EXTRA MURAL RESEARCH

Diabetes mellitus - Defining scope and clinical approach for homoeopathic management

N. L. Tiwari* & Prashant Tamboli

Dr. M. L. Dhawale Memorial Trust, Mumbai

Abstract

The study was undertaken to explore if there was a definite role of homoeopathic medicines in the management of Diabetes Type 2 and, if so, to determine the role of Constitutional and Organ remedies in its management. The comprehensive role of the individual susceptibility and miasm in the management of diabetes was also been studied.

90 patients were studied by Randomized Single Blind Clinical Trial by dividing them into three groups – Constitutional, Organ and Placebo. In the later part of the study the Cross over design was adopted between the Constitutional group and the Placebo group. Results showed that at the end of the first 6 months of the trial, 67% patients improved from the constitutional group while the comparable figures from the Organ group and the Placebo group was 37% and 7% respectively. At the end of the trial 70% from the constitutional group improved as compared to 10% from the Organ remedy group and 7% from the placebo group.

The study confirmed the efficacy of homoeopathic treatment in Diabetes type 2 and also established the indications for adopting the Constitutional and the Organ remedy approach to its management. In the process, the need to incorporate the study of individual susceptibility and miasmatic expressions in determining successful homoeopathic management and the parameters of assessing the susceptibility has been clearly defined.

Key words: diabetes, research, constitutional medicines, organ remedies, susceptibility, miasm

Introduction

Diabetes Mellitus Type 2 is a very common disorder found in the Asian Indian. In 2000 AD there were 31.7 million Indians having Diabetes. By 2025 AD India would be having the largest number of Diabetics in the world. As per one estimate, by 2030 AD 79.4 million people in this country will be having this disorder.-2

Diabetes Type 2 occurs either due to decreased production of insulin or because of its improper utilization due to peripheral resistance. In addition, truncal obesity, hypertension and dyslipidemia are the contributing factors.^{3,4} The common symptoms are increase in urination, thirst and appetite with weight

loss, weakness and non-healing of wounds. A number of patients remain asymptomatic. Hence diagnosis is clinched on the basis of the blood glucose levels.^{5,6} According to American Diabetes Association, a fasting blood glucose level of more than 126 mg% is the diagnostic criteria for Diabetes.⁷

Individualization is at the heart of a sound practice of Homoeopathy. Man as a whole is ill and not any of his parts has been the central tenet of the science. An individual is rendered susceptible to the deleterious actions of the environmental forces due to a progressive failure of the processes of adaptation. Logically, an accurate diagnosis of deranged susceptibility is central to the understanding of the problem of Diabetes. As mentioned above, the expressions of diabetes varies from cases to case. Therefore, it is mandatory to study the state of susceptibility which is responsible for all

*Address for correspondence:

N. L. Tiwari

Dr. M. L. Dhawale Memorial Trust

B.M.C. Holistic Mother & Child Care Centre

3rd Floor, Room No. 5, Harishankar Joshi Marg, Dahisar (East),

Mumbai - 400068

disease expressions. Our literature shows that both Constitutional as well as Organ medicines are useful in controlling the blood sugar levels. 9,10 Which is the most appropriate approach? We need to apply the principles of individualization and totality to determine the answer. This study focuses on this central issue.

Objectives

Primary

To demonstrate the role of homoeopathic medicines in the management of Type 2 Diabetes Mellitus (without any microvascular complications) & exploring the effectiveness of Constitutional medicines / Organ remedies in cases of Type 2 Diabetes Mellitus.

Secondary

- > To understand the role of susceptibility in deciding the management of diabetes
- To study the indications of commonly prescribed remedies.

Materials and Methods

Randomized single blind clinical trial was conducted during the period 2002 to 2005 at the clinical centres of the Dr. M. L. Dhawale Memorial Trust, Mumbai. 90 patients without microvascular complications were selected from around 314 diabetics. They were divided randomly into three treatment groups - the Constitutional group, the Organ group and the Placebo group. Minimum observation period was of 6 months. Baseline scores of blood glucose levels and other symptoms were compared with the results obtained at the end of the observation period. Consequently, 15 randomly selected patients from the Constitutional group and the Placebo group were crossed over. There was a wash-out period of 4 weeks before the new treatment was started. These cases were observed for a minimum period of 3 months. Those who were already on Allopathic medicines were asked to continue due to ethical considerations. Subsequently, after periodical evaluation by the diabetologist, the doses of those patients were adjusted on the basis of the blood glucose level and the signs and symptoms and those changes noted in the progress report. Table 8 gives the details of status of OHA.

Method

 There were 30 patients in each group, i.e. Constitutional, Organ & Placebo group were

- enrolled by simple random method.
- Each selected case was recorded on the Standardized case record with a special attachment evolved particularly for this study.
- Diet & exercise These are two most important variables. General diet instructions were given to the patients. Approximately 60-70% carbohydrates, 15-25% proteins & 15-25% fats were allowed. They were advised to distribute total calories in three time zone, i.e. 33% for breakfast & mid morning, 33% for lunch & tea, 33% for dinner & before going to bed. They were asked to follow these for 30 days. Baseline assessment was done. Subsequently they were asked to follow the same diet. Every day's diet and exercise schedule was recorded by each patient in a diary.
- The indicated constitutional remedy and organ remedy was prescribed after forming the totality. Repertorization, and in some cases the structuralization method, was used to arrive at the remedy through either of the approaches, viz. Kent, Boenninghausen or Keynote depending on the case. The repertories of Kent, Boenninghausen, Complete repertory to Hom. MM by E W Berridge 2nd edition and Synthesis 8.1 by Frederik Schroyens were used.
- Follow-up was taken on a special follow-up sheet which included symptoms of diabetes, symptoms of other diseases, other characteristic symptoms, examination findings, e.g.—weight, blood pressure, peripheral pulsations, vibration, etc. investigations, diet and exercise record-all of this data helping in assessment of susceptibility
- Each case was evaluated by the Homoeopathic Physician along with a General Physician (MD – Allopathic), Ophthalmologist, Dietician and Pathologist.
- Baseline investigations done in each case were-Fasting and Post - Prandial Blood sugar, Glycoslated haemoglobin, Urine sugar, urine ketones, urine albumin, Lipid profile, Complete Blood Count, Serum Creatinine, Serum Uric acid, Microalbuminuria, X-ray chest, Electrocardiogram, USG abdomen and detailed Ophthalmic check up.
- Subsequently, assessment of response was done through lab test of FBS/ PPBS – monthly and in some cases weekly in the initial part of the treatment, Glycoslated hemoglobin (3-monthly) and Lipid profile-(6 monthly).
- Assessment was done at the end on the following basis:
 - Symptomatic level evaluation
 - Changes at the blood glucose levels
 - Status of oral hypoglycemic agent

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Assessment Criteria

There is lot of variability in the presentation of diabetes. It is also difficult to correlate the intensity of diabetes on the basis of the severity of symptoms. Hence they were graded from 0 to 3 according to their severity.

Presenting symptoms

These were categorized according to the following criteria. In cases where the patient was not fulfilling all the parameters of the particular grade e.g. patients having absolutely no symptoms except higher level of blood glucose level then the blood glucose level remained the primary grading criteria.

Susceptibility assessment

Individualization is the main principle of homoeopathic science. Man as a whole is ill and not any of his parts has been the central tenet of the science. An individual is rendered susceptible to the deleterious actions of the environmental forces due to progressive failure of his processes of adaptation. Logically, an accurate diagnosis of deranged susceptibility is central to the understanding of the problem of all constitutional disorders including Diabetes.

Understanding of susceptibility was concluded as low, moderate or high based on the following parameters: 12

 Predisposition – Family history of diabetes, other illness and past history

- 2. Disposition Mental and physical attributes
- 3. Precipitating factors Available: Yes / No, if yes then Physical / Mental
- Onset of the disease Sudden / Gradual
- Character of expressions Asymptomatic / Symptomatic, if symptomatic then characteristic / common symptoms
- 6. Pace of the disease- Gradual / Rapid
- 7. Progress of the disease Complications: Yes / No
- 8. Previous and current medications and its response.
- 9. Other diseases present with diabetes.
- 10. Qualified Mental Symptoms Present / Absent
- 11. Sensitive to environmental stimuli Characteristic expression and intensity
- 12. General vitality: Examination findings.

High Susceptibility: Capacity of the individual to throw up a good number of characteristics and to limit the extent of changes at the level of tissues to a functional zone.

Moderate susceptibility: Individual throws moderate number of characteristics and the changes at the tissue level may not be limited to the functional zone; yet it shows the capacity to prevent irreversible structural changes.

Low Susceptibility: Poor capacity to throw up characteristics and is generally unable to prevent structural changes at the tissue level.

Table 1: Grading of Diabetes Symptoms

Grade	Weakness	Appetite	Thirst	Urination	Blood Glucose (mg%)
0	No weakness	Appetite normal	Normal thirst	Normal frequency for patient	FBS - < 126 PPBS - < 140
1	Weakness after hard work but not daily	Increased appetite sometimes,	Increased thirst daily & 0-1 at night than his/ her during day	Every 5-6 hourly Increased	FBS – 127 – 140 PPBS – 141 – 180
2	Weakness after doing daily work times day	Feeling hungry and feels like eating 7-8 hourly / 2 times at night	Thirst increased, every 3-4	Every 3-4 hourly in day / night 2 times	FBS -141 - 180 PPBS - 181 - 220

Grade	Weakness	Appetite	Thirst	Urination	Blood Glucose (mg%)
3	Persistent Weakness	Feeling hungry, eating after food/ lunch	Constantly feeling thirsty during day / more than 2 times at night	Every 2 hourly during day / night > 2 times	FBS - > 180PPBS - > 220 PPBS - > 220

Miasmatic assessment

Disease is an evolutionary phenomenon. Usually the changes reflecting ill health in an individual start from a functional disturbance and gradually extend to irreversible structural changes. Disease also passes through phases of Psora, Sycosis, Tubercle and Syphilis till the final dissolution occurs through the failure of the Vital Force to assert itself over the environmental circumstances. Diseases are also influenced by the predisposing factors in terms of past and family illness. In order to correctly apply Hahnemannian Pathology to Practice, we need to integrate it fully with the current concepts of Psychology and Pathology – functional and structural. Therefore the *fundamental miasm* was

derived from the family and the past history of the patient and the dominant miasm from the expressions of diabetes and the concomitant presence of other illnesses.

Outcome assessment

The outcome was measured as per the predetermined criteria. Symptoms and blood glucose levels usually show a lot of fluctuations. Often the symptoms and the blood glucose levels do not correlate. Therefore the following grading as shown in Table 5 was used for assessing the outcome.

Table 2: Outcome assessment criterion

Improvement	Marked	Moder <mark>ate</mark> i <mark>mprovemen</mark> t	No Improvement improvement
Symptoms	Grade 0	Reduce <mark>d in grade but n</mark> ot grade 0	No change or increased grade
BGL	Grade 0	Reduced in grade but not grade 0	No change or increased grade
Associated Complaints	Grade 0	Reduced in grade but not grade 0	No change or increased grade

Results

Table 3: Susceptibility assessment before treatment

Susceptibility	Constitutional group	Organ group	Placebo group
Low	12	14	13
Moderate	13	10	12
High	05	06	05

Table 4: Miasmatic factors-Fundamental Miasm

Fundamental Miasm	Constitutional Group	Organ group	Placebo group	Total
Psora	02	00	00	02
Sycotic	16	21	24	61
Tubercular	12	09	06	27
Syphilitic	00	00	00	00

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Table 5: Miasmatic factors-Dominant Miasm

Dominant Miasm	Constitutional Group	Organ group	Placebo Group	Total
Psora	00	00	00	00
Sycotic	21	16	20	57
Tubercular	09	14	10	33
Syphilitic	00	00	00	00

Table 6: Response to treatment across groups as per outcome assessment

Time	Response	Constitutional group		Organ group		Placebo Group	
	Improvement	Symptoms	BGL*	Symptoms	BGL*	Symptoms	BGL*
At the end	Nill	10	10	22	19	26	25
of 6 months	Moderate	5	14	7	8	1	2
	Marked	15	6	1	3	3	3
Cross over	Nill	14	15	_	_	7	4
	Moderate	1	0	_	_	7	8
	Marked	0	0	_	_	1	3
At the end	Nill	5	9	24	27	27	28
of the	Moderate	12	11	5	2	2	2
treatment	Marked	13	10	1	1	1	0

^{*}BGL: Blood Glucose Level

Table 7: Response to treatment across the groups as per the changes

Result	Constitutional group %		Organ group %		Placebo Group %	
	6 months	End of treatment	6 months End of treatment		6 months	End of treatment
Improved Not Improved	67 33	70 30	37 63	10 90	10 90	7 93

Constitutional group Vs. Placebo group p < 0.0001

Constitutional group Vs. Organ group p < 0.0044

Organ group Vs. Placebo group p < 0.3329

Table 8: Status of Oral Hypoglycemic Agents

Status of OHA	Constitutional Group	Organ Group	Placebo Group
Before yes	13	14	12
After Reduced	1	2	2
After Same	4	9	6
After Increased	0	2	3
After Stopped	8	1	1

Medicines prescribed

Table 9: Constitutional Remedies Prescribed (Including 15 crossover samples)

Remedy	Prescribed in	Improvement	Remedy	Prescribed in	Improvement
		seen in			seen in
Ars. alb.	1	1	Lycopodium	1	1
Bryonia	1	1	Mag. carb.	1	1
Calc. carb.	11	8	Mag. mur.	1	1
Calc. fluor.	4	3	Mag. sulph.	1	1
Calc. iod.	1	1	Nat. mur.	6	4
Causticum	1	0	Nat. sulph.	1	1
Ferr. met.	2	1	Pulstilla	1	0
Kali bich.	2	1	Silicea	7	5
Kali carb.	3	2			

Table 10: Organ remedies prescribed

Remedy	Prescribed in	Improveme	ent seen in
		In 6 Months	Till the end of Rx.
Syzigium jamb.	14	6	3
Gymnema syl.	8	3	1
Cephalendra ind.	8	2	0

Table 11: Susceptibility and Result in terms of improvement

Susceptibility	Constitut <mark>io</mark> nal %		Organ%	
	6 months	At the End	6 months	At the End
Low	30	25	50	67
Moderate	50	45	38	34
High	20	30	12	00

Table 12: Potency selected – as 1st prescription

Potency	Total patients in	Percentage	
30	09	30	
200	21	70	

Table 13: Correlation of Dominant Miasm and Potency prescribed in the constitutional group

Dominant Miasm	Starting Potency	Cases	Cases improved
Sycotic	30	8	7
	200	13	6
Tubercular	30	1	1
	200	8	7

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Table 14: Impact of Miasm on diabetes

Dominant Miasm	Psora	Sycosis	Tubercular	Syphilitic
Onset	Rapid Cause effect gap less	Slow, Cause effect gap – more, Delayed age	Rapid , Cause effect gap – less Early age	Silent
Signs and Symptoms	Weakness + Sensations ++	Obesity, Mild or asymptomatic dyslipidemia	Weakness +++ Weight Loss ++ Expressions ++	Less Characteristic Pathology ++
Progress	Normalcy as soon as stress reduces	Gradual, Complications slow	Infections & Fast complications	Complications ++ Bleeding Ulcerations ++
BGL	Sharp rise & Fall	Less fluctuations	Wide, erratic fluctuations	High

Statistical Significance

Chi-Square test with Yates correction was applied to assess statistical significance of the results. The difference between Constitutional group Vs Placebo group and Constitutional group Vs. Organ group was found statistically significant.

Discussion

This study shows that the homoeopathic medicines are indeed effective in the management of Diabetes mellitus type 2. Table 6 and 7 clearly show the efficacy of homeopathic medicines as compared to placebo. Analysis of results shows that the symptomatic improvement was more than a mere change in the blood glucose levels. This pattern was observed during longterm management of cases in both the Constitutional group as well as in the Organ group. However, in the case of the Organ group the six month responses showed the blood glucose levels better than the state of the symptoms. Another observation was that the patients of the Constitutional group improved progressively with the duration of the treatment. On the contrary, in the Organ group, the effects were not sustained. The results obtained in the 1st six months of treatment were better, the effects wearing off with long term medication. This indicates that Organ remedies act differently than do the Constitutional medicines. From the homoeopathic point of view, this could only occur due to differential responsiveness of the underlying susceptibility. Therefore, assessment of susceptibility was of importance.

Susceptibility and Diabetes

Susceptibility is the inherent capacity in all living beings to react to stimuli in the environment and represents the fundamental quality that distinguishes the living from the non-living.¹³

An organism (man) in perfect balance represents health. This state of balance, even in the presence of adverse environmental factors, is a resultant of different internal processes which maintain optimum health. Normal susceptibility in a state of good health is characterized by good nutrition and a healthy outlook towards life. Abnormal susceptibility, on the other hand, affects these in the first instance and interferes with the process of adaptation thereby leading to the development of disease. Thus signs and symptoms are the only indications of abnormal susceptibility.¹⁴

The process of anabolism and catabolism are determined by the nature of susceptibility. The final individuality, which we perceive as attributes in the emotional, intellectual and physical sphere, is also determined by the susceptibility. Thus constitutional type is a good measure of susceptibility.

In the process of understanding various aspects of susceptibility, we have to understand physical health (patient as a person – general characteristics), mental expressions and the disease expressions.

The results were analyzed as per this understanding of susceptibility. Table 11 shows the relationship between the response to the trial and the corresponding state of susceptibility. Those cases which responded to the Organ remedies were exhibiting a low susceptibility level. This was observed consistently at six months and at the end of the treatment. In contrast, the Constitutional group responders had moderate or high susceptibility. From this observation, we can conclude that susceptibility might be having an important role in deciding the management plan,

however further study is required by taking large number of sample.

Miasm and Diabetes

Most of the cases were showing a Sycotic miasmatic load. Miasmatic classification helped in understanding the impact of the fundamental as well the dominant miasm on the expressions as well as on the progress of diabetes. The impact of miasmatic activity was seen in:

- Onset of Diabetes
- Progress of Diabetes tendency to have complications
- Expressions in terms of signs and symptoms
- Effect on Blood glucose levels

Miasm and Age of onset of Diabetes

In this study patients had onset of diabetes between ages 35 to 65 years. When the data was analyzed, according to the onset of diabetes from the miasmatic point of view, we found that miasmatic correlation helps in accurate understanding of age of onset.

It was observed in the study that the combination of both fundamental & dominant miasm makes the influence on the onset of the diabetes. In 57 cases the fundamental and dominant miasms both were Sycotic. Out of these 57 cases, in 46 cases the onset of diabetes was between 45 to 65 years. Out of these 46 cases, 29 cases had onset of diabetes between ages 51 to 65 vears. This was then compared with the cases where both the fundamental and dominant miasm were tubercular. The combination of both fundamental and dominant tubercular miasm was noted in 27 cases. Out of these 27 cases, 25 cases had onset of diabetes between ages 35 to 50 years. Out of these 25 cases, 15 cases had the onset of diabetes between ages 35 to 45 years. Therefore, we can conclude that when the fundamental and dominant miasms both were Tubercular, there is an earlier onset of diabetes as compared to the cases having Sycotic miasm. However, the data is low for making a definite conclusion, and large sample study is required to assess this aspect.

Influence on Potency selection

The influence of miasm was also observed in terms of potency selection. Table 12 shows that 70% of patients required 200 C potency. Table 13 shows the correlation of dominant miasm with the effective potency. Where the dominant miasm was Sycotic, the proportion of cases needing 30 C and 200 C potency was approximately 40:60. But, when the dominant miasm was Tubercular, the same ratio changes to

approximately 10:90. Similarly, while impacting miasm on clinical presentation, blood glucose level and progress is tabulated in Table 14. This study confirms the principles regarding susceptibility and miasm laid down by our Masters- Kent, Stuart Close, Robert and M. L. Dhawale.

Conclusion

- Homoeopathic Medicines are effective in the management of Diabetes Mellitus Type 2.
- Both Constitutional and Organ remedies have been found useful in the management of Diabetes Mellitus Type 2 but, constitutional medicines give a sustained relief in the symptoms and in the blood sugar levels on long term management. Organ remedies are useful in the reduction of blood glucose levels in the short term management of Diabetes Type 2.
- Susceptibility determines the management of Diabetes.
 - O Constitutional medicines act better if the susceptibility is moderate to high.
 - O Organ medicines are effective where the susceptibility is on the lower side.
- In this study,
 - Calcarea carb., Nat. mur. and Silicea were the most frequently indicated constitutional remedies
 - Syzygium jamb. was the most frequently indicated organ remedy.
 - O 200 C potency was required in most of the cases.

Further Studies

This study showed that that the individual susceptibilities had role in the management of diabetes. The study also showed that dominant miasmatic activity influenced the onset and the course of the diabetes. These both studies require further studies by taking large number of samples.

Acknowledgements

- Department of AYUSH for providing funds under EMR scheme.
- Prof. (Dr.) C. Nayak, Director, CCRH: We are grateful to him for his constant encouragement which motivated us in completing the study.
- Dr. Eswara Das, Deputy Advisor (Homoeopathy), Department of AYUSH. As a member of PEC, his valuable inputs helped in making this study more scientific.

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- Dr. V. K. Gupta, former Principal, Nehru Homoeopathic Medical College & Hospital, New Delhi As a member of PEC, his inputs on the homoeopathic principles and management helped us in making valid conclusions.
- Dr. D. P. Rastogi, former Director, CCRH. His pioneered work on diabetes helped in management of the cases.
- Dr. K. P. Muzumdar, Chairman, Drug Standardization Committee, CCRH. For his untiring efforts of evaluating our study and writing Foreword for the study.
- Dr. Anil Khurana, Asst. Director, CCRH. His timely advises and meticulous analysis inspired us in completing this vast study.

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