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Original Article

A Cohort Study of SGLT-2 Gliflozins and its Effect on Glycaemic Index in CHF Patients With and Without Diabetes

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ABSTRACT

Background: Although there are many treatment options available, SGLT-2 inhibitors are emerging as effective agents in the treatment of congestive heart failure (CHF) patients with and without diabetes. This study aims to measure the glycaemic index maintained by Dapagliflozin in CHF patients with and without diabetes. **Materials and Methods:** A 12-months cohort study was conducted in tertiary care hospital. The study included 150 participants diagnosed with CHF and based on the study criteria. Data collected from patient records and lab data were analysed by Student *t*-test. **Results:** The overall difference in means of FBS, PPBS and HbA_{1C} between the two groups were statistically significant with a *p*-value of 0.0067, 0.0034, 0.0046 (*p* value<0.05, 95% confidence interval) with no hypoglycaemic episodes and other adverse effects. **Conclusion:** Thus, our study highlights the importance of stable glycemic index managed by SGLT2 inhibitor Dapagliflozin with negligible hypoglycemic effects posing a positive outcome in CHF patients with and without diabetes.

Keywords: Congestive Heart Failure, Diabetes Mellitus, SGLT-2 Inhibitors.

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INTRODUCTION

Congestive Heart failure (CHF) is a pathophysiological condition of heart characterized by insufficient amount of blood pumped by heart creates oxygen demand in the body and coronary system. CHF effects about 26 million people with high morbidity and mortality worldwide. Some studies reported that about 64.34 million people have CHF and cost of illness over $346 billion each year. Thus, in consequences CHF leads to increase in healthcare costs, limits daily activities and lowers quality of life of the patients. Also, according to ACC/AHA and New York Heart Association (NYHA), CCHF is classified into Stage 1 to Stage 4 from no symptoms to severe HF in ACC/AHA and symptoms with strenuous exercise to symptoms even at rest as per NYHA. Whereas early diagnosis and treatment reduce the consequences (Benjamin *et al.*, 2017; Heidenreich *et al.*, 2022; Swedberg and Kjekshus, 1988; Virani *et al.*, 2020). The underlining pathophysiology includes the body tries to compensate to keep blood flowing, but over time these mechanisms fail leading to stimulation of the RAAS system activates, causing blood vessels to tighten and the body to hold on to salt and water. Less blood pumping from the heart triggers more stress hormones, increasing heart strain and oxygen demand. This cycle leads to heart cell death, reduced pumping ability, and fluid buildup in the lungs (*Heart Failure* (Congestive Heart Failure) - *StatPearls* - *NCBI Bookshelf*, n.d.). The CHF patients are often having Type 2 Diabetes mellitus (T2 DM) as a comorbidity which worsens the disease condition towards multiple organ damage in future if un treated (Rosano *et al.*, 2017). CHF is treated majorly with antihypertensive medications such as Beta blockers (Carvedilol, Metoprolol), Angiotensin Receptor Blocker+Neprilysin Inhibitors (ARNI's), Angiotensin Receptor Blockers (ARB'S - Ramipril, Captopril), Calcium Channel Blockers (CCB's) etc., with effective and promising results (Lam *et al.*, 2021). Diuretics provide symptomatic control for patients but have no impact on patient mortality. Other currently available therapies, while effective in improving outcomes in CHF with reduced ejection fraction, do not improve outcomes in CHF with preserved ejection fraction (Ehrenkranz *et al.*, 2005; Yancy *et al.*, 2013). Nowadays a new treatment alternative is also in the race for the treatment of CHF which is basically an anti-oral hypoglycaemic agent that is Sodium Glucose Transporter-2 inhibitors (SGLT2-is) such as Dapagliflozin Empagliflozin etc., (Heidenreich *et al.*, 2022). These agents reduce reabsorption of glucose in the kidneys and facilitate its excretion in the urine by inhibiting the high-capacity glucose transporter SGLT2 located in the proximal convoluted tubule, thereby lowering glucose levels independently of insulin

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action (Hsia *et al.*, 2017; Hummel *et al.*, 2011; Lee *et al.*, 2007; Wilding *et al.*, 2018; Wright, 2001). This mechanism of action is dependent on blood glucose levels and, unlike the actions of thiazolidinediones (mediated through GLUTs), is independent of the actions of insulin. Thus, there is minimal potential for hypoglycaemia, and no risk of overstimulation or fatigue of the beta cells (Nauck, 2014). Thus, this study aimed to explore the effect of Dapagliflozin on glycaemic index in CHF patients with and without diabetes.

MATERIALS AND METHODS

Study design and study settings

This was a cohort study conducted in tertiary care hospital and research centre in rural settings for a period of 12 months (August 2024 to July 2025). The hospital settings provide multi-speciality facilities for various health issues and the hospital is accessible to more than three cities.

Study participants inclusion and exclusion criteria

Patients with age above 18 years, diagnosed with cardiac diseases and treated with Dapagliflozin were included in the study. After the explanation of all the specific methods, those who were willing to give written consent were included in the study

Patients with less than 18 years of age, not diagnosed with cardiac issues those who were not willing to give informed consent were excluded from the study. And patients had right to withdraw from study at any point of the study without any explanation.

Sampling and sample size calculation

Convenience sampling technique was used for the sample size in this study. We estimated a minimum sample size of 150 participants, where 75 patients having CHF with diabetes and 75 patients having CHF without diabetes.

Data collection

The patients admitted in the cardiology department were included in the study as per the defined inclusion and exclusion criteria, the demographics details and clinical data such as patient history, age, diabetic status, cardiac heart failure status, comorbidities, laboratory reports including glycaemic effect Fasting Blood Sugar (FBS), Post-Prandial Blood Sugar (PPBS), and calculated HbA_{1C} levels were obtained from the patient's and their records, using a pre-designed data collection for three consequent measurements as follows 3 months, 6 months and 9 months. The effect dapagliflozin was assessed to measure the glycaemic changes in CHF patients with and without diabetes (Supplementary File S1).

Ethical Approvals

The study was conducted in accordance with the Ethical guidelines for biomedical research on human participants and Declaration of Helsinki; after obtaining approval from the Institution Ethics Committee (IEC/AH&RC/AC/10/2025) and we reported this article as per the STROBE Checklist (Elm *et al.*, 2007). And after explanation of specific of the study informed consent was obtained from the study participants.

Statistical analysis

All the collected data were entered into Microsoft Excel sheets, thoroughly verified, and analysed Statistical Package for the Social Sciences (SPSS) free version 25.0 developed by IBM (Armonk, 2017). The categorical and continuous data were presented as frequency with percentages and mean with standard deviation respectively. Paired student t-test statistical methods was used to compare and analyse the glycaemic effect of dapagliflozin drug in cardiac patients with or without diabetes.

RESULTS

Demographic characteristics of the patients

A total of 150 patients with CHF were included of which 120 (80%) were males and 30 (20%) were females; most of the patients 61(34%) belongs to 60-70 of age group and also, median age of 48(32%) belongs to 70-80 years of age group. It was observed that most patients were in NYHA Class II (65.3%), showing mild symptoms followed by, about 30% were in Class III, indicating moderate limitation. Only 4.6% were in Class IV, reflecting severe heart failure and none were in Class I.

Also, Hypertension was the most common comorbidity seen in 87 patients (58%), type 2 diabetes was more common, seen in 66 patients (44%), while type 1 diabetes was present in 9 patients (6%). And anaemia, gout, and seizure were the least comorbidities each found only with 6 patients (4%). Among the 150 CHF patients, 75 patients (50%) were diabetic, while the remaining 75 patients (50%) were non-diabetic.

The medication history was found to be, Tab Rosuvastatin, Tab aspirin and Tab ticagrelor were the most commonly used, prescribed to 129 patients (86%), 120 patients (80%) and 102 patients (68%) respectively. Tab nicorandil and Tab carvedilol were prescribed to 81 patients (54%) each. Tab spironolactone + torsemide was used in 72 patients (48%) and Tab metoprolol succinate in 45 patients (30%). Among the CHF patients it was found that the brand, Tab Zucapride (Dapagliflozin) 10mg BD was the most commonly prescribed used by 96 patients (64%), whereas the brand, Tab Dapaglifloss (Dapagliflozin-10 mg) were the least prescribed that is 3 patients (2%) as provided in Table 1.

Glycaemic index among CHF patients with diabetes

Among 75 CHF patient with diabetes the effect of dapagliflozin drug was found as, The Fasting Blood Sugar (FBS), PPBS, HbA_{1C} showed a gradual decrease from 154.36 mg/dL at baseline to 132 mg/dL at 9 months, 172.9 mg/dL at baseline to 148.8 mg/dL at 9 months and the HbA_{1C} reduced from 7.2% at baseline to 6.5% at 9 months, indicating improved long-term glucose control.

Glycaemic index among CHF patients without diabetes

Among 75 CHF patient without diabetes the glycaemic effect of dapagliflozin drug was found that the Fasting Blood Sugar (FBS) PPBS, HbA_{1C} were remained fairly stable, around 109 mg/dL at baseline to 107 mg/dL at 9 months, 120 mg/dL at baseline to 116.6 mg/dL at 9 months and 5.8% at baseline and 5.7% through 9 months, indicating good glycaemic control without hypoglycaemic effects (Figures 1-3).

Mean difference and statistical significance

The mean Fasting Blood Sugar (FBS), PPBS and calculated HbA_{1C} were consistently higher in patients with diabetes compared to those without diabetes at all measured timelines that is 3 months, 6 months and 9 months. The overall difference in means of FBS, PPBS and calculated HbA_{1C} between the two groups were statistically significant with a *p*-value of 0.0067, 0.0034, 0.0046 (*p* value <0.05, 95% confidence interval) as given in Table 2.

Table 1: Distribution of demographic details and clinical parameters.

Characteristic	Variables	Frequency	Percentage
Gender	Male	120	80%
	Female	30	20%
Age	20-30	3	2%
	30-40	6	4%
	40-50	12	8%
	50-60	17	18%
	60-70	61	34%
	70-80	48	32%
	80-90	3	2%
Comorbidities	Type-1 Diabetes	9	3.1%
	Type-2 Diabetes	66	23%
	Hypertension	87	30.5%
	IHD	36	12.6%
	Anaemia	6	2.1%
	AKI	9	3.1%
	CVA	18	6.3%
	Hypothyroidism	15	5.2%
	CH F	15	5.2%
	Gout	6	2.1%
	COPD	12	4.2%
	Seizure	6	2.1%
Types of diabetes	Type 1	9	12%
	Type 2	66	88%
Diabetes status	With Diabetes	75	50%
	Without Diabetes	75	50%
Brand of Dapagliflozin	Tab Zucapride	96	64%
	Tab Zucapride M	24	16%
	Tab Vildapride D	3	2%
	Tab Dapaglifloss	3	2%
	Tab DAPA	12	8%
	Tab Glucreta	12	8%

Table 2: Association of Means of Glycaemic index.

Glycaemic measure	Time interval	With diabetes	Without diabetes	Mean difference	*p*-value
FBS	Baseline	154.36	109	45.36	0.0067
	3 months	154	106	48	
	6 months	139	108	31	
	9 months	132	107	25	
PPBS	Baseline	172.9	120	52.9	0.0034
	3 months	171.7	117	54.7	
	6 months	160.19	119.5	40.69	
	9 months	148.8	116.6	32.2	
HbA_{1C}	Baseline	7.2	5.8	1.4	0.0046
	3 months	7.1	5.7	1.2	
	6 months	6.7	5.7	1	
	9 months	6.5	5.7	0.8	

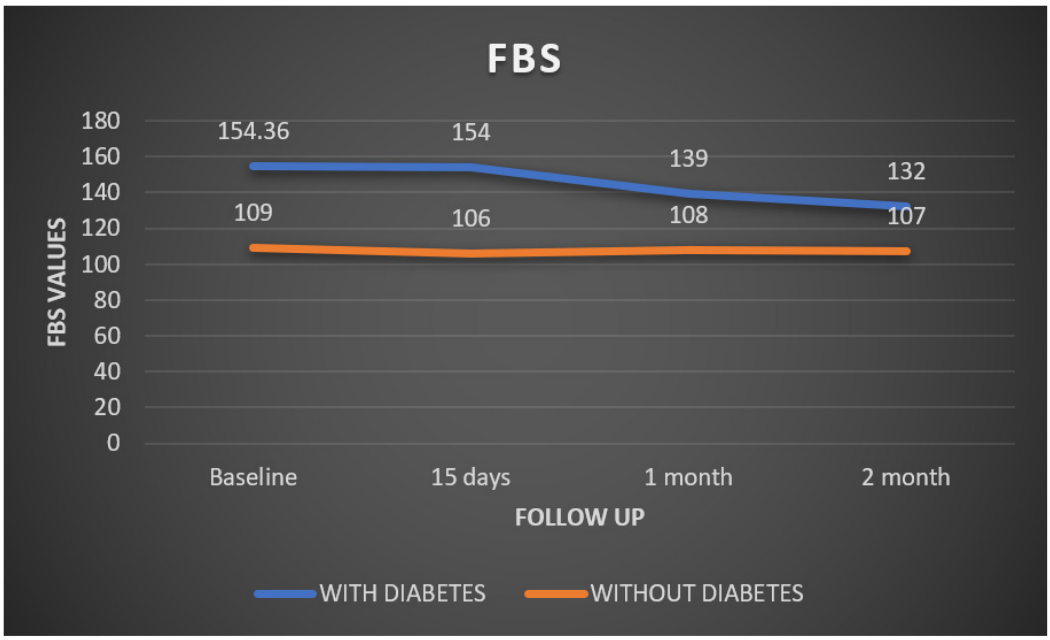

Figure 1: Stable glycaemic values of FBS managed by SGLT2-gliflozins.

DISCUSSION

Although the prevalence estimated to be increase from 4.3% in 2010 to 8.5% in 2030 among older people and the comorbidities such as diabetes worsens the condition (Fadini *et al.*, 2015; Van Nuys *et al.*, 2018). Many strategies for the management of the same are on the path of research. Thus, the findings of this study emphasize the critical role of Dapagliflozin in the management of glycaemic levels in both CHF patients with and without diabetes. It was observed most of the patients 61(34%) belongs to 60-70 of age group with more in males (80%) than females (20%). A similar study by Martinez F A *et al.*, found mean age of population to be (26.2%) were 55 to 64 years of age, followed by 36.2% of 65 to 74 years of age (Martinez *et al.*, 2020). Also, Das P *et al.*, reported the similar results with HF events more in males 57.33% compared to females 42.6% (Dsa *et al.*, 2022). In our study the many of the patients were found to be with more NYHA Class II (65.3%) to NYHA IV, which is supported by Mark C *et al.*,(McMurray *et al.*, 2019). We observed that the CHF patients with diabetes were 50% compared to CHF patients without diabetes in this study, although a meta-analysis conducted by Wang Y *et al.,* found that the prevalence of diabetes was of 25-40% in chronic and as well as in acute CHF patients (Wang *et al.*, 2015).

In the study, the Dapagliflozin given in CHF patients with and without diabetes resulted in fairly stable glycemic index measured through the FBS, PPBS and HbA_{1C} based on the assessment of 3 months, 6 months and 9 months intervals, which is embraced

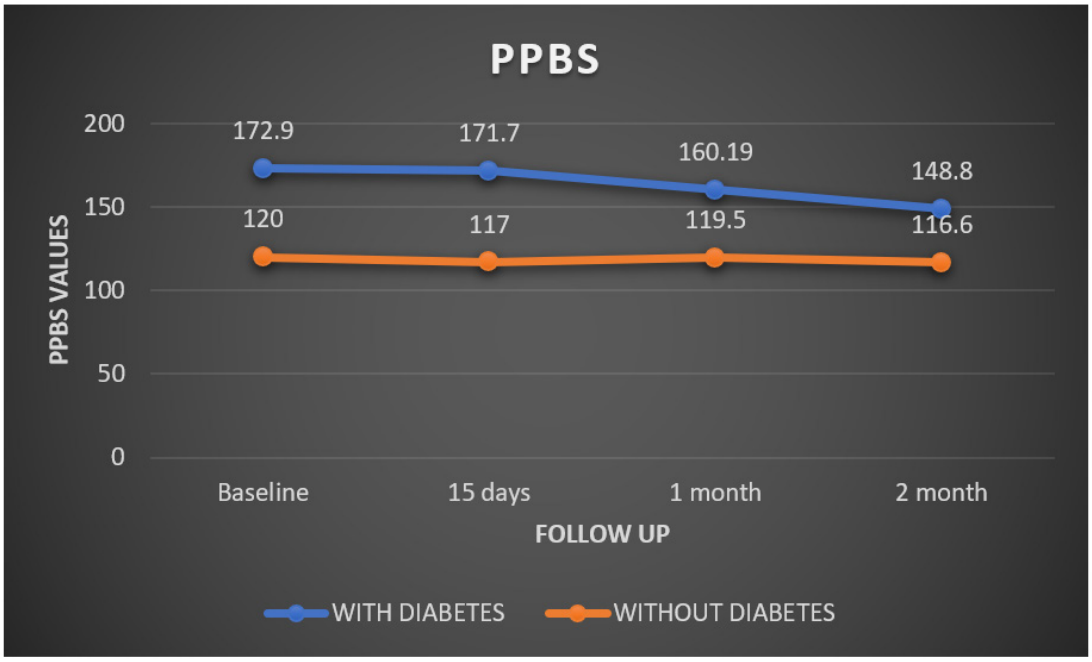

Figure 2: Stable glycaemic values of PPBS managed by SGLT2-gliflozins.

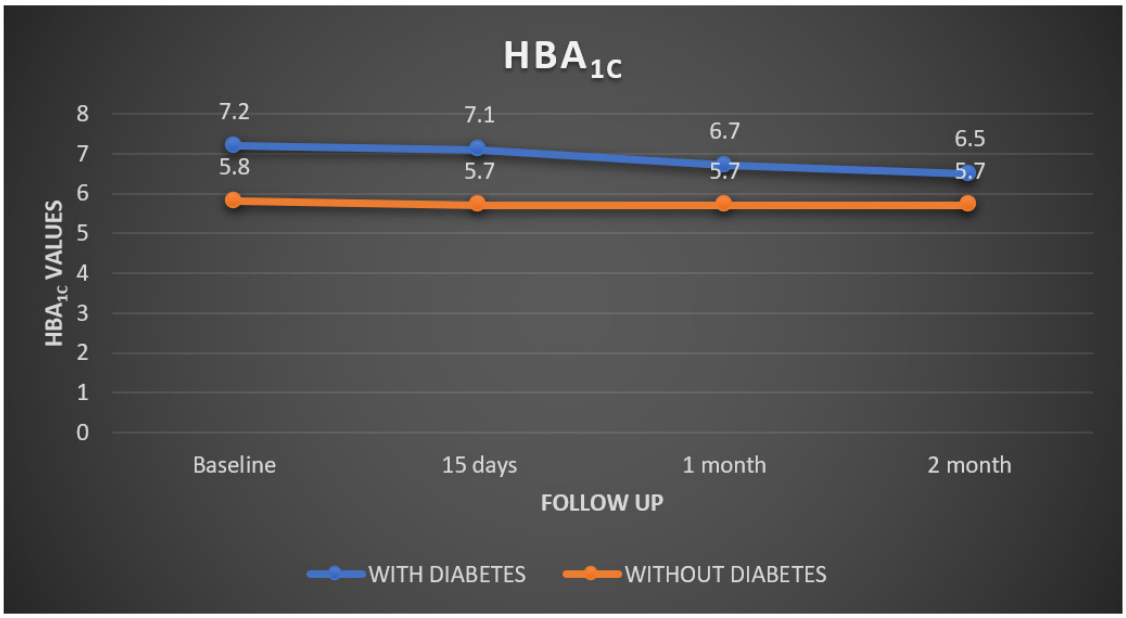

Figure 3: Stable glycaemic values of calculated HbA_{1C} managed by SGLT2-gliflozins.

by many studies that, despite given for CHF patients to improve ejection fraction this SGLT-2 inhibitors maintains the glycemic index of the CHF patients in stable state (Heidenreich *et al.*, 2022; Steiner, 2016; Zelniker *et al.*, 2019). And also, this study mainly sheds light on the less or negligible probability of SGLT2 is associated adverse effects such as hypoglycemia, diabetic ketoacidosis and others, thereby reducing the burden of the same in CHF patients improving the quality of life of the CHF patients, similar results are promoted by Bhatt D L *et al.*, and Jackson AM *et al.*, in their studies (Bhatt *et al.*, 2021; Jackson *et al.*, 2020).

The finding of stable glycemic index in all patients gives evidence for clinical decision-making, also it answers a conflict of interest stating the high incidence of hypoglycemia in Heart failure patients introduced with SGLT2i irrespective of Diabetic Status. The real-world cohort used and statistically significant results add strength to our findings over the clinical trial results that answer only the regulatory requirements. The multiple follow-ups of the cohort at three intervals of 3 months, 6 months and 9 months add precision of our findings. The convenient sampling method adopted and single centered study site from a rural area may listed as the limitation of the study to be acknowledged.

CONCLUSION

CHF is one of the leading causes for morbidity and mortality worldwide with comorbidities such as diabetes pose a challenge on treatment of the same. Although SGLT2 is proven by many studies to be effective approach in the treatment of patients with CHF patients with and without diabetes, the glycemic index is one of the often-overlooked parameters. Thus, our study highlights the importance of stable glycemic index managed by SGLT2 inhibitor Dapagliflozin with negligible hypoglycemic effects.

ABBREVIATIONS

SGLT-2: Sodium Glucose Transporter-2; **CHF:** Congestive Heart Failure; **FBS:** Fasting Blood Sugar; **PPBS:** Post-Prandial Blood Sugar; **HbA1C:** Hemoglobin A1C; **T2DM:** Type 2 Diabetes Mellitus; **ACC/AHA:** American College of Cardiology/American Heart Association; **NYHA:** New York Heart Association; **RAAS:** Renin-Angiotensin-Aldosterone System; **ARNI:** Angiotensin Receptor Blocker and Neprilysin Inhibitors; **ARB:** Angiotensin Receptor Blockers; **CCB:** Calcium Channel Blockers.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL APPROVAL

The study was conducted in accordance with the Ethical guidelines for biomedical research on human participants and Declaration of Helsinki, after obtaining approval from the Institution Ethics Committee (IEC) with IEC no: IEC/AH&RC/AC/10/2025.

INFORMED CONSENT STATEMENT

Informed consent was obtained from all subjects involved in the study.

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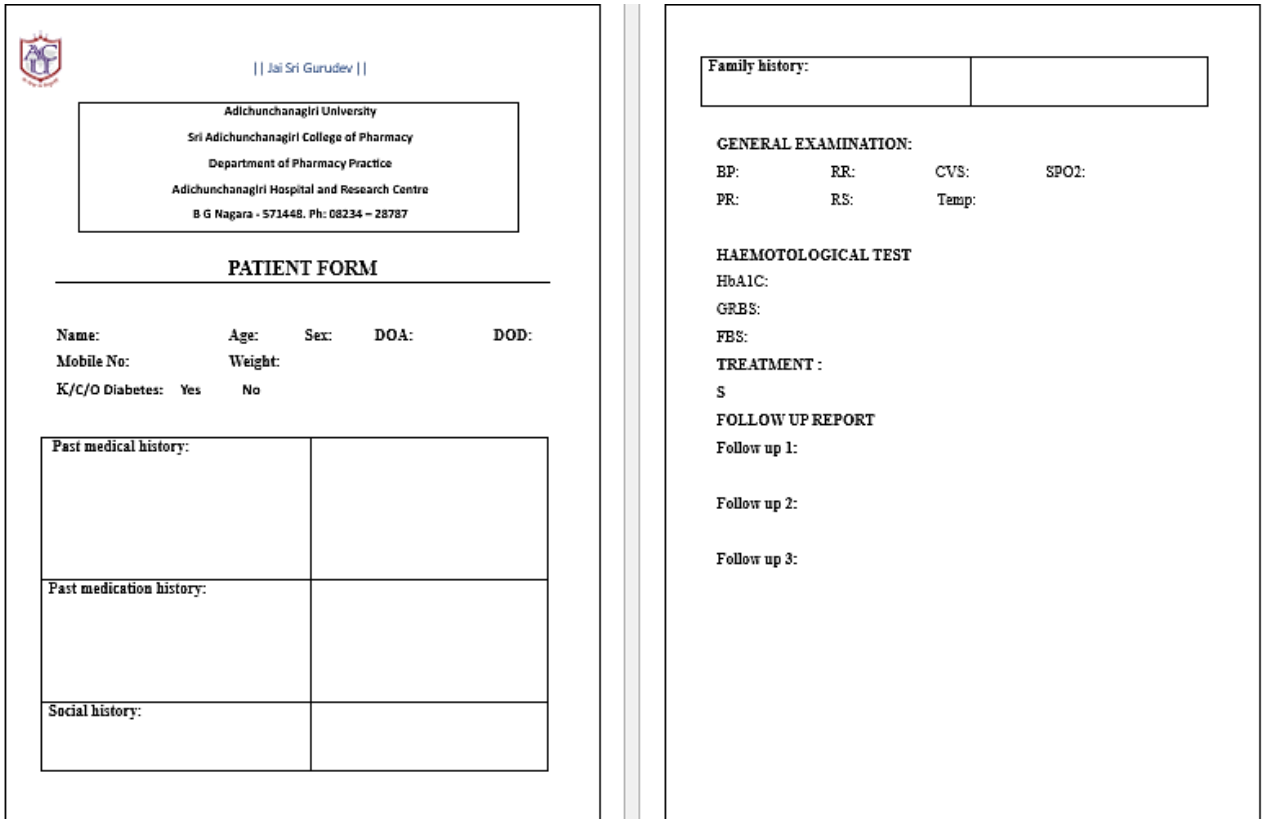

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PATIENT FORM

Name: Age: Sex: DOA: DOD:
Mobile No: Weight:
K/C/O Diabetes: Yes No

Past medical history:	
Past medication history:	
Social history:	

Family history:	

GENERAL EXAMINATION:
BP: RR: CVS: SPO2:
PR: RS: Temp:

HAEMOTOLOGICAL TEST
HbA1C:
GRBS:
FBS:
TREATMENT :
S
FOLLOW UP REPORT
Follow up 1:

Follow up 2:

Follow up 3:

Supplementary File S1: Data Collection Form.