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Reduced urine albumin excretion in community based collaborative care in elderly Chinese with type 2 diabetes

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Recruitment status
No longer recruiting

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05/08/2011

Overall study status
Completed

Last Edited
14/09/2011

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Protocol serial number
YuB052

Study information

Scientific Title
Improved urine albumin excretion in community-based collaborative care in elderly Chinese with type 2 diabetes: a randomized controlled trial

Study objectives

Type 2 diabetes mellitus (T2DM) is increasingly developed with advancing age and has become one of the most common chronic non communicable diseases in elderly population. The aims of treatment for elderly diabetic patients are at glycemic control and risk factor modification to reduce the risk of complications from diabetes and a substantial number of diabetes-related morbidity and mortality. The evidence-based studies have demonstrated that rates of disease and death can be reduced more by targeting cardiovascular risk factors than by intensively managing hyperglycemia in diabetics. The elderly patients can benefit from long term intensive multi factorial diabetic control.

Although more effective treatment regimens became widely available, several reports documented little improvement in glycemic control in adults in the US with diabetes. In the National Health and Nutrition Examination Survey, approximately half of cohorts with diabetes met the American Diabetes Association glycemic goal. In other larger reported population, only 2-10% of diabetic patients achieved the combined ADA goals for glycemia, lipids, and blood pressure. Although glycemic control, treatment for diabetes and patient care were improved in recent years in china, the rates of treatment and control of DM were still low [13]. It was reported recently that only 35% of patients had fasting plasma glucose <126mg/dl and about 40.2% met the International Diabetes Federation (IDF, 2005) glycemic goal (HbA1c < 6.5%). An observational study showed, in Hong Kong Chinese patients with type 2 diabetes, 36.7% reached the blood pressure goal (<130/80mmHg), 28.6% attained the LDL cholesterol goal (<2.6 mmol/l), and 43.7% achieved the A1C goal (<7.0%), while only 6.3% attained all three targets. Contributing to these poor outcomes is believed to be related to current medical system that is poorly designed to manage chronic diseases that require frequent, intensive follow up and detailed patient counseling and education. The barriers to providing optimal diabetes care in the system include insufficient time to monitor and treat the complex clinical issues during visits, general lack of behavioral change skills, and lack of guideline adherence. Additionally, geriatric patients have complex problems such as depression, poor physical performance, reduced cognitive function, difficult social situations, comorbidities, polypharmacy, and limited family and financial support. These age-associated states more likely reduce the frequency of visiting to hospital and the ability to carry out treatment.

In face of increasing number of diabetics, physicians or specialists are increasingly allotted less time with each patient in China. Their behaviors are passive and their services are intermittent for patients because they only provide medical regimens and advices on regular visits in hospital clinics. Thus, the present medical system associated with diabetes in the elderly make it difficult to achieve multiple goals in limited visits.
The gap between these practical benefits or recommended care targets and the realities of an individual situation and care delivery models makes diabetes care for the elderly with diabetes more challenging. Recently, many models or approaches have been tried to improve the diabetes care, such as the case management and the chronic case model. Some published studies appeared to demonstrate their effectiveness, but others did not. The exact reason for the discrepancies in care remains uncertain. In the last few years, community health care service with general practice has been developed in China. On the basis, combined with the conceptual framework of structured diabetes shared care, we developed a dynamic and sustained diabetes management approach for the elderly with T2DM, which made the integrated treatment for the elderly patients become a proactive and continuous diabetes care. This article addresses and evaluates the effectiveness of the diabetes care model dedicated to improving clinical outcomes for elderly, medically underserved patients with diabetes in community primary care practices over an 18 month period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the Military General Hospital of Chengdu PLA, 22 October 2009 ref: 2009keyano1

Primary study design
Interventional

Study design
Randomized, single-blind, group-controlled single centre clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sustained type 2 diabetes management for the elderly

Interventions
1. Twenty six patients randomized to intervention group were followed by each of the five multidisplinary diabetes care teams established in the four assigned communities
2. Each team included one primary care physician, two trained nurses and one clinical staff
3. The total 18 month follow-up to individuals was conducted
4. At the study entry, intervention patients were invited and had an initial visit with specialists, and the electronic individual diabetes care record (or registry) was established and the individual therapeutic project directed by the specialists was worked out after assessment of the recorded DM data based on the baseline examination
5. The care team followed up actively on diabetes care management protocols, which mainly included:
5.1. Exercise prescription: The individual patient was asked to have walking for 30 to 40 minutes daily at least three days weekly, at 110 to 120 steps per minute with exercise heart rate less than 100 bumps per minute, adjusted for patient ability.
5.2. Diabetes dietary advice: Ten reference diet options were supplied based on the daily overall calorie requirement which was determined according to age, height, desired weight and physical activity of individual patient.
5.3. Drug therapy regimens: Oral hypoglycemic agents include metformin (for overweight patients), glipizide and glyburide (for patients with normal weight). If goal for glycemia is not met, metformin should be combined with a sulphonylurea before starting insulin. For most patients with hypertension, antihypertensive drugs including angiotensin-converting enzyme inhibitors(ACEI) or angiotensin receptor blocker(ARB), bata blocker or/and calcium channel blockers were applied. Thiazides were given to hyprtensive patients over 70 years of age. ACEI or ARB was also adminstered to the patients with albuminuria as well as with blood pressure more than or equal to (>/=) 130/80 mmHg. Albuminuria, including micro- and macroalbuminuria, was defined as urinary albumin excretion rate(UAER)>/=30 mg/d. Lipid-lowering pharmacologic agents were administered to patients with diet resistant hyperlipidaemia.Subcutaneuos injection of human gene recombination insulin was performed if patients tended to fail oral hypoglycemic agents. The physicians were responsible for determining the initial insulin dosages and for making any dosage changes.
5.4. Monitoring: Capillary blood glucose concentration, blood pressure and weigh were detected monthly by nurses. The physycian was requested to define, together with the patient, the best

possible goals for glycemia, blood pressure and body mass index(BMI) with three predefined categories. At each monthly follow-up, the physican was asked to compare the achievements with the goal and consider changing either goal or treatment accordingly. In patients with weiht gain, the care provider was prompted to get agreement on a small, realistic weight reduction and follow up on this. However, a specific relative body weight was not strived for. The aim is normalisation of glycemia, blood pressure and BMI. For some patients, it will be impossible or even inappropriate to try to achieve the ideal goal, but prolonged symptoms of hyperglycemia or hypoglycemia must not be accepted for any patient.

5.5. Proactive management support: The team members provided patients with one-on-one education regarding diabetes self-management skills needed to carry out medical regimens, guide health behavior change, and provide emotional support, tailored to the needs of the individual patients. The physicians made timely treatment decision for adjustments of hypoglycemic or/and antihypertensive medications, and helped patients confer with specialists as needed in person or by telephone.

Generally, the care providers notified patients of schedualed visits via phone and contaced them in the community health care service centers where the patients lived in conjunction with their routine primary care visits on a monthly basis, unless more frequent assessment or recommendations were neede. Any patient who missed his or her appointment was reschedualed or visited at home. The computerized patient registry system allowed the care providers to have data of the results recording in flow sheet and up-to-date information regarding their patients. After the check-up, the physician discussed the results with the patient in detail, and decided how to act upon them accordingly. The patients were refered to the specialist in tertiary hospital by the two-way referral approach if they had poor control or needed some specific treatment or detection. There is no on-site diabetes education programs in these community health care service centers to reduce the probability of cross-contamination in both groups.

The control group was kept as a natural control; that is, they only visited tertiary hospitals and received diabetes treatment in a specialty clinic, including irregular or regular follow-up visits with specialists (e.g. endocrinologists or diabetologists). The decisions visiting to specialists were made by patients themselves.

6. Teatment goals for intervention group:

6.1 Fasting capillary whole blood glucose (mmol):

6.1.1. Good control: </=7.0

6.1.2. Acceptable control: </=8.0

6.1.3. Poor control: >8.0

6.2. Non-fasting capillary whole blood glucose (mmol/L):

6.2.1. Good control: </=9.0

6.2.2. Acceptable control: </=11.0

6.2.3. Poor control: >11.0

6.3. Systolic blood pressure (mmHg):

6.3.1. Good control: </=130

6.3.2. Acceptable control: </=140

6.3.3. Poor control: >140

6.4. Diastolic blood pressure, mmHg

6.4.1. Good control: </=80

6.4.2. Acceptable control: </=90

6.4.3. Poor control: >90

6.5. BMI (kg/m2)

6.5.1 Good control: </=24

6.5.2 Acceptable control: </=25

6.5.3 Poor control: >25

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Insulin, metformin, sulphonylurea

Primary outcome(s)
1. Changes in HbA1c level (target range <7.0%)
2. Changes in low density lipoprotein-cholesterol (LDL-C) concentration (target range <2.6mmol /L)
3. Changes in systolic and diastolic pressure (target range <130/80mmHg)
4. Change in urinary albumin excretion rate (UAER) (target range <30mg/d)
5. The HbA1c level was measured by a high-performance liquid chromatographic assay(Primus), with a normal reference range of 4.0% to 6.0%
6. Blood pressure was measured twice with a mercury sphygmomanometer in the right arm with the patient in a sitting position after a rest of 5 minutes
7. Serum LDL-C and urinary albumin concetration were determined by standard biochemical methods using a chemistry analyzer (Beckman Coulter Synchron clinical system DXC-800)

Key secondary outcome(s)
1. Measurement of:
1.1. Fasting plasma glucose (FPG)
1.2. Total cholesterol (TC)
1.3. Triglyceride (TG)
1.4. High density lipoprotein-cholesterol (HDL-C)
1.5. Depression screening by the Center for Epidemiologic Studies Depression Scale (CES-D)
2. Plasma glucose, TC, TG and HDL-C were determined by standard biochemical methods using a chemistry analyzer(Beckman Coulter Synchron clinical system DXC-800).
3. Depressive symptoms were evaluated by the CES-D scale which contains 20 items (range 0-60) where a score >16 is considered depressed

Completion date
31/10/2007

Eligibility

Key inclusion criteria
1. Ages 60 and 80 years of age
2. Most recent HbA1c in the prior 6 months was more than or equal to 7.0%
3. Inhabitants in the respective community for more than or equal to 2 years
4. Participants with pubilic medical insurance
5. The proportion ratio is comparable in gender

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Senior

Sex
All

Key exclusion criteria
1. Patients with cancer
2. Patients with severe cirrhosis
3. Patients with malignant hypertension
4. Patients with severe concurrent illness that would substantially limit life expectancy or require extensive systemic treatment
5. Patients with cognitive, language or hearing impairment severe enough to preclude participation
6. Additionally, patients were also excluded if his or her family member was a physician or nurse

Date of first enrolment
01/04/2004

Date of final enrolment
31/10/2007

Locations

Countries of recruitment
China

Study participating centre
270 Rongdu Road
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Sponsor information

Organisation
Ministry of Health of the Peoples Republic of China (China)

ROR
https://ror.org/01mv9t934

Funder(s)

Funder type
Government

Funder Name
The Scientific Research Projects of special-purpose funds for the Healthcare of China

Funder Name
Ref: YuB052

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration