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New research findings on reversion of prediabetes

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Abstract
The present research article describes the clinical trial finding of a herbal formulation in reverting prediabetes condition, where the blood glucose value remain constant or above 155 or 140 mg/dL respectively for one and two hours after OGTT before treatment which was used for the diagnosis of prediabetes. Three month usage of the herbal preparation has brought down the blood glucose value below the above mentioned units when the subjects were challenged once again by OGTT. Prediabetes is a silent phenomenon and OGTT method of blood glucose determination is considered authentic. The blood glucose value scale used in the study has come with clear evidence of follow up study published elsewhere where the significance proportion of patients with prediabetes based on OGTT turned out to be diabetic in due course of time. The herbal formulation evaluated had reverted prediabetes and the reversion was statistically significance with p value, $p < .05$. Details are presented in the article.

Keywords: Prediabetes reversion, anti-diabetic drug, OGTT, blood glucose scale

Introduction
Diabetes mellitus has already emerged as a 'killer medical problem' with no treatment except managing the disease through combination of approaches. Early detection of diabetes mellitus was difficult for a while and hence the possibility of preventing the disease was far from reach, till the advent of extensive research in diabetes mellitus [1].

The aberration in positive energy metabolic disorder is often silent and hence the blood glucose build up is difficult to notice in the early stage [2]. In several cases, extreme hypoglycaemia is also observed which was once considered as non-diabetic condition but later it was found that high insulin secretion was one the reasons for high hypoglycemic condition [3].

The high level of insulin bound to cause cells to go fatigue with insulin and such condition would later switch to type 2 diabetes mellitus [4]. In the recent years, rigorous research on diabetes mellitus has paved way for understanding the early diagnosis of risk group of the disease in the population. The glucose metabolism being normal; post prandial and random, but when challenged with high glucose (OGTT), the glucose metabolism may show absolute aberration [5]. However the prospective follow up study has proved that statistically significant proportion of the population who failed in glucose metabolism, post OGTT have turned out to be positive for type 2 diabetes mellitus [6].

Once the aberration of glucose metabolism is detected early through OGTT, the possibility of preventing/reducing the impending manifestation of diabetes mellitus in future can be achieved with least drug intervention.

Challenge before the medical fraternity is how to identify 'the risk group' that might suffer from prediabetes with no signs and symptoms of the disease. Only through such early diagnosis, a mitigation strategy can be adopted to prevent/reduce/avoid the possible episode of diabetes mellitus.

Type 2 diabetes mellitus known to follow family history where the offspring of diabetic parents are likely to become diabetic [7]. Certain medical conditions also known to predispose the disease, besides the lifestyle related issues such as obesity, sedentary lifestyle, overeating etc.

Therefore creating sufficient awareness among such population and early diagnosis of the prediabetes condition may help to prevent/reduce/avoid the possible episode of type 2 diabetes mellitus in future [8].

In the present study, a herbal formulation has been evaluated for reverting prediabetes condition over 3 months of usage. The measurement of OGTT value was taken to understand the clinical difference before and after treatment and the details are presented in the article.

Materials and Methods

The clinical trial was done after the approval of IEC and CTRI registration. CTRI/2024/03/064661.

Details of the herbal formulation

The herbal formulation (D-Co-D) is composed of the following medicinal herbs such as *Andrographis paniculata, Syzygium cumini, Tinospora cordifolia, Momordica charantia, Cyperus rotundus, Zingiber officinale, Piper nigrum, and Adhatoda vasica*.

Study population

For the present study, we have screened 100 subjects, between the age group of 25-52 years, belong to either gender. 50 subjects with proven pre-diabetic condition as established by OGTT was included in the trial after obtaining informed consent form. The details of the prediabetes subjects are given below in the table.

Gender	Age (years)/ number			Total
	25-35	36-45	46-52	
Male	8	10	8	26
Female	8	7	9	24

Body weight of the subjects ranged between 68 to 80 kg
Diagnosis of prediabetes condition
All the subjects were given 75g of glucose after 8 hours of fasting. The blood glucose value was measured after 1hr and 2 hr. The blood glucose value above 155 mg/dL after 1hr and above 140 mg/dL after 2 hr was considered positive for prediabetes.

Inclusion criteria

- Pre-diabetic population as per OGTT
- Fasting and post prandial blood glucose value being normal
- HbA1c value being normal
- Proven intermediate hyperglycemia by 1 & 2 hour value by OGTT
- The people who does not suffer from any medical conditions and the treatment with any drugs being used which does not affect the pre-diabetic trigger

Exclusion criteria

- Established pre-diabetic population taking anti-diabetic drugs
- Those who are taking any form of blood sugar reducing drugs
- Those who are pre-diabetic but suffer from other medical conditions

Duration of treatment

All the subjects with prediabetes confirmed by OGTT where given the herbal preparation (500mg in tablet dosage form) for 3 months as two BD per day.
All the diet regulations and other overall practices being same without any alteration or modification of the respective subjects, during the study period.
On day 90, OGTT was performed on all subjects and the blood glucose value after 1hr and 2hr was taken and compared with standard. The data was analysed by student t test for statistical significance.

Results

Blood glucose profile of male subjects before treatment

All the 26 male subjects showed well controlled fasting blood glucose value whereas the postprandial blood glucose (PPBG) showed a very marginal increase, however the HbA1c value remain normal. Table - 1

Table 1: Blood sugar profile before treatment- Male subjects (n=26)

Subjects	Age in years/ values								
	25-35			36-45			46-52		
	FBG	PPBG	HbA1c	FBG	PPBG	HbA1c	FBG	PPBG	HbA1c
1	82	118	5.7	83	121	5.8	90	127	5.9
2	87	120	5.6	88	123	5.8	100	130	5.8
3	90	121	5.7	92	125	5.8	92	131	6.0
4	81	120	5.7	95	129	5.7	99	128	5.8
5	88	125	5.5	99	131	5.8	97	124	5.7
6	85	128	5.6	82	130	5.9	92	119	5.8
7	82	122	5.7	86	119	6	91	120	6
8	84	126	5.6	85	122	6.1	94	121	5.9
9	0	0	0	88	121	5.8	0	0	0
10	0	0	0	89	129	5.7	0	0	0

Blood glucose profile of male subjects after 3 months of treatment

3 months after treatment all the male subjects showed a marginal decrease in FBG, PPBG and HbA1c suggesting the effect of herbal preparation in increasing glucose metabolism. Table 2.

Table 2: Blood sugar profile after 3 month treatment- Male subjects (n=26)

Subjects	Age in years/ values								
	25-35			36-45			46-52		
	FBG	PPBG	HbA1c	FBG	PPBG	HbA1c	FBG	PPBG	HbA1c
1	81	116	5.7	81	120	5.7	90	126	5.8
2	85	118	5.5	85	118	5.7	88	129	5.7
3	91	120	5.6	87	122	5.6	99	130	5.9
4	82	119	5.5	91	124	5.5	99	127	5.7
5	87	124	5.4	93	128	5.7	88	121	5.7
6	89	127	5.5	85	126	5.8	92	118	5.6
7	82	124	5.6	90	120	5.9	90	119	5.9
8	88	123	5.6	83	121	6	92	120	5.9
9	0	0	0	85	120	5.7	0	0	0
10	0	0	0	85	118	5.6	0	0	0

Blood glucose profile of female subjects before treatment

All the 24 female subjects showed well controlled fasting blood glucose value whereas the postprandial blood glucose (PPBG) showed a very marginal increase, however the HbA1c value remain normal. Table - 3

Table 3: Blood sugar profile before treatment- Female subjects (n=24)

Subjects	Age in years/ values								
	25-35			36-45			46-52		
	FBG	PPBG	HbA1c	FBG	PPBG	HbA1c	FBG	PPBG	HbA1c
1	84	121	5.6	89	122	5.7	90	129	5.8
2	86	119	5.7	88	125	5.8	100	131	5.9
3	89	120	5.6	80	130	5.8	92	129	5.9
4	90	125	5.7	90	118	5.9	99	127	5.8
5	91	129	5.7	95	130	5.8	97	125	6
6	82	127	5.6	93	129	5.7	92	120	5.7
7	88	129	5.7	83	121	6	95	119	6.1
8	87	122	5.6	0	0	0	96	125	6
9	0	0	0	0	0	0	89	122	5.9
10	0	0	0	0	0	0	0	0	0

Blood glucose profile of female subjects after 3 months of treatment

3 months after treatment all the female subjects showed a marginal decrease in FBG, PPBG and HbA1c suggesting the effect of herbal preparation in increasing glucose metabolism. Table 4.

Table 4: Blood sugar profile after 3 month treatment- Female subjects (n=24)

Subjects	Age in years/ values								
	25-35			36-45			46-52		
	FBG	PPBG	HbA1c	FBG	PPBG	HbA1c	FBG	PPBG	HbA1c
1	82	120	5.5	88	120	5.6	88	124	5.7
2	85	117	5.6	91	121	5.5	95	129	5.7
3	88	119	5.5	89	128	5.7	91	125	5.6
4	89	122	5.5	87	115	5.7	95	123	5.8
5	85	127	5.5	91	131	5.6	95	122	5.9
6	81	125	5.6	93	120	5.5	90	121	5.5
7	90	128	5.5	81	119	5.8	88	117	6
8	86	121	5.6	0	0	0	90	121	5.8
9	0	0	0	0	0	0	92	119	5.7
10	0	0	0	0	0	0	0	0	0

OGTT values of male subjects before treatment

All 26 male subjects showed blood glucose value of above 155mg/dL and 140mg/dL after 1 and 2 hour respectively confirming the prediabetes condition. Table 5

Table 5: OGTT value in male subjects before treatment (n=26)

Subjects	Age in years/ glucose values					
	25-35		36-45		46-52	
	1 hr	2 hr	1 hr	2 hr	1 hr	2 hr
1	158	147	159	148	160	151
2	159	148	160	149	161	152
3	161	147	159	148	158	150
4	159	150	158	151	160	149
5	162	149	160	150	161	153
6	159	151	160	150	159	149
7	158	152	159	151	160	148
8	160	148	161	150	162	152
9	0	0	162	149	0	0
10	0	0	160	152	0	0

OGTT values of male subjects after3 months of treatment

All the male subjects showed the blood glucose value well within or below 155mg/dL and 140mg/dL after 1 and 2 hours respectively after OGTT, suggesting the prediabetes reversion ability of the herbal preparations. Table- 6

Table 6: OGTT value in male subjects after 3months of treatment (n=26)

Subjects	Age in years/ glucose values					
	25-35		36-45		46-52	
	1 hr	2 hr	1 hr	2 hr	1 hr	2 hr
1	155	139	145	137	150	140
2	150	132	152	135	159	141
3	153	140	150	132	155	145
4	151	142	151	141	151	138
5	153	135	155	148	152	139
6	150	145	156	139	150	133
7	152	142	150	140	151	131
8	151	130	152	141	153	142
9	0	0	153	139	0	0
10	0	0	156	141	0	0

OGTT values of female subjects before treatment

All 24 female subjects showed blood glucose value of above 155mg/dL and 140mg/dL after 1 and 2 hour respectively confirming the prediabetes condition. Table 7

Table 7: OGTT value in female subjects before treatment (n=24)

Subjects	Age in years/ glucose values					
	25-35		36-45		46-52	
	1 hr	2 hr	1 hr	2 hr	1 hr	2 hr
1	155	145	160	147	161	150
2	154	149	161	145	159	150
3	156	148	160	148	162	149

4	160	151	159	150	161	148
5	160	150	161	148	160	151
6	158	152	162	148	158	146
7	159	150	160	145	161	147
8	161	151	0	0	163	150
9	0	0	0	0	162	151
10	0	0	0	0	0	0

OGTT values of female subjects after3 months of treatment

All the female subjects showed the blood glucose value well within or below 155mg/dL and 140mg/dL after 1 and 2 hours respectively after OGTT, suggesting the prediabetes reversion ability of the herbal preparations. Table 8.

Table 8: OGTT value in female subjects after 3months of treatment (n=24)

Subjects	Age in years/ glucose values					
	25-35		36-45		46-52	
	1 hr	2 hr	1 hr	2 hr	1 hr	2 hr
1	145	135	155	136	150	142
2	150	130	158	130	155	139
3	151	133	157	132	156	140
4	155	142	154	141	155	138
5	156	139	158	138	151	140
6	151	140	158	135	152	135
7	152	139	155	131	157	138
8	155	142	0	0	152	140
9	0	0	0	0	155	139
10	0	0	0	0	0	0

Statistical significance in OGTT value at 1 hour, before and after 3 month treatment - Male subjects

Treatment 1	Treatment 2
N1: 26	N2: 26
df1 = N - 1 = 26 - 1 = 25	df2 = N - 1 = 26 - 1 = 25
M1: 159.8	M2: 152.04
SS1: 38	SS2: 180.96
s21 = SS1/(N - 1) = 38/(26-1) = 1.58	s22 = SS2/(N - 1) = 180.96/(26-1) = 7.54

The t-value is 12.84562. The p-value is < .00001. The result is significant at $p < .05$.

Statistical significance in OGTT value at 2 hour after 3 month treatment - Male subjects

Treatment 1	Treatment 2
N1: 26	N2: 26
df1 = N - 1 = 26 - 1 = 25	df2 = N - 1 = 26 - 1 = 25
M1: 149.77	M2: 138.73
SS1: 70.62	SS2: 513.12
s21 = SS1/(N - 1) = 70.62/(26-1) = 2.82	s22 = SS2/(N - 1) = 513.12/(26-1) = 20.52

The t-value is 11.6482. The p-value is < .00001. The result is significant at $p < .05$

Statistical significance in OGTT value at 1 hour, before and after 3 month treatment - female subjects

Treatment 1	Treatment 2
N1: 24	N2: 24
df1 = N - 1 = 24 - 1 = 23	df2 = N - 1 = 24 - 1 = 23
M1: 159.71	M2: 153.88
SS1: 112.96	SS2: 232.62
s21 = SS1/(N - 1) = 112.96/(24-1) = 4.91	s22 = SS2/(N - 1) = 232.62/(24-1) = 10.11

The t-value is 7.37242. The p-value is < .00001. The result is significant at $p < .05$.

Statistical significance in OGTT value at 2 hour, before and after 3 month treatment - female subjects

Treatment 1	Treatment 2
N1: 24	N2: 24
df1 = N - 1 = 24 - 1 = 23	df2 = N - 1 = 24 - 1 = 23
M1: 148.71	M2: 137.25
SS1: 98.96	SS2: 332.5
s21 = SS1/(N - 1) = 98.96/(24-1) = 4.3	s22 = SS2/(N - 1) = 332.5/(24-1) = 14.46

The t-value is 12.96049. The p-value is < .00001. The result is significant at $p < .05$.

Discussion

The medical fraternity at the global level have evolved a new consensus on the early detection of prediabetes in order to revert/reduce/prevent the possible episode of diabetes mellitus. But the early detection of prediabetes remain a challenge due to the blood glucose parameter in most prediabetes subjects remain normal with that of non-diabetic individual.[1] Further hypoglycemic state is often misunderstood as non-diabetic condition whereas such situation could be due to hypersecretion of insulin [3].

Hypersecretion of insulin often reduce blood glucose instantly even after a good meal but the excess insulin thrust is likely to impair glucose metabolism efficiency of the cells and such individuals may turn diabetic in due course of time [4].

In the recent years, intense research has happened in the field of diabetes mellitus and have found that blood glucose value after 1 and 2 hour of OGTT test is above 155mg/dL and 140mg/dL respectively are to be considered as early markers of prediabetes.[9] The prospective follow up study of statistically significant proportion of subjects who were positive for prediabetes based on the above marker standard, turned out to be patients of diabetes mellitus in due course of time. Based on the above findings it was hypothesized that OGTT value of above 155mg/dL and 140mg/dL after 1hr and 2hr respectively must be considered prediabetes and if such subjects are treated appropriately along with strict diet regimen and regular exercise the possibility of diabetes mellitus can be prevented.

Metformin is also the drug of choice for treating prediabetes [10] however if we could identify herbal/ botanical preparations to increase glucose metabolism, the prediabetes can be reverted without drug intervention and the botanical preparation can be integrated into every day diet/nutritional/ supplement regimen.

In the present study, we have evaluated a herbal preparation for its ability in reverting prediabetes through a comprehensive clinical trial. The subjects were diagnosed and recruited based on the criteria of the blood glucose value of 155mg/dL and 140mg/dL after 1 and 2hr of OGTT and then the herbal preparation (500mg in tablet dosage form) 2BD per day was administered for 90 days.

On day 90, the OGTT value was taken from all the subjects and compared with the standard that is 155mg/dL and 140mg/dL after 1 and 2hr of OGTT.

All the 50 subjects (26 male and 24 female) showed significant reduction in blood glucose value which fell within or below 155mg/dL and 140mg/dL after 1and 2hr of OGTT clearly suggesting the prediabetes reversion ability of herbal preparation. The statistical analysis by student t test has shown the difference in blood glucose value after treatment at 1hr and 2hr of OGTT on day 90 was statistically significant with p value less than $p< .05$.

In order to avoid possible error due to body weight of the subjects we took care to empanel all the subjects 68 to 80 kg as the glucose used for OGTT test was 75gm and hence body weight of the subjects needs to be considered [11].

Our earlier laboratory research on the herbal preparations has proved the significant anti-diabetic effect of the herbal formulation by enzymatic assay, cell culture assay and other biochemical studies [12-20].

Findings of the clinical trial clearly suggests that the present herbal preparation may be useful in both treating diabetes mellitus and reverting prediabetes. However more intense research are required to establish the global acceptance for the formulation.

Conflict of Interest

Not available

Financial Support

Not available

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