



Correlation between diabetic neuropathic pain on quality of life with type IDM patients–An observational study

Nishant Kawde¹, Mahendra Singh Lodhi², Ronald Prabhakar³, Akshay Chougule⁴

¹ Intern, College of Physiotherapy, MMC, WH, Miraj, Maharashtra, India

² Assistant Professor, College of Physiotherapy, MMC, WH, Miraj, Maharashtra, India

³ Professor, Incharge Principal, College of Physiotherapy, MMC, WH, Miraj, Maharashtra, India

⁴ Assistant Professor, College of Physiotherapy, MMC, WH, Miraj, Maharashtra, India

Abstract

Background: Diabetes Mellitus is defined as heterogenous metabolic disorder characterized by common feature of chronic hyperglycaemia. Due to change in life style of low activity and high calorie diet with genetic susceptibility it's incidence is estimated at 7% of adult population (approximately 65% million people) in India. Diabetic neuropathic curbs physical activity and have effect on ADLs like maintaining balance, inability to stand and walk, loss of mobility and independence.

Material and Methodology: Both males and females (n=32) are from tertiary care hospital in Miraj taluka were included in this study. Participants were screened based on selection criteria. Data collection was done by using Neuropathic Pain Rating Scale and SF 36 questionnaire.

Result: Correlation revealed a strong negative relationship between neuropathic pain score and SF 36 score for quality of life ($r= 0.91, p<0.001$) for all male subjects and very strong negative relationship between neuropathic pain and SF 36 score for QOL($r= 0.873, p< 0.001$) for all female subjects There is significant difference between males and females in both Neuropathic Pain Rating Scale score and SF 36 score. Correlation analysis revealed a very strong negative relationship between neuropathic pain score and SF 36 score for quality of life ($r= 0.89, p<0.001$) so it suggests that as pain increases quality of life decreases.

Conclusion: The study concludes that as pain increases QOL decreases.

Keywords: diabetes mellitus (DM), neuropathic pain rating scale (NPS), SF 36 quality of life questionnaire, correlation

Introduction

Diabetes Mellitus (DM) is defined as a heterogeneous metabolic disorder characterized by common feature of chronic hyperglycaemia [1]. Due to change in life style of low activity and high calorie diet with genetic susceptibility it's incidence is estimated at 7% of adult population (approximately 65% million people), in India.

DM is classified into two groups: Type 1 DM: It comprises about 10% cases of DM. Also called as insulin-dependent DM (IDDM), Type 2 DM: It comprises about 80% cases of DM. Also called as Non – insulin dependent DM (NIDDM) [1]. Obesity, habitual physical inactivity, race, hypertension, dyslipidaemia, vascular disease, genetic syndromes are the risk factors for diabetes mellitus [1].

Neuropathy can be defined as any disease of the nerves which involve peripheral nerves. Diabetic Neuropathy is an all-inclusive term for any DM associated disorder of the peripheral and autonomic nervous system or cranial nerves. In diabetic neuropathy lower extremity is mostly involved. Foot Insensitivity and ulceration are the most common symptoms [2]. The literature report reveals that 50 % to 66 % of the patients will develop Peripheral neuropathy at some point during their life time [3].

DM is the primary cause of morbidity and mortality worldwide. Renal disease, IHD, gangrene of lower limb and blindness in adults are some serious complications of DM along with peripheral neuropathy. Diabetic neuropathic pain curbs the physical activity and have an effect on the ADL'S

like maintaining balance, inability to stand and walk. An individual's life is impacted considerably because of chronic painful symptoms and may be associated with anxiety, depression, loss of mobility and independence [4]

The common pathology in type 1 DM is destruction of beta cell mass usually developing to absolute insulin deficiency. Elicitation of immune system against beta cell antigens and initiation of pro-inflammatory responses issues in developing of type 1 DM. After antigen presenting cells (APCs) and beta-cell antigens to the immune system, chronic immunological responses transpire due to inefficient regulation of immunological reactions, which instigate to destruction of beta-cells via directed by virus and physiological mechanisms. This causes liberation of antigens and initiation of immune responses in opposition to other beta-cells. These antigens are presented to thymus cells (T cells) by dendritic cells (DCs). When auto reactive T cells have escaped thymic negative selection an auto-immune response occurs. Auto reactive cytotoxic T and B cells are stimulated by auto reactive T cells, activated by DCs. Ultimately due to the collective cooperation of DCs, macrophages, T, B, and natural killer (NK) cells effector mechanism of beta-cell destruction takes place [7].

The fundamental pathological changes for neuropathy are segmental demyelination. There is loss of myelin segment between two consecutive nodes of Ranvier in segmental demyelination, but axon remains intact. Proliferation of schwann cells around axons producing 'onion bulbs' found

in hypertrophic neuropathy are associated with schwann cell proliferation generally of demyelination and remyelination [1].

Acute metabolic complications comprises of ketoacidosis, hyperosmolar nonketotic coma and hypoglycaemia and late metabolic complications comprises of atherosclerosis, diabetic microangiopathy, diabetic nephropathy, diabetic neuropathy, diabetic retinopathy and infections [1].

QOL was defined by WHO as “the condition of life resulting from the combination of the effects of the complete range of factors such as those determining health, happiness, education, social and intellectual attainments, freedom of action, justice and freedom of expression” [8] It is anticipated that DM is considerable health problem and complications encompasses peripheral neuropathy, renal disease, IHD, gangrene of the lower limb. Also reports reveals that following 5 years 26% of people develop peripheral neuropathy and by 10 years, 41% of people with DM develop neuropathy and 50% to 66% of the patients eventually develop peripheral neuropathy at some point during their life time [4]. Purpose of study will be to find correlation of diabetic neuropathic pain in type 1 DM patients on quality of life.

Aim: To find out correlation between Neuropathic pain on quality of life in patients with type 1 Diabetes mellitus

Objectives

1. To assess neuropathic pain in patients with type 1 Diabetes mellitus via Neuropathic pain scale (NPS).
2. To assess quality of life in patients with type 1 Diabetes mellitus via SF – 36 Questionnaire.
3. To find the correlation of neuropathic pain on quality of life.

Materials and Methods

An ethical approval was taken by the ethical committee of the institution before undertaking the study and a written consent was taken from the subjects explaining the entire procedure of the study before recruiting them in the study.

Study design: Observational study

Sample size: A total of 32 patients were recruited in the study, both male and female were taken equally i.e. 16 males and 16 females. Sample size was calculated considering an allowable error of 20% with the confidence interval set at 95% by the following formula based on the

Results:

Inclusion criteria

- Patients with type 1 Diabetes mellitus (Both Male and Female).
- Neuropathic symptoms such as tingling, burning and shooting pain often with

Exclusion criteria

- Patients with type 2 Diabetes mellitus.
- Neuropathic pain of non- diabetic origin.
- Musculoskeletal Disorders.

Randomisation

Setting and location of the study: Tertiary care hospital and private hospitals

Allocation: Subjects were allotted according to inclusion criteria

Implementation: The method of Randomisation and

allocation of the samples in the study was done by the researchers themselves.

Procedure

Ethical clearance was obtained from the institutional ethical committee. Written consent was taken from the participants. Participants were screened on the basis of inclusion and exclusion criteria. After clearing of doubts and explaining the benefits to the subject, the subject was personally interviewed on the basis of the SF-36 health related quality of life questionnaire and Neuropathic pain scale (NPS).

Statistical analysis

Statistical analysis was done using the software SPSS20. Pearson Correlation

Test was used to analyse correlation between SF36 and Neuropathic Pain Scale whereas Unpaired t test was done to compare between gender of subjects having type 1 DM according to Neuropathic pain score and SF 36 score for quality of life.

Results

SPSS software was used for statistical analysis, Correlation analyses revealed a very strong negative relationship between Neuropathic pain score and SF 36 Score for quality of life ($r=-0.89$, $p<0.001$) So, it indicates that as pain increases, quality of life decreases. Unpaired t test was done to compare between gender of subjects having type 1 DM according to Neuropathic pain score and SF 36 score for quality of life. Mean Neuropathic pain score of male subjects (49.69) was lower than mean score for female subjects (54.25). Mean SF 36 score for quality of life of male subjects (19.74) was higher than mean score for female subjects (14.79). Correlation between Neuropathic pain score and SF 36 Score for quality of life of subjects With type 1 DM according to their gender was done using Pearson Correlation test, correlation analyses revealed a strong negative relationship between Neuropathic pain score and SF 36 Score for quality of life ($r=-0.91$, $p<0.001$) for male subjects and very strong negative relationship between Neuropathic pain score and SF 36 Score for quality of life ($r=-0.87$, $p<0.001$) for female subjects. So, it indicates that as pain increases, quality of life decreases.

Table 1: Gender distribution of subjects with type 1 DM

Gender	Frequency	Percentage
Females	16	50
Males	16	50
Total	32	100

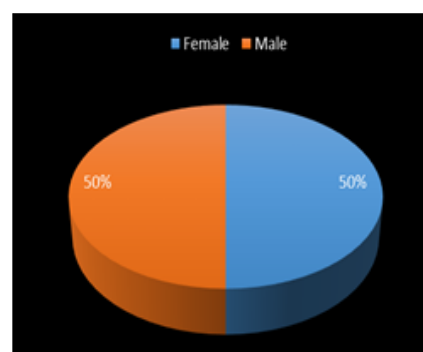


Fig 1: Pie diagram representing gender wise distribution of subjects with type 1 DM.

Table and fig 1 shows that, there were 16(50%) female subjects and 16 (50%) male subjects with type 1 DM.

Table 2: Correlation between Neuropathic pain score and SF 36 Score for quality of life of subjects with type 1 DM

Neuropathic pain score-	SF 36 Score
Pearson Correlation	p value
-0.89	<0.001

Correlation analyses revealed a very strong negative relationship between Neuropathic pain score and SF 36 Score for quality of life ($r=-0.89, p<0.001$) So, it indicates that as pain increases, quality of life decreases.

Table 3: Descriptive statistics of subjects with type 1 DM according to their gender as per Neuropathic pain score and SF 36 Score for quality of life and its comparison using unpaired t test.

Group Statistics	Gender	N	Mean	Std. Deviation	Unpaired t statistic	p value
Neuropathic pain score	Males	16	49.69	8.29	1.5	0.14
	Females	16	54.25	8.87		
SF 36 Score	Males	16	19.74	9.16	1.34	0.19
	Females	16	14.79	11.62		

Unpaired t test was done to compare between gender of subjects having type 1 DM according to Neuropathic pain score and SF 36 Score for quality of life It was found that:

- Mean Neuropathic pain score of male subjects (49.69) was lower than mean score for female subjects (54.25).
- Mean SF 36 score for quality of life of male subjects (19.74) was higher than mean score for female subjects (14.79).

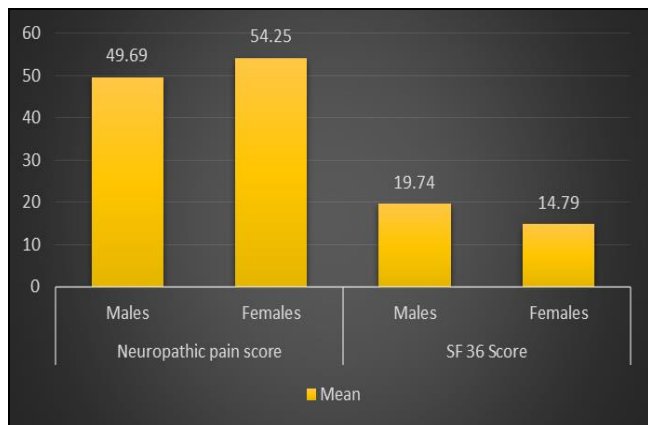


Fig 2: Average Neuropathic pain score and SF 36 Score for quality of life of according to gender of subjects with type 1 DM

Table 4: Correlation between Neuropathic pain score and SF 36 Score for quality of life of subjects with type 1 DM according to their gender

Gender	Neuropathic Pain Score	SF 36 Score
	Pearson Correlation	p value
Males	-0.91	<0.001
Females	-0.87	<0.001

Correlation analyses revealed a strong negative relationship between Neuropathic pain score and SF 36 Score for quality of life ($r=-0.91, p<0.001$) for male subjects and very strong negative relationship between Neuropathic pain score and

SF 36 Score for quality of life ($r=-0.87, p<0.001$) for female subjects. So, it indicates that as pain increases, quality of life decreases.

Discussion

The intention of the study was to CORRELATE BETWEEN DIABETIC NEUROPATHIC PAIN ON QUALITY OF LIFE WITH TYPE I DM PATIENTS in this study 32 participants both male(n=16) and female(n=16) were taken equally. After taking the ethical clearance from the ethical committee of COP, WH, MMC, participants were recruited according to selection criteria.

Table 1 and figure 1 shows gender wise group distribution of subjects with type I DM. There were 16(50%) female subjects and 16(50%) male subjects with type 1 DM. Table 2 shows that there were correlation between Neuropathic pain score and SF 36 for quality of life of subjects with type I DM. Correlation analyses revealed a very strong negative relationship between Neuropathic pain score and SF 36 Score for quality of life ($r=-0.89, p<0.001$) So, it indicates that as pain increases, quality of life decreases. The result we got is similar to the study done by Mark P jensen, Marci J Chodroff, Robert H.Dworkin in 2007. The study revealed that presence and severity of neuropathic pain are associated with greater impairments in number of important HRQoL domains. Also similar results were found in a study done formerly in UK in 1996 by SJ Benbow, M E Wallymahmed, I A MacFarlene. The study revealed that chronic neuropathic pain impaires quality of life. This result is similar to the study done in India by Dhanraj Navatre, Akshya Limaye in year 2020. The result of this study showed that as diabetic neuropathic pain increases in Type II DM patients’ quality of life decreases. The limitation of There study was that they did not considered patients with type 1 DM which we have considered in our study.

Table 3 shows descriptive statistics of subjects with type 1 DM according to their gender as per Neuropathic pain score and SF 36 Score for quality of life and its comparison using unpaired t test. It was found that, Mean neuropathic pain score for male subjects (49.69) was lower than mean score for female subjects (54.25). Mean Sf 36 score for quality of life of male subjects is (19.74) was higher than mean score for female subjects (14.79). We can conclude by this, that male subjects are stronger in bearing pain then female subjects, consequently the quality of life of male subjects is better than that of female subjects.

This result is similar to study done formerly in USA in 1998 by Joseph Riley III, Roger B Filingim *et al*. In this study we found that sex differences in response to noxious stimuli, females displaying greater sensitivity to pain than male.

Table 4 shows that correlation between Neuropathic pain score and SF 36 Score for quality of life of subjects with type 1 DM according to their gender. Correlation analyses revealed a strong negative relationship between Neuropathic pain score and SF 36 Score for quality of life ($r=-0.91, p<0.001$) for male subjects and very strong negative relationship between Neuropathic pain score and SF 36 Score for quality of life ($r=-0.87, p<0.001$) for female subjects. So, it indicates that as pain increases, quality of life decreases.

The result of this study matches with the study done previously by M.P. Wrobel, A. Szymborska *et al* in 2008. This study has proven that reduce in pain intensity,

improves quality of life and increase in the pain intensity threshold reduces the quality of life. The result of this study is similar with the study done by Mark P Jensen, Marci J Chodroff, Robert H. Dworkin in 2007. The study reveals that presence and severity of neuropathic pain are associated with greater impairments in number of important HRQoL domains.

Conclusion

Our study supported the alternate hypothesis i.e., significant correlation was found between diabetic Neuropathic pain on quality of life. The study proves that as diabetic neuropathic pain increases in Type 1 DM Patients quality of life decreases.

Limitations and Suggestions

Limitations

1. This study has not included patients with type II Diabetes.
2. Sample size is too small.

Suggestions

1. Sample size could be increased.
2. DM type 2 patients could be considered.

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