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A PROSPECTIVE OBSERVATIONAL STUDY ON EVALUATION OF EFFECT OF PATIENT COUNSELLING BY CLINICAL PHARMACIST IN IMPROVING MEDICATION RECONCILIATION IN PATIENTS WITH CIRRHOSIS AT A TERTIARY CARE HOSPITAL.

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ABSTRACT

Title: A prospective observational study on evaluation of effect of patient counselling by clinical pharmacist in improving medication reconciliation in patients with cirrhosis at a tertiary care hospital. **Scope of experiment:** Liver cirrhosis is the only major cause of death still increasing year-on-year. Complex medication therapy, chronic nature of the disease and many other factors specific in this population, cause decreased patient compliance. The clinical pharmacist can play an essential role in improving medication adherence and reducing the incidence of various complications and recurrent hospitalisations. **Objective:** The study is to assess the effectiveness of patient counselling in improving medication adherence among livercirrhosis patients based on disease severity. **Method:** A total of 100 patients with clinically diagnosed liver cirrhosis who had visited gastroenterology clinic during the study period and meeting the inclusion criteria were included in the study.. Patients were educated for a period of 6 months. Patients adherence score was observed on baseline and endvisit. Patients medication adherence was evaluated by Morisky-8 item medication adherence questionnaire. Parametric and non-parametric tests were used. **Result:** Patient education resulted in better improvement in patients adherence score. Medication adherence was found to be improved significantly ($p < 0.000$). Conclusion: Patient counselling improved medication adherence among cirrhosis patients.

KEYWORDS: Prospective, Cirrhosis, Patient counselling, Medication reconciliation.

INTRODUCTION

Cirrhosis" derives from the Greek word κίρρος, meaning gross (tawny, nodular, and firm) describes microscopic appearance of the chronically diseased and physiologically burned out and dysfunctional liver.[1] In breif, cirrhosis (end-stage liver disease) is a chronic, ongoing, long-term disease of the liver.[2] The main causes of livercirrhosis are sustained excessive alcohol consumption, Viral hepatitis B and C and fattyliver disease-however, there are many other possible causes. Liver cirrhosis causes significant morbidity and mortality, mainly due to complications [hepatic encephalopathy, ascites, hepatorenal syndrome, portal hypertension, variceal haemorrage, hepatocellular carcinoma][1,4] Centres for disease control and prevention's National Center for Health Statistics, estimates cirrhosis as the 12th leading cause of death overall and the fifth leading cause of death for patients aged 45 to 54 yrs.[3] The progression to cirrhosis is very variable and may occur over weeks or many years. Around 80-90% of the liver parenchyma needs to be destroyed before there are clinical signs of liver failure.[2,1] Child pugh score is a scoring system to measure the severity of chronic liver disease inclusive of cirrhosis. The intension is to provide a system with which clinicians can objectively communicate about liver function. The point scores are added up and classified as: Grade – A (mild): 5-6 points, Grade – B (moderate): 7-9 points, Grade – C (severe): 10-15 points.[11]

Table 1: Child pug score

Points	1	2	3
Ascites	None	Small or diuretic controlled	Tense
Encephalopathy	Absent	Mild	Significant
Albumin (g/L)	>3.5	2.8-3.5	<2.8
Bilirubin (mg/dL)	<2	2-3	>3
PT (sec > control) *or*	<4	4-6	>6
INR	<1.7	1.7-2.3	>2.3

INR, International normalized ratio; *PT*, prothrombin time
Class A: 5 to 6 points; class B: 7 to 9 points; class C: 10 to 15 points

In medicine, compliance (also reconcillation adherence or capacitance) describes the degree to which a patient correctly follows medical advice.[6] A WHO study estimates that only 50% of patients suffering from chronic diseases in developing countries follow treatment recommendations. This may affect patient health and affect the wider society when it causes

complications from chronic diseases, formation of resistant infections, or untreated psychiatric illness[5,8] Medication non- adherence is a growing concern among the health care professionals because of increasing evidence that it is prevalent and associated with adverse outcomes and higher costs of care.[7] Non-adherence is not solely a patient problem but is impacted by both care providers and the healthcare system. Now a days, measurement of patient medication adherence and use of interventions to improve adherence are rare in routine clinical practice.[7,8]

One of the intervention which help to improve medication adherence is the patient counselling. Patient counselling is defined as "providing medication information orally or in written form to the patients *or* their representatives on directions of use, advice on side effects, precautions, storage, diet and life style modifications.[9] Patients with a poor understanding of their disease and medication regimen and their personal consequences of non- adherence are more likely not to take their medications properly.[10] Patients should be educated about the benefits of treatment and what may happen if medications are not taken as prescribed. Counselling should be tailored to address a patient's specific diseases [eg.,Avoid taking OTC medications such as NSAIDs (nonsteroidal anti-inflammatory drugs)namely aspirin,ibuprofen,and naproxen that can further worsen livercirrhosis]. To enhance adherence, key points of the medication regimen should be reinforced, such as how the medication works, the proper dosage schedule and administration (e.g., show patients how to use an inhaler), effective medication reminders, limiting the number of medications prescribed simultaneously, what to do if doses are missed or delayed, proper storage and common and serious adverse events. Clinical pharmacist can improve adherence by simplifying information for all patients and assuming that most patients have difficulty understanding medical terminology.[7,8,9] Clinical pharmacist involvement in the care of cirrhotic patients has been associated with improved patient outcomes, including enhanced adherence, reduced pill burden and dosing frequency and decreases in medication errors.[10]

METHODOLOGY

Study design

Single-centre, open labelled, randomized, prospective, observational and Interventional study.

Study period

October 2014 - March 2015

Study population

A total of 100 patients with clinically diagnosed liver cirrhosis who had visited gastroenterology clinic during the study period and meeting the inclusion criteria were selected as the study population.

Inclusion criteria

- All the patients visited in the gastroenterology department with liver cirrhosis during the study period after obtaining informed consent.
- All patients aged above 18yrs.

Exclusion criteria

- Patients those who are not cooperative.
- Patients with liver transplantation.

Study site

A 360 bedded tertiary care setting, Department of Gastroenterology, COSMOPOLITAN HOSPITALS Pvt. Ltd., Thiruvananthapuram.

Data collection

The relevant data were collected while accompanying the clinician 6 days in a week and also from inpatient medical records. All the case records were reviewed and the details were collected during the particular hospital stay. A performa were designed for obtaining and evaluating drug use pattern, medication adherence and Severity of cirrhosis. The Performa contains relevant details such as demographics, past medical history, past medication history, diagnosis, severity score, laboratory investigations, therapeutic plan.

Data analysis

The collected data were recorded in Microsoft excel sheet.

The medication adherence data were collected with the use of Morisky medication adherence scale Medication adherence before and after patient education were noted and the improvement score is analysed.

Statistical techniques

The data were entered in Microsoft Excel format and and the statistical analysis was done

using Statistical Package for the Social Sciences (SPSS). Chi-square test, Paired t-test, are the statistical techniques used.

RESULT

A total of 100 patients who satisfied inclusion criteria were enrolled for the study.

1. Sex distribution of patients

Among the study subjects of 100 cirrhosis patients, 77 (77%) patients were male and 23(23%) patients were female.

Male patients may have greater susceptibility to cirrhosis when compared to female subjects. Men are 2-fold more likely to die from liver cirrhosis than women due to over consumption of alcohol, which is more in men than women.[12]

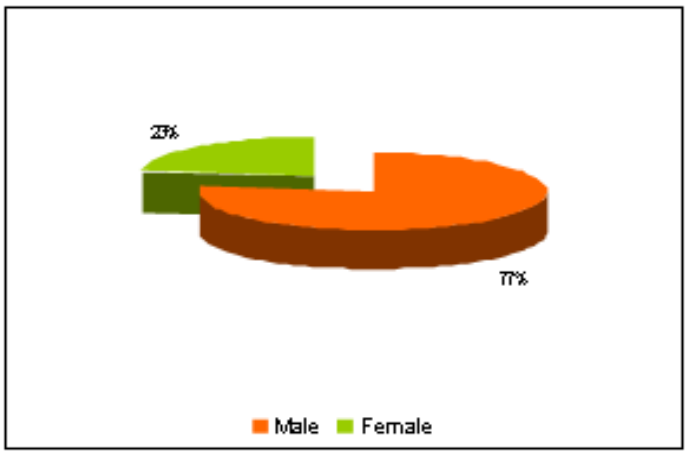

Fig. A: Percentage distribution of the sample according to sex

2. Age distribution of patients

Among the study subjects of 100 cirrhosis patients, 26 patients were between the age group of 30-49 (26%), 51 patients were between the age group of 50-69 (51%), 23 patients were between the age group of ≥ 70 (23%).

The prevalence of cirrhosis may increase with age as the liver size and blood flow decreases. The ability of liver to metabolise decreases with aging. Thus, some drugs are not inactivated as quickly in older people as they are in younger people.

Also the livers ability to withstand stress decreases. Repair of damaged liver is also slower in older people. The production and flow of bile decrease with aging.[14]

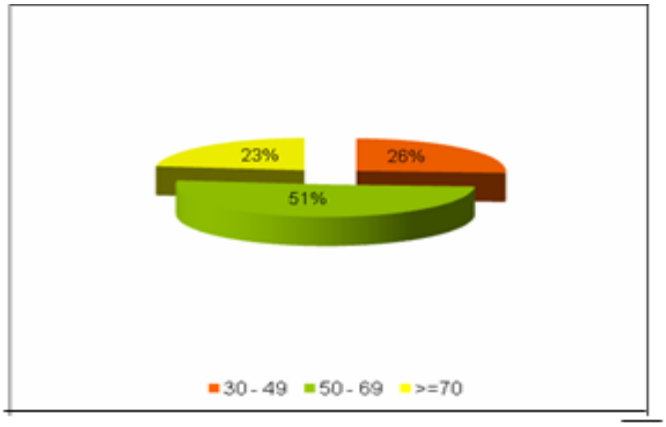

Fig. B: Percentage distribution of the sample according to age

3. Habits

Smoking

Among the study subjects of 100 cirrhosis patients, 11 patients were active smokers (11%), 10 patients were passive smokers (10%), 16 patients were ex-smokers (16%), 63 patients were non- smokers (63%).

Although smoking, does not have a direct effect on liver function, harmful chemicals in cigarette smoke increases oxidative stress of the system after reaching the liver, causing irreversible damage to liver cells.[2]

Alcohol

Among the study subjects of 100 cirrhosis patients, 44 patients were alcoholic (44%), 9 patients were ex-alcoholic (9%), 6 patients were occasionally (6%), 41 patients were non-alcoholic (41%).

Both acute and chronic alcohol consumption can affect liver function. Chronic consumption of alcohol results in the secretion of pro-inflammatory cytokines (TNF- alpha, interleukin-6, Interleukin-8) oxidative stress, lipid peroxidation and acetaldehyde toxicity. These factors cause inflammation, apoptosis and eventually fibrosis of liver cells leading to cirrhotic liver. Alcohol also reduces the production of antioxidants which are the body natural defences against free radicals. The liver damage caused by alcohol is related to the length of time and the quantity of alcohol consumed at a given time.[1]

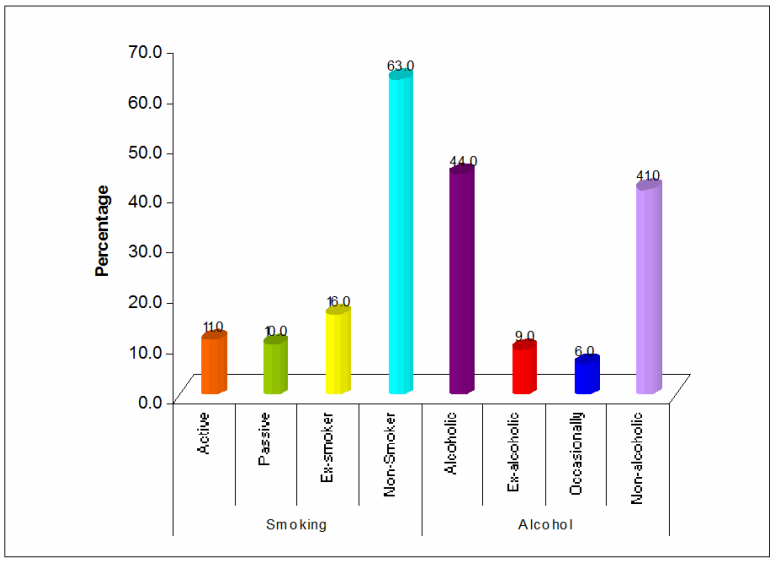

Fig. C: Percentage distribution of the sample according to habits

4. Causes of cirrhosis

Among the study subjects of 100 cirrhosis patients, 57 patients had alcohol as main cause for cirrhosis (57%), 9 patients had hepatitis-C (9%), 7 patients had hepatitis-B (7%), 4 patients had autoimmune hepatitis (4%), 8 patients had NAFLD (8%), 5 patients had NASH (5%), 2 patients had smoking (2%), 5 patients had drug use (5%), 1 patient had hemochromatosis (1%), 1 patient had wilson disease (1%), 2 patients had family history (2%) and 1 patient had idiopathic cause (1%).

Alcoholism is the one of the most common cause of liver cirrhosis. The liver cells break down alcohol but too much alcohol may damage the liver cells. The heavy intake of alcohol can increase the risk of developing cirrhosis. The persistant (chronic) infection with HCV or HBV causes long term inflammation in the liver. This eventually leads to liver scaring and cirrhosis. In auto immune hepatitis, the immune system makes antibodies against liver cells which can lead to damage and result in cirrhosis. Some are inherited diseases such as haemochromatosis (abnormal build up of iron in liver and other parts of body) and Wilson disease (abnormal build of copper in the liver & other parts of body) cause damage to liver cells. NSAID'S such as acetaminophen, aspirin, diclofenac, naproxen etc. may cause liver injury.[13,11]

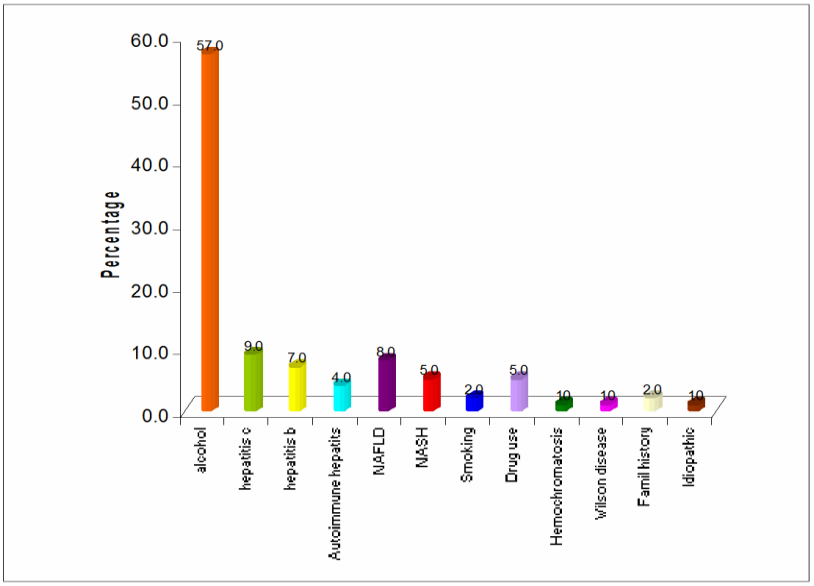

Fig. D: Percentage distribution of the sample according to causes of cirrhosis

5. Disease severity categorization

According to child pugh score, the severity is divided into three: A- mild, B- moderate, C- severe. Among the study subjects of 100 cirrhosis patients, 52 patients had grade A (52%), 36 patients had grade B (36%), 12 patients had grade C (12%).

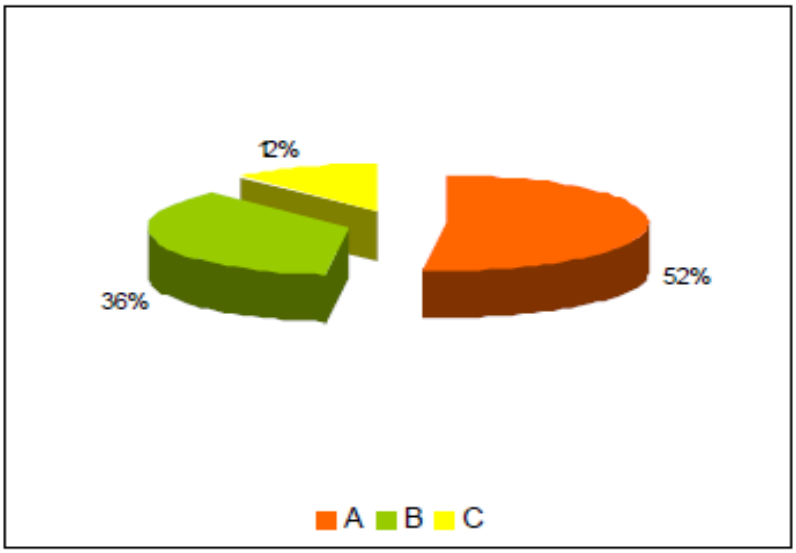

Fig. E: Percentage distribution of the sample according to severity

EFFECTIVENESS OF COUNSELLING ON MEDICATION ADHERENCE

Effectiveness of counselling on medication adherence based on severity

Table 2: Distribution of level of adherence based on severity

Severity	Medication Adherence	Before counselling		After counselling		Chisquare test χ^2	P
		No: of patients	Percen-tage	No: of patients	Percen-tage		
A	High adherence	0	0.0	36	69.2	6.52**	0.000
	Medium adherence	0	0.0	15	28.8		
	Low adherence	52	100.0	1	1.9		
B	High adherence	0	0.0	24	66.7	5.44**	0.000
	Medium adherence	1	2.8	12	33.3		
	Low adherence	35	97.2	0	0.0		
C	High adherence	0	0.0	8	66.7	3.22**	0.001
	Medium adherence	5	41.7	4	33.3		
	Low adherence	7	58.3	0	0.0		
Total	High adherence	0	0.0	68	68	8.97**	0.000
	Medium adherence	6	6	31	31		
	Low adherence	94	94	1	1		

**: - Significant at 0.01 level.

Perception of patients on medication adherence was found to be increased after counselling and is significant ($p<0.000$).

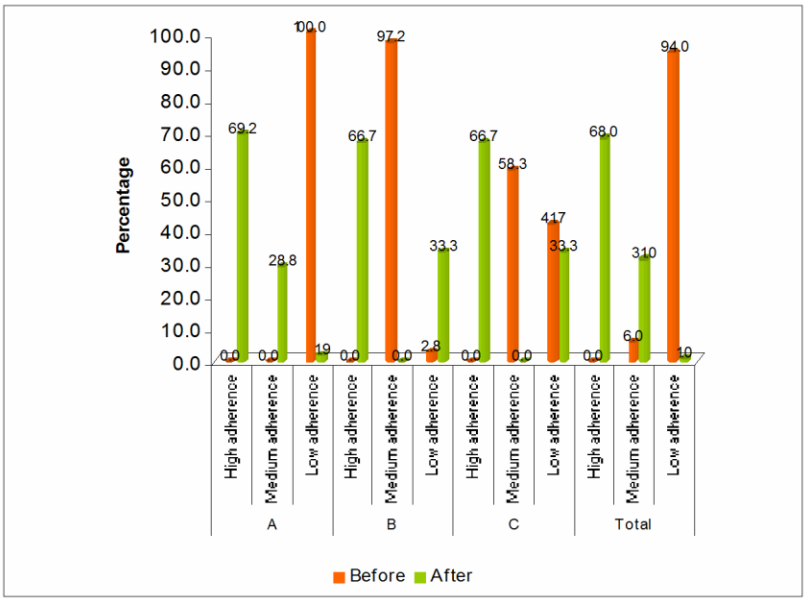

Fig. F: Distribution of level of adherence

Before counselling low adherence was found to more in grade A, grade B & grade C patients. After counselling high adherence was found to be increased in grade A, grade B, & grade C

patients. On comparing the medication adherence based on severity grade-A, grade B & grade C patients were well adhere to their medications.

CONCLUSION

The results of this study can be concluded as follows;

Patient knowledge about disease & its management was very less at first counselling. After counselling the patient is well aware about their disease its severity & their importance in adhering to treatment regimen for achieving better treatment outcomes. Multiple medicines taken for co-morbid diseases during treatment make them less adherent to medications. Awareness of medicines and usage make them more adherent. The severity of cirrhosis was assessed by using child pugh score and was categorised as: Grade A (mild), Grade B (moderate) and Grade C (severe). On comparing medication adherence, of cirrhosis patients with disease severity, grade A & grade B patients were found to be more benefited than grade C patients.

The improvement in adherence indicate the positive impact of counselling and education provided to cirrhosis patients. The counselling was more useful for illiterate patients. The role of clinical pharmacist in providing information to patients is significant especially in Indian population. The clinical pharmacist act as a bridge between physician and patients. It is very clear from the reports of this study, patient counselling provided was very effective in enhancing the medication adherence and overall quality of life of patients.

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