

Evaluation of the secondary complications in patients of type-II diabetes mellitus (TIIDM) on allopathic, alternative or combination of medicine system: A cross sectional study

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Abstract: Progression of diabetes mellitus may leads to secondary complications. Management of such complication is a major challenge for diabetologists. Objective of current study was to evaluate the development of chronic complications in patients of type-II diabetes by comparing their treatment options. This cross sectional study was conducted in outpatient facilities of Karachi from July 2017 to July 2018. 201 type -II DM patients were enrolled in the study. Study was divided into four arms of treatment; herbal, homeopathic, allopathic and combination. Outcome measures were development of acute and chronic complications. Data was analyzed by SPSS 22 version. Finding of study reveals that relative risk reduction of diabetic coma is 50% (p=0.0001) with combination treatment, relative risk reduction of retinopathy is 52% (p=0.0001) with herbal treatment, relative risk reduction of nephropathy is 58% (p=0.0001) with combination treatment, relative risk reduction of hypertension is 49% (p=0.0001) with herbal treatment, relative risk reduction of myocardial infarction is 15% (p=0.0001) with herbal treatment and relative risk reduction of neuropathies is 27% (p=0.0001) with combination treatment and relative risk reduction of other complications is 12% with allopathic treatment (p=0.20). Finding of study reveals that risk of acute and chronic complications in type-II DM patients is low if they use either herbal system of medicine or combination of different systems of medicine.

Keywords: Diabetes mellitus, chronic complications, treatment, medicine, risk reduction.

INTRODUCTION

Type II diabetic mellitus is a metabolic syndrome which is linked with various health related issues. The complications associated with diabetes mellitus, are divided into acute and chronic Complications (Ullah *et al.*, 2015, Lefebvre *et al.*, 2015, Ahmad, 2016). The most common acute diabetic complications are; diabetic coma, which may be further divided into ketosis or diabetic ketoacidosis (DKA) (Khan *et al.*, 2017), non-ketonic hyperglycemic-hyperosmolar coma (NKHHC) (Chang *et al.*, 2017) and lactic-acidosis (LA) (Kawanishi and Ishida, 2002). Another complication is Hypoglycemic coma (HC) (Gosmanov *et al.*, 2018). Chronic Complications are also categorized as micro-vascular complications (Khullar *et al.*, 2017) and macro-vascular complications (Huang *et al.*, 2017). According to one report diabetic retinopathy is higher than 28.78% in Pakistan (Mumtaz *et al.*, 2018). Major reason of diabetic retinopathy is poor control of blood glucose and hypertension. During the first two decades nearly half patients with diabetes develop retinopathy due to type-II diabetes (Zheng *et al.*, 2018).

Another imperative area for concern of chronic complication is diabetic nephropathy (Papadopoulou

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Marketou *et al.*, 2017). It is a common cause of renal failure (Krolewski *et al.*, 2017). The prevalence of diabetic nephropathy is 34% in Pakistan (Ahmedani *et al.*, 2005a). Diabetic nephropathy may also lead to cardiovascular issues, the presence of protein that is 0.5 g/24 hours indicates nephropathy (Gross *et al.*, 2005). Nephropathy in diabetic patients is also due to a poor glycemic control and hypertension (Ahmedani *et al.*, 2005b). Poor glycemic control affects arteries of kidneys and filtration process i.e. why around 40% of patient suffering from type-II diabetes develop kidney disease (Levey *et al.*, 2005). Poor glycemic control also leads to another chronic complication i.e. diabetic neuropathy. Peripheral neuropathy is a very common issue which frequently harms nerves of feet and legs (Parasoglou *et al.*, 2017). Autonomic neuropathy affects the heart, urinary bladder, stomach, intestine, sex organs and eyes (Pop-Busui *et al.*, 2017). Similarly rediculoplexus neuropathy or diabetic amyotrophy affects the nerves of thighs, hip, buttocks and legs. Mononeuropathy or focal neuropathy damage specific nerves of face, middle body and common in elderly individuals (Parasoglou *et al.*, 2017).

Among macro vascular complications, most devastating is atherosclerosis (Yahagi *et al.*, 2017) which may results in

collapse of peripheral or coronary vascular system (Boyle, 2007). In addition to atheroma development, there is a strong evidence of hypercoagulability and increase threat of vascular obstruction and cardiovascular events. Due to this reason cardiovascular disease is the primary cause of death in people with either type-I or type-II diabetes (Paterson *et al.*, 2013).

As different systems of medicine are offered in Pakistani society to patients i.e. why the main objective of current study is to evaluate the development of chronic complications in patients of type-II diabetes by comparing their treatment options. These patients were offered to use either allopathic medicine alone or alternative medicine alone or combination of medicines.

MATERIAL AND METHOD

Study design & duration

The cross sectional study was conducted in the outpatient clinics at multiple medical centers, homeopathic clinics and Matabs of herbal practitioners (Hakeem) in Karachi to determine the development of secondary complications after type-II DM diagnosis. These patients were already on different system of medicines since many years. The duration of study is from July 2017 to July 2018 with retrospective follow up of patient's records of 3-10 years. Patients are recruited from the consultant clinics of allopathic, homoeopathic physicians and hakeems.

Sample size of study

Sample size of study was calculated by precision analysis technique (Aparasu, November 2016). 201 patients with confirm diagnosis of type -II DM were included in the study. These 201 patients were divided into four groups based upon treatment type; Group 1 Allopathic medicine, Group 2 Homoeopathic medicine, Group 3 Herbal medicine and Group 4 Combination of any 2 or more of above mentioned systems of medicine.

Inclusion criteria

Patients have confirmed diagnosis of type – II DM.

Exclusion criteria

Pediatric and type – I diabetic populations, gestational diabetes, diabetes insipidus, latent autoimmune diabetes in adults (LADA).

Data collection

Data was collected by pre-designed, structured questionnaires. Informed consent was taken from the patients before the interview. The first section of questionnaire was consisted of patient's demography. The second section consisted of a medical overview of the patients and development of chronic complications like hypertension, nephropathy, neuropathy, retinopathy and laboratory tests like Fasting Blood Sugar (FBS), Random Blood Sugar (RBS). In last section, management of type –

II DM included both therapeutic and non-therapeutic measures.

Ethical approvals

The ethical approval for the study was obtained from the Institutional Bioethics Committee, University of Karachi with project reference number is IBC KU 23 and Interactive Rsch. & Development, IRB-IRD # IRD_IRB_2017_03_018, IRB#1 – IRD is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP) with registration number IRB 00005148. Study is also approved by Board of Advanced Studies and Research of University of Karachi.

STATISTICAL ANALYSIS

Collected data was processed on Statistical Package for Social Sciences (SPSS version 22) for analysis. Frequencies and proportions were computed for descriptive statistics. For parametric data (ratio data), One way ANOVA and student t-test was employed to determine the significance between variables at p-value of 0.05.

RESULTS

Overall secondary complications in type – II DM patients. (fig. 1).

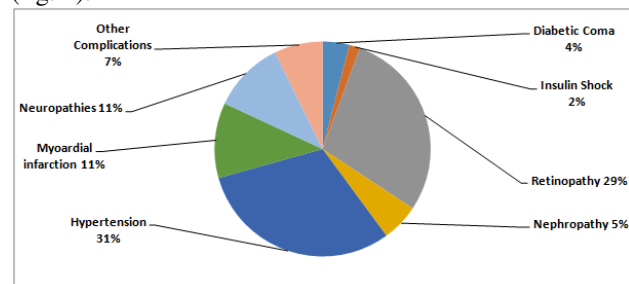


Fig. 1: Overall Secondary complications in all patients regardless of treatment options (n= 201)

Comparison of glycemic control in different systems of medicine (table 1).

Reported complications and their comparison in different system of medicines (table 2)

DISCUSSION

It is a bleak reality that poor control of diabetes and prolong duration leads to secondary complications (Madmoli *et al.*, 2019, Lotfy *et al.*, 2017). Although there are various methods to keep our self healthy and live a normal life, however, diabetes related complications are inevitable i.e. why current study examines occurrence of complications among patients of type-II DM while on treatment by different systems of medicine. Demographic finding of study reveals no significant difference in mean

Table 1: Demography of patients and comparison of glyceemic control in different systems of medicine

Characteristics	Allopathic	Homoeopathic	Herbal	Combination
Mean Age in Years	55	52	48	52
Male	29	9	29	37
Female	66	3	10	18
Height in feet	5.2	5.2	5.3	5.2
Married	71	12	32	51
Unmarried	1	0	4	1
Divorced	0	0	2	0
Widow	23	0	1	3
Mean Fasting Blood Glucose Level	176mg/dL	117mg/dL	129mg/dL	135mg/dL
Mean Random Blood Glucose Level	231mg/dL	161mg/dL	195mg/dL	217mg/dL
Mean HbA1c	8.7%	6.4%	6.5%	7.1%
Mean Duration of Disease in Years	10	3	3	8

Table 2: Complications reported in different system of medicines and statistical significance

Type of complication	No. of cases of complications (%)				Relative Risk Reduction	Significance level at <0.05
	Allopathic	Homoeopathic	Herbal	Combination		
Diabetic Coma	13 (14%)	---	---	04 (07%)	50%	p=0.0001
Insulin Shock	07 (07%)	---	---	---	100%	---
Retinopathy	70 (74%)	06 (50%)	15 (38%)	31 (56%)	52%	p=0.0001
Nephropathy	18 (19%)	---	---	06 (11%)	58%	p=0.0001
Hypertension	80 (84%)	03 (25%)	16 (41%)	32 (58%)	0.70	p=0.0001
Myocardial infarction	33 (35%)	---	02 (05%)	13 (24%)	15%	p=0.0001
Neuropathy	39 (41%)	01 (08%)	---	06 (11%)	27%	p=0.0001
Other Complications	15 (16%)	---	07 (18%)	09 (16%)	-88%	p=0.2000

age, height, fasting blood sugar, random blood sugar and HbA1c (table 1).

It is interesting to observe that highest proportion of complications are pertaining to allopathic system of medicine (table 2, fig. 1), however, we cannot overlook this factor that 47% (n=95) patients in study were taking allopathic medicines. It seems that use of alternative medicines alone or along with allopathic medicine reduce the incidences of complications associated with type II diabetes mellitus with improved glyceemic control, whether it is fasting blood glucose levels, random blood glucose level and HbA1C. Similar findings of fasting blood sugar and HbA1C reduction are also reported in India (Sreedevi et al., 2017).

Most of the literature reported that acute complications of type-II DM like insulin shock and diabetic coma are imperative to be considered as they may be related to vital organs failure (Breuker et al., 2017). Study reveals that incidences of diabetic coma are significantly lower in patients taking combination of different system of medicines compare to allopathic medicines alone (p=0.0001) (table 2). Risk ratio analysis reveals that relative risk reduction (RRR) of diabetic coma with combination therapy is 50%. As expected insulin shock is

only pertaining to allopathic medicine and its incidences are 7%, while other systems of medicine do not offer insulin therapy. It is worthwhile that even a single case of diabetic coma was not reported among patients taking herbal or homeopathic system of medicine, which reveals that these medicines does not cause severe hyper or hypoglycemia (table 2). However, many authors believe that safety and efficacy of alternative medicine should be assessed based upon evidence based rather than myths (Kesavadev et al., 2017).

Pertaining to retinopathy, which is most common in the diabetic patients, comparison of different systems of medicine found statistically significantly lowest proportions in herbal system of medicine (38%) in comparison to combination treatment (56%), homeopathic treatment (50%) and allopathic treatment (74%) (p=0.0001) (table 2). Based upon these findings, those patients on herbal system of medicine are claimed to have significantly lowest risk of retinopathy and RRR of retinopathy with herbal therapy is 52%. Another lethal complication associated with Type-II DM is nephropathy. The study pointed out that risk of nephropathy is significantly lower (11%) among combination treatment group compare to group taking allopathic system of medicine (19%) (p=0.0001) (table 2) that is why RRR of

nephropathy with combination therapy is 58%. Interestingly, no single case was reported of nephropathy in patients taking either homeopathic or herbal systems of medicine during study period. On contrary to our findings, study conducted in Egypt for herb reveals that *Nigella sativa* increased the risk of nephropathy (El Rabey et al., 2017). Diabetes retinopathy is the most common complication and around 10,000 cases per annum of blindness register in United State only due to this complication (Fowler, 2008).

As far as concerned with hypertension which is most fatal complication and leads to various micro-vascular and macro-vascular complications, significantly lower number of cases were observed in patients taking homeopathic medicines (25%) compare to herbal (41%), combination (58%) and allopathic (84%) ($p=0.0001$) (table 2) and RRR of hypertension with homeopathic therapy is 30%. Despite these findings it is not assumed that homeopathic system of medicine is best in reducing the risk of hypertension among type-II DM patients because of its sample size in whole study is just 06% ($n=12$). Sample size of sufficient power is observed in patients taking herbal system of medicine i.e. 19% ($n=39$) and with herbal system of medicine RRR of hypertension is 49% (table 2). So it advisable to claim that herbal system of medicine has significantly lowest risk of hypertension compare to other treatment options. Similarly myocardial infarction, which is also a life threatening issue among patients of type-II DM (Cosentino et al., 2018). Pertaining to myocardial infarction herbal system of medicine has the significantly lowest number of incidences (5%) compare to combination (24%) and allopathic (35%) system of medicine ($p=0.0001$) and RRR of myocardial infarction with herbal system of medicine is 15% (table 2). It is also proved in animal model that natural products attenuate the risk of diabetic cardiomyopathy (Uddandrao et al., 2018).

Developments of neuropathies are also long term complications associated with diabetes mellitus. Current study further identified that homeopathic system of medicine has the significantly lowest incidences (8%) and risk ratio analysis estimated RRR of neuropathies with homeopathic system of medicine is 20%, however because of lack of power in this arm, it better to consider combination medicines (11%) has the lowest risk of neuropathies compare to allopathic system (41%) ($p=0.0001$) (table 2), where RRR of neuropathy is 27%. Various miscellaneous complications like erectile dysfunction, loss of libido, fatigue, vertigo are also noted in the study. No significant difference was observed in these complications among different system of medicine ($p=0.20$), however, RRR of these complication is in favor of allopathic system of medicine i.e. 12% (table 2).

In current study overall evaluation of development of complications regardless of treatment options was reported to be highest for hypertension (31%), followed

by retinopathy (29%), myocardial infarction and neuropathies (11%), other complication (7%), nephropathies (5%), diabetic coma (4%) and insulin shock (2%). So it is postulated that patients on type-II DM has high risk for the development of hypertension followed by retinopathy as a chronic complication (fig. 1).

CONCLUSION

Risk of acute and chronic complications like myocardiopathy, neuropathy, retinopathy, vasculopathy or nephropathy in type-II DM patients is low if they use either herbal system of medicine or combination of different systems of medicine.

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