



MICROALBUMINURIA REDUCTION WITH EARLY PHARMACOTHERAPEUTIC INTERVENTION FOR BLOOD PRESSURE CONTROL IN CASES OF HYPERTENSIVE T2DM SUBJECTS.

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ABSTRACT

Objective:

A prospective randomized observational study to assess the importance of early intervention with pharmacotherapy to control B.P. in T2DM having microalbuminuria, and its reduction in comparison to a delayed initiation for the same.

Materials and methods:

Patients with T2DM, HTN, and Microalbuminuria, on treatment for Diabetes but drug naïve for HTN were selected and divided into two groups.

Group A was advised LSM for B.P. control but no pharmacotherapy.

Group B gave the same advice plus Azilsartan 40 mg/day.

UACR, B.P., and HbA1c were recorded on every visit.

Second visit (3 months)

Group A added on Azilsartan 40 mg/day to control the B.P. to target.

Group B advised titration of Azilsartan dosage for the same.

On the third visit (6 months) all the three parameters were recorded as before.

Results:

(n=66) completed the study. (A=36 and B=30).

The data analysis showed that at the end of 6 months ~33% of the patients in Group A could become non-microalbuminuric in comparison to ~67% of the patients in Group B. Reduction in microalbuminuria could be achieved in ~72% of patients from Group A, whereas ~87% of patients could achieve the same in Group B.

Conclusion:

From the results of this study, it could be concluded that early initiation of pharmacotherapy in hypertensive T2DM patients to reduce B.P. helped to achieve a significantly beneficial effect on microalbuminuria reduction when compared to delayed initiation for the same even when the glycaemic goals and LSM were targeted with equal aggression in both the groups.

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INTRODUCTION:

In my present study, a real-world prospective randomized observational study,

there was an attempt to assess the importance if any, of early intervention with pharmacotherapy, to control elevated blood

pressure in subjects of T2DM who were having microalbuminuria, in its reduction in comparison to a delayed initiation for the same. The outcome would help to co-relate the importance of achieving B.P. targets early in the course of disease progression of T2DM subjects as outlined in various trials. It would also help to reflect the importance of alterations in the co-morbidity for ESRD in the natural history of T2DM subjects.

MATERIALS AND METHODS:

The inclusion criteria were -

- Non-Pregnant Adults (>18 years of age),
- T2DM (HbA1c \geq 7.5% but < 10 %),
- Hypertensive (B.P. > 130/80 mm of Hg but < 160/100 mm of Hg),
- Drug naïve (for hypertension)
- Microalbuminuric (UACR of 30-300 mg/gm)
- eGFR (CKD-EPI) \geq 60mL / min / 1.73m²

Informed consent with validated documents as mandated was collected from the patients who fitted the above-mentioned criteria. The patients included, were divided into two groups, A and B.

On the first visit

Those in Group A were given standard up-titration of anti-hyperglycaemic treatment to target the glycaemic goal of HbA1c < 7% and advised to follow DASH regimen and lifestyle modification for hypertension control, but no pharmacotherapy was initiated for hypertension.

Group B was given the same advice but in addition, prescribed the ARB – Azilsartan in 40 mg/day.

All patients were receiving/prescribed a statin in both the Groups A and B which was continued for the entire duration of the study (six months). Microalbumin level (UACR), was recorded for each patient along with their B.P. and HbA1c. Patients in both groups were followed up and advised to come back for the second visit after three months.

On the second visit

Those in Group A were continued on standard titration of anti-hyperglycaemic

treatment to target the glycaemic goal of HbA1c < 7% and added on Azilsartan in 40 mg/day to control the B.P. to target goal of <130/80 mm of Hg.

Those in Group B were also advised titration of anti-hyperglycaemic treatment as above and up-titration of the dosage for Azilsartan to 80 mg, if 40 mg/day of Azilsartan did not help to achieve the target B.P. goal of < 130/80 mm of Hg.

UACR was recorded for each patient along with their B.P. and HbA1c, like the first visit.

Patients in both groups were followed up and advised to come back for the third visit after three months.

On the third and final visit (6 months after the first visit).

UACR was recorded for each patient along with their B.P. and HbA1c, like the previous two visits.

RESULTS AND DISCUSSION:

A total number of patients completing the study were sixty-six (n=66), 36 in Group A and 30 in Group B.

The data were analyzed and it showed that at the end of 6 months only 12 out of 36 (~33%) of the patients in Group A could become non-microalbuminuric in comparison to 20 out of 30 (~67%) of the patients in Group B. Reduction in microalbuminuria could be achieved in 26 out of 36 (~72%) of patients from Group A, whereas 26 out of 30 (~87%) of patients could achieve the same in Group B (p<0.001).

CONCLUSION:

From the results of this study, it could be well co-related that early initiation of pharmacotherapy in hypertensive T2DM patients to reduce B.P. helped to achieve a significantly beneficial effect on microalbuminuria reduction when compared to delayed initiation for the same even when the glycaemic goals were targeted with equal aggression and lifestyle modification in both the groups.

CONFLICTS OF INTEREST: None

Table no. 1

GROUP A

SERIAL NUMBER	SEX	AGE	1 st VISIT			2 nd VISIT (3 months)			3 rd VISIT(6 months)		
			B.P. mm of Hg	HbA1C %	UACR mg/gm	B.P. mm of Hg	HbA1C %	UACR mg/gm	B.P. mm of Hg	HbA1C %	UACR mg/gm
1	F	47	140/92	7.8	42	140/90	7.2	50	126/76	7.0	38
2	F	54	150/88	8.1	72	152/94	7.8	84	138/84	7.5	92
3	M	42	148/94	7.6	51	142/90	8.0	60	130/80	7.8	74
4	M	53	138/86	7.8	48	130/82	7.4	34	120/70	7.2	28
5	M	39	152/90	7.9	84	160/96	7.8	92	140/80	7.4	64
6	F	41	142/86	8.6	64	140/88	7.9	86	128/78	7.4	50
7	F	59	156/92	7.6	44	150/90	7.9	52	136/84	7.1	36
8	M	62	136/84	8.2	46	130/80	7.6	38	124/72	7.0	20
9	F	38	148/90	7.7	76	150/90	7.4	84	132/80	7.5	82
10	M	46	138/88	8.0	68	146/94	7.8	76	128/80	7.2	42
11	F	55	156/100	7.9	104	150/96	8.1	120	142/88	7.8	136
12	M	64	154/94	8.7	88	160/100	7.9	98	140/86	7.6	64
13	F	36	146/96	7.9	90	140/92	7.5	76	130/78	7.0	28
14	F	47	136/86	8.5	72	134/82	7.6	72	122/70	6.8	18
15	M	58	146/96	8.1	110	150/100	7.7	126	134/82	7.3	82
16	M	62	142/84	8.2	62	140/80	7.8	64	130/72	7.1	38
17	F	64	150/92	8.6	46	146/90	7.9	52	130/80	7.6	56
18	F	53	136/82	7.6	33	128/80	7.2	31	118/72	6.8	26
19	F	45	152/100	7.9	68	148/94	7.1	62	132/84	6.2	50
20	M	46	142/86	8.4	56	140/90	7.8	58	130/80	7.2	28
21	F	37	138/90	8.1	36	132/84	7.0	38	122/74	6.5	22
22	F	59	140/94	8.4	48	150/100	6.9	72	138/86	6.8	53
23	M	44	156/96	7.8	72	150/90	6.9	68	140/82	7.1	74
24	M	52	148/88	7.6	60	136/84	6.8	43	126/78	6.3	26
25	F	38	132/90	9.8	44	130/88	8.2	44	124/76	7.5	20
26	F	44	142/94	8.8	53	146/90	8.0	58	140/82	7.3	68
27	M	47	140/82	7.7	36	132/80	7.2	28	130/72	6.6	20
28	M	49	134/86	8.0	32	128/80	7.4	22	116/70	6.8	15
29	F	36	156/96	8.2	62	150/90	7.7	40	140/82	7.1	32
30	M	55	144/88	7.8	54	140/82	7.0	61	132/76	6.4	43
31	M	48	138/88	9.0	36	138/90	7.9	40	128/80	7.2	48
32	M	52	148/92	8.1	52	146/90	7.3	38	132/82	7.1	33
33	F	43	142/86	7.6	48	140/84	7.5	40	130/76	7.3	26
34	M	59	152/94	8.7	74	148/90	8.1	72	132/84	7.9	76
35	M	43	144/86	7.8	66	136/82	7.1	51	126/72	6.8	40
36	F	39	150/100	8.2	68	142/94	7.6	62	138/86	7.2	60

Table no. 2

GROUP B

SERIAL NUMBER	SEX	AGE	1 st VISIT			2 nd VISIT (3 months)			3 rd VISIT (6 months)		
			B.P.	HbA1C	UACR	B.P.	HbA1C	UACR	B.P.	HbA1C	UACR
			mm of Hg	%	mg/gm	mm of Hg	%	mg/gm	mm of Hg	%	mg/gm
1	F	47	142/84	7.9	48	130/76	7.2	28	128/72	6.8	18
2	F	54	150/90	7.8	62	132/80	7.4	34	120/76	7.2	20
3	M	42	138/88	8.8	56	126/80	8.0	42	120/76	7.5	32
4	M	53	148/92	8.1	78	140/84	7.8	92	136/80	7.6	116
5	M	39	152/100	8.4	98	144/86	8.2	76	130/80	7.9	53
6	F	41	144/86	7.6	42	138/72	7.2	32	130/70	7.0	24
7	F	59	136/84	8.2	76	128/72	7.6	38	120/70	7.4	18
8	M	62	156/94	7.7	68	142/92	7.0	42	132/84	6.8	22
9	F	38	144/96	8.3	104	132/84	7.8	54	130/78	7.1	28
10	M	46	136/82	7.6	32	124/70	7.1	18	120/64	6.6	12
11	F	55	154/96	7.9	84	144/82	7.4	50	130/78	7.2	30
12	M	64	148/94	7.8	72	140/80	7.1	30	130/74	6.9	24
13	F	36	140/82	8.6	64	130/76	8.1	32	124/70	7.4	16
14	F	47	150/88	8.0	58	150/90	7.6	86	142/84	7.2	108
15	M	58	134/86	7.7	42	126/80	7.1	28	122/74	6.6	18
16	M	62	144/84	7.8	40	132/80	7.1	30	122/72	6.8	24
17	F	64	150/92	8.9	56	140/84	7.8	33	130/76	6.7	28
18	F	53	146/90	7.9	44	138/82	7.4	32	130/80	7.1	15
19	F	45	160/96	8.2	62	150/90	7.2	40	136/80	6.6	34
20	M	46	138/86	8.7	38	128/80	7.6	28	120/70	7.0	20
21	F	37	148/94	7.8	64	140/84	6.9	43	130/76	6.6	30
22	F	59	146/88	9.8	43	132/78	7.9	30	128/76	7.2	18
23	M	44	132/84	8.1	36	124/80	7.2	24	120/72	6.7	16
24	M	52	152/88	9.2	52	150/90	8.8	64	140/86	8.1	72
25	F	38	146/90	8.3	48	136/82	7.8	36	130/74	7.1	26
26	F	44	156/94	7.6	58	142/90	8.2	68	146/92	7.9	72
27	M	47	142/86	7.9	39	134/80	7.1	30	128/76	6.8	22
28	M	49	134/90	8.8	62	122/84	8.1	46	118/76	7.6	28
29	F	33	140/92	9.0	51	130/84	7.6	32	126/78	7.0	20
30	M	51	158/86	8.3	68	142/80	7.8	52	132/76	6.9	32

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