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Assessment of Clinical Pharmacist Interventions on Therapeutic Efficacy in Individuals Afflicted with Diabetic Neuropathy

J.T Rudra[1*], K Keerthana[2], M Jaya Ramudu[3], K R Divya[4], D Sai Likhitha Naidu [5]
Department of pharmacy practice, Balaji college of pharmacy, Anantapuramu , Andhra Pradesh 515001

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ABSTRACT
Introduction: Diabetes is the major complication in the world. Complications of diabetes are getting more worsen to the population who are not having better medication adherence. Diabetic neuropathy is one of the major complications of diabetes. **Methods:** A prospective randomized control trail was conducted over six months of time period, at tertiary care hospital over 264 subjects by dividing the subjects into interventional group and control group. Data was collected through the case sheets of patients. And the collected data is statistically analysed through the software called instat, by using chi-square test and T-test. **Results:** Our study includes 264 subject population in the study. Among 264 population they divided into Interventional group and Control group. Clinical pharmacist played the role in counselling the interventional group and that is compared to the control group. After 3 visits of follow up the interventional had significant control of GRBS and reduction of symptoms and significant adherence compared to control group. **Conclusion:** Our study concludes that prospective randomized control trail provides valuable insights to assess the impact of clinical pharmacist interventions on therapeutic efficacy in individuals diagnosed with diabetic neuropathy. These findings underscore the importance of clinical pharmacist interventions in management and improving the quality of life of diabetic neuropathy patients.

INTRODUCTION:

Diabetes: Diabetes is a chronic, auto Immune condition that occurs when the body's own immune system attacks and destroys the insulin producing beta cells of the pancreas.1 According to WHO, Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively. use the insulin it produces.

Signs and Symptoms: Feeling constantly tired, Craving for food all the time, Feeling thirstier than usual, Paying more visits to bathroom, Experiencing blurred vision, Weight gain around belly [belly fat], Slow healing of wounds, Numbness of hands, Fatigue.

Diabetic Neuropathy: Diabetic neuropathy is a major complication in diabetic Patients. It is a neurodegenerative disorder that damage nervous system caused due to high blood sugar levels in patients having Diabetes Mellitus. It can affect any nerve in the body leading to tingling and numbness of the parts supplied by the nerve[1].

Classification Of Diabetic Neuropathy:
DNP is classified into 4 types:

1. PERIPHERAL NEUROPATHY
2. AUTONOMIC NEUROPATHY
3. PROXIMAL NEUROPATHY
4. MONO/FOCAL NEUROPATHY

Peripheral Neuropathy: Peripheral neuropathy is the most common form of diabetic neuropathy. Feet and legs are often affected first, followed by hands and arms.

- Signs and symptoms of peripheral neuropathy include:
- Numbness or reduced ability to feel pain or temperature changes, especially in feet and toes.
- A tingling or burning feeling.

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- Sharp, jabbing pain that may be worse at night.
- Extreme sensitivity to touch — for some people even the weight of a bedsheet can be painful.
- Muscle weakness.
- Loss of reflex response. Serious foot problems, such as ulcers, infections, and bone and joint damage[2].

Autonomic Neuropathy: The autonomic nervous system controls blood pressure, heart rate, sweat glands, eyes, bladder, digestive system, and sex organs. Diabetes can affect the nerves in any of these areas,
Possibly causing symptoms including:

- Bladder problems, including frequent urinary tract infections, loss of bladder control (urinary incontinence) or trouble emptying the bladder (urinary retention).
- Constipation, uncontrolled diarrhoea[2].
- Slow stomach emptying (gastroparesis) leading to nausea, vomiting, sensation of fullness and loss of appetite.
- Difficulty in swallowing.
- Erectile dysfunction in men[2].

Proximal Neuropathy: Unlike peripheral neuropathy, which affects the ends of nerves in the feet, legs, hands and arms, proximal neuropathy affects nerves in the thighs, hips, buttocks, or legs. This condition is more common in people who have type 2 diabetes and in older adults. Symptoms are usually on one side of the body, though in some cases symptoms may spread to the other side, too. Most people improve at least partially over 6 to 12 months[2].

- This condition is often marked by symptoms including:
- Severe pain in the buttock, hip, or thigh.
- Weak and shrinking thigh muscles.
- Difficulty rising from a sitting position[3].

Mono/Focal Neuropathy:
Mononeuropathy involves damage to a single, specific nerve. The nerve may be in the face, torso, arm, or leg. Mononeuropathy, which may also be called focal neuropathy, often comes on suddenly. It's most common in older adults. Although mononeuropathy can cause severe pain, it usually doesn't cause any long-term problems. Symptoms usually lessen and disappear on their own over a few weeks or months.

Symptoms depend on which nerve is involved, and may include:

- Double vision or difficulty focusing your eyes.
- Paralysis on one side of the face.
- Pain in shin or foot.
- Pain in the front thigh.

Sometimes mononeuropathy occurs when a nerve is compressed. Carpal tunnel syndrome is a common type of compression neuropathy in people with diabetes. Symptoms of carpal tunnel syndrome include:

- Numbness or tingling in your fingers or hands, especially in your thumb, index finger, middle finger, and ring finger[3].

Clinical Pharmacist: Clinical Pharmacists are licensed practitioners with advanced education and training who practice in all types of patient care settings with a focus on comprehensive medication management[4].

Role of Clinical Pharmacist: The role of a clinical pharmacist includes:
Patient counselling.

- Rationalising patient drug usage.
- Working with Physicians to develop treatment plans.
- Monitoring Adverse reactions and side effects.
- Collaborating with the pharmacy to dispense the right medication.
- Documenting treatment plans and patient progress
- Maintaining medical records
- Ward round participation
- Patient monitoring/ Drug monitoring
- Medical Audit
- Drug Information[5`qw].

What is Known?

- Diabetic Neuropathy is one of the major complications in patients who are having diabetes. It affects 50-90% patients who are having long term diabetes.
- Males are more likely to develop Diabetic Neuropathy.
- Studies states that 15-30% of diabetic patients experience painful diabetic neuropathy. Diabetic Neuropathy damages the Nervous system, that leads to foot ulcers and gangrene.

WHAT IS UNKNOWN?

- The study is based on the knowledge gaining and educating the patients about better available treatment options for Diabetic Neuropathy.
- To study about tests which helps to detect the disease condition.
- Untreated or neglected Diabetic Neuropathy may leads to the damage of other organ systems like Digestive system, Cardiovascular system, Urinary system, and the patients are more likely to get chronic kidney diseases.

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- This study is to provide the preventive measures to the patients by understanding their early signs and symptoms.

Review of literature:

1. Øalexandra Halalau, Melda Sonmez, Ahsan Uddin 4, Patrick Karabon, Zachary Scherzer, Scott Keeney Was Conducted A Study On Efficacy Of A Pharmacist-Managed Diabetes Clinic In High-Risk Diabetes Patients, A Randomized Controlled Trial - "Pharm-Md": Impact Of Clinical Pharmacists In Diabetes Care which is published in the year of 2022 march, this study states that when combined with standard of care alone, the addition of pharmacist managed care for patients with type 2 diabetes mellitus is linked to notable improvements in HbA1c. The follow-up data's missingness reduced the secondary outcomes analyses' power.

2. Che Aishah Nezariah Ismail Conducted A Review On The Issues And Challenges In Diabetics Study Neuropathy Management A Narrative Review published on online June 15 2023 in the world general of diabetics generally these study focus on the current aspects regarding diabetic neuropathy especially issues pertaining to the treatment and current challenges in the management diabetic neuropathy with some suggested recommendation on strategies to slow down diabetic neuropathy progression in order to increase the understanding of diabetic neuropathy and give ideas for improvement of treatment and management of diabetic neuropathy the increasing prevalence of diabetic neuropathy and its complicate among diabetic neuropathy patient is alarming and can be costly to individual.

3. Eval Feldman, Md, Phd, Feremy M Shetner Conducted A Study On Management Of Diabetic Neuropathy published on the august 30 2022 and updated on oct 2023 this study helps the patient with diabetic neuropathy should be treated with a systematic step wise approach that includes glycaemic control and control of the metabolic syndrome education and counselling on foot care and safety measure and symptomatic treatment of pain.

4. A Study On Assessment Of Pain And Impact Of Care Among Patients With Painful Diabetic Peripheral Neuropathy, which is published in the year of 2014, January this study states that in this patient population, DPN may be underdiagnosed and undertreated, which gives a chance for pharmacists to support patients with diabetes in achieving their quality-of-care objectives.

5. A Study On Individual Patient E4ducation For People With Type 2 Diabeties Mellitus which is published in the year of 2009 this study states that when comparing individual glycaemic control education to conventional care, this comprehensive review indicates that there may be benefits for a subgroup of patients whose baseline haemoglobin A1c is higher than 8%. Overall, though, it didn't seem like there was much of a difference between regular care and individualized instruction.

6. Silvio Iozucchi Md, Julo Rosenstock Md Etal Conducted A Study On Diabetic Neuropathy published on 16 November 2010 in general of clinical endocrinology metabolism volume this is the generalised study on the disease and disease related issue and sign and symptoms related to diabetic neuropathy.

7. Christie Schumacher, Scott E Glosner Was Conducted A Study On Assessment Of Pain And Impact Of Care Among Patients With Painful Diabetic Peripheral Neuropathy, which is published in the year of 2014, January this study states that in this patient population, DPN may be underdiagnosed and undertreated, which gives a chance for pharmacists to support patients with diabetes in achieving their quality-of-care objectives.

AIM:

The Aim of this study is to evaluate the impact of Clinical Pharmacist Interventions on the therapeutic efficacy in individuals afflicted with Diabetic Neuropathy.

OBJECTIVES:

- To assess the effectiveness of clinical pharmacist interventions in improving neuropathic symptoms among individuals with diabetic neuropathy.
- To investigate the role of clinical pharmacist interventions in enhancing medication adherence among individuals suffering from diabetic neuropathy.
- To identify and resolve medication-related problems through clinical pharmacist interventions in diabetic neuropathy patients.
- To analyse the association between clinical pharmacist interventions and overall therapeutic outcomes in individuals with diabetic neuropathy.

METHODOLOGY:

Study Design: This study adopts a prospective, randomized controlled trial (RCT) design to assess

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the impact of clinical pharmacist interventions on therapeutic efficacy in individuals diagnosed with diabetic neuropathy

PARTICIPANTS:
INCLUSION CRITERIA: -Individuals aged 18 years or older. -Diagnosis of diabetic neuropathy confirmed by clinical examination and relevant diagnostic tests. -Willingness to participate in the study and provide informed consent.
EXCLUSION CRITERIA: - Patients with severe cognitive impairment or psychiatric disorders that may affect their ability to comply with the study protocol. -Individuals with other significant neurological or systemic diseases that may confound the evaluation of diabetic neuropathy.

RECRUITMENT AND RANDOMIZATION: - Participants meeting the inclusion criteria will be recruited from outpatient clinics specializing in diabetes care. - Randomization will be performed using computer-generated random numbers to allocate participants into two groups: the intervention group and the control group.

INTERVENTION:
Primary Intervention: Participants allocated to the intervention group will receive comprehensive pharmaceutical care provided by clinical pharmacists. Pharmaceutical care will include medication therapy management, adherence counselling, lifestyle modifications advice, and education on self-management of diabetes and neuropathy.

Secondary Intervention: Participants in the control group will receive standard care as per the clinic's protocol, which may include routine medical consultations and prescriptions from physicians. They will not receive additional pharmaceutical care from clinical pharmacists.

Outcome measures:
Primary Outcome: Change in therapeutic efficacy, assessed through measures such as improvement in neuropathic symptoms, glycaemic control (HbA1c levels), and medication adherence.

Secondary Outcome: Frequency of medication-related problems identified and resolved by clinical pharmacists. - Patient satisfaction with the pharmaceutical care received.

Data Collection: Baseline assessments were conducted before randomization, including demographic information, medical history, neuropathy symptoms, and medication regimens. - Follow-up assessments were scheduled at regular intervals (e.g., 3 months, 6 months) to evaluate the primary and secondary outcomes.

- Data was collected through patient interviews, medical record reviews, and validated assessment tools/questionnaires.

Statistical Analysis: Data was analysed using appropriate statistical methods, including descriptive statistics, chi-square tests, t-tests, and multivariate regression analysis. - The significance level will be set at $p < 0.05$.

Ethical Considerations: The study was conducted in accordance with the principles outlined in the Declaration of Helsinki. - Ethical approval was obtained from the institutional review board Balaji College of Pharmacy. - Informed consent was obtained from all participants before enrolment in the study.

RESULTS:
Our study is Assessment of the clinical pharmacist interventions on therapeutic efficacy in individual afflicted with diabetic neuropathy, in our study we included 264 subject population who are divided into Control group (132) and Interventional group (132) according our inclusion and exclusion criteria.

Table:1 Demographics of The Subject Population

GENDER	INTER4VENTIONAL GROUP	CONTROL GROUP
MALE	75(56%)	75(56%)
FEMALE	57(43%)	57(43%)
AGE	**INTERVENTIONAL GROUP**	**CONTROL GROUP**
35-45	44(33%)	49(37%)
45-55	46(34%)	44(33%)
55-65	30(22%)	23(17%)
65-75	12(9%)	17(12%)

The above table shows the data of Interventional group contains 75(56%) of males and 57(43%) of female population are participating and in Control group 75(56%) of males and 57(43%) of females are participating in our study. This table shows the different age group.

- 35-45 are 44(33%) in Interventional group, 49(37%) in Control group.
- 45-55 are 46(34%) in Interventional group, 44(33%) in Control group.
- 55-65 are 44(33%) in Interventional group, 23(17%) in Control group.
- 65-75 are 23(17%) in Interventional group, 17(12%) in Control group.

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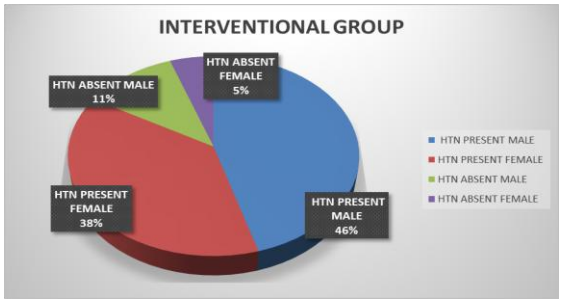

Figure: 1 Interventional Group Having Comorbid Condition

The above chart shows the data of Interventional group contains Hypertension, this includes 60(46%) of male population,50(38%) of female population having Hypertension. And 15(11%) of male population,7(5%) of female population is not having Hypertension.

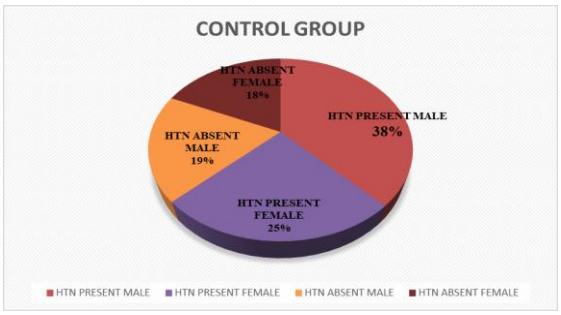

Figure:2 Control Group Having Comorbid Conditions

The above chart contains information about Control population having 50(38%) of male population,33(25%) of female population having Hypertension. And 25(19%) of males and 24(25%) of females not having Hypertension.

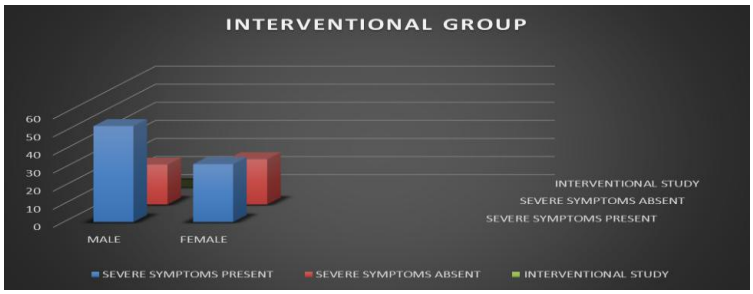

Figure :3 Interventional Group Having Severe Symptoms

The above bar graph shows the data belongs to Interventional group population,53(40%) males and 32(24%) of females having severe neuropathic symptoms like cellulitis, gangrene and limb amputation. And remaining 22(16%) of males and 25(18%) of females doesn't have any severe diabetic complications.

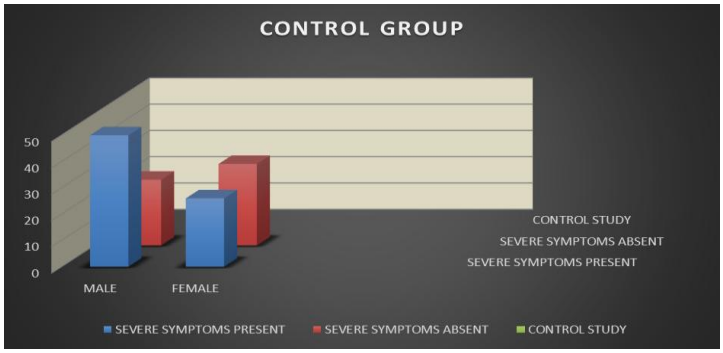

Figure: 4 Control Group Having Severe Symptoms

The above bar graph shows the data belongs to Interventional group population,50(37%) males and 26(19%) of females having severe neuropathic symptoms like cellulitis, gangrene and limb amputation. And remaining 25(18%) of males and 31(23%) of females doesn't have any severe diabetic complications.

GENDER	MALE	FEMALE
T METFORMIN+T GLIMIPRIDE	51(38%)	14(10%)
T METFORMIN	14(10%)	43(32%)
INSULIN	10(7%)	0(0%)

Table: 6 Medications Taken By Interventional Group

Above tables shows the information about the

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medication taken by the subject population in Interventional group

- 51(38%) of males and 14(10%) of females having dual therapy (T METFORMIN +T GLIMIPRIDE)
- 14(10%) of males and 43(32%) of females having monotherapy (T METFORMIN)
- 10(7%) of males having INSULIN.

GENDER	MALE	FEMALE
T METFORMIN+T GLIMIPRIDE	48 (36%)	46(34%)
T METFORMIN	26(19%)	11(8%)
INSULIN	1(0.7%)	0(0%)

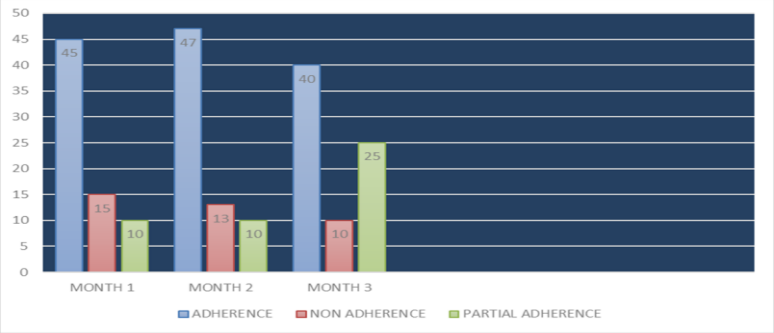
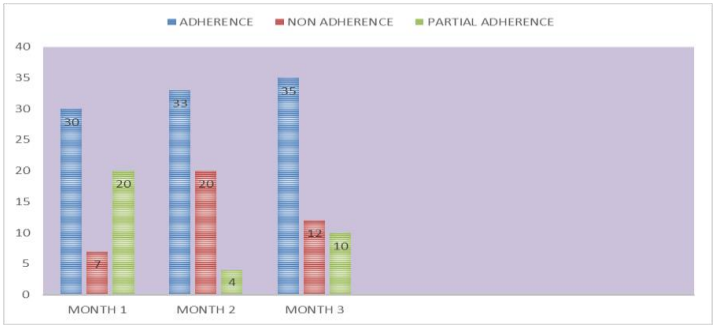


Table: 8 Medication Adherence of Male Subjects in Interventional Group

Above bar graph shows the adherence of male in Interventional group for the time-period of 6 months.

VARIABLE	MONTH 1	MONTH 2	MONTH 3
ADHERENCE	45(60%)	47(62%)	50(66%)
NON-ADHERENCE	15(20%)	13(17%)	10(13%)
PARTIAL ADHERENCE	10(13%)	10(13%)	15(20%)

Table: 9 Medication Adherence of Female Subjects in Interventional Group



Above bar graph shows the adherence of female in Interventional group for the time period of 6 months.

Table: 10 Medication Adherence of Male Subjects In Control Group

Table:7 Medications Taken By Control Group

Above tables shows the information about the medication taken by the subject population in Interventional group

- 48{36%} of males and 46(34%})of females having dual therapy {T METFORMIN +T GLIMIPRIDE}
- 26(19%) of males and11(8%) of females having monotherapy {T METFORMIN}
- 1{0.7%} of males having INSULIN.

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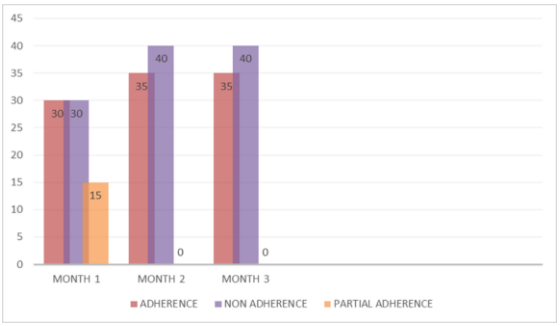
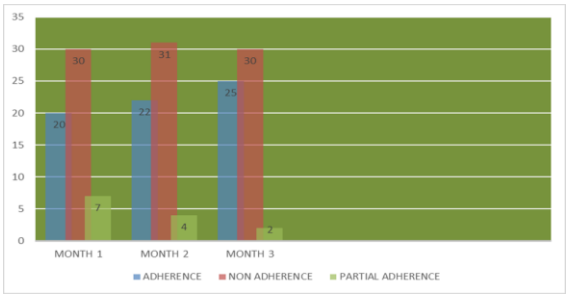
VARIABLE	MONTH 1	MONTH 2	MONTH 3
ADHERENCE	30(40%)	33(44%)	40(53%)
NON-ADHERENCE	7(9%)	20(26%)	10(13%)
PARTIAL ADHERENCE	20(26%)	4(5%)	7(9%)



Above bar graph shows the adherence of male in Control group for the time period of 6 months.

Table: 11 Medication Adherence Of Male Subjects In Interventional Group

VARIABLE	MONTH 1	MONTH 2	MONTH 3
ADHERENCE	30(40%)	35(46%)	40(53%)
NON-ADHERENCE	30(40%)	40(53%)	35(46%)
PARTIAL ADHERENCE	15(20%)	0(0%)	0(0%)



Above bar graph shows the adherence of female in Control group for the time period of 6 months.

Table: 12 Overall Parameters In The Study

VARIABLE	MONTH 1	MONTH 2	MONTH 3
Adherence	20(35%)	22(38%)	25(44%)
Non-adherence	30(52%)	31(54%)	30(52%)
Partial adherence	7(12%)	4(7%)	2(4%)

Table:13 Significance Of Hypertension In Male And Female Of Interventional Group

S.NO	VARIABLE	INTERVENTIONAL GROUP		CONTROL GROUP	
1	AGE 35-45 45-55 55-65 65-75	44(33%) 46(34%) 30(22%) 12(9%)		49(37%) 44(33%) 23(17%) 17(12%)	
2	GENDER • MALE • FEMALE	75(56%) 57(43%)		75(56%) 57(43%)	
3	HYPERTENSION • PRESENT • ABSENT	MALE 60(46%) 15(11%)	FEMALE 50(38%) 7(5%)	MALE 50(38%) 25(19%)	FEMALE 33(25%) 24(25%)
4	SYMPTOMS • PRESENT • ABSENT	MALE 53(40%) 22(16%)	FEMALE 32(24%) 25(18%)	MALE 50(37%) 26(19%)	FEMALE 25(18%) 31(23%)
5	MEDICATION • Metformin+ Glimepiride • Metformin • Insulin	MALE 51(38%) 14(10%) 10(7%)	FEMALE 14(10%) 43(32%) 0(0%)	MALE 48 (36%) 26(19%) 1(0.7%)	FEMALE 46(34%) 11(8%) 0(0%)
6	ADHERENCE • ADHERENCE • NON- • PARTIAL ADHERENCE	MALE 50(66%) 10(13%) 15(20%)	FEMALE 40(53%) 10(13%) 7(9%)	MALE 40(53%) 35(46%) 0(0%)	FEMALE 25(44%) 30(52%) 2(4%)

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VARIABLES	MALE	FEMALE	P VALUE
HYPERTENSION PRESENT	60(46%)	32(24%)	0.1338
HYPERTENSION ABSENT	15(11%)	25(18%)	

The above table shows the significance of Hypertension in Interventional group between male and female subjects, and p value of Hypertension is 0.1338.

Table: 14 Significance of Hypertension in Male And Female Of Control Group

Variables	Male	Female	P value
Hypertension present	50(37%)	25(18%)	0.2715
Hypertension absent	26(19%)	31(23%)	

The above table shows the significance of Hypertension in Control group between male and female subjects, and p value of Hypertension is 0.2715.

Table: 15 Significance of Male Vs Grbs in Interventional Group

GENDER MALE	BASE LINE VISIT	1 ST VISIT	2ND VISIT	P VALVE
MEAN	263.6	237.2	225.4	0.0001

The male subjects had significant results in GRBS levels.

Table:16 P Value of Female Vs Grbs in Interventional Group

Gender Male	Base line visit	1 st visit	2nd visit	P valve
Mean	256.6	230.9	219.4	0.0001

The female subjects had significant results in GRBS level.

Table: 17 P Value Of Male Vs Grbs In Control Group

GENDER MALE	BASE LINE VISIT	1 ST VISIT	2ND VISIT	P VALVE
MEAN	264	260	263	0.325

The male subjects don't have significant results in GRBS levels.

Table:19 Significance of Adherence in Male and Female of Control Group

VARIABLES	MALE	FEMALE	P VALUE
ADHERENCE PRESENT	40(53%)	25(44%)	0.3464
NON ADHERENCEABSENT	35(46%)	30(52%)	

The above table shows the significance of adherence in Control between male and female subjects, and p value of adherence is 0.3464.

DISCUSSION:

Summary of Findings:

Our prospective randomized control trail study explored to assess the impact of clinical pharmacist interventions on therapeutic efficacy in individuals diagnosed with diabetic neuropathy. We found significant difference between interventional group and control group regarding GRBS levels, medication adherence and reduction of neuropathic symptoms.

Impact Of Clinical Pharmacist On Diabetic Neuropathy Patients Our findings states that medication adherence of interventional group is significantly more adherence than of control group, and the GRBS levels are more control in interventional group compared to control group.

These results highlight the importance of clinical pharmacist interventions on therapeutic efficacy and in individuals having diabetic neuropathy.

Clinical Implications:

Clinicians should consider the GRBS levels and have to resolve the medication related problems occurred. And have to check the adherence of subjects frequently.

Further investigation is needed for in depth study according to involvement of the clinical pharmacist intervention in management of diabetic neuropathy and increasing in quality of life of the patient.

Limitations And Further Directions:

Our study has few limitations regarding category of people should include. Future research can utilize the following study, and along with these longitudinal studies to establish the in-depth role of the clinical pharmacist on diabetic neuropathy.

Comparing to previous studies our study gives the information regarding the role of clinical pharmacist in counselling of patients, and improving quality of life of patients. Previous studies not clearly explained the key role of the clinical pharmacist in diabetic neuropathy.

Our study helps for the further investigations for clear and in-depth establishment of the importance of clinical pharmacist role in diabetic neuropathy patients.

CONCLUSION:

Our study concludes that prospective randomized control trail provides valuable insights to assess the impact of clinical pharmacist interventions on therapeutic efficacy in individuals diagnosed with diabetic neuropathy. These findings underscore the importance of clinical pharmacist interventions in

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management and improving the quality of life of diabetic neuropathy patients.

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