Institute of Health Management Research, Jaipur

STATUS OF CARDIAC CARE PATIENT SUPPORT PROGRAMME ON HEART FAILURE PATIENTS

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INTRODUCTION

The pharmaceutical companies are getting more inclined towards patient support programs (PSPs) which assist patients and/or healthcare professionals (HCPs) in more desirable disease management and cost-effective treatment. The utmost objective of these programs is patient care.

The lack of adherence of patients to prescribed medicines is a huge challenge to pharmaceutical industry worldwide. Therefore, bridging this gap of adherence is utmost necessity for pharma organizations to preserve their brand value and sale loss. A PSP is assistance for patient or interaction with patient carers outlined to aid in management of medication and disease outcomes. It also involves interaction with HCPs for support to the patients.

Heart failure is a chronic disease and for patients suffering with chronic diseases, a better understanding of a health care programme that seeks to improve quality of life of the patient is desirable. A more patient- focused program which seeks to improve the well-being of the patients is needed. Win-for-patients cardiac care is a patient support programme initiated by **Novartis** with an objective to support heart failure patients to manage their lifestyle, adhere to physician’s advice and achieve better outcomes. The main objective of this research is to study the impact of this programme on patients who are enrolled and are on Vymada therapy.

PATIENT SUPPORT PROGRAMME

A patient support programme is an organised system where a marketing authorisation holder receives and collects information relating to the use of its medicinal products. Examples are post-authorisation patient support and disease management programmes, surveys of patients and healthcare providers, information gathering on patient compliance, or compensation/re-imbursement schemes.

Majority of patient support programmes (PSP) fall into one of three categories with the following objectives:

To support patients and help them take their medications as prescribed (compliance/adherence)

To help patients understand their condition and provide advice on managing disease e.g. lifestyle (exercise or diet), disease education

To provide a service or financial assistance or reimbursement support for patients also known as patient assistance programs)

Reports of adverse events are usually obtained incidentally to the main purpose of the programme

Not designed to “actively solicit” adverse event reports

•General questions related to the well-being of patients may stimulate the reporting of safety information

•Patients may also voluntarily mention an adverse event on their own initiative during the course of the interaction or at another time through other means (e.g. dedicated PSP phone line/email or general company contact number/email).

PSP – compliance /adherence

• Programmes are designed to use multiple methods of interaction and multiple media to assist in improving compliance

• Factors which may contribute to non-adherence include:

– Forgetfulness

– Confusion due to a complex treatment regimen

– Struggle with self-administration

– Cost

– Side effects

– No perceived benefit

• Some of these factors lead to intentional non-adherence and others to unintentional non-adherence.

• Combinations of interactions with the patient may be used in a single programme

• Each contact has the potential for generating adverse event information

Interactions to minimise unintentional non-adherence may include:

– Patient education

– Assistance administering the medication (homecare programmes)

– Reminders via SMS text messaging or mobile apps

• New generation of PSPs aimed at minimising intentional non-adherence using health psychology to affect behavioural change through understanding the patients' attitudes and beliefs and typically involve:

– Education and counselling where a counsellor talks to a patient about their illness and treatment as opposed to providing material in print (although this may be done in addition)

• Interaction type impacts the likelihood of adverse event reporting

PSPs – Disease Management

- Not product specific; patients can be on different medications
- Patient education to increase disease awareness and improve disease management
- Typically conducted through groups sessions using educational material
- Aim to improve individual quality of life through education, e.g – Diabetes disease management programmes typically provide education on the role of diet and exercise, self monitoring of blood sugar, taking medication, reducing risks of complications from diabetes etc.
- Adverse Events may be mentioned voluntarily during the course of the interactions Examples of PSPs
- A wide variety of PSPs use multiple methods of interaction and media; " no one size fits all"
- Each PSP takes into account not only the illness or medication but also the characteristics of the patient involved
- Digital media is used increasingly which fits better with patient lifestyles (i.e. mobile apps or SMS text messages, social media etc).

Patient Support Programme for cardiac care

Win-For-Patients cardiac care is a patient support programme initiated by **Novartis** with an objective to support heart failure patients to manage their lifestyle, adhere to physician's advice and achieve better outcomes. The programme is started in association with a Heart failure drug named Vymada or Entresto. Novartis runs patient support programme for 204 chronic ailments including cardiac, oncology, respiratory and visionary aliments. As per pharma code of conduct; a pharma associate cannot interact with the patient directly hence the programme is implemented by a Healthcare service provider Organization; Indegene. The programme was launched in 2016.

The training and implementation part of the programme is completely handled by Indegene. Win-For-Patients cardiac care is an integrated care for patients suffering from chronic heart failure. The major components of this programme include;

- Support for adherence to and compliance with physician's advice
- Education and counselling to patients and caregivers
- Team of qualified and committed educators for patient support
- Home delivery of medicine through participating pharmacies

The major targeted outcomes of the programme include;

- Ensures adherence to physician’s advice to improve health outcome
- Empowers patients to manage heart failure more actively
- Supports caregiver for enhanced quality of care
- Provides value add to patients

NEED FOR CARDIAC CARE PATIENT SUPPORT PROGRAMME

1) AE Reporting

An Adverse Event (AE) is any untoward medical occurrence in a patient or clinical-trial subject administered with a Medicinal Product / Medical Device, and which does not necessarily have to have a causal relationship with this treatment.

If the patient encounters any problem or side effect during the therapy medication; it is important that the event should be reported; so that it can be eliminated.

As per the pharma code of conduct, the pharma company associates cannot directly interact with the patient, and hence a Third party is appointed for implementing the patient support programme who can interact with patients and report adverse event.

2) Improving therapy Adherence in patients

According to recent studies negligence among patients in adhering to the therapy is high which majorly contributes to increase rehospitalization in Heart failure patients.

To ensure therapy adherence in patients; the programme is of major value and importance.

With respect to recent findings by Novartis Vymada in association with Win-For-Patients cardiac care is known to have reduced 53% rehospitalization in heart failure patients and supposedly have increased the life expectancy of patients by 5 Years.

3) Counselling benefits to patients

The patients are counselled on various topics like- diet, exercise, symptom management and stress management. Along with periodic tele counselling, the patients are also given inputs like water bottle (to keep a track of the fluid intake), salt sachets to monitor salt intake, booklets on stress management, symptom management, exercise and activities and dietary recommendations to understand the disease better.

This supports patients and their caregivers to manage their symptoms effectively.

MODE OF OPERATION OF WIN-FOR-PATIENTS CARDIAC CARE PROGRAMME

Patient counsellor meets the empanelled doctors with the pharma associates and explains the patient support programme and its benefits to the doctor and takes permission for counselling the patients in his/her OPD.

If the doctor permits the counsellor visits the Doctor's OPD

The doctor refers the Heart failure patients to the counsellors.

The counsellor interacts with the patient and the caregiver and collects some brief insights about the patient; like how long the patient is diagnosed with heart failure, current medications and currently prescribed medications.

The counsellor obtains consent from the patient for enrolling in the programme. If the patient agrees, the patient is initially explained the benefits of the programme and then counselled on Heart failure.

The patient is counselled on critical topics like;

- Living with heart failure
- Symptoms management and monitoring
- Importance of adherence
- Tips on diet
- Managing stress better
- Tips on exercise

After counselling the patient is enrolled in the programme through a supported software named optimax.

OBJECTIVE

1. To assess the status of cardiac care patient support programme on Heart Failure patients
2. To assess the role of patient counsellor’s in ensuring therapy adherence through patient support programme.
3. To know the satisfaction level of patients receiving counselling through patient support program .

METHODOLOGY

- **Study Design-**

The study design adopted for this research is Descriptive cross-sectional study design.

- **Setting of the study-**

The study was conducted in Udaipur district of Rajasthan.

- **Study period-**

The duration of the study was 3 months (4th February to 3rd may).

- **Study population-**

The study included Heart failure patients enrolled in the Win-for-patients cardiac care programme.

- **Sample Size-**

54 Heart failure patients were included in the study. The data of the patients was obtained from the Optimax entries (Software tool for exercising patient follow up by the counsellors)

- **Data Collection-**

The data was collected from enrolled patients through designed structured questionnaire telephonically and face to face.

- **Data collection tool-**

For this study, the research instrument used was a questionnaire consisting of relevant questions related to the study topic.

- **Inclusion Criteria-**

Heart failure patients enrolled into Win for patients' cardiac care programme.

- **Exclusion Criteria**

Heart Failure patients who are not on Vymada therapy.

- **Data Analysis Technique:**

The technique used for the purpose of data analysis is MS Excel. After the whole data was collected from the respondents, it got analysed and the interpretations were formulated in MS Excel by taking the help of various graphs and pie charts.

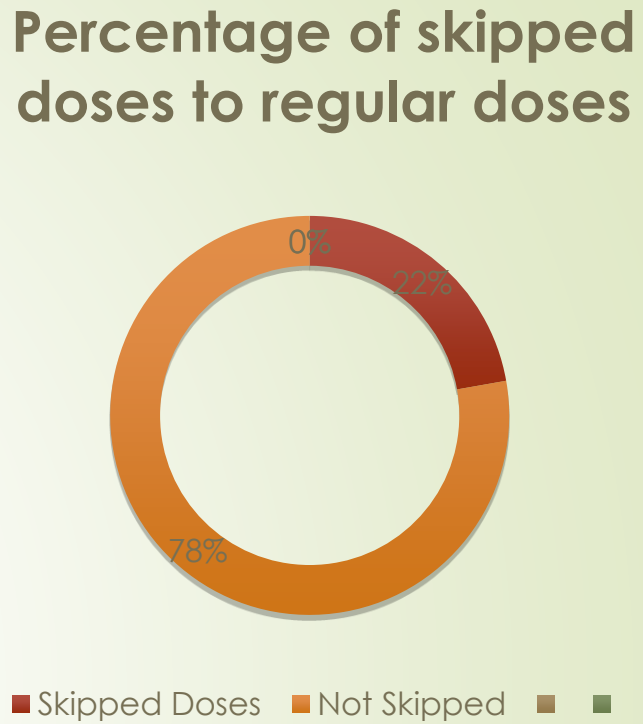
ANALYSIS OF DATA

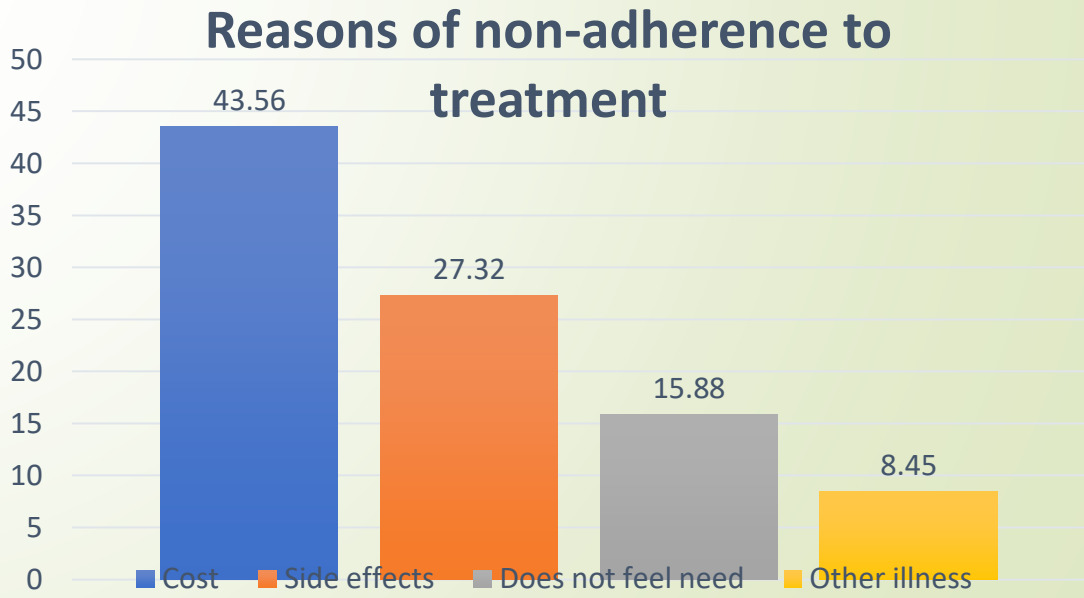
Out of the total 54 patients enrolled into the programme 22% patients reported case of Skipped dose in the last one week.

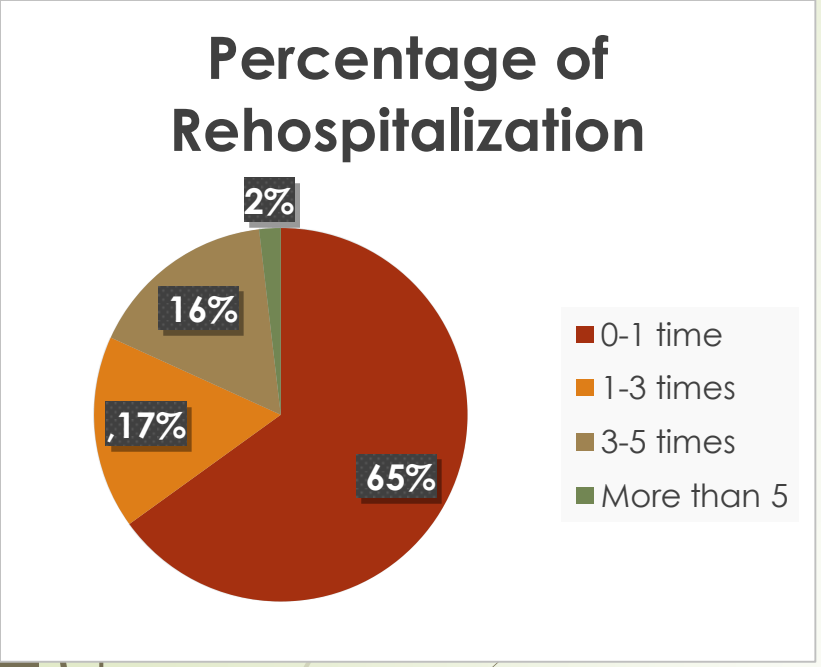
Out of the total 54 patients 22% patients reported that they have skipped therapy Doses in the last one week.
The respondents were asked reason for their non-compliant behaviour in which cost was the major reason which recorded 43.56% responses.
Further 27% respondents showed non-adherence because of some adverse event
The heart failure medication has 3 major side effects;

- Hypotension
- Hyperkalaemia and dizziness.

Further the respondents reported non compliance because they had started Recovering and did not feel the need and one reason was they were facing other illness Like kidney disorders, diabetes and hypertension which are usually associated with Heart failure

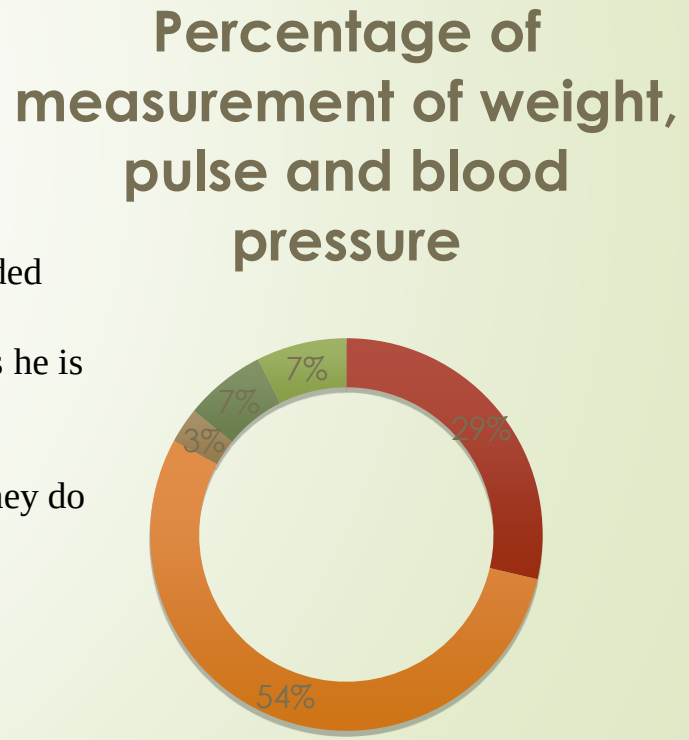




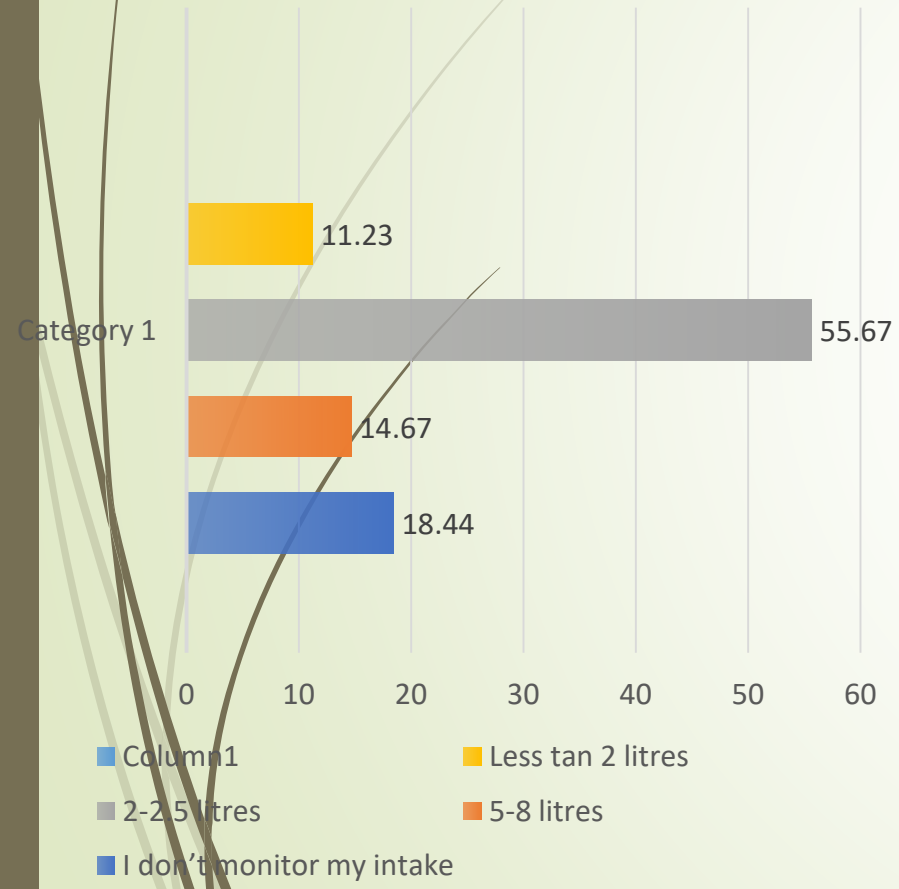


- Rehospitalization is very common in heart failure patients because of symptom worsening. This adds to lot of financial and mental burden on patients and their families.
- Out of the 54 respondents 65% patients were hospitalized 0-1 time in the last 3 months and only 2% patients responded that they were hospitalised more than 5 times.
- The major reason for rehospitalization in heart failure patients is because of lack of proper management the symptoms might get worsen and the patient might require immediate medical attention.

- The heart failure management programme includes an important topic of symptom management In heart failure patients.
- The patients are provided with a booklet which explains the symptoms of heart Failure. The patient is also provided counselling on this aspect.
- Then the patient is asked to measure weight, pulse rate and blood pressure and also Note the additional symptoms he is facing.
- This helps in understanding the recovery status which works well for both; doctor as well as patient.
- Out of the total 54 respondents; 54% responded that they measure 2-3 times in a week, only 7% responded that they do this on daily basis. Simultaneously 7% responded that they never track their symptoms.
- Once a week and never while 3% responded that they track their symptoms 4-5 times.

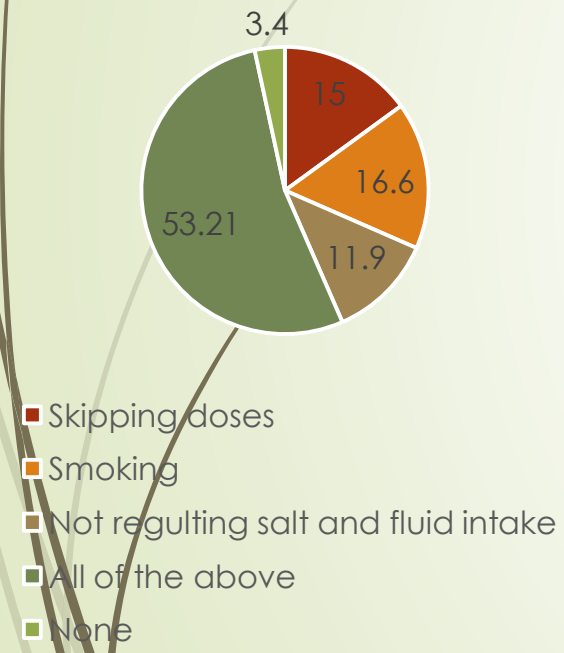


PERCENTAGE OF FLUID INTAKE



- Heart failure patients who are currently diagnosed and have initiated the medications in the past 3 months, the patient is advised to restrict his fluid intake because the fluid starts getting accumulated in the body. Because of this the patient starts gaining weight and encounters swelling mostly in lower legs. If the patient is on diuretics it is mandatory to restrict the fluid intake of the patient to 2-2.5 litres per day.
- Among the 54 patients enrolled all patients were advised to restrict their fluid intake. This data was obtained from the system entries in the software.
- About 55% respondents responded 2-2.5 litres fluid intake per day which is considered ideal for heart failure patient.
- The patients who responded less than 2 litres were patients with EF less than 15% and hence they are advised more fluid restriction while the patients who responded 5-8 litres were around 15% and these patients were on therapy for long time so they were advised by the doctor to increase their fluid intake little.
- 18% patients do not monitor their intake, which can further lead to symptom worsening

Percentage of patient knowledge about factors contributing more to worsening of heart failure symptoms

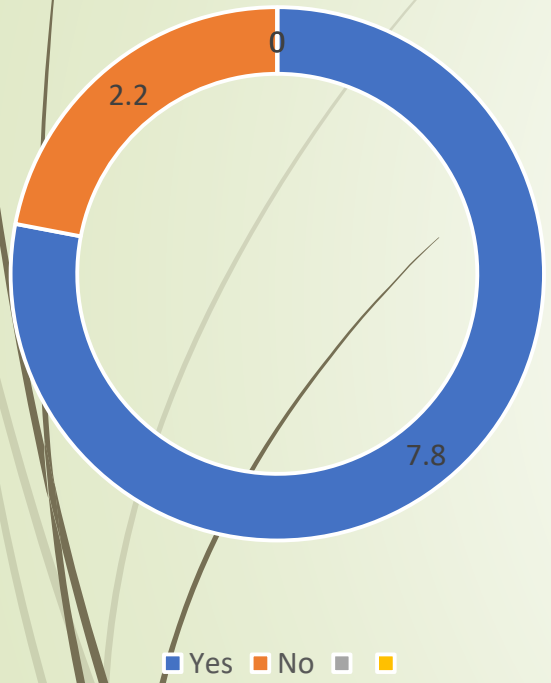


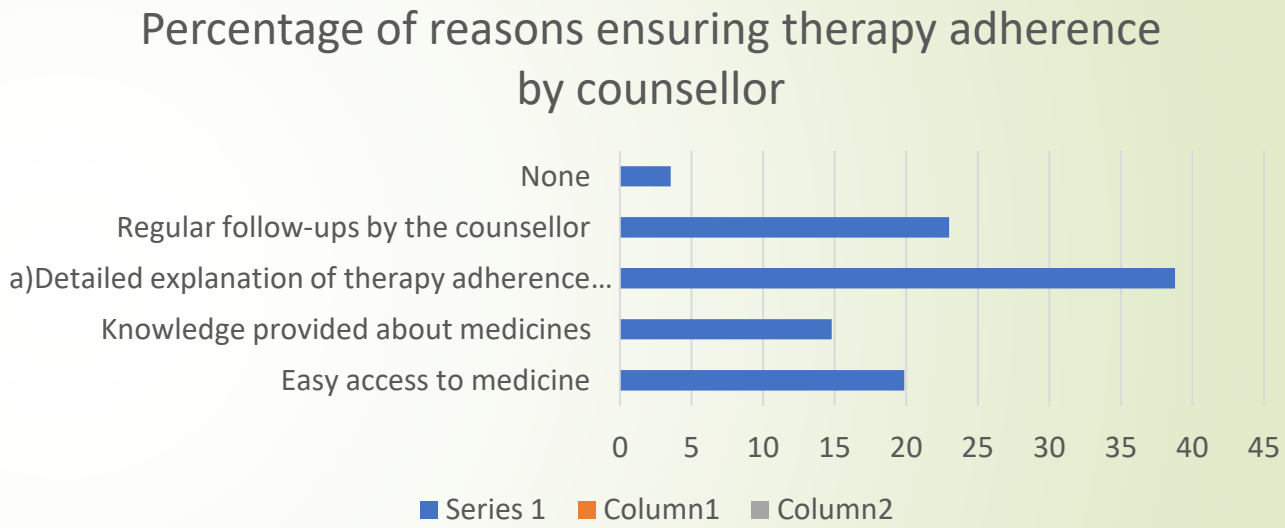
- The presented graph shows the patient knowledge and understanding of heart failure Symptoms and management.
- The three mandatory compliant issues are listed and the patient is asked to choose the Most affecting factor to heart failure.
- Out of the total 54 patients surveyed,

Around 53% patients responded all of the above which was the ideal choice of option.
The remaining respondents who chose only one option out of the three might be in a practice Of non compliance to therapy and symptom management.

Percentage of benefit of counselling in ensuring therapy adherence

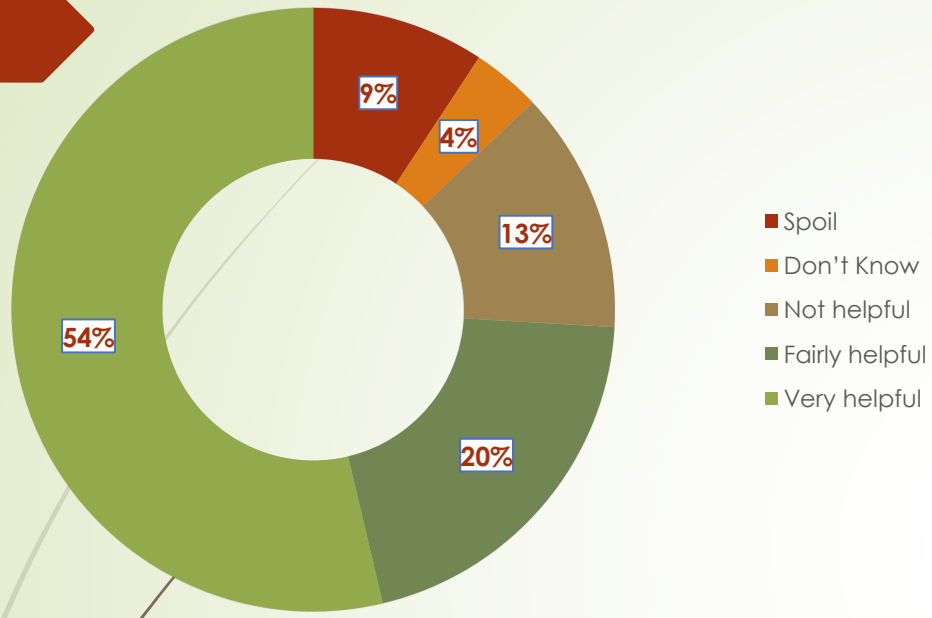
The pie chart reflects patients response on patient perspective on benefit of counselling in ensuring therapy adherence
Out of 10% ; 7.2% responded with yes saying that they take their medicine on time.





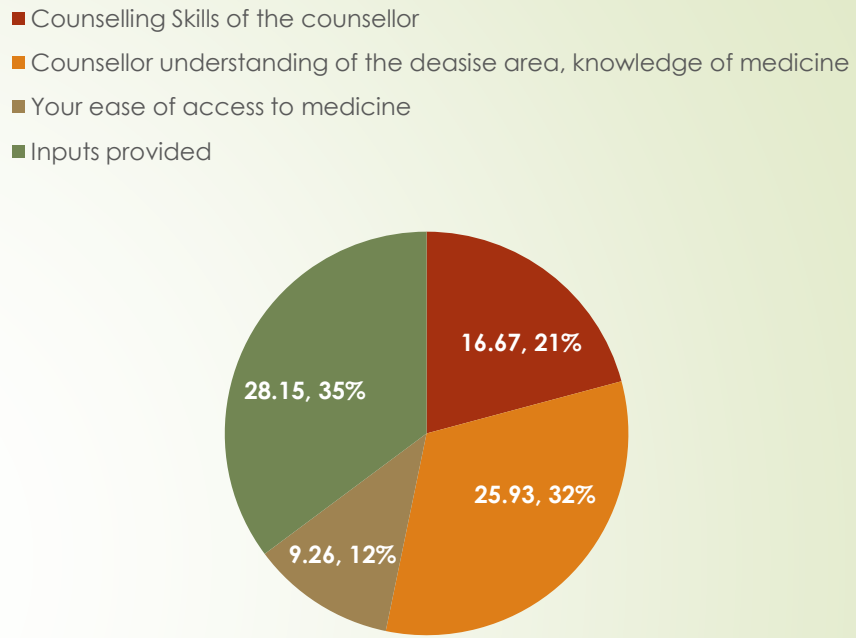
- Out of the 54 patients the highest rated response was for the detailed explanation of therapy adherence by counsellor, around 40%
- After that the second highest respond was recorded for regular follow-ups and visits by the counsellor, Around 23%
- 15% responded on knowledge provided on medicines which is also very important and around 20% responded for easy availability of medicine on discounted price directly through stockist or online pharmacies .

PERCENTAGE OF PATIENT SATISFACTION



Out of 54 patients only 54% respondents rated the programme satisfactory with very helpful response

SATISFACTION WITH RESPECT TO VARIOUS PARAMENTERS



Around 21% respondent responded with satisfactory counselling service
Which indicated that the counselling is not up to the mark

RESULT

Due to advancements in healthcare industry, nowadays, the patients have approached to more information, which can be profuse and also empowering. If patients are aware of the processes to steer healthcare services, understanding of the rationale behind specific treatment, adherence to treatment course and disease management, then it can make a big difference to patient's expedition. The patients require persistent inspiration and support for adherence to supervision plan, especially in cases of management of chronic disease

- The data analysis shows that out of the total 54 patients included in the study the adherence rate of therapy was much higher than the non-adherence. Further the reason for non-compliance were studied which showed the major reason was cost of the therapy following the side effects.
- To reduce rehospitalization is also one of the objective of patient support programme which was recorded by 65% patients by zero or one readmission in hospital.
- The compliance towards symptom tracking was studied which showed 54% patients fill the symptom tracker twice or thrice in week and only 7% fill it daily. This shows non compliant behaviour of patients towards symptom tracking.
- Only 18% patients showed non compliance in fluid restriction. Which shows that counselling was effective in this area of PSP.
- It was observed that 53% respondents had knowledge of symptom worsening.
- About 7.8% respondents out of 10 feel that counselling has provided them benefits of ensuring therapy adherence. Out of the 54 patients the highest rated response was for the detailed explanation of therapy adherence by counsellor, around 40%
- After that the second highest respond was recorded for regular follow-ups and visits by the counsellor, Around 23%
- 15% responded on knowledge provided on medicines which is also very important and around 20% responded for easy availability of medicine on discounted price directly through stockist or online pharmacies .
- Out of 54 patients only 54% respondents rated the programme satisfactory with very helpful response
- Around 21% respondent responded with satisfactory counselling service

CONCLUSION

- This study of 54 patients provides the first assessment of the impact of patient support programme on treatment adherence and decrease rehospitalization further reducing cost implications and adverse events in patients suffering from heart failure.
- The data provides support for prescribing physicians to encourage enrolments in win-for-patients cardiac care for chronic conditions and for pharmaceutical companies to further develop and invest more in-patient support programmes.
- The success of the cardiac therapy depends on the patient compliance, to ensure improvement in heart failure symptoms.
- Educating the patient before the initiation of therapy, and providing counselling on HF symptom management, lifestyle modification and importance of therapy adherence, and continuously monitoring and supporting adherence can reduce the burden of the doctor to spend more time on examination and diagnosis of patient.

Recommendations

- In order to increase more compliance in patients the cost of the therapy needs to be modified. More research should be done on reducing the side effects of the therapy.
- To initiate more reduction in hospitalization patient should be encouraged by doctors and nurses to manage their symptoms effectively and show compliance for therapy as well as heart failure management advice.
- The compliance on fluid restriction part needs to be improved through more effective counselling on this aspect.
- The patient knowledge on symptom tracking must be enhanced through improved counselling.
- As the programme is new much research has not been done and its effectiveness is not much because the doctors are not showing much interest in the programme.
- The gap between Doctors and counsellors should be reduced.

LIMITATIONS:

- This is a kind of pilot study and it was conducted out only in a specific geographical area.
- The size of the sample that was taken for the study was short, so it has affected the accuracy of the outcomes.
- The time during which study was performed was of short duration, so more data from the respondents could not be collected.
- Time duration of the interview was short due to the working hours of the respondents.

DISCUSSION

- This study shows that patient support programme is of great importance in managing heart failure symptoms.
- Patient's perspective on impact of the programme was gathered which revealed that the programme has achieved better outcomes with respect to increased therapy adherence and decreased rehospitalization.
- Through Symptom tracking and fluid restriction management of heart failure has become easy and symptoms which worsen the heart have also reduced.
- Patient support programmes should become an integral part of every therapy dealing in chronic ailments. Role of counsellors should be more specific when counselling heart failure patients.

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