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14. ABSTRACT
During this research period, we have identified patients over age 70 with diabetes and poor glycemic control as defied by A1c>8%, and randomized them to either geriatric diabetes intervention team (GDT) or attention control group. Subjects in GD group underwent comprehensive geriatric assessment and have individualized intervention plan formed. The interventions are now being implemented with help of a geriatric life specialist (GLS). Intervention by GDT includes focused strategies to overcome barriers in the areas of clinical care, education, social environment, and finances. In addition, study subjects in GDTarm also underwent cerebral blood flow study. At the end of 6 months of intervention, goal is to develop support network that will empower patients to sustain improvements seen during the intervention. The subjects in the control group will have similar contact time as GDT group with research diabetes team without geriatric expertise. Clinical functional, quality of life and economical outcome measures in both groups are assessed at baseline and will be compared at 6 and 12 months intervals. These time points (0, 6 and 12 months) patients will also be evaluated for effect of improved glycemic control on change in the cerebral perfusion. The first patient was recruited on January 8, 2008, and there are no findings at this time.

15. SUBJECT TERMS
Diabetes, Elderly, glycemic control, Cerebral Perfusion, care management

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Introduction:

Subject: Research regarding older adults and, in particular, those with diabetes, lags far behind research on other population segments. Considering the projected increase in elderly patients with diabetes, it is important to study novel but practical strategies to achieve better glycemic control and to improve quality of life in this population. **Purpose:** To test whether short-term focused intervention by a geriatric multidisciplinary team with the addition of a geriatric life specialist is superior to usual care (with attention control) in improving glycemic, functional, economic and quality of life parameters in elderly patients with diabetes, and whether these interventions will have persistent effects on outcome measures. In addition, the study will also evaluate improvement in cerebral perfusion in elderly with type 2 diabetes following six months intervention and assess whether changes in cerebral perfusion persist at a one-year follow up. **Scope of the research:** In this study, patients over age 70 with diabetes will be randomized to care by either geriatric diabetes intervention team (GDT) or attention control group. Subjects in GDT group will undergo comprehensive geriatric assessment and will have individualized intervention performed with help of a geriatric life specialist. Intervention by GDT will include focused strategies to overcome barriers in the areas of clinical care, education, social environment, and finances. At the end of 6 months of intervention, the goal is to develop a support network that will empower patients to sustain improvements seen during the intervention. After 6 months of independence period (no contact from GDT), outcome parameters will be measured again to see if improvement at 6 months is sustained after 12 months. The subjects in the other group will have similar contact time as the GDT group, but with a research diabetes team without geriatric expertise. Improvement in clinical, functional, quality of life and economical outcome measures in both groups will be compared at 6 and 12 months intervals. At these time points (0, 6 and 12 months) patients will also be evaluated for effect of improved glycemic control on cerebral perfusion.

Project Tasks:

Task 1: Program Set-up & training and recruitment of study subjects (Mos. 0-21): at Joslin Clinic

During this initial year of the study, we have been working with Human Research Protection office (HRPO) at the USAMRMC, to modify our protocol for compliance with applicable federal, DOD, and Army human subjects protection regulations. As per the suggestions by the Human Subject Protection Scientist at the HRPO, we designed detailed protocol procedures for the intervention group as well as attention control group. We designed telephone dialogue scripts, brochures and fliers for the study recruitment process. We also modified protocol, consent forms and assent form as necessary. After the changes were completed, protocol was than resubmitted to Joslin Institutional Review Board, and the Beth Israel Deaconess Medical Center (BIDMC) for their portion of the study. We have finalized all the outcome measurement tools for clinical, functional and psychosocial parameters. Initial approval of the study protocol to begin Joslin part of the study was received on 12/31/2007. Final approval of the whole study protocol including the portion of the study to be performed at the BIDMC was received on 2/8/2008.

- Program development, recruitment of geriatric life specialist and training of the geriatric life specialist (Mos. 0-3)

As we continued to work with HRPO, we developed the program setup and we described, developed and/or modified many of the outcome measurement tools for clinical, functional and psychosocial parameters. In addition, we developed database with forms and data management tools. A research assistant was recruited and trained to administer different assessment tools. A geriatric lifestyle specialist was hired and trained for participation in the intervention arm.

- Identification of study subjects from electronic medical records and recruitment (Mos. 3-21)

Once we received approval for the Joslin part of the study, we started screening eligible patients for recruitment. From the electronic medical records, we identified patients who have been treated at the Joslin Clinic for at least one year period, but who continue to have sustained poor glycemic control as measured by A1c >8% twice in a row. It has been 4 months since overall protocol approval by the HRPO and we have been successful in recruiting 11 patients in the study. 7 patients are randomized to the intervention arm and 4 patients are randomized to the control arm.

Problems with the task: Recruitment this winter was not as robust as we had expected. Inclement weather had caused many cancellations in the elderly patients with diabetes. Our recruiting efforts have picked up and we currently have 6 patients awaiting baseline 1 screening. We have also realized that patients have been declining enrollment due to transportation difficulties. This is because many of our seniors do not drive, find the public transit systems too difficult to maneuver, and feel the cost of using the senior van services, $8-$10 round trip to be prohibitive. We are trying to resolve this problem by facilitating transportation by rides and senior service specialized vans.

Task 2: Baseline assessment (Mos. 4-21): at Joslin Clinic

- Baseline clinical & survey information collected
- Baseline functional assessment by geriatric diabetes team (GDT) members at the Joslin clinic including nurse practitioner, dietitian and nurse educator.

At the present time, we are screening eligible patients for recruitment. There are 11 patients currently enrolled in the study. All 11 subjects have completed 2 baseline visits with the research assistant, and 2 of the 11 have completed their 3-month evaluation. The research assistant attended a seminar to learn advanced Access data entry and analysis. He has created forms to enter the data and has begun data entry for the subjects mentioned above.

Task 3: Team assessment and active intervention by Geriatric care ambassador (geriatric life specialist (GLS) (mos. 4-27) at Joslin Clinic

- Multidisciplinary team meetings to discuss barriers and care plans
- Interventions by GLS and nurse practitioner, including home visits
- GLS performs monthly telephone visits with patients
- Monthly evaluation of care plan by GDT based on GLS tele-visits
- Monthly team meeting to discuss ongoing plan and improvement

A geriatric lifestyle specialist was hired and trained for participation in the intervention arm. She works with the GDT and provides the team with a home assessment and performs interventions as directed. The seven study patients have completed assessment by the Geriatric Diabetes Team. Geriatric Diabetes Team members have assessed and identified barriers to diabetes management in these patients during the team meetings. Interventions and strategies to overcome the barriers were conveyed to the Geriatric Life Specialist. The Geriatric Life Specialist has made home visits to 6 of the study patients, with the 7th to follow within the week. These visits are follow-up with phone calls to assist in implementing the interventions and strategies uncovered at the assessment and home visit.

Task 4: Outcome parameters assessment and start of independence period (Mos. 10-33):

- Repeat baseline measures on control & intervention groups and assess outcome parameters (mos. 10-27)
- Patients undergo 6 months of independence trial without contact form GDT (mos. 28-33)

All our patients are still undergoing intervention period. All of them had a baseline assessment performed. Three subjects also had a 3 months outcome parameter assessment performed. None of the study subjects are in independent period yet.

Task 5: Cerebral vascular studies at baseline, after 6 months of active intervention and 6 months of independence period. (Mos. 3-33) SAFE laboratory at Beth Israel Medical Deaconess Medical Center

- Cerebral perfusion tests including transcarnial Doppler studies, and cerebral vasoreactivity measurement evaluation. SAFE laboratory by Dr. Vera Novak

The subjects, who are randomized to the intervention arm of the study, are also scheduled to have a cerebral blood flow study performed at the SAFE lab at BIDMC as per part B of the protocol. Five study subjects have completed this portion of the study. One study subject could not complete the study due to uncomfortable feeling and the study procedure was stopped. All the rest of the subjects have tolerated the study procedure well.

Task 6: Analysis of data and information distribution. (Mos. 34-36): Joslin Clinic

- Data analysis, conference presentations, preparations for publication

As the final approval of the study from HRPO was received 4 months ago, and with limited number of patients enrolled, we have not yet performed data analysis. We plan to perform interim analysis during the next 6 months period to submit an abstract for the national conferences especially American Diabetes Association and American Association of Diabetes Educators.

Key research accomplishments:

None so far

Reportable Outcomes:

None so far

Conclusion:

Research and literature focused on management of diabetes in elderly patients is scant. We have developed innovative procedure to assess barriers to self-management in elderly patients with diabetes. Time-consuming study methodology requiring many revisions has been completed. In addition, enrolling elderly patients in to the study also required different approach. We do now have a robust procedure in place to perform this study and bring it to conclusion while gaining important information. We plan to perform interim data analysis for publication during next 6 months.

References:

We have submitted 2 manuscripts for publication at this time. The decision from the journals is pending.

1. Munshi M, Hayes M, Sternthal A, Ayres D: Effective use of serum c-peptide level in elderly patients with diabetes to simplify regiment without compromising glycemic control Sumitted to Journal of American Geriatric Society.

2. Munshi M, Hayes M, Grande L, Yang L, Milberg W, Weinger K: Screening for Subtle Executive dysfunction in elderly patients with diabetes. Submitted to Diabetes Medicine.

Appendices:

None

Supporting Data:

None