

Efficacy of Ayurveda Formulation Ayush-82 (IME-9) in Newly Diagnosed Type 2 Diabetics: Retrospective Analysis of Individual Data

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Abstract

Ayush 82 is formulated and clinically proven by Central Council Research in Ayurveda Sciences, M/o of AYUSH, GOI for diabetic care. Recently Right Sugar (Chaturbhuj Pharmaceutical), IME-9 (Kudos Ayurveda) and BGR-34 (AIMIL Pharmaceutical) have drawn the attention of many diabetic consumers as these products are developed from scientific organizations of government and highlighted in electronic and print media. IME-9 (Kudos Ayurveda) developed from Ayush 82 of Central Council Research in Ayurveda Sciences, M/o of AYUSH, GOI. Most of the patients consuming IME-9 attend Ayurvedic hospitals and clinics for evaluation of their blood sugar level to know the efficacy of the drug and for consultation. Therefore, an initiative was taken to analyze the safety and efficacy of IME-9 in newly diagnosed diabetic patients taking an IME-9 tablet or have a primary prescription of the same. IME-9 was able to reduce (96%) the blood glucose of all newly diagnosed cases, whereas glycosylated haemoglobin level was reduced in all newly diagnosed cases except in one. Total 12 (48%) patients have shown the improvement of blood glucose and glycosylated haemoglobin (up to 7). It is also observed that in three cases blood glucose level was increased after 2 weeks of treatment and significant reduction of blood glucose was found after the 8th week. So IME-9 may be the first line choice of herbal treatment of newly diagnosed cases along with a change in lifestyle.

Keywords: Ayush 82; IME-9; BGR-34; Glycosylated haemoglobin; Blood sugar

Introduction

Diabetes is fast growing disease and got the status of a potential epidemic in India with more than 62 million diabetic individuals currently diagnosed with the disease [1]. Many patients are tempted to look for Ayurveda remedies as their life-long therapy for diabetic and its complications. More than 50% diabetic patients taking OHA (Oral hypoglycemic agents) and herbs concomitantly but only about 05% patients consult Ayurveda doctor before starting any herbal medicine for diabetes. Studies highlight the high prevalence of self-medication of herbal/Ayurveda medicine by patients with T2DM concomitantly with prescribed medication [2,3]. Diabetic patients purchase Ayurveda medicines through online shopping, marketing network, on phone call, and through teleshopping [4]. Direct to consumer advertisement (DTC) through electronic and print media on Ayurveda proprietary medicines are thought to be a good way to attract chronic diseases suffers and a good source of high return in short time by pharmaceutical companies [5]. The pharmaceutical companies involved in DTC, hesitate to pursue their products through doctor's prescription because they have no/insufficient evidence, rather they sold as OTC (Over the counter) sale products [6]. Ayurveda and other forms of alternative medicine for diabetes are increasingly visible in the public domain; with some officials describing them as effective and emphasizing a supposed absence of side-effects are maximum hype with minimum science [7].

It can affect glucose metabolism, but evidence for their clinical use in patients with diabetes is scarce [8,9]. Every 4th member from diabetic patients in India used herbs/Ayurveda and yoga for their ailments in their life time.

Sometimes they co-administrated with conventional antidiabetic drugs with herbal products, in where possibilities of drug-herb interactions, that may antagonist or synergistic to the drug [10-12]. Efficacy of Ayurveda remedies and Panchakarma procedures of thirty clinical trials were reviewed and found a significant improvement in mild to moderate hyperglycaemia¹². Recently Right Sugar (Chaturbhuj

Pharmaceutical), IME-9 (Kudos Ayurveda) and BGR-34 (AIMIL Pharmaceutical) have drawn the attention of many diabetic consumers as these products are developed from the government scientific organization and highlighted in media [13,14]. Right sugar (Chaturbhuj Pharmaceutical) and IME-9 (Kudos Ayurveda) developed from Ayush 82 of Central Council Research In Ayurveda Sciences, M/o of AYUSH, GOI [15-17] whereas BGR-34 launched commercially by the Council of Scientific and Industrial Research (CSIR) laboratory and published clinical data are not available on various search engines and PubMed [18]. Right Sugar (Chaturbhuj Pharmaceutical) has chosen the platform of advertisement in leading newspaper of many states and the union territory of India; whereas IME-9 has commenced marketing through television. Many patients have come to our hospital and questioning the credibility of Right sugar and IME-9 preparations. Most of the patients consumed IME-9 and have come for an evaluation of blood sugar. Retrospective studies were conducted in Chinese traditional medicine to generate clinical evidence of prescribing medication on diabetic but is rarely seen in Ayurveda [19-22]. Therefore an initiative was taken to analyze the safety and efficacy of IME-9 in newly diagnosed diabetic patients taking the medicine i.e IME-9.

Methods

The clinical records of CARIHD, Bhubaneswar were used as the database. The newly diagnosed cases of T2DM consuming either as a

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prescription drug or as self-medication drugs are included only in the study. The patients who met the inclusion criteria were from 1st Sep 2016 to 31st March 2017 were enrolled in the study. The diagnostic criteria referred to WHO T2 DM diagnostic criteria (1999)²² and Ayurveda guidelines for prevention and management of diabetes [23]. The other inclusion criteria include patients of either gender or age in between 18 yrs to 70 yrs with a confirmed diagnosis of T2DM and not more than two years. The patient should under diet control and exercise or herbal medication. Patients using monotherapy or multiple OHA or under insulin therapy are excluded from the study. The individual data of the recruited subjects were analysed in terms of the individual attributes and changes noticed in the blood sugar and glycosylated haemoglobin level.

The individual data analysis is a preferable method when data are scanty and no relation established among them [24]. Sometimes individual attributes are ignored in the statistical mean analysis. There is a limitation of retrospective analysis in drug efficacy as there are no control groups still retrospective analytical studies are observed in diabetic research [25].

Results and Discussion

Total 210 diabetic patients attended the OPD during the study period. Only 67(32%) patients were consuming IME-9. 32 (47%) Patients received the IME-9 as a primary prescription drug, whereas rest of patients 35 (53%) had been used the medicine from telemarketing and came for a free supply. 34 patients met the inclusion criteria as decided before and nine patients discontinued the analysis without stating the cause of dropout. Total twenty-five patients had completed the 12 weeks of management (Figure 1).

Among 25 patients, 18 (72%) patients were male and 10 (40%) patients have the family history of diabetes. It observed that 04 (16%) patients were below 40 yrs of age and 9 (36%) patients were below 50 yrs of age. It revealed that 8 (32%) patients have a maximum duration of impaired blood sugar (2 yrs) and only 01 patient diagnosed accidentally in our hospital. 16(64%) patients have BMI more than 25 [26-29] (Table 1).

IME-9 was able to reduce the blood glucose of all newly diagnosed cases but glycosylated haemoglobin reduced in all newly diagnosed (96%) cases except in case no-5. Total 12(48%) patients have shown the improvement in blood glucose and glycosylated haemoglobin (up to 7) level. It also observed that in three cases blood glucose level increased after 2 weeks of treatment and significant reduction of blood glucose was found after 8th weeks (Table 2). No adverse effect was found in observed patients during the study.

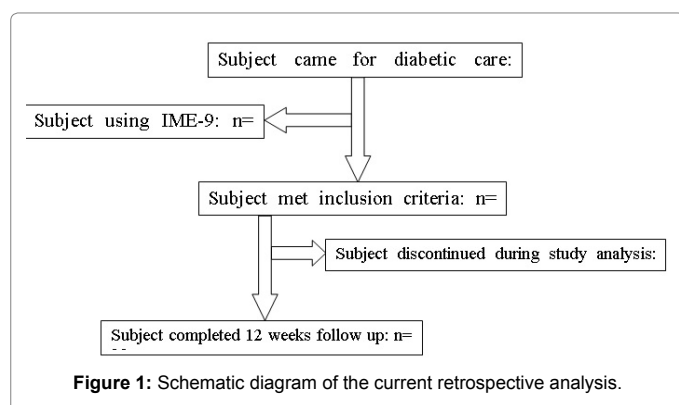


Figure 1: Schematic diagram of the current retrospective analysis.

Sl. No.	Age in years	Sex	BMI	Parental history	Duration of disease
1.	33	M	26.2	Absent	One week
2.	46	F	25.6	Absent	11 months
3.	48	F	24.8	Present	Two days
4.	52	F	32.8	Present	2 month
5.	50	M	22.4	Present	2 years
6.	34	M	25.6	Present	45 days
7.	47	F	23.6	Absent	Two months
8.	77	M	22.1	Absent	30days
9.	56	M	26.2	Absent	120 days
10.	41	M	25.2	Present	6 months
11.	62	M	23.2	Absent	60 days
12.	47	M	25.8	Present	One year
13.	60	M	22.2	Absent	2years
14.	48	M	25.6	Present	2 years
15.	38	F	32.4	Absent	02 years
16.	41	M	23.4	Present	02 years
17.	45	M	27.8	Absent	18 months
18.	53	M	22.8	Absent	Two years
19.	56	M	32.6	Present	One year five months
20.	61	M	32.4	Present	60 days
21.	59	F	31.6	Present	One week
22.	74	M	20.4	absent	02 months
23.	57	M	28.4	Absent	Two years
24.	38	M	26.2	Absent	Six months
25.	44	M	25.6	Absent	2 years

Table 1: Individual data of age, sex, BMI, parental history and duration of disease in observed cases.

Pt No.	D0			2 nd Week		4 th Week		8 th Week		12 th Week		
	FBS	PPBS	HbA1C	FBS	PPBS	FBS	PPBS	FBS	PPBS	FBS	PPBS	HbA1C
1	160	238	8.8	160	213	133	166	87	107	90	117	6.8
2	129	257	9.0	130	250	132	218	122	198	118	173	7.2
3	220	442	13.8	160	313	164	298	152	216	114	168	6.8
4	295	350	13.2	280	360	250	300	210	280	212	284	9.6
5	386	482	8.5	390	510	380	490	300	412	286	392	13.6
6	325	450	8.9	300	400	200	385	114	325	112	225	7.6
7	280	420	13.2	190	310	200	300	102	260	100	184	7.2
8	196	290	9.6	155	210	160	192	140	184	112	136	6.4
9	155	270	8.6	112	255	118	198	102	170	96	166	7.2
10	357	550	13.3	220	347	180	317	150	270	98	142	7.0
11	109	257	7.8	110	218	116	215	98	198	97	167	7.0
12	160	222	7.8	168	220	117	202	94	193	79	110	6.8
13	253	392	13.2	258	412	224	358	176	260	168	218	8.6
14	194	276	8.6	212	258	92	135	98	146	96	160	7.2
15	384	524	14.6	250	412	217	360	212	342	198	378	10.6
16	295	350	9.6	216	250	130	188	133	198	132	198	7.2
17	212	356	10.2	240	370	186	324	156	256	144	232	7.8
18	194	284	8.2	190	280	184	273	124	205	98	178	7.0
19	178	312	7.8	200	242	168	212	164	256	142	264	8.2
20	210	398	13.8	298	407	256	410	213	368	189	366	13.4
21	160	218	7.4	87	150	142	202	154	198	86	146	6.8
22	220	442	10.2	160	385	168	346	164	298	90	117	6.4
23	180	223	7.8	112	180	98	164	134	168	140	180	7.0
24	160	202	7.2	NA	NA	112	178	96	154	112	146	6.8
25	198	388	12.6	NA	NA	89	176	94	180	91	162	6.6

Table 2: Individual patient's observation of blood sugar and glycosylated haemoglobin before and after treatment.

Conclusion

So, Ayush 82 may be the first line of herbal treatment option for newly diagnosed cases along with a change in lifestyle. A large population-based study is recommended.

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