Assessment of Adverse Drug Reaction's From The Treatment Charts of A Hospitalised Patients Suffering With Cardiac Arrhythmias And Complications Due To Adverse Drug Reaction's

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Abstract: Cardiac Arrhythmia is a condition in which the heart's normal rhythm is disrupted. The heart may beat too slowly, too quickly or with an irregular rhythm. Most arrhythmias are harmless, but some can be serious and potentially fatal. Disturbed heart rhythms can restrict blood being pumped around the body, which may cause damage to the brain, heart and other organs. Common causes of arrhythmia are stress, caffeine, tobacco, alcohol, diet pills and cough and cold medicines. Adverse drug reaction is defined as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product.

"Materials and Methods:

Study design: This study was a prospective observational study conducted in tertiary care hospital.

Study population: The study was done in the patients of intensive care unit and acute medical care unit who are suffering with cardiac arrhythmias and complication of anti-arrhythmic drugs.

Study procedure: The data is collected from the patients with patient profile form and patient consent form.

Study duration: The study was conducted for 4 months i.e. from December 2017 to March 2018.

Study material: Patient consent form: Consent was collected by using self designed patient consent form and consent was made into three languages English, Telugu, Hindi.

Ethical approval: The study was approved by institutional ethical committee and tertiary care hospital committee, which has followed all the guidelines of the committee.

Results: Out of 132 patients 90 are willing to give information of the condition and tabulated.

Discussions: Out of 132 patients 90 patients are willing to give information out of which male and females are more and age group of 55-60 suffered more. Maximum people with education level are tertiary and the reason for developing arrhythmias is due to complications of cardio vascular disease. Symptoms developed were fluttering chest pain, tachycardia, bradycardia and chest pain, loss of appetite and the different classes of anti-arrhythmic drugs prescribed for cardiac arrhythmias are mainly beta blockers and calcium channel blockers. The Comorbidity conditions of the patients were hypertension, diabetes mellitus, hyperthyroidism most of the ADR's are treated with different classes of drugs.

Conclusions: Adverse drug reactions are avoidable cause of patients harm. Findings obtained in the present study revealed that there is significant number of adverse drug reactions. The most commonly ADR's are Chest pain, hypotension, Nausea, diaphoresis, Headache, fatigue, weakness, dizziness. Improving the coverage and accuracy of adverse drug reactions can improve delivery of safe and cost effective patient care.

Understanding the mechanism of adverse drug reaction will assist all the clinicians in avoiding these serious, often preventable events. Clinical Pharmacist should play a key role in monitoring the adverse drug reactions, drug interactions, current medication charts of the patients.

Keywords: Cardiac arrhythmias, adverse drug reaction, co-morbidity, atrial fibrillation, atrial flutter, supra ventricular tachycardia.

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I. Introduction

Cardiac Arrhythmia is a condition in which the heart's normal rhythm is disrupted. ^[1] The heart may beat too slowly, too quickly or with an irregular rhythm. Most arrhythmias are harmless, but some can be serious and potentially fatal. ^[2] Disturbed heart rhythms can restrict blood being pumped around the body, which may cause damage to the brain, heart and other organs. ^[3]Common causes of arrhythmia are stress, caffeine, tobacco, alcohol, diet pills and cough and cold medicines. ^[4]

Initial symptoms of arrhythmia include: heart palpitations, a skipped beat or a 'fluttering' sensation in the chest. ^[5] The longer the arrhythmia lasts, the more likely that this condition can affect the way the heart works, causing a range of secondary symptoms . ^[6] These include: Fatigue, Blackouts, Dizziness, and Breathlessness, Rapid heartbeat or pounding, Chest pain. ^[7] In extreme cases, certain types of arrhythmia can cause sudden cardiac death . ^[8]

Adverse drug reaction:

Adverse drug reaction is defined as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product." [9]

Adverse drug effect:

"A potentially harmful effect resulting from an intervention related to the use of a medicinal product, which constitutes a hazard and may or may not be associated with a clinically appreciable adverse reaction and/or an abnormal laboratory test or clinical investigation, as a marker of an adverse reaction." [10]

The terms 'adverse drug effects' and' adverse drug reactions' are commonly used interchangeably, but they have different implications. ^[11]

Adverse drug reactions arise when a compound (e.g. a drug or metabolite, a contaminant or adulterant) is distributed in the same place as a body tissue (e.g. a receptor, enzyme, or ion channel), and the encounter results in an adverse effect (a physiological or pathological change), which results in a clinically appreciable adverse reaction. [12]

Both the adverse effect and the adverse reaction have manifestations by which they can be recognized: adverse effects are usually detected by laboratory tests (e.g. biochemical, haematological, immunological, radiological, pathological) or by clinical investigations (e.g. endoscopy, cardiac catheterization), and adverse reactions by their clinical manifestations (symptoms and/or signs). [13]

This distinction suggests five scenarios: (i) adverse reactions can result directly from adverse effects; (ii) adverse effects may not lead to appreciable adverse reactions; (iii) adverse reactions can occur without preceding adverse effects; (iv) adverse effects and reactions may be dissociated; and (v) adverse effects and reactions can together constitute syndromes. [14]

II. Materials And Methods

Study design: This study was a prospective observational study conducted in tertiary care hospital.

Study population:

The study was done in the patients of intensive care unit and acute medical

Care unit who are suffering with cardiac arrhythmias and complication of

Anti - arrhythmic drugs.

Study procedure:

The data is collected from the patients with patient profile form and patient consent form.

Study duration:

The study was conducted for 4 months i.e. from December 2017 to March 2018.

Inclusion criteria:

- ➤ All the patients suffering with cardiac arrhythmias.
- > Patients age above 45- 60.
- > Of both sexes.
- > Insane minded.
- ➤ Who are willing to give information.

Exclusion criteria:

- ✓ Off sane minded.
- ✓ Pregnancy women.
- ✓ Suffering with sexual diseases.
- ✓ Lack of interest.
- ✓ Paediatrics.

Study material:

Patient consent form:

Consent was collected by using self designed patient consent form and consent was made into three languages English, Telugu, Hindi.

Ethical approval:

The study was approved by institutional ethical committee and tertiary care hospital committee, which has followed all the guidelines of the committee.

Data analysis:

A data was analyzed by demographic details reason for admission and frequency as stay in ICU. Prescribed medications, and severity in conditions. Complications during treatment and survival rate, laboratory values drugs prescribed was analyzed by statistical software's the data was analyzed by using ms – excel and Microsoft word (2007) and result was given by percentage.

Adverse drug reactions are classified into six types (with mnemonics): dose-related (Augmented), non-dose-related (Bizarre), dose-related and time-related (Chronic), time-related (Delayed), withdrawal (End of use), and failure of therapy (Failure).

III. Results

Out of 132 patients 90 are willing to give information of the condition and tabulated below:

Table: 1 -The demographic details of the patients with percentages:

DEMOGRAPHICS	NO.OF PATIENTS	FREQUENCY (%)
Age		
45 - 50	30	33.3%
50 – 55	21	23.3%
55-60	39	43.3%
Sex		
Male	46	51.1%
Female	44	48.8%
Marital status		
Married	90	100%
Unmarried	0	0
Educational level		
Primary	23	25.5%
Secondary	22	24.4%
Tertiary	45	50%
Nutritional status		
Poor	20	22.2%
Average	29	32.2%
Good	41	45.5%
Hygiene conditions		
Average	35	38.8%
Good	40	44.4%
Excellent	15	16.6%
Ethnicity (Indian)	90	100%

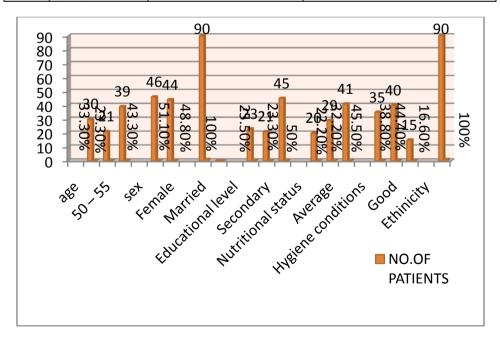


Table: 2 -Reasons for arrhythmias with complaints of cardiovascular disorders with percentage:

REASON	NO. OF PATIENTS	FREQUENCY (%)
Coronary artery disease	10	11.1%
2. Changes in heart muscle.	6	6.6%
3. Injury from a heart attack.	4	4.4%
 Healing process after heart surgery. 		
5. High blood pressure	2	2.2%
6. hyperthyroidism	12	13.3%
7. hypothyroidism	1	1.1%
8. Smoking	2	2.2%
9. Drug abuse	23	25.5%
10. Stress	8	8.8%
11. Diabetes	10	11.1%
12. Sleep apnea	2	2.2%
13. Genetics	5	5.5%
	5	5.5%

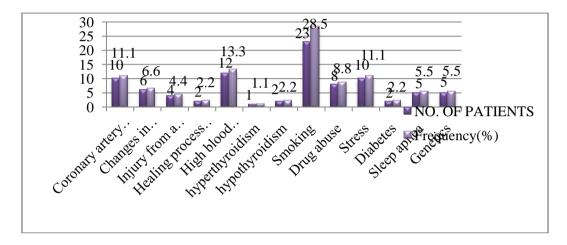


 Table no: 3-The Symptoms Developed Due To Arrhythmias While Admitted In The Hospital:

Symptom	No. Of Patients	Frequency (%)
1. fluttering in chest	12	13.3%
2. Tachycardia	10	11.1%
3. Bradycardia	6	6.6%
4. Chest pain	15	16.6%
5. Shortness of breath	8	8.8%
Lightheadedness or dizziness	13	14.4%
7. Sweating		
8.Fainting(syncope)/ near fainting	20	22.2%
	6	6.6%

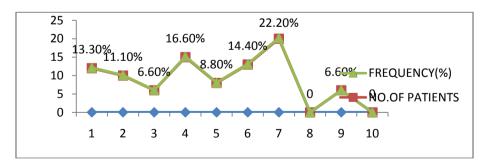


Table no: 4 - The Ranges of heart rate for the people during different conditions was tabulated as below:

S.NO	CONDITION	HEART RATE
1.	Normal resting heart rate	60 to 100 beats per minute (bpm)
2.	Athletic individuals, a normal resting heart rate	40 to 60 bpm
3.	Bradycardia	< 60 bpm
4.	Tachycardia	Above 100 bpm.
	I . Atrial or Supraventricular Tachycardia's	100-300 bpm.
	Ii . Sinus Tachycardia	>100bpm

Table no: 5- the different heart rhythms and beats during Arrhythmias was tabulated as below:

CONDITION	HEART RHYTHM	HEART RHYTHM	
Atrial Fibrillation	100 to 175 beats per minute		
Atrial Flutter: I. Type-I atrial flutter	240 to 340 beats/minute.		
II. Type-II atrial flutter	340-440 beats/minute		
Atrial Tachycardia	100-250 bpm.		
Complete Heart Block	<100/40 bpm		
Supraventricular Tachycardia	100-300 bpm		
Ventricular Fibrillation	No pulse		
Ventricular Tachycardia	170b.p.m		
Wolff-Parkinson-White Syndrome	60-100b.p.m		

Table no: 6- The Side effects of anti arrhythmic drugs prescribed for the cardiac arrhythmias:

SIDE EFFECT	NO. OF PATIENTS	FREQUENCY (%)
Vorsening arrhythmias	9	10%
vorsening armytimias	10	11.1%
Allergic reaction	20	24.4%
Chest pain	12	13.3%
1	2	2.2%
Fainting	5	5.5%
Swelling of the feet or legs	5	5.5%
Blurred vision	9	10%
Bluffed Vision	8	8.8%
Shortness of breath	10	11.1%
Abnormally fast heartbeat	4	4.4%
•	3	3.3%
Abnormally slow heartbeat		
Dizziness or lightheadedness	12	13.3%
Cough	5	5.5%
Bitter or metallic taste or change in taste		
Loss of appetite	6	6.6%
Increased sensitivity to sunlight		2.272
Diarrheoa or constipation		

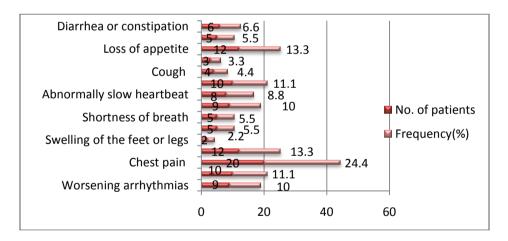


Table no: 7- The Treatment regimen for cardiac arrhythmias with frequency:

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DRUGS	NO. OF PATIENTS	FREQUENCY (%)	
Amiodarone	45	50%	
Flecainide	15	16.6%	
Procainamide	3	3.3%	
Sotalol	6	6.6%	
Metoprolol	14	15.5%	
Verapamil	7	7.7%	

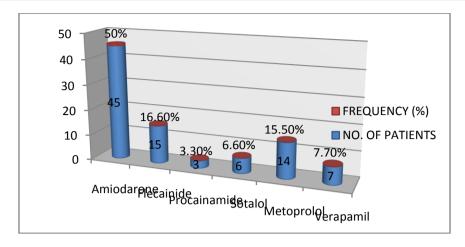


Table no: 8 Various classes of drugs and adverse effects of the drugs used in the treatment of cardiac arrhythmias:

CLASS DRUGS ADVERSE EFFECTS				
1. Beta blockers	Acebutolol Atenolol Bisoprolol Metoprolol Nadolol Propranolol Sotalol Esmolol	Chest pain, hypotension, Nausea, diaphoresis, headache, fatigue, weakness, dizziness, CHF, bradycardia, vertigo, rashes, hyperglycemia, Decreased libido.		
2. Calcium channel blockers				
	Amlodipine Diltiazem Felodipine Isradipine Nicardipine Nifedipine Nisoldipine Verapamil	Lightheadedness, hypotension, fainting		
3. Potassium channel openers	Amiodarone Amizilide Dronedarone Dofetilide Ibutilide	Malaise, headache, Pro-arrhythmias, anorexia, photosensitivity reactions, dyspnea, insomnia, hypotension, drowsiness		
4. Sodium channel blockers	Flecainide Lidocaine Procainamide Propafenone Quinidine	Torsade de points. Blurred vision, headache, heart failure, tremors, seizures, parasthesias, methemoglobinemia, cinchonism, hepatotoxicity, myelosuppression,		
5. Anticoagulants	Warfarin Aspirin Tirofiban	pain, swelling, hot or cold feeling, skin changes, or discoloration anywhere on your body; sudden and severe leg or foot pain, foot ulcer, purple toes or fingers; sudden headache, dizziness, or		

weakness;
unusual bleeding (nose, mouth, vagina,
or rectum), bleeding from wounds or
needle injections, any bleeding that will
not stop.

Table no: 9 The Commonly used drugs with doses and frequency of the patients:

DRUG DOSE NO. OF PATIENTS FREQUENCY				
DRUG	DOSE	NO. OF PATIENTS	(%)	
1. Beta blockers			(70)	
Acebutolol	400-800mg	10	11.1%	
Atenolol	25-50mg	12	13.3%	
Bisoprolol	5-10mg	13	14.4%	
Metoprolol	25-200mg	9	10%	
Nadolol	40-80mg	6	6.6%	
Propranolol	10-80mg	7	7.7%	
Sotalol	40-80mg	20	22.2%	
Esmolol	100mg/10ml inj	13	14.4%	
2.Calcium channel blockers	- · · · · · · · · · · · · · · · · · · ·			
Amlodipine	5-10mg/day	5		
Diltiazem	30-420mg	27	5.5%	
Felodipine	10mg/day	36	30%	
Isradipine	2.5-10mg/day	15	40%	
Nicardipine	20-40mg/day	4	16.66%	
Nifedipine	30-60mg/day	15	4.44%	
Nisoldipine	8-40mg/day	7	16.66%	
Verapamil	80-480mg/day	13	7.77%	
3.Potassium channel openers	gg		14.44%	
Amiodarone	400-1600mg/day	15	16.6%	
	<i>g</i> ,			
Amizilide	5-10mg/day	36	40%	
	2 ,			
Dronedarone	400mg	7	7.7%	
Dofetilide	125-500microgram	13	14.4%	
Ibutilide	0.1mg/ml	15	16.6%	
4. Sodium channel blockers				
Flecainide	50-300mg	27	30%	
Lidocaine	50-300mg	15	16.6%	
Procainamide	0.5-1.0g/day	13	14.4%	
Propafenone	150-300mg/day	7	7.7%	
Quinidine	200-600mg/day	4	4.4%	
5. Anticoagulants				
XX . C .	1.10			
Warfarin	1-10mg	27	200/	
Aspirin	75mg	27	30%	
Tirofiban	5-12mg	15	16.6%	
		13	14.4%	

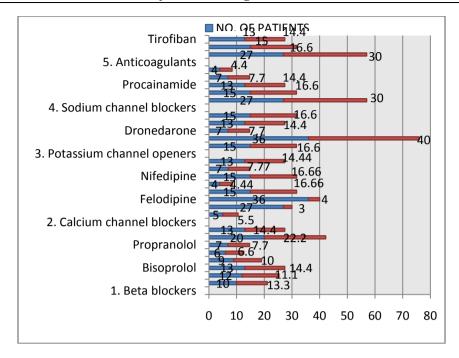


Table no: 10 -The drugs used for Co morbid conditions along with Cardiac Arryhthmias with doses:

DISEASE	DRUGS	-	DOSES
Hypertension:	Telmisartan	Olmesartan	Oral tab:20,40,80 mg
	Hydrochlorothiazide	Atenolol	Oral tab:5,20,40 mg
	Propranolol	Amlodipine	Oral tab:12.5,25,50mg
	Losartan	Ramipril	Oral tab:25,50,100mg
	Metoprolol succinate		Oral tab:10-80mg
			Oral tab:5-10mg
	Metformin		Oral tab:25-50mg
	Glimepiride		Oral tab:1-5mg
	Sitagliptin		Oral tab:50-100mg
Diabetes mellitus:	Pioglitazone		
	Voglibose		0.5-0.85g tab
			1-6mg
	L-thyroxin sodium		100mg
	Methimazole		15-45 mg
			0.2-0.3mg
Hyperthyroidism:			
	Meloxicam		12.5-150micrograms
	Diclofenac		5-10mg
	Ibuprofen		
Osteoarthritis	Acetaminophen		
	Methyl prednisolone		7.5-15mg
	glucosamine		25-250mg
	Aspirin		200-800mg
			325-650mg
			4-125mg
	prednisolone		500-750mg
	Hydroxychloroquine		80-600mg
	sulfasalazine		
Rheumatoid Arthritis:	Azathioprine		
	Leflunomide		5-15mg
	methotrexate		200mg
			500mg
			50-100 mg
			10-20mg
			2.5-25mg

Table no: 11- The Treatment for advese drug reactions developed due to cardiac arrhythmias drugs:

S.NO	ADVESRE DRUG EVENTS	TREATMENT
1.	Headache	Acetaminophen Ibuprofen
2.	Weakness	Prozac-oral Fluoxetine –oral

3.	Cough	Guaifenesin Dextromethorphan
4.	Constipation	Lactulose Linzess (linaclotide)
5.	Edema	Furosemide (lasix)
6.	Chest pain	Pantaprazole Glyceryl tri nitrate Atenolol
7.	Nightmare	Prazosin
8.	Paraesthesia	Gabapentin Prednisone
9.	Impotence	Sildenafil Tadalafil
10.	Insomnia	Eszopiclone (lunesta) Diazepam Anti-histamines (sort term relief)
11.	Epigastric pain	Antacids -ranitidine H2-blockers- omeprazole NSAIDs –paracetamol
12.	Hypotension	Fludrocortisone Midodrine
13.	Palpitation	Propranolol Atenolol Acebutolol
14.	Nausea and vomiting	Aprepitant (Emend®) Dolasetron (Anzemet®) Ondansetron (Zofran®) Ranitidine (Zantac®)

Table no: 12 Number of patients suffered with several adverse drug reactions with drugs prescribed for cardiac arrhythmias with frequencies:

S.NO	ADVERSE EFFECTS	NO. OF PATIENTS	FREQUENCY(%)
1.	Headache	40	44.4%
2.	Weakness	35	38.8%
3.	Cough	30	33.3%
4.	Constipation	25	27.7%
5.	Edema	19	21.1%
6.	Chest pain	18	20%
7.	Nightmare	15	16.6%
8.	Paraesthesia	15	16.6%
9.	Impotence	14	15.5%
10.	Insomnia	14	15.5%
11.	Epigastric pain	14	15.5%
12.	Hypotension	14	15.5%
13.	Palpitation	12	13.3%
14.	Nausea and vomiting	10	11.1%

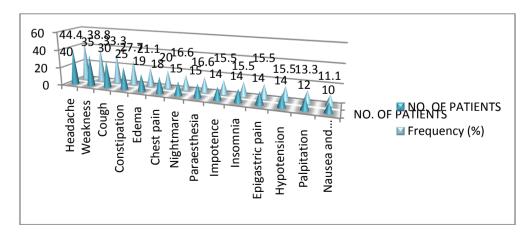


Table no:13 The outcomes observed for cardiac arrhythmias with treatment:

THERAPY EFFECT	NO. OF PATIENTS	FREQUENCY (%)
No effect	2	2.2
Poor	55	61.1
Average	30	33.3
Excellent	9	10

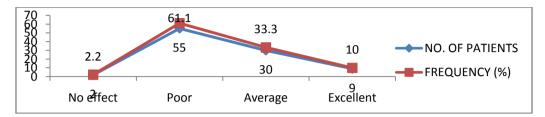


Table no: 14 - Number of patients recovered from cardiac arrhythmias after treatment:

Recovery	No. Of Patients	Frequency
Recovered	67	74.4%
No response	2	2.2%
Died	9	10%
Shifted to higher centre	12	13.3%

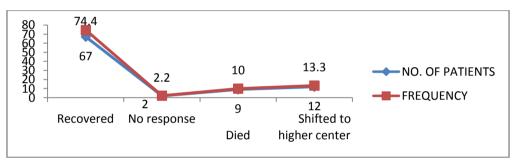
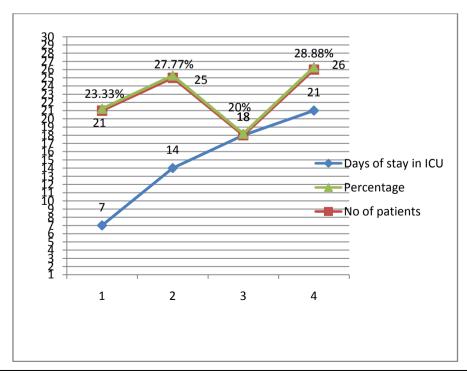


Table: 15- The Days of stay in ICU:

Days of stay in ICU	No of patients	Percentage	
7	21	23.33%	
14	25	27.77%	
18	18	20%	
21	26	28.88%	



IV. Discussion

Out of 132 patients 90 patients are willing to give the information out of which 46 (51.1%) were male and 44 (49%) were females with the age group of 45-50 were 30 (33.3%), 50-55 were 21 (23.3%), 55-60 were 39 (43.3%), marital status of the patients were married 90 (100%), maximum number of people have been in educational level is in tertiary care about 45 (50%) and minimum were secondary 22 (24.4%), nutritional status of the patients was maximum good 41 (45.5%) and minimum were average 29 (32.2%), with hygienic conditions of good 40 (44.4%) and minimum with average 35 (38.8%) and all the patients belong to ethnicity of India 90 (100%). The reasons for developing arrhythmias with the complaints of cardiovascular problem of coronary artery disease 10 (11.1%), changes in heart muscle 6 (6.6%),injury of heart due to heart attack 4 (4.4%), healing process after heart surgery 2 (2.2%), high blood pressure 12 (13.3%), hyperthyroidism 1 (1.1%), smoking 23 (25%), drug abuse 8(8.8%), stress 10 (11.1%), diabetes mellitus 2 (2.2%), sleep disturbances 5 (5.5%) and genetically altered during birth are of 5 (5.5%).

The symptoms developed due to arrhythmias while admitted in the hospital were observed were fluttering chest pain 12 (13.33%), tachycardia 10 (11.11%), bradycardia 6 (6.6%), chest pain 15 (16.66%), sweating 20 (22.22%) and fainting 6 (6.66%) were seen after admission in the hospital. The ranges of heart rate for the patients was mentioned.

The different heart rhythms and beats during hospital stay were monitored with different condition and maximum was observed or no patients in ventricular fibrillation.

The side effects of anti arrhythmic drugs prescribed for cardiac arrhythmias with different side effects was observed were mostly chest pain 20 (22.22%), loss of appetite 12 (13.33%), fainting 12 (13.33%), allergic reactions 10 (11.11%), Dizziness/lightheadedness 10 (11.11%), abnormally increased heart rate 9 (10%), decreased heart rate 8 (8.88%), diarrhoea /constipation 6 (6.66%), shortness of breath 5 (5.55%), blurred vision 5 (5.55%) with cough 4 (4.44%), metallic or bitter taste 3 (3.33%) and swelling of feet's/legs of 2 (2.22%) people were observed. The treatment regimen for the cardiac arrhythmias is of mainly amiodarone of 45 (50%), flecainide 15 (16.66%), metaprolol 14 (15.55%), verapamil 7 (7.77%) and procainamide 3 (3.33%) which is mainly used to treat cardiac arrhythmias. The different classes of anti-arrhythmic drugs prescribed for cardiac arrhythmias are mainly beta blockers, calcium channel blockers, potassium channel openers, sodium channel blockers and anti coagulants were the drugs classes mainly prescribed for the treatment of cardiac arrhythmias. The most commonly used drugs for the treatment of cardiac arrhythmias was tabulated with the usage and dose frequency and availability. The comorbid conditions of the patients were hypertension, diabetes mellitus, hyperthyroidism, osteoarthritis, rheumatoid arthritis with different drugs to the patients along cardiac arrhythmias drugs was mostly detected drugs was prescribed. Mostly the adverse drug reactions developed with cardiac arrhythmia was treated with drugs and mostly the adverse drug reactions are headache, weakness, cough, constipation, edema, chest pain, nightmare, paraesthesia, impotence, insomnia, epigastric pain, hypotension, palpitation and nausea and vomiting.

The number of patients suffered with several adverse drug reactions and most number of people suffered with percentage was decreased most of adverse drug reactions are mainly headache 40 (44.44%) and weakness 35 (38.88%), cough 30 (33.3%), constipation 25 (27.77%), chest pain 18 (20%), nightmares 15 (16.66%), paraesthesia 15 (16.66%), impotence 14 (15.55%) and so on last is nausea, vomiting 10 (11.11%). The treatment out comes due to cardiac arrhythmia for the patients were mainly poor 55 (61.11%), average 30 (33.33%), excellent 9 (10%) least no effect 2 (2.22%) was observed in our study.

The patient recovered from cardiac arrhythmias adverse drug reactions combinations were mostly 67 (74.44%) recovered, 12, shifted to higher center and 9 (10%) died during the treatment. We have also found that maximum number of patients (26) were in ICU is for 21 days.

V. Conclusions

Adverse drug reactions are avoidable cause of patients harm. Findings obtained in the present study revealed that there is significant number of adverse drug reactions. The most commonly ADR's are Chest pain, hypotension, Nausea, diaphoresis, Headache, fatigue, weakness, dizziness. This highlights necessity for the presence of clinical pharmacist to rationalize the therapy and minimize adverse drug reactions.

The topic of adverse drug reactions has received a great deal of recent attention from the regulatory, scientific, and healthcare communities worldwide. With their detailed knowledge of medicine, clinical pharmacist has the ability to relate the unexpected symptoms experienced by patients to possible adverse effects of their drug therapy. Blood levels of drugs, particular those with narrow therapeutic indices and significant toxicities, which may lead to serious clinical problems, can also be monitored. Improving the coverage and accuracy of adverse drug reactions can improve delivery of safe and cost effective patient care.

Understanding the mechanism of adverse drug reaction will assist all the clinicians in avoiding these serious, often preventable events. Clinical pharmacist should play a key role in monitoring the adverse drug reactions, drug interactions, current medication charts of the patients.

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Conflict of interest:

Yes

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