

Carbothera therapy and factors that affect its efficacy to treat diabetic foot

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ABSTRACT

DM is a metabolic disorder of multiple aetiology, of chronic hyperglycaemia with carbohydrate, protein and fat metabolism disturbances, resulting from defects in insulin secretion, insulin, action, or both. People with diabetes are at increased risk of peripheral arterial disease and neuropathy, as well as having a higher risk of developing infections and decreased ability to clear infections. Therefore, people with diabetes are prone to frequent and often severe foot problems and a relatively high risk of infection, gangrene and amputation., now a days we use a new modality to treat diabetic foot which called carbothera which is soda –spa as carbon dioxide dissolved in worm water, named as Soda path. 800 patients were included in this study which was performed in diabetic and endocrine centre in Iraq \ Thi qar during the period from (2017_2020) randomly, exclusion criteria was patients with neuropathy, burn and fungal infection...The patients was male and female and their age was ranging from 7 to 82, all of them underwent investigations in form of random blood sugar, glucoseurea, renal function test, hba1c...the instrument was used is autoanalyzer, and specific type of kits. In our study we found a great relationship between sessions number and smoking, sex, occupation and history of injury on the other hand there was no significant association with age, concomitant disease, address and type of therapy.



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1. INTRODUCTION

1.1 Definition

The term diabetes mellitus describes a metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both [1]. The long-term effect of diabetes mellitus include progressive development of specific complications as retinopathy with potential blindness, nephropathy that may lead to renal failure, and/or neuropathy with risk of foot ulcers, amputation, Charcot joints, and features of autonomic dysfunction, including sexual dysfunction. People with diabetes are at increased risk of cardiovascular, peripheral vascular and cerebrovascular disease [2].

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1.2 Classification

1. The insulin-dependent, ketosis-prone type of diabetes
 2. The noninsulin-dependent, nonketosis-prone types of diabetes,
 3. The types of diabetes caused by other conditions or found in increased frequency with other conditions (implying an etiologic relationship)
 4. gestational diabetes
 5. Individuals with plasma glucose (PG) levels intermediate between those considered normal and those considered diabetic be termed to have impaired glucose tolerance [3].
- American study provided benchmark estimates on the national prevalence of diagnosed type 1 diabetes (0.5%) and type 2 diabetes (8.5%) among US adults. Among US adults with diagnosed diabetes, type 1 and type 2 diabetes accounted for 5.6% and 91.2%, respectively [4].

However with the increasing incidence of childhood obesity and concurrent insulin resistance, the number of children diagnosed with type 2 diabetes has also increased worldwide.

Diabetic foot: People with diabetes are at increased risk of peripheral arterial disease and neuropathy, as well as having a higher risk of developing infections and decreased ability to clear infections. Therefore, people with diabetes are prone to frequent and often severe foot problems and a relatively high risk of infection, gangrene and amputation [5].

Motor, sensory and autonomic fibers may all be affected in people with diabetes mellitus. Because of sensory deficits, there are no protective symptoms guarding against pressure and heat and so trauma can initiate the development of a leg ulcer [6]. Absence of pain contributes to the development of Charcot foot, which further impairs the ability to sustain pressure. Motor fiber abnormalities lead to undue physical stress, the development of further anatomical deformities (arched foot, clawing of toes), and contribute to the development of infection. When infection complicates a foot ulcer, the combination can be limb-threatening or life-threatening. Detection and surveillance of diabetic neuropathy are an essential routine part of a diabetic annual review. Many modalities of therapy now a day for diabetic foot, some of them use medical therapy only, surgical therapy or both [7].

we need to know the infectious microorganism [8].

New mode of therapy which is called carbothera [9].

carbothera: soda-spa refers to the warm water that dissolves dioxide, another name for it is soda bath. On the other hand, artificial soda-spa refers to carbon acid hot water with clean carbon dioxide dissolved in it. from the perspective of the properties of carbon dioxide, the hot water with high temperature cannot dissolve carbon dioxide with high concentration. Currently, this equipment is introduced in various fields such as medical institutions, medical service facilities, hydrotherapy facilities, the Beauty Parlor, fitness club, Hairdressing Parlor and so on.

1.3 Epidemiology

Foot disease affects nearly 6% of people with diabetes [10]

The results of cross-sectional community surveys in the UK showed that 5.3% (type 2) and 7.4% (types 1 and

2 combined) of people with diabetes had a history of active or previous foot ulcer. An annual incidence of 2.2% was found in a large community survey in the UK, and up to 7.2% in patients with neuropathy. Painful diabetic neuropathy is estimated to affect between 16% and 26% of people with diabetes. The incidence of major amputation is between 0.5 and 5.0 per 1,000 people with diabetes [7].

The aim of study: To find the efficacy of carbothera to treat diabetic foot and to find the effective parameters that interfere with efficient carbothera therapy (age, sex, occupation, agricultural factors, duration history of injury, type of treatment that used to control DM and presence of concomitant diseases).

2. Patients and method

Across sectional study, performed in diabetes and endocrine centre in Iraq \ Thi qar during the period from (2017_2020).

All the patients have diabetes, some of them was type one diabetes mellitus and some of them was type 2 diabetes mellitus.

Age of patients was ranged from (7 _82) years old. We divide the patient regarding their age in to three groups 1. less than 15 years, 2. between 15-45 years, 3. more than 45 years.

Height, weight, and systolic and diastolic blood pressure were measured. Blood pressure was measured with a standardized sphygmomanometer after at least 5 min of rest, according to the Hypertension Detection and Follow-up Program protocol. Body mass index (BMI) was calculated by dividing weight (kg) by height (m) squared.

After a 12-h fast, blood glucose, total cholesterol, triglyceride, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein-cholesterol (LDL-C) and VLDL, blood urea and serum creatinine levels were measured using the hexokinase method (AU 5400 Autoanalyser; using minividas instrument (made in Italy). The patients were investigated for Hb. HbA_{1c} HbA_{1c} was measured with high-performance liquid chromatography (HLC-723 G7; Tosoh Corporation, Tokyo, Japan) according to the standardized Diabetes Control and Complications Trial assay. GUE was done also for every patient. Body mass index was divided into five groups (<20, 20-24.9, 25-29.9, 30-34.9, and >35). HbA_{1c} was divided into three groups (<7, 7-7.9, >8).

History of atherosclerosis including history of coronary artery disease, CVA, peripheral arterial insufficiency. Fasting blood samples were obtained for blood sugar (venous blood samples taken after overnight fast of a minimum of 8 hrs.). The kit used for biochemistry was biomerieux (France) while the kit used for blood sugar was randox, s.cholesterol and s.triglyceride was bioLABO, other component of lipid profile had been studied also. 111 patients had metabolic syndrome and 115 had no metabolic syndrome. Metabolic syndrome was assessed according to the US National Cholesterol Education Program Adult Treatment Panel III (2001) that was modified at 2004.

HbA_{1c} was measured by immune-turbi-dimetric assay with a Cobra Integra 800 automatic analyzer (Roche Diagnostics, Basel, Switzerland) with a reference value of 4.4–6.0%. The methodology was aligned with the Diabetes Control and Complications Trial (DCCT) and National Glycohemoglobin Standardization Program (NGSP) standards. general urine examination was assessed.

2.1 Selection criteria

We chose the patients randomly without specific selection criteria

2.2 Exclusion criteria

We exclude from the study (1) patients that use carbothera to treat neuropathy (burning and tingling sensation): Because our subject is not about using carbothera for treatment of neuropathy, (2) Burn: Because the mechanism of burn is different from that in diabetic foot, and there's no relation between diabetes and burn, (3) Fungal infection, athletic foots, because those patients need special antifungal therapy and special care beyond our subject.

2.3 Ethical clearance

Verbal consent had obtained from all participant with in the study

2.4 Statistical analysis

SPSS version 26, has been used for the data analysis, where quantitative variables assessment done through estimation of frequency, percentages, mean, standard deviation, standard error, ANOVA, while qualitative variables presented inform of figures that drown by Excel sheet 2010, while analysis including chi-square, P value lesser than 0.05 consider as significant, while lesser than 0.001 consider as highly significant.

3. Result

As shown in (table 1), age frequencies (<15 =3, 0.4%, 15_45 =118 ,14.8%, >45 =679 ,84.9%), Mean =28.450 +- 13.4, male was 426, 53.2%, Female 374 ,46.8, self employer =244 ,30.5%, house wife =360 ,45%, retired =196 ,24.5 %, urban =526 , 56.8%, rural =274 ,34.2 %, history of injury (duration of injury), One week =27 ,3.4%, Week _month =227 , 28.4%, Month _2 months = 272 , 34 %, 2months _3 months = 126 , 15.8 %, >3months = 148 , 18.4%, Type of treatment : Insulin = 457 , 57.1%, Oral hypoglycemic agent =330 , 41.3%, Diet = 13 , 1.6%, Smoking : Smokers = 144 , 18%, Non- smoker = 656 , 82%, Concomitant diseases : Only diabetes = 516, 64.5%, Another atherosclerotic diseases as HT, cardiovascular diseases and cerebrovascular diseases = 284 , 35.5%, Session numbers : every session continues for about half hour in every alternative day, The patients subjected to close follow up, we give the patient a chance of ten sessions that can be repeated frequently till complete healing. The frequency of sessions was as follows: <10 =189, 32.6%, 11_20 = 404, 50.5%, 21_30 = 85, 10.6%, 31_40 = 44, 5.5%, >40 = 78, 9.8%

Tables (1): Socio- demographic variables of studied population

Socio- demographic variables		Frequency	Percent
Age	<15	3	.4
	15-45	118	14.8
	>45	679	84.9
Gender	Male	426	53.3
	Female	374	46.8
	Self-employer / employer	244	30.5
occupation	Housewife	360	45.0
	Retired	196	24.5
	City center	526	65.8
	Out of center	274	34.3
Total		800	100.0

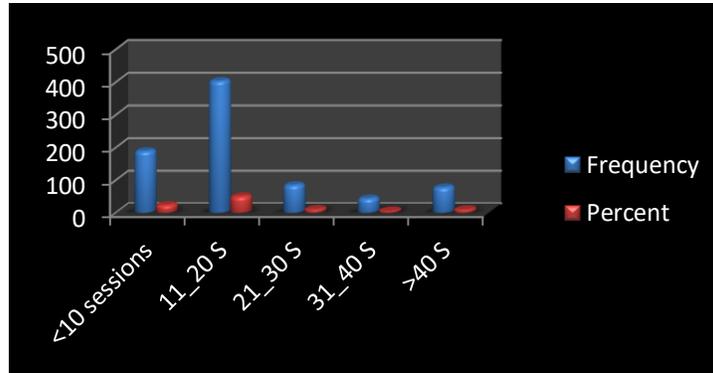


Figure 1: Number of sessions of carbothera to diabetic foot

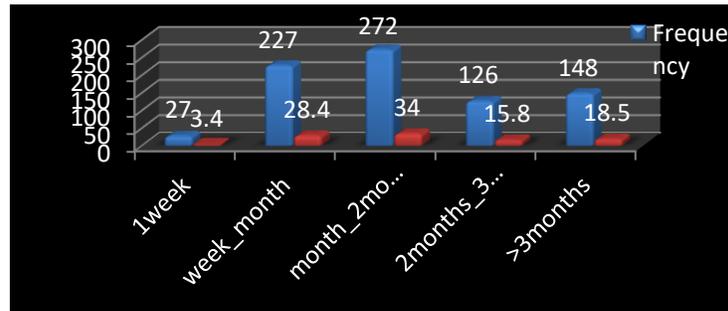


Figure 2: Duration of diabetic foot injury

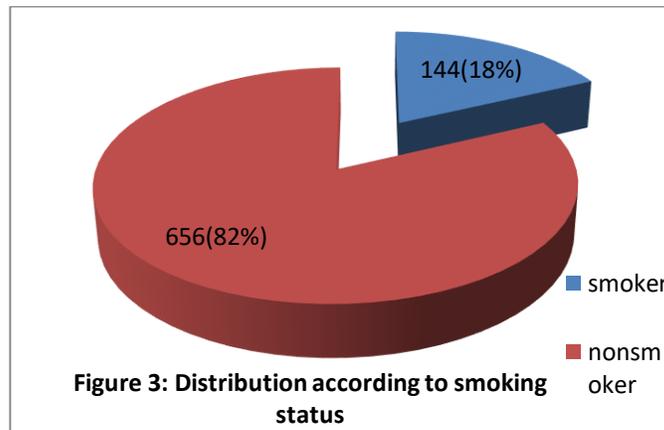


Figure 3: Distribution according to smoking status

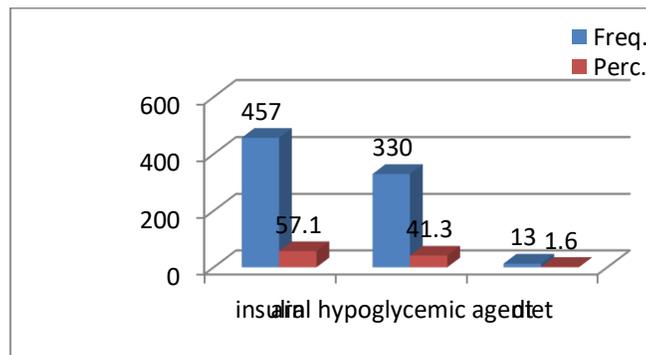


Figure 4: Types of treatment modalities of DM

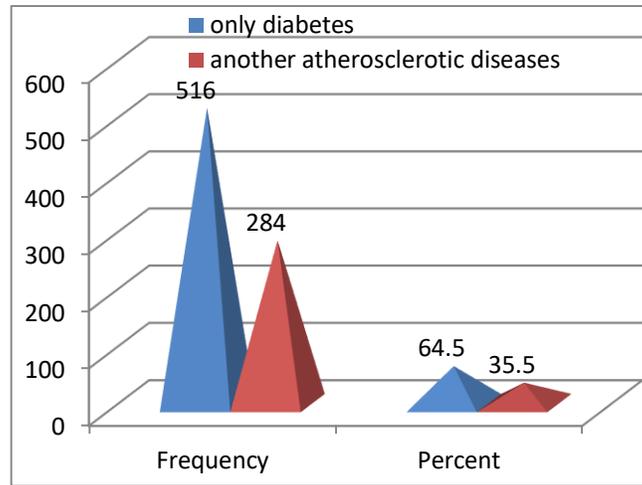


Figure 5: Concomitant diseases with DM.

Relationship between number of sessions of carbothera and age (table 2), we found no association between them, as in the first group <15 years, the number of patients although it was very low but, the number of sessions increase, while in the 2nd group 15_45 it find that there`s increase from 25 to 63 patients then decrease to 13 then to 6 patients, which mean no clear or significant association was present, the same also occur in the third group >45 years.

Table 2: Association between number of sessions and age

Sessions number	age			Total
	<15	15-45	>45	
<10	1	25	163	189
	.5%	13.2%	86.2%	100.0%
11_20	2	63	339	404
	.5%	15.6%	83.9%	100.0%
21_30	0	13	72	85
	.0%	15.3%	84.7%	100.0%
31_40	0	6	38	44
	.0%	13.6%	86.4%	100.0%
>40	0	11	67	78
	.0%	14.1%	85.9%	100.0%
Total	3	118	679	800
	.4%	14.8%	84.9%	100.0%

Relationship between number of sessions of carbothera and sex (table3):

We found number of male patients more than female in the second group (11_20 sessions) and in the 3rd (21_30), 4th and 5th and great association was found which was statistically significant (p= 0.001) (chi_square =16)

Table 3: Association between number of sessions and gender

Sessions number	Gender		Total
	Male	Female	
<10			
11_20			
21_30			
31_40			
>40			
Total			

Sessions number	Male	Female	
<10	78	111	189
	41.3%	58.7%	100.0%
11_20	223	181	404
	55.2%	44.8%	100.0%
21_30	49	36	85
	57.6%	42.4%	100.0%
31_40	27	17	44
	61.4%	38.6%	100.0%
>40	49	29	78
	62.8%	37.2%	100.0%
Total	426	374	800
	53.3%	46.8%	100.0%

3. relationship between number of sessions of carbothera and location (address) of the patients. No relationship with no statically significance was found as it evident in (table 4), the number of patients increase first then decrease and return to increase in both groups, and that was ($p = 0.4$) ($\text{chi_square} = 4.4$)

Table 4: Association between number of sessions and address

Sessions number	Address		Total
	City center urban	Out of center Rural	
<10	129	60	189
	68.3%	31.7%	100.0%
11_20	256	148	404
	63.4%	36.6%	100.0%
21_30	53	32	85
	62.4%	37.6%	100.0%
31_40	33	11	44
	75.0%	25.0%	100.0%
>40	55	23	78
	70.5%	29.5%	100.0%
Total	526	274	800
	65.8%	34.3%	100.0%

4. relationship between number of sessions of carbothera and occupation (table5)

This is very important table in which we can see the number of patients decrease from 404 then to 85 then to 44 patients in general look. More evident in house wives that decrease from 175 to 36 patients then to 17 patients. We found that there`s significant association between session numbers and occupation ($\text{chi_square} = 20$, $p \text{ value} = 0.024$). The number of patients that get benefit from the sessions is decreasing that mean the gain will be less from the carbothera.

Table 5: Association between number of sessions and occupation

Sessions number	occupation			Total
	Self -employer /employer	Housewife	Retired	
<10	50 26.5%	104 55.0%	35 18.5%	189 100.0%
11_20	133 32.9%	175 43.3%	96 23.8%	404 100.0%
21_30	28 32.9%	36 42.4%	21 24.7%	85 100.0%
31_40	14 31.8%	17 38.6%	13 29.5%	44 100.0%
>40	19 24.4%	28 35.9%	31 39.7%	78 100.0%
Total	244 30.5%	360 45.0%	196 24.5%	800 100.0%

5.relationship between sessions numbers of carbothera and duration time of injury (table 6). It's clear in the first number of patients (<10) increase gradually from 12 to 67 patients then to 81patient, also in the second number, 3rd, 4th, and 5th one that was very significant statistically (0.000). there`s highly significant association between session numbers and history of injury (chi-square =56, p value =0.000) (table 6)

Table 6: Association between number of sessions and history of injury

Sessions number	History of injury					Total
	1week	Week-month	month_2months	2months_3months	>3months	
<10	12 6.3%	67 35.4%	81 42.9%	14 7.4%	15 7.9%	189 100.0%
11_20	12 3.0%	104 25.7%	138 34.2%	73 18.1%	77 19.1%	404 100.0%
21_30	2 2.4%	28 32.9%	18 21.2%	13 15.3%	24 28.2%	85 100.0%
31_40	0 .0%	12 27.3%	12 27.3%	9 20.5%	11 25.0%	44 100.0%
>40	1 1.3%	16 20.5%	23 29.5%	17 21.8%	21 26.9%	78 100.0%
Total	27	227	272	126	148	800

	3.4%	28.4%	34.0%	15.8%	18.5%	100.0%
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6. relationship between sessions number and type of therapy(table7) that used for control diabetes. Although there is decrease in number of patients from <10 sessions to second and third group in IDDM still the same decrement also occur in NIDDM and diet therapy. We found that there`s no significant association between session numbers and type of therapy (chi_square = 4.5, p value =0.954) (table 7).

Table 7: Association between number of sessions and types of treatment

Sessions number	Treatment			Total
	Insulin	Oral hypoglycemic agent	Diet	
<10	116	71	2	189
	61.4%	37.6%	1.1%	100.0%
11_20	219	177	8	404
	54.2%	43.8%	2.0%	100.0%
21_30	49	34	2	85
	57.6%	40.0%	2.4%	100.0%
31_40	27	17	0	44
	61.4%	38.6%	.0%	100.0%
>40	46	31	1	78
	59.0%	39.7%	1.3%	100.0%
Total	457	330	13	800
	57.1%	41.3%	1.6%	100.0%

7.relationship between session numbers and smoking (table 8). Very significant relationship and association between number of sessions and smoking status. Which is clear that decrement in number of patients in second row from 330 to 65 then 32, while in smoker there is decrement in patients number from 74 to 20 indicate the great benefit of carbothera therapy for the non smoker versus smoker one (p=0.002). (chi-square = 12.7)

Table 8: Association between number of sessions and smoking status

Sessions number	Smoking		Total
	Smoker	nonsmoker	
<10	20	169	189
	10.6%	89.4%	100.0%
11_20	74	330	404
	18.3%	81.7%	100.0%

21_30	20 23.5%	65 76.5%	85 100.0%
31_40	12 27.3%	32 72.7%	44 100.0%
>40	18 23.1%	60 76.9%	78 100.0%
Total	144 18.0%	656 82.0%	800 100.0%

8.relationship between sessions number and other concomitant atherosclerotic diseases (table 9). We divided the patient into two groups, those with diabetes mellitus alone and those with diabetes and other concomitant atherosclerotic diseases. No clear association was found and the patients number decrease in both groups. We found that there`s no significant association between sessions numbers and concomitant diseases. (chi_square =1.4, p value =0.88).

Table 9: Association between number of sessions and Concomitant diseases

Sessions number	Concomitant disease		Total
	only diabetes	another atherosclerotic diseases	
<10	122 64.6%	67 35.4%	189 100.0%
11_20	259 64.1%	145 35.9%	404 100.0%
21_30	54 63.5%	31 36.5%	85 100.0%
31_40	32 72.7%	12 27.3%	44 100.0%
>40	49 62.8%	29 37.2%	78 100.0%
Total	516 64.5%	284 35.5%	800 100.0%

4. Discussion

In our study we took 800 patients, all of them are diabetic whether type one or type two, We had been tested the association of sessions number of carbothera with different parameters. First one was the age, ranged from (7_82) years old and we found that there`s no any significant relation between the age and sessions number that mean the age doesn't affect the therapy with carbothera.

Second one was the sex with male number about 426, female number 374

We found that there`s significant association between sessions number and sex, it could be due to that most of females are house wives who are less vulnerable to trauma and have more rest and care to their foot, male

still have to continue working or less customized therapy than female and we have to put in our mind that male is a risk factor for DM, atherosclerosis and their job, less rest and care make them vulnerable to trauma more than female.

Third association was between sessions number and address, there was no significant association. Whether the patient live in rural or urban area make no difference both of them subjected to the same environment and the near equality between the two lifes.

The fourth about association of sessions number and occupation

There was significant association between them because some occupations are more traumatic to patients feet that make them need even more number of sessions so that they can heal and that regarding housewife discussed previously.

The fifth was between number of sessions and duration of injury, we found that there was a highly significant association between them, cause longer period of injury, more damage to the vascularity and to the tissue, and that need even more sessions number so can heal

The sixth was about the association between number of sessions and type of therapy, and there was no association. as far as there is good control of DM the type of therapy make no change, the second point is that both IDDM and NIDDM are subjected to trauma.

The seventh was between smoking and sessions number, and there was highly significant association, because the smoking itself cause atherosclerotic and ischemic changes that can cause even more damage and delay in healing process.

The eighth was about association between sessions number and concomitant diseases, there`s no significant association because diabetes itself is a tragedy, cause more co morbidity, more atherosclerotic changes also may become the leading cause for hypertension and cerebrovascular accident and ischemic heart disease. One study performed in AlKufa medical college where they didn't discuss the therapy with carbothera. Our study is original and we didn't find such a study because carbothera is a new mode of therapy.

5. Conclusion

1. Carbothera is very important in treatment of diabetic foot.. it`s a new modality with a great benefit for the patient.
- 2.If the patient exceed 40 session the benefit from the sessions will be less although preserved.
3. we concluded that there`s no need to make the patient of diabetic who use oral therapy to use insulin to enhance the treatment of their injury, unless their blood sugar is poorly controlled with oral therapy. Even if controlled by diet, it`s so enough and there`s no need to use insulin.
- 4.smoker patients get less benefit than non smoker one regarding carbothera therapy
- 5.female better than male regarding healing and possible dressing and customized therapy.
- 6.early therapy make better results.
7. continuous working make the therapy with carbothera longer in its duration.

6. Recommendations

1. all patient with diabetic foot should have their chance for carbothera therapy.
- 2.smoking must be stopped because they will get less benefit from carbothera than the others.

3. male must take their foot care just like the female.
4. retired patient must look after their foot and visit their doctors regularly.
5. male must take rest during the sessions of carbothera.
6. good control DM is the most important one and no matter the type of therapy insulin, oral therapy or diet.
7. early therapy and early visits to the doctor make less trauma, less cost effectiveness and less stress to the patient and medical staff.

7. Acknowledgments

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