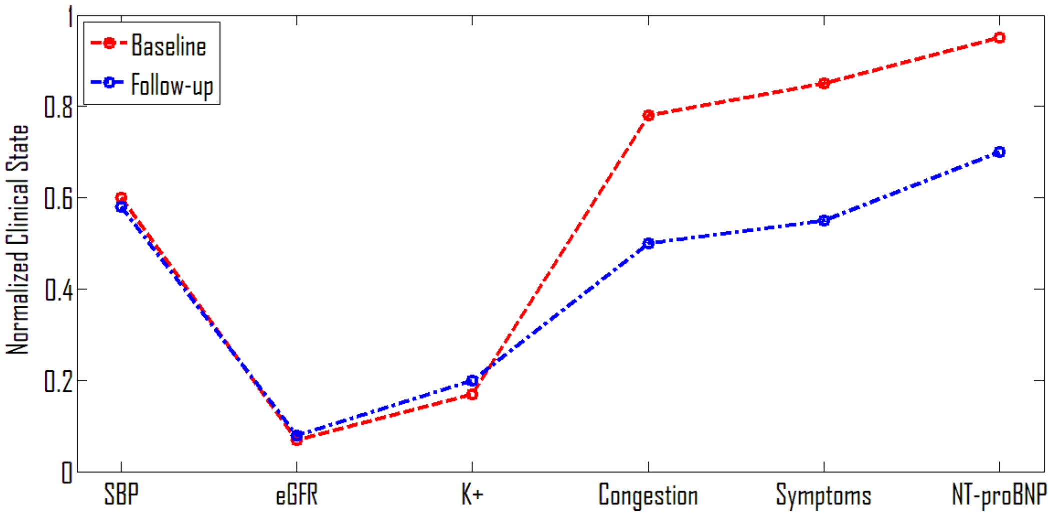
21–40	Low dose / cautious start
41–60	Moderate dose
61–80	Standard-to-high intensity
81–100	Aggressive escalation with close monitoring

Figure 10. Normalized Clinical Profile Across Follow-up



The figure (10) provides a comparative picture of the patients' normalized clinical profile (at baseline and follow-up) based on the six following variables: SBP, eGFR, Potassium, Congestion, Symptoms & NT-Pro-BNP. The SBP was mostly unchanged at follow-up (only slightly lower than at baseline), whereas both eGFR and Potassium were marginally higher at follow-up compared to baseline, thus providing evidence for maintained hemodynamic and biochemical balance during treatment. Most importantly, there is significant downward movement in Symptom Burden, Congestion, and NT-Pro-BNP levels from baseline to follow-up. This indicates a reduction in volume status and clinical condition as well as a reduction in biomarkers of heart failure. Of note, the drop in congestion and NT-Pro-BNP levels are large enough to support the idea that the Therapeutic Strategy employed by physicians resulted in adequate De-congestion and better Management of Heart Failure, without having a detrimental effect on Renal Function or Blood Pressure. Therefore, overall the data contained within this figure provide further evidence that follow-up care resulted in clinically meaningful improvement while maintaining parameters related to safety within an acceptable range.

IV. VALIDATION PLAN

The results of this study will support validation at three different levels of the system. Face validity will be demonstrated by comparing the output of the algorithms to the actual medical decision made by cardiologists. Retrospective validity will be established through testing for agreement between fuzzy- consistency scores (using chart reviews) and actual prescribing decisions. Outcome validity will be shown as increased fuzzy-consistency scores are associated with reduced number of hospitalizations, decreased residual congestion and improvement in either NT-proBNP or functional class. For assessment of performance of the system, it is recommended that you calculate the average absolute dosing error, expert-agreement rate, and rate of violation of safety rules; also, determine if there has been an increase in hospitalization rates during follow-up.

V. CONCLUDING REMARKS

This fuzzy inference model provides a viable clinical decision-making strategy for individualized prescription of heart failure medications when therapeutic decisions may be complicated by variability in physiological conditions, risk states with commonality, and conflicting safety factors. This model combines data from renal function, cardiac function, blood chemistry (electrolytes), symptoms and biomarkers into one logical and understandable rule based

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structure which generates specific suggestions regarding loop diuretic dose increases, safe initial doses or titration of ARNI and MRA eligibility while maintaining critical safety limits. Numerical examples and subsequent simulations demonstrated that the model could reasonably represent real-world treatment plans; i.e., rapid baseline decongestive therapy, cautious pharmacologic augmentation in the setting of severe renal dysfunction and delayed treatment adjustments as fluid status improved and the patient remained stable. Thus, the study demonstrates how fuzzy logic can provide useful cognitive assistance in providing "precision medicine" for the management of patients with heart failure who have multiple comorbidities.

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