



# IJCP

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## **Editorial**

International Journal of Community Pharmacy (IJCP) is one of the online indexed journals. IJCP is officially indexed in Budapest Open Access Initiative and Directory of Open Access Journals. We are in the process of indexing with other groups, so that we can improve the accessibility of our journal to professionals across the world.

Further, I am happy to announce that Golden Jubilee celebrations of Manipal College of pharmaceutical sciences is coming up next year 2012. We have wide range of programs such as QIP programs, Summer school training programs, industry institute interaction programs and national cricket pharmacy matches to be organized. We believe, this is a great opportunity for fellow pharmacist, faculties and students to get together and also to keep them updated with the latest developments in our field. Details regarding the golden jubilee celebrations are available at [www.manipal.edu](http://www.manipal.edu) website, also we will keep you updating regarding the same in the forthcoming issues.

**Regards**

**Prof N Udupa**

**Editor In Chief, IJCP**

## MESSAGE FROM ACPI

Dear Friends,

Association of Community Pharmacist of India congratulates the first batch of Pharm. D Post Baccalaureate, graduated in the month of July 2011 onwards from different Institution. At the same time, ACPI ventured into two umbrella associations by initiating ISPOR Manipal Chapter and Association of Practicing Pharmacist and Clinical Pharmacologist. Much infrastructure and caution are the requirement of the time to provide patient safety and deliver the optimum output in therapeutics. With the associations let us dream the patients in our country do not suffer due to the absence of support by the clinical pharmacist, hospital pharmacist and community pharmacist.

Prof Anantha Naik Nagappa,

President,

ACPI

# IMPLEMENTATION OF DIETARY COUNSELLING FOR LOW SOCIOECONOMIC CANCER PATIENTS; A REVIEW

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## **Abstract:**

Nutritional status has an important effect on quality of life and sense of wellbeing in patients with any type of cancer. Recent data have more definitively indicated that nutritional counselling could lead to increased quality of life of patients with different types of cancers. The main intention of our review is to initiate dietary counselling in a multidisciplinary team approach including a physician, nurse, pharmacist, dietician, social worker, psychologist and physiotherapist help improve overall symptoms for lower socioeconomic cancer patients. The method used to identify and appraise published and unpublished review drawing on our experience and reporting of reviews are described. This process allows the researcher to describe the quality of life of cancer patients on evidence base, summarise and compare the reviews' conclusions and discuss strength of these conclusions. Challenges and possible solutions are found to be the source, quality assessment, implication for practice in a tertiary care hospital, economic crisis, religion barriers. Our review highlighted the usefulness of dietary counselling in cancer patients. The dietary advises described here could help clinician to review and implicate individual nutritional status for cancer patients with lower socioeconomic status.

Key words: Nutritional status, quality of life, multidisciplinary team, dietary counselling.

## **Introduction**

Nutritional status is a well established and important factor in the identification of the risks associated with cancer treatment as well as in affecting an individual's response to treatment pattern.<sup>1</sup> Due to heterogeneity of cancer energy expenditure is difficult to predict in cancer patients.<sup>2</sup> Current evidence continues to lend support to strong relations between nutritional status and various clinical outcomes, including quality of life, survival, and the ability to tolerate treatment.<sup>3</sup> The study by Ravasco et al<sup>4</sup> specifically tested the impact of dietary counselling in patients with colorectal cancer who were undergoing radiotherapy. Notably, there is considerable variability in the risk for malnutrition after the diagnosis of cancer, among various cancer types and subgroups of the patient population. In contrast to this the opposite situation may arise like women diagnosed with breast cancer often gain, rather than lose weight during the initial treatments.<sup>5</sup> In case of breast cancer survivors, the focus of dietary counselling and lifestyle intervention is generally to promote healthy and ideal weight management in the overweight or obese patients by an alteration of food intake and increased physical activity.<sup>6,7</sup>

## **Quality of life (QoL) outcomes**

Quality of Life (QoL) is an outcome that is especially important for patients with cancer. Nutritional status has an important effect on quality of life as well as sense of wellbeing in cancer patients.<sup>8</sup> Because of side-effects or their disease, patients get difficulty in eating and often avoid social interactions with family members, friends and neighbours resulting in further depression of appetite.<sup>9</sup> Some factors such as mouth pain, hoarseness, avoidance of eating in public, and unclear speech, have been associated with poorer overall quality of life in cancer patients.<sup>9</sup>

Current data showed that nutritional counselling could lead to increase in the overall quality of life of patients with different types of cancers especially lower socioeconomic groups. Ravasco and colleagues<sup>10</sup> found that patients with head, neck, and gastrointestinal tumours groups could increase their energy intake, quality-of life scores, with the exception of pain scores substantially during radiotherapy after receiving nutritional counselling. Similarly, Isenring and co-workers<sup>8</sup> found that patients with head and neck cancer receiving early intensive-nutritional counselling had less weight loss, better nutritional status, and quality of life than did those who did not receive such counselling. These patients were also more satisfied with their care.

**Table No: 1 Symptom-related nutritional interventions<sup>24</sup>**

Symptom	Intervention
Constipation	Gradual increase in fibre intake, increased physical activity, fibre supplement then stool softener, then laxative
Diarrhoea	Avoidance of high – fat foods, caffeine, alcohol, tobacco, strong spices, consumption of banana, rice, apple sauce, toast diet, increased fluid intake
Dumping syndrome	Small, frequent meals, higher protein and fat content of meals, fluids between meals, limitation of simple carbohydrates
Early satiety	Avoidance of excessive intake of fat and fibre; small, frequent meals (every 2 h); increased protein and carbohydrate content of meals; fluids between meals
Nausea	Avoidance of foods with strong odours, high-fat foods, and strong spices; fluids between meals; cold foods that might be better tolerated
Stomatitis or mucositis	Avoidance of acidic, spicy, rough, or salty foods, consumption of bland, soft, cooked foods, capsaicin candy
Taste changes	Tart foods, highly flavoured seasonings, plastic utensils and Dishes, marinated foods
Vomiting	Progress from no oral intake to clear liquid, full liquid, and then soft foods; maintenance of fluid intake (include juice and broth in this recommendation)
Xerostomia	Fluids with meals, moistened or pureed foods, papaya juice, avoidance of caffeine, alcohol, and commercial mouthwashes

### **Involvement of Health care team**

The responsibility of nutritional counselling to cancer patients is not only restricted to the dietician alone. The complete management requires the input of different healthcare professionals.<sup>11</sup> As a fact that most cancer centres do not have a dietician on staff.<sup>11,12</sup> Multidisciplinary teams including a physician, nurse, pharmacist, dietician, psychologist, social worker, and physiotherapist can help to provide a complete care and improve overall symptoms and sense of wellbeing.<sup>13</sup> these methods could be used by oncology nurses, advance-practice nurses, and oncologists without the assistance of a trained nutritional professional to assess nutritional risk.<sup>12</sup> referral of patients who are at nutritional risk to a registered dietician or nutrition professional can assist with individualised nutritional intervention and follow-up.<sup>14</sup> This

will be more useful for poor patients who can't afford much money for treatment. The joint commission on accreditation of healthcare organisation of USA assess nutritional status when warranted by patient's condition and educate patients about nutritional interventions if necessary.<sup>15</sup>

**Table No: 2 Examples for different coloured foods<sup>25</sup>**

Colour	Examples
Red	Tomatoes, raspberries, watermelon, kidney beans, strawberries, red onions, radishes, red peppers, guava
Purple	Aubergines, red grapes, aduki beans, blueberries, red cabbage, plums, beetroot, pomegranate
Orange	Carrots, oranges, mangoes, apricots, sweet potatoes, pumpkin, orange peppers, butternut squash, papaya
Yellow	Pineapples, sweetcorn, peaches, chicory, bananas, yellow peppers, plantain
Green	Spinach, cabbage, avocados, peas, pears, green peppers, courgettes, marrows, fresh herbs, lettuce, watercress, dasheen leaves

### **Benefits to cancer patients**

A systematic review by Baldwin and colleagues<sup>16</sup> showed that dietary counselling simply can't manage malnutrition and this review indicated greater benefit from oral nutritional supplements. Literature showing that outcomes in patients with cancer who receive nutritional intervention based on the medical nutrition therapy protocols illustrated less weight loss and lean body mass,<sup>17</sup> a less deterioration in nutritional status and physical functioning.<sup>8,10</sup> A major intervention is the initiation of liquid nutritional supplements in the treatment of cancer-induced weight loss.<sup>16,18</sup> The use of these supplements seems to provide a demonstrable benefit in poor patients who are malnourished, especially those with a body-mass index of less than 20 kg/m<sup>2</sup>.<sup>16,19</sup> According to a Cochrane review of nutritional intervention with the energy and proteins produce a considerable weight gain, reduction in mortality, and shorter hospital stays by illness.<sup>18</sup>

### **Nutrition therapy**

The main goals of medical nutrition therapy are to maintain adequate weight, preserve lean body mass by enhancing calorie and protein intake, and to improve quality of life by minimising treatment related symptoms.<sup>20</sup> Energy expenditure and consumption is difficult to predict in patients with cancer.<sup>2</sup> Variability is caused by the presence of heterogeneity of cancer and by the host response to tumours.<sup>2,21</sup> Weight loss in patients with cancer cannot be accounted for by diminished food intake alone and it is not always reversed with increased oral intake of food and nutritional supplements.<sup>22</sup> Planning of nutritional interventions in patients with cancer needs assimilation of information related to all parts of patient care including their financial background. Concerns to be taken about host response, physiological abnormalities associated with the tumour and symptoms of disease, side-effects of anticancer treatment that have the potential to affect nutritional intake.<sup>20</sup> In addition, the functioning of gastrointestinal tract, type of anticancer treatment, quality of life and especially cost-effectiveness must also be considered.<sup>23</sup> Symptom-related nutritional interventions<sup>24</sup> are shown in the Table No:1.

**Table No: 3 Smart Menu Choices<sup>26</sup>**

Prefer	Don't prefer
Hard or processed, or soft cheeses only if they are made from pasteurized milk	Cheese made from unpasteurized milk
Fully cooked and smoked seafood	Raw or undercooked seafood
Hot dogs reheated to steaming hot	Cold hot dogs
Grilled sandwiches in which the meat or poultry is heated until steaming	Sandwiches with cold deli or luncheon meat
Fully cooked fish which is firm and flaky	Raw or undercooked fish
Fully cooked eggs with firm yolk and whites	Soft-boiled eggs, as the yolks are not fully cooked

**Economical diet for cancer patients:**

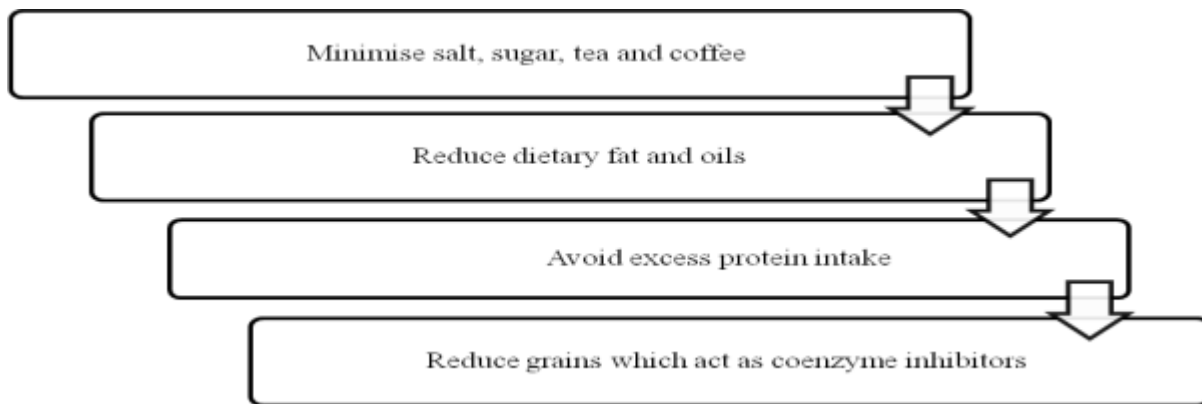
Cooking: Enamel, cast iron, or stainless steel cookware are better for cooking rather than aluminium pans or aluminium foil as it will contribute to heavy metal toxicity in the blood. Boiling of vegetables makes to lose all essential nutrients into the water. So as to prevent this liquidise them up and turn the water into soup. The quantity main five food groups to be taken are shown<sup>25</sup> in the Fig No: 1.

Main meals: Ideally, for everyone midday and evening meal, 50% should be raw to ensure all the enzymes digest the vitamins and minerals. Vegetables to steam and stir fry include Courgette – Carrots, Broccoli – Fennel, Cauliflower – Asparagus, French Beans - Baby Corn, Cabbage – Garlic, Celery – Onion, Peppers - Mange Tout, Steamed Potatoes – pesto, ginger – carrots, Orange and sesame seeds - Celery. Eating a wide range of different coloured fruit and vegetables as is a good way of increasing the intake of these vitamins and minerals. We should try to include all of the different colours in our weekly diet. Examples for different coloured foods<sup>26</sup> are shown in Table No: 2. A good celebration - Christmas, Birthdays, Easter and Weddings with fine rich food should be a pleasure and not ruin our health maintenance programme. Tuck into the colourful garnishes - cherry tomatoes, green and black grapes, and sweet pepper sticks that everyone else leaves alone.<sup>24</sup> The smart menu choices<sup>26</sup> are shown in Table No: 3.

It is better to avoid sugar substitutes such as saccharin and canderel. Sweet alternatives like apple and Pear Spread, Honey, wild Blueberries Pineapple and Ginger or Blackcurrant Peach and Sun dried fruits (Papaya Pineapple Mango or Dates Prunes Apricots) can be preferred. Hundreds of processed products contain salt often even if they are not savoury. So Use freshly ground pepper, Celery seed, Potassium salt, Kallo organic low salt stock cubes, Meridian reduced salt yeast extract. Drinking still water is good. As fizzy water contains carbon dioxide it raises the pH of the stomach making it less acidic and less able to digest protein. We can improve the taste of tap water with a water filter. Water is also the basis of the blood, without enough fluid content the blood volume will decrease and the body will suffer.

**Changing to a balanced Diet**

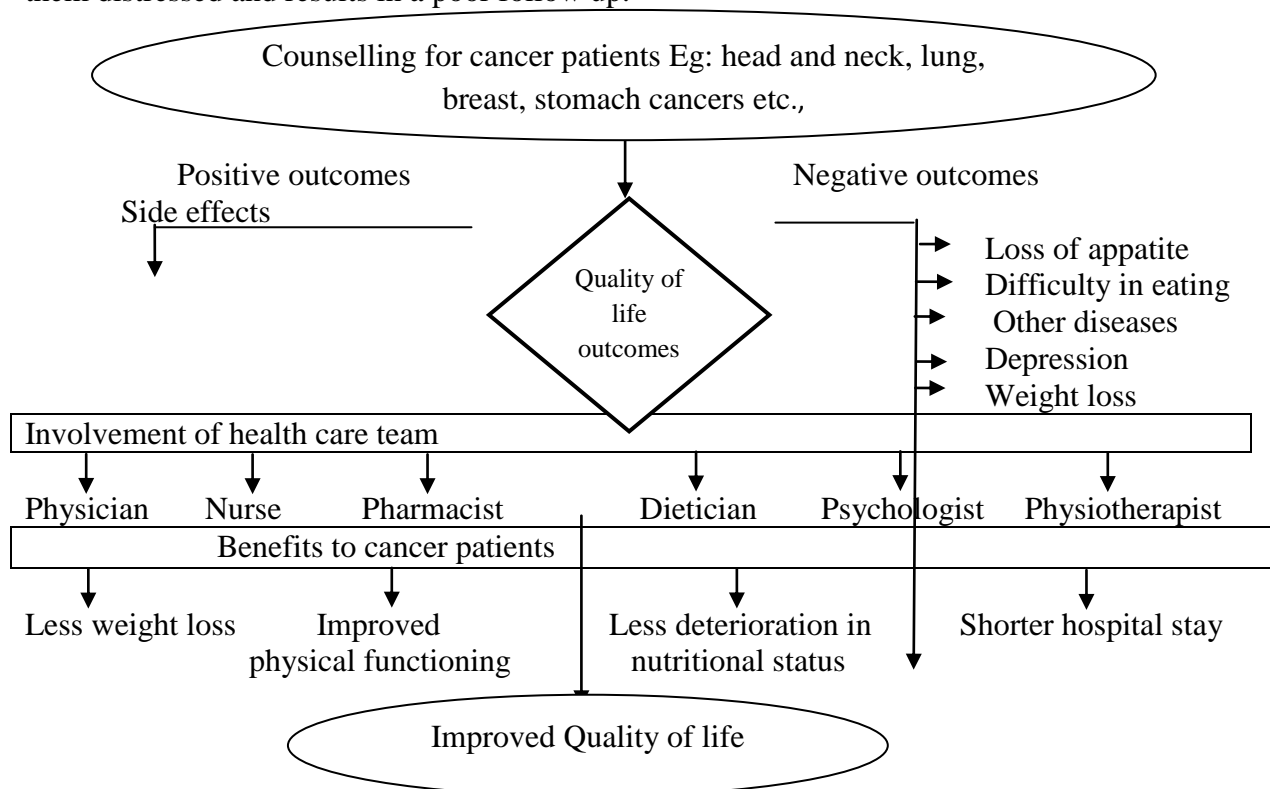
There is considerable variability in the risk for malnutrition and weight loss after the diagnosis of cancer. Referral of poor patients who are at nutritional risk to a registered dietician or nutrition professional can assist with individualised nutritional intervention and follow-up.



Steps involved in Changing to a balanced diet

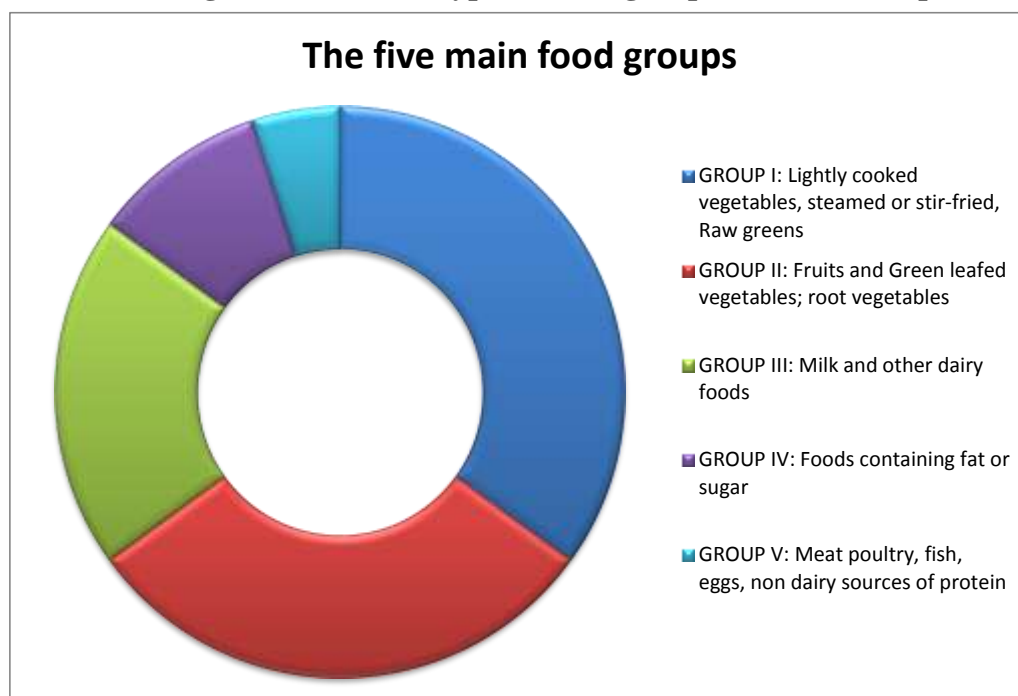
### Challenges and barriers

Dietary counselling among the cancer patients with low socio economic status has considerable barriers which are challenging the implementation. Those barriers include source, quality assessment, implication for practice in a tertiary care hospital, religion barriers, family/community responsibilities, transportation, financial resources, perceived risks/benefits of dietary change after diagnosis, concern about side effects of the intervention, fear/feelings about cancer. The misbelieves of cancer patients regarding side effect profile of their treatment make them distressed and results in a poor follow up.



Summary showing the impact of dietary counselling process

**Fig No: 1 Different types of food groups that has to be preferred<sup>25</sup>**



### **Conclusion**

Nutrition can play a major role in the management of cancer patients from the initial stage of treatment to the longterm continuum of care. Individuals who have been diagnosed with cancer are often suggested to change their diet pattern and seek nutritional guidance. Individualised dietary counselling can be successful in enabling patients to maintain good status, which is accompanied by a reduction in symptoms and improve health related quality of life. By teaching the self-monitoring and overcoming the common barriers to selecting a healthy diet, patients can able to set their own goals. Guidance given in food preparation, engaging in role playing with patients and giving social support during treatment show a major impact on cancer patients. Appropriate diet management among poor patients can prevent muscle wasting and help prevent nutrition-related side effects and complications in all type of cancer patients. At the same time it also improve their ability to fight infections, maintains energy and strength, and promotes rapid recovery and healing. Our review highlighted the usefulness of dietary counselling in cancer patients. The dietary advises described here could help clinician to review and implicate individual nutritional status for cancer patients with lower socioeconomic status.

### **Acknowledgements**

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## **THE FUTURE OF PRESCRIPTION: E-PRESCRIPTION**

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### **Introduction**

Today prescription drugs have become an integral part of the medical health care system. Now a day's most of the patient who visit a doctor comes out with a prescription in hand. Most patients are accustomed with pieces of paper from their doctors with a prescription written on them. In year 2007 more than 3.5 billion prescriptions were written by medical practitioner. Today's prescriptions are expected to create larger number of errors. Recent report from the "Nonprofit Institute of Medicine" showed that in America itself more than 1.5 million patients are affected by errors in prescription. This number might have grown to more than 4 billion by 2010. Mainly errors are caused by miscommunication resulting from unclear handwriting, instructions, telephonic conversions and other ambiguities. So, now it's urgent need to avoid such kind of fatal errors for improving safety of drugs and promoting best practices. For this in July 2006 itself "The Institute of Medicine" recommended that all prescriptions should be written electronically by 2010. Although this goal is not achieved, progress to adopt, implement this technology nationwide is accelerating and is expected to become standard practice in the coming years.

### **What is e-prescribing?**

Electronic prescription (e-prescription) is a form of computerized physician order entry. e-prescribing is considered as the best way to electronically connect patients, healthcare providers and pharmacists. By using the e-prescription method community pharmacist can maintain day to day record about the medications which is ultimately useful for the Patient Medication Record (PMR). It is a tool for prescribers to electronically send an accurate, error-free and understandable prescription directly to a pharmacy. It also provides warning about the drug-drug interactions, allergic reaction by the help of PMR. Positive prescribing offers number of benefits to patients like increased convenience by sending the prescription automatically to the pharmacy and avoiding unnecessary trips which helps to improve the ability of a physician to prescribe a drug covered by insurance at different levels and policies.

### **Need of e-prescription**

In handwritten prescriptions there are chances of extreme errors which are very much harmful to the patients. The current paper-based system of handwritten prescriptions causes errors due to poor handwriting, unclear abbreviations and dosage regimens directed by the medical practitioner. The traditional prescriptions always create errors about the medication strength, schedule, spelling mistakes and wrong dispensing due to similar pronunciation of the medicines. The main reason behind these errors is the number of similar name and similar strength of drugs available in the market. Also due to the improper writing of the prescription, proper reading and handling of the prescription is difficult for the pharmacist which results in adverse drug events that are fatal to the patient. The small mistakes reduce efficiencies of medication and drive up healthcare costs.

According to Joint Commission on Accreditation of Healthcare Organizations 7,000 people die per year as a result of medication errors caused by inadequate coordination between the medical

practioners and pharmacists. The survey of “Institute of Medicine” also indicates that more than 1.5 million Americans are suffered annually by medication errors. These can be minimized up to 25 percent by proper handling of the prescriptions. So there is need of such system which avoids such medication errors and useful to maintain the all records of the drugs prescribed to the patient. This problem is totally recovered by the new pattern of e prescribing.

## **Advantages and disadvantages of e-Prescribing**

### **Advantages**

#### **Patient Benefits**

- Increased safety and reduced medication errors.
- Reduction in waiting time at the pharmacy.
- No need for online or phone ordering.
- Optimized prescription drug benefits.
- Reduced cost of therapy when generics are used versus branded drugs.
- Proven to save time and lives.

#### **Health Care Provider Benefits**

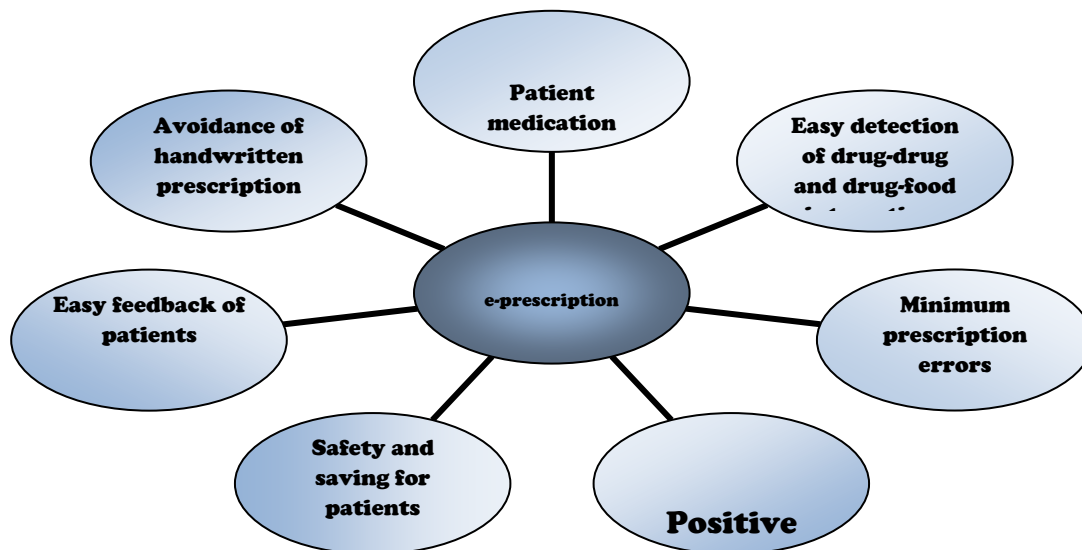
- Easy access to medication history.
- Easy for detection of drug-drug interactions and allergic reactions.
- Improved efficiency and easy for practice work.
- Immediate access to patient drug formulary for decision-making.
- Fewer follow-up phone calls to the pharmacy.
- Proper counseling of the patient.

#### **Pharmacy Benefits**

- Increased safety for the patient.
- Reduced errors due to data entry mistakes or unreadable prescriptions.
- Increased processing efficiency.
- Reduced health care provider callbacks.

### **Role of e prescription for improve the quality of care**

- Verifies automatically dosage forms and side effects and treatment protocol.
- Prevent adverse drug interactions by displaying PMR.
- Easy confirmation of prescriptions as per formulary guidelines of PTC.
- Easy selection of drug .
- Elimination of misreading of handwritten drug and dosage regimen.
- Instant transmit of orders to pharmacies resulting in decreased filling and waiting time for the patient.
- Reduction in calls from pharmacy to physician in concern with prescription.
- Improving office efficiency by automating manual tasks.
- Updating existing systems to comply with standards and regulations on e-prescribing.
- Providing complete patient medication history across ambulatory, acute and emergency care settings—from evidence based order entry to safe medication administration.



**Fig. 1: Advantages of e-prescription**

**Disadvantages:**

Controlled substances: such kind of drugs cannot be prescribed for certain situations like severe pain where oxytocin is used. Such kind of substances cannot be transmitted electronically to pharmacies. In such cases physicians has to print and sign these prescriptions and forward it to the pharmacy.

**Complacency:** The physician, patient and pharmacist should not consider that there is total absence of errors in e-prescription. Although this is the advanced technique in prescribing but the concern about the patient medication record is very much important aspect for physician as well as for patient. The need of awareness in concern with medication should not be eliminate.

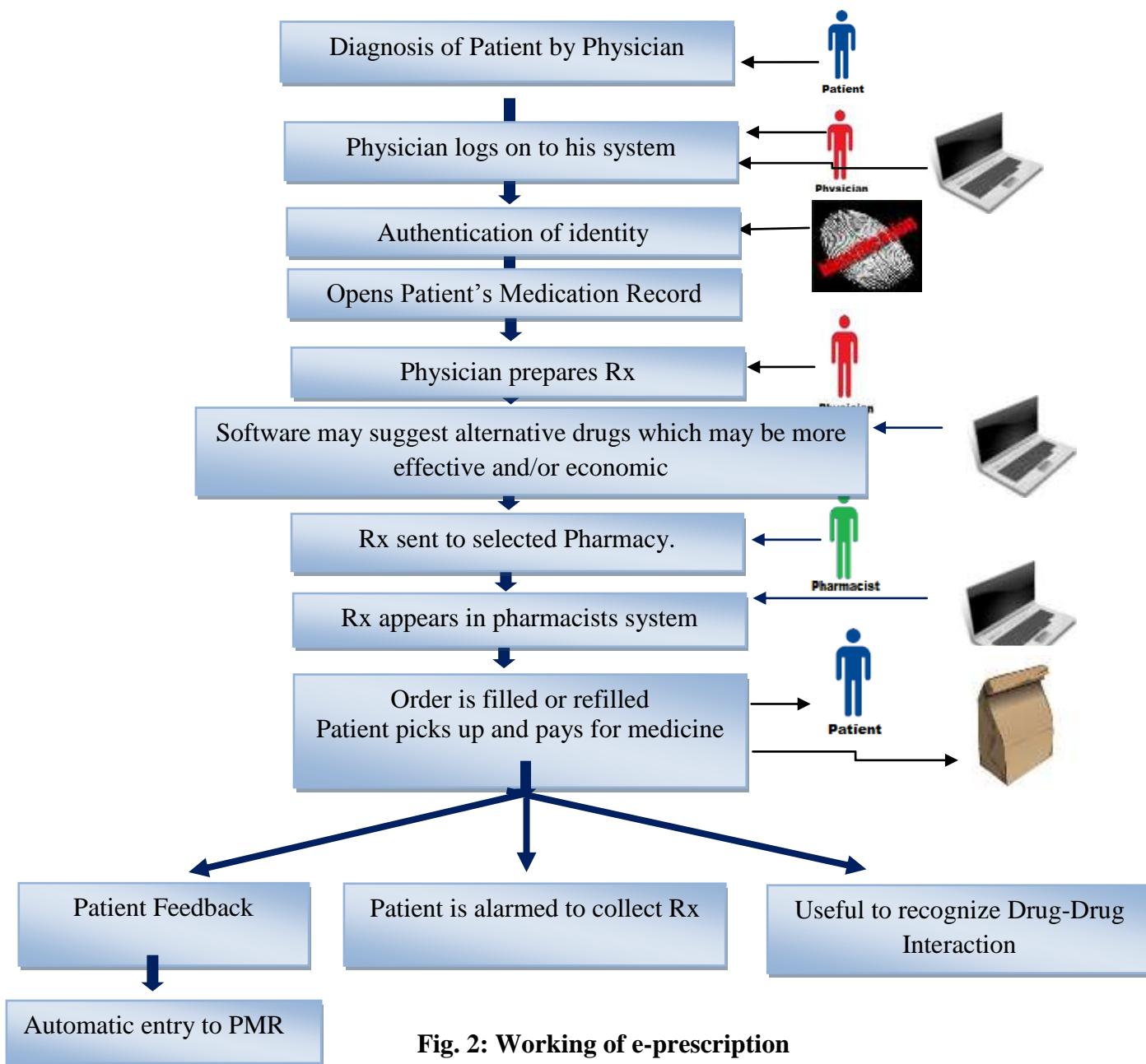
**Lack of complete information:** e-prescribing systems may not have information on all the medications that a patient is taking due to simultaneous drug therapy or food or drink items taken by the patient. Without e-prescribing it is even more difficult to have an accurate and complete medication history for patients because it is helpful to find out the multiple providers who write prescriptions for them.

**Difference in e-prescribing from traditional prescription**

Most patients are already adjusted with traditional paper prescriptions from doctors. Patients take these prescriptions to local pharmacy and wait for the pharmacist to fill the prescription. While in e-prescribing, computer technology is used to simplify and improve the traditional paper-based prescription. In this system everything is worked out electronically over a secure system in a standard format. In e-prescribing pattern patients no longer have to make separate rounds to drop off and pick up a prescription. It is always ready when the patient arrives to the pharmacy. When physicians and pharmacists use e-prescribing instead of traditional paper prescriptions the number of unfilled prescriptions significantly decreases and it is easier for patients to have a properly filled prescriptions.

**Working of e-Prescription:** The different kinds of devices are preferred for writing the prescription such as laptops, desktop personal computers and other technology. The writing of e-

prescription is carried out in systematic way. After examining a patient and deciding to prescribe a certain drug the physician will enter information into a device in a standard format. The doctor logs on to the system and authenticates his identity by use of passwords or biometric identifications (fingerprinting or physical security card) and enters the medication. This avoids dispensing of illegal prescriptions. Physician looks up in the system for patient's data which contains medical history and insurance coverage. The physician selects an appropriate drug for preparing prescription. Software may suggest alternative drug which is more effective or less costly. Lastly prescription is transmitted electronically from the doctor's computer to the pharmacist's computer through a secured network. As pharmacist receives prescription then proper dispensing to patient is carried out.



**Fig. 2: Working of e-prescription**

## **Widespread use of e-prescribing**

### **Physicians**

Use of e-prescribing is growing quickly and it will be the standard practice in the coming years. About 85,000 medical practitioners in 2008 used e-prescription. This shows that most of physicians are willing to write e-prescription for the correct diagnosis and maintenance of proper records.

### **Pharmacies**

In developed countries most of the renowned retail pharmacies are accepting e-prescriptions through the Secure Pharmacy Health Information Exchange including all chain pharmacies such as CVS, Walgreens, Wal-Mart and Rite Aid. Smaller independent pharmacies are also currently e-prescribing the medicines. From the point of safety most of the patients also prefer the practitioners who using the e prescribing. Most insurance companies and pharmacy also support e-prescribing. They provide the pre-prescribing information such as medication history, eligibility and formulary and benefit information. This is the reason why most of the patients also willing to take the benefit of e prescribing. According to a 2007 Gorman Group study pre-prescribing process accounts for 70% of the safety and savings for the patient. In general e-prescribing is more common in metro cities and with large physician groups and less common in rural communities or small physician groups.

### **Software:**

There are many software's used for e-prescribing technology amongst which few are Prescription Pad, Sequel Systems, OmniMD etc by using such kind of softwares one can maintain detailed patient medication record which essential for safety and efficacy of the medication.

Following are some sites which gives detailed information about the software's

- <http://www.prescriptionpad.in/Home.aspx>
- [http://www.sequelmed.com/Products/electronic\\_prescribing.aspx](http://www.sequelmed.com/Products/electronic_prescribing.aspx)<http://www.omnimd.com/html/prescription.html>

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# THE ROLE OF PHARMACEUTICAL CARE IN DIABETES MANAGEMENT

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## Abstract

The prevalence of type-2 diabetes has grown over the past decade. We performed a study to determine whether a patient counseling for Diabetes patients regarding disease, medication, diet/nutrition and exercise can improve glycemic control, lipid profile and associated complications with an aim to evaluate the impact of pharmaceutical care on the clinical outcomes of patients and the effect of a pharmacist intervention on improving diabetes control. Patients were registered into 'control' and 'intervention' groups by randomization at three primary health centers. The study was an open-label parallel study. Medical records were prospectively reviewed. Capillary blood glucose level, blood pressure and demographic data were collected at baseline and at the follow-up visits. Pharmacists gave counseling to the intervention group during every visit and their health-related quality of life (HRQoL) was assessed with the Ferrans and Powers questionnaire. Statistical Analysis test were used to compare the results. The intervention group ( $n = 35$ ) showed well-controlled BMI, whereas the control group ( $n = 15$ ) showed significant increase in the BMI. ANOVA showed that from the second follow-up onward there was significant decrease in blood glucose levels. Overall, the HRQoL scores increased by 45% in the intervention group and decreased by 2% in the control group. The pharmaceutical care program was effective in improving the clinical outcome and HRQoL of diabetes patients. This study provides an economically feasible model for programs that aim to improve the health status of people with type-2 diabetes.

**Keywords:** diabetes mellitus, pharmaceutical care, patient counseling, body mass index.

## Introduction

Diabetes mellitus (DM) is a group of metabolic disorders characterized by hyperglycemia. Diabetes is accepted worldwide as a major public health problem, being the fourth leading cause of death in developed countries<sup>[1]</sup>. Many pharmaceutical care programs have been established in various countries to enhance clinical outcomes and the health-related quality of life (HRQoL). These programs were implemented by pharmacists, with the cooperation of the physicians and other health care professionals.<sup>[1], [2], [3]</sup> However, such programs are not very common in the

Indian scenario. The community pharmacist is a professional with knowledge of medicines and health care and is easily accessible to patients throughout the day. The pharmacist can, therefore, in collaboration with doctors and other health care professionals, contribute to the improvement of diabetic patients' quality of life by informing and educating patients, answering their questions and, at the same time, monitoring the treatment they receive and carrying out their own assessments of patients' health.<sup>[4]</sup> India is becoming the diabetes capital of the world, with an estimated 30 million diabetics today<sup>[5]</sup> and the numbers set to increase to 73 million by 2025.<sup>[6]</sup> With good glycemic control, several long-term, life-threatening complications of diabetes can be prevented.<sup>[7]</sup> The community pharmacist's involvement in diabetes care is justified by his or her position as a key member of the health care team; the need is to work together with other health professionals to prevent diabetes and its complications.<sup>[4]</sup> Pharmaceutical care is to improve patient health outcomes by ensuring effective, safe, and cost-effective drug therapy. Pharmacists are in a prime position to ensure that use of medications by the patients safely and appropriately<sup>[8], [9], [10]</sup>. Patients with diabetes and their families provide 95% of their care themselves; as a consequence, an educational effort to improve self-management is the central components of any effective treatment plan. Patient counseling is an important task for achieving pharmaceutical care by providing medication related information orally or in written form to the patients or their representatives, on topics like direction of use, advice on side effects, precautions, storage, diet and life style modifications<sup>[11], [12]</sup>. It should include an assessment of whether or not the information was received as intended and that the patient understands how to improve the therapeutic efficacy<sup>[13], [14]</sup>. Several guidelines specify the points to be covered by the pharmacist while counseling the patients<sup>[15], [16], [17]</sup>.

Numerous clinical trials have established that lifestyle interventions can lower blood pressure or decrease the intake of antihypertensive medications<sup>[18]</sup>. Nutritional counseling forms an essential component in the management of diabetes<sup>[19]</sup>. However, unless these diets are highly enriched with fiber, they may impair glucose tolerance, increase triacylglycerol levels, and decrease HDL concentrations<sup>[20]</sup>. A standard recommendation for diabetic patients, as for nondiabetic individuals, is that physical activity includes a proper warm-up and cool-down period. The possible benefits of physical activity for the patient with type 2 diabetes are substantial, and recent studies strengthen the importance of long-term physical activity programs for the treatment and prevention of this common metabolic abnormality and its complications<sup>[21]</sup>. The patient should be cautioned not to skip meals at any time and to follow regular diet patterns to prevent hypoglycemia.

### **Epidemiology:**

The prevalence of diabetes is rapidly rising all over the globe at an alarming rate<sup>[22]</sup>. In 2001, the "International Diabetes Federation" (IDF) estimated the number of diabetes patients worldwide at 177 million<sup>[23]</sup>. It is believed that in 2010 six per cent of the world's population will have diabetes<sup>[24]</sup>. The World Health Organisation (WHO) forecasts 366 million diabetics by 2030<sup>[25]</sup>. If anything, the European origin populations are the anomaly, being substantially protected from type 2 diabetes compared to other world populations but despite the greater burden of diabetes in non-European populations, the majority of participants in trials of pharmacological agents are of

European origin: little attempt is made to consider whether intervention efficacy, and thresholds for treatment can, and should, be identical in all patient groups.

Finally, apart from a detailed discussion of interventions designed to reduce the risk of diabetes *per se*, and a discussion of the UK Prospective Diabetes Study (UKPDS), there is no section on interventions designed to reduce the risk of diabetes-related vascular complications, even though epidemiology has been at the forefront of some of these studies, and many have reported only recently, quite substantially changing the way we treat diabetes.

The first authentic data on the prevalence of diabetes in India came from the multicentric study conducted by the Indian Council of Medical Research (ICMR) in the early seventies <sup>[26]</sup>. This study reported a prevalence of 2.3% in the urban and 1.5% in the rural areas. According to the Diabetes Atlas 2006 published by the International Diabetes Federation, the number of people with diabetes in India around 40.9 million is expected to rise to 69.9 million by 2025 unless urgent preventive steps are taken.

## **Methodology**

This 6-month, prospective, open-label study was conducted with type 2 diabetic patients from three primary health centers (PHCs) of district Kanpur in Uttar Pradesh (India) after getting ethical clearance. After getting written consent from the patients they were allocated into 'control' and 'intervention' groups by 1:2 randomizations.

### **Inclusion and exclusion:**

Adult patients aged over 18 years and taking medications for type 2 DM for at least the past 12 months were included.

Pregnant women were excluded from the study.

### **Instruments:**

The questionnaire for collecting the demographic data of the patients and for assessing health-related quality of life (HRQoL) was prepared with reference to Ferrans and Powers Quality of Life Index-Diabetes version III. <sup>[8]</sup> This questionnaire was distributed to the patients in two languages Hindi and English.

A Pulsatum - Digital biosensor blood glucose monitor was validated and used to measure the capillary blood glucose level.

Blood pressure (BP), body weight, and height were recorded with standard instruments.

All the baseline information and demographic data were collected in the prescribed format by direct interaction with the patients of both groups. To avoid bias, a lab technician at the respective PHC interviewed the patients and assisted them in filling up the HRQoL forms. Then

the capillary blood glucose level (fasting) was measured and documented; BP was also checked. Following this, the intervention group patients were given counseling about diabetes and health care; the control group received no counseling. The intervention group was followed up every month (for 5 months). At each visit, capillary blood glucose and BP were measured and documented and brief counseling was given. At the end of study the HRQoL form was filled up again for both the groups of patients in a similar fashion. At the end of the study the capillary blood glucose and BP were measured for the patients of the control group and documented. Then the same counseling that was given to intervention group of patients was also given to the control group.

### **Statistical Analysis:**

All the data were analyzed using the computer software SPSS version 0.9 and MS Excel. The HRQoL data were analyzed using the Excel program of Ferrans and Powers.

### **Results**

A total of 104 patients in the intervention group and 50 patients in the control group completed the study. The demographic data like sex, age, body weight, height, body mass index (BMI), marital status, education, occupation, disease duration and habits of smoking and alcohol at baseline are comparable between the two groups. The mean body weight of the intervention group at baseline was  $55.75 \pm 8.61$  kg, which was reduced to  $54.28 \pm 8.12$  kg at the end of the study; this difference is highly significant ( $P = 0.0001$ ). The BMI profile showed that the patients in the intervention group have well-controlled BMI, whereas the control group showed considerable increase in the BMI. At the end of the study, the mean capillary blood glucose level in the intervention group reduced to about 25 mg/dl from the baseline value, which was highly significant ( $P = 0.0001$ ). In the control group, the mean capillary blood glucose level was increased to about 15 mg/dl from the baseline, which is also extremely significant ( $P = 0.0001$ ). The mean values of systolic and diastolic BP were significantly increased from the baseline values in the control group. In the intervention group, a decrease of about 9 units from the baseline in the mean value of systolic BP and an increase of 2 mm Hg in the diastolic pressure was observed. Here, the increase in the diastolic value may be due to the combined effect of nonhypertensive diabetic patients and hypertensive diabetic patients. The mean capillary blood glucose levels of the intervention group in five consecutive follow-ups were treated for analysis of variance (ANOVA - single factor) with baseline values ( $F$  value = 3.84); this showed that there is no significant difference between the first follow-up and baseline ( $F = 0.47$ ). But follow-ups 2, 3, 4 and 5 months showed significant differences ( $F = 14.24, 24.70, 22.49$  and  $37.63$ , respectively).

The overall HRQoL score was increased by about 45% from the baseline in the intervention group. Individual areas like the health/function, socioeconomic, psychological/spiritual and family domains show positive changes, ranging from 17-71%. In contrast, the overall HRQoL score of the control group was decreased by about 2% and except the family domain all other domains show negative changes.

**Effect of counseling on fasting plasma glucose level (FPG):**

The baseline value of FPG of Group-I was  $220.8 \pm 10.59$  and it reduced significantly up to  $195.0 \pm 3.04$  after 3 month. The baseline value of FPG Group-II of was  $225 \pm 25$  and it reduced significantly upto  $138 \pm 3.7$  after 3 month. The baseline value of FPG of Group-III was  $228 \pm 28$  and it reduced significantly upto  $140 \pm 3.2$  as compared baseline. . There were significantly reductions in FPG found in all three groups.

**Effect of counseling on postprandial plasma glucose level (PPG):**

The baseline value of PPG of Group-I was  $280 \pm 9.6$  and it reduced up to  $226 \pm 3.6$  after 3 month. The baseline value of PPG of Group-II was  $311 \pm 31$  and it reduced up to  $230 \pm 3.7$  after 3 month. The baseline value of PPG of Group-III was  $326 \pm 37$  and it reduced significantly up to  $230 \pm 3.1$  after 3 month.

**Effect of counseling on glycosylated hemoglobin (HBA1C):**

The significant reductions in the glycosylated hemoglobin level were observed among all the three groups. The HbA1c was found to be reduced more significantly in group II patients who are on oral hypoglycemic triple combination therapy.

**Effect of counseling on BMI:**

The baseline values of BMI of G-I, Group-II and Group-III were  $25 \pm 0.70$ ,  $24 \pm 1.1$  and  $23 \pm 0.36$  respectively. There was no large difference in BMI of final values and small decrease in values. There was significantly reduction of BMI of Group-I value.

**Effect of counseling on cholesterol:**

The baseline value of cholesterol of G-I, Group-II and Group-III were  $134 \pm 8.6$ ,  $129 \pm 9.8$  and  $171 \pm 5.3$  and it reduced  $117 \pm 5.1$ ,  $114 \pm 4.4$  and  $152 \pm 3.7$  after 3 month. The values of cholesterol were not significantly reduced in Group-I but significantly reduced in Group-III.

**Effect of counseling on triglyceride:**

The baseline value of triglyceride of Group-I was  $145 \pm 16$  and it reduced significantly up to  $124 \pm 16$  after 3 month. The baseline values of Group-II and Group-III were  $141 \pm 15$  and  $167 \pm 13$  and it reduced significantly up to  $117 \pm 9.8$  and  $148 \pm 7.6$  after 3 month respectively. The values of triglyceride were significantly reduced in Group-II and Group-III.

### **Effect of counseling on high density lipoprotein (HDL):**

The baseline values of HDL of Group-I, Group-II and Group-III were  $40 \pm 1.2$ ,  $37 \pm 1.0$ ,  $39 \pm 1.3$  and increased up to  $48 \pm 2.4$ ,  $43 \pm 5.3$  and  $50 \pm 2.6$  after 3 month respectively. The values of HDL were increased in Group-II and Group-III.

### **Effect of counseling on low density lipoprotein (LDL):**

The baseline value of LDL of Group-I was  $77 \pm 6.8$  and reduced up to  $49 \pm 4.9$  after 3 month. Also the baseline value of LDL of Group-II and Group-III were  $69 \pm 9.9$  and  $98 \pm 7.7$  and reduced up to c after 3 month respectively. The value of LDL was significantly reduced in Group-I and Group-III.

### **Discussion**

The pharmacist's involvement in diabetes care is justified by his or her position as a key member of the health care team; he or she needs to work together with other health professionals to prevent diabetes and its complications.<sup>[4]</sup> It is assumed that such pharmacist-involved diabetic care programs cannot actually be conducted in practice, but this should be refuted and the benefit should go to the rural patients who form the majority in developing countries like India. This study has shown that pharmaceutical care will help to improve glycemic control and other vital parameters like BMI and, more importantly, such professional care will help to improve the overall HRQoL of diabetic patients. The results are comparable with that of similar studies conducted in the Western world.<sup>[1],[2]</sup> The 6-month study duration is long enough to assess the changes in the parameters. However, we could not estimate the glycosylated hemoglobin in this study as was done in other studies conducted in developed countries. Even today, in India, the common clinical practice when monitoring diabetes mellitus is to measure fasting blood glucose. Therefore we should not underestimate the value of such investigations. Thus, as an experimental attempt, we provided pharmaceutical care to a small group of patients and proved that such services can add value to the health care provided. With the wealth of graduate pharmacists in developing countries like India, such 'pharmaceutical care' models should be fine-tuned and implemented, which will be another milestone for the profession of pharmacy. The management of Diabetes Mellitus not only requires the prescription of the appropriate nutritional and pharmacological regimen by the physician but also intensive education and counseling of the patient. Diabetes is a chronic disease with altered carbohydrate, lipid and protein metabolism. The chronic complications of diabetes are known to affect the quality of life of diabetic patients. Various factors like understanding of the patients about their disease, socioeconomic factors, dietary regulation, self-monitoring of blood glucose are known to play a vital role in diabetes management.<sup>[27], [28], [29]</sup> The present study was carried out for 10 months. Of the 10 months patients was selected in first 4 months. Selected patients were categorized into three groups. Total 35 patients were selected for counseling regarding disease, medication, personal hygiene, diet and exercise at hospital. The values of all parameter were recorded before and after the counseling. A total 35 patients were included into the study out of which 30 patients were completed the study successfully and dropout rate was five patients. The selected 30 patients were distributed in to three groups such as Group-I on double combination (n-11), Group-II on triple combination (n-12) and Group-III on insulin (n-7). All these distributed patients in each

group already on the same combination and same insulin from 1-2 years but there is no significant reduction in FPG, PPG, BMI, HbA1c and lipids profile by before result chart because of resistance to the medication and patient Noncompliance. Also there is no awareness about Diabetes disease, foot care, eye care, teeth care, self monitoring of glucose, diet and exercise. Also patient feedback form shows that there were less awareness in patients about personal hygiene and Life style modification. In the present study according to sex distribution curves, the ratio of Male: Female were 6:5 in G-I, 5:7 in G-II and 2:5 in G-III respectively. The female quantity was more than male. The Mean age of G-I, G-II and G-III were  $55 \pm 1.4$ ,  $54 \pm 2.2$  and  $55 \pm 2.4$  respectively and mean duration of Diabetes Mellitus of Group-I, II and III were  $4.9 \pm 0.44$ ,  $5.3 \pm 0.49$  and  $6.3 \pm 0.42$  respectively. The baseline values of BMI of Group-I, II and III were  $25 \pm 0.71$ ,  $24 \pm 1.1$  and  $23 \pm 0.36$  and it reduced up to  $24 \pm 0.69$ ,  $23 \pm 0.96$  and  $23 \pm 0.19$  after 3 month. There is not significant reduction in BMI of patients due to no large weight reduction within three month. There were significantly reductions in FPG found in all groups due to there is positive impact of regular diet control and exercise on fasting plasma glucose. The cholesterol values were not significantly reduced in Group-I but significantly reduced in Group-III. The baseline values of LDL of Group-I, II and III were  $77 \pm 6.8$ ,  $69 \pm 9.9$  and  $98 \pm 7.7$  reduced up to  $49 \pm 4.9$ ,  $69 \pm 9.9$  and  $98 \pm 7.7$  after 3 month as compared to baseline. The value of LDL was significantly reduced in Group-I and Group-III than in Group- II. In the present study baseline values of HbA1c of Group-I, II and III were  $9.2 \pm 0.6$ ,  $10 \pm 2.2$  and  $9.9 \pm 0.84$  respectively and it reduced significantly up to  $8.2 \pm 0.4$ ,  $8.7 \pm 0.49$  and  $8.7 \pm 0.71$  after 3 month as compared with baseline values. The significant reductions in the glycosylated hemoglobin level were observed among all the three groups. The HbA1c were found to be reduced more significantly in Group-II and Group-III subjects who are on oral hypoglycemic triple combination therapy and on insulin with counseling. There were significant reductions in HbA1c in Group-I by  $1.0 \pm 0.2$  %, in Group-II by  $1.3 \pm 1.71$ % and in Group-III by  $1.2 \pm 0.13$ % after 3 month as impact of patient counseling.

## Conclusion

Diabetes is a chronic illness that requires a combination of pharmacological and nonpharmacological measures for better glycemic control. Patient adherence to medication and lifestyle modifications plays an important role in diabetes management. The majorities of individuals with type 2 diabetes were overweight, did not engage in recommended levels of physical activity, and did not follow dietary guidelines for fats, fruits and vegetable consumption. Additional measures are needed to encourage regular physical activity and improve dietary habits in this population. This study provides evidence that a community-based patient counseling regarding Disease, medication and Life style modification for type 2 diabetic patients, can be effectively implemented in developing nations and that important health indicators significantly improve. In particular, BMI and Glycemic levels decreased. The decreased glycosylated hemoglobin should translate into a reduced risk of further complications. The knowledge of the subjects visiting the first time was found to be inadequate. This probably is due to inadequate information, non-availability of educational material and improper guidance. The reasons of the poor knowledge need to be further studied in detail in these populations. Similar results were also observed in different educational modules. It means it is concluded that continuous education programmes and counseling should be conducted for Diabetic patients to emphasize and re-emphasize the importance of risk factor, prevention, adherence to medication

and behavioral changes to prevent recurrences of disease, their progression, and ultimately minimize hospitalization. Overall outcome would be cost effectiveness in health care system and better life of the sufferer.

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