Telemedicine-Based Digital Retinal Imaging *vs* Standard Ophthalmologic Evaluation for the Assessment of Diabetic Retinopathy

ZHIJIAN LI, MD, CHENGQING WU, PhD, J. NWANDO OLAYIWOLA, MD, DANIEL ST. HILAIRE, BS AND JOHN J. HUANG, MD

ABSTRACT—*Objective:* To study the cost benefit analysis of using a telemedicine-based digital retinal imaging evaluation compared to conventional ophthalmologic fundus examination of diabetic patients for diabetic retinopathy. *Methods:* In this study, diabetic patients from Community Health Center, Inc. (CHCI), a large multi-site Federally Qualified Health Center) were evaluated by teleophthalmology using the Canon CR-1 nonmydriatic fundus camera. Digital images were acquired in the CHCI offices and saved on the EyePACS® server network. The images were later evaluated by retinal specialists at the Yale Eye Center, Yale University Department of Ophthalmology and Visual Science. The costs for the standard of care ophthalmic examinations were calculated based on 2009 Medicaid reimbursement rates. The process of telemedicine-based diagnosis was based on a take-store-forward-visualize system. The cost of telemedicine-based digital retinal imaging examination included cost for devices, training, annual costs and a transportation fee. Current Medicaid reimbursement, transportation, and stafflabor costs were used to calculate the conventional retinal examination cost as a comparison. *Results:* Among the 611 patients digital retinal images screened in the first year of this program and for whom data are available, 166 (27.2%) cases of diabetic retinopathy were identified. Seventy-five (12.3%) patients screened positive with clinically significant disease and were referred for further ophthalmological evaluation and treatment. The primary direct cost of the telemedicine was $3.80, $15.00, $17.60, $1.50, and $2.50 per patient for medical assistant, ophthalmologist, capital cost (Equipment + Training), equipment maintenance, and transportation fee, respectively. The total cost in the telemedicine-based digital retinal imaging and evaluation was $40.40. The cost of conventional retinal examination was $ 8.70, $65.30, and $3.80 per patients for round-trip transportation, 2009 national Medicaid Physician Fee Schedule allowable for bilateral eye examination, and medical assistant personnel, respectively. The total costs of conventional fundus examination were $77.80. An additional conventional ophthalmologic retinal examination was required for 75 (12.3%) patients with clinically significant disease on telemedicine evaluation, which involves an averaged additional cost of $ 9.55 per patient for all the patients in the study. If the cost of subsequent examination was added, the total cost of telemedicine-based digital fundus imaging was $49.95 per patient in our group of 611 patients evaluated. *Conclusions:* Our cost analysis indicates that telemedicine-based diabetic retinopathy screening cost less ($49.95 *vs* $77.80) than conventional retinal examination and the telemedicine-based digital retinal imaging examination has the potential to provide an alternative method with greater convenience and access for the remote and indigent populations. Diabetes mellitus and diabetic retinopathy are growing problems in the United States and worldwide. Large scale adoption of

ZHIJIAN LI, MD, Yale University, Department of Ophthalmology and Visual Sciences, New Haven; Department of Ophthalmology, First Hospital, Harbin Medical University, Harbin, Heilongjiang 150001, China; CHENGQING WU, PD, Yale University, School of Epidemiology and Public Health, New Haven; J. NWANDO OLAYIWOLA, MD, MPH, FAAFP, Community Health Center, Inc, Middletown; DANIEL ST. HILAIRE, BS, Community Health Center, Inc, Middletown; JOHN J. HUANG, MD, Yale University, Department of Ophthalmology and Visual Sciences, New Haven.

telemedicine should be encouraged as a means toward providing improved access, increasing compliance with annual evaluation, at a low cost for patients with diabetes with direct access to an eye care specialist.

Introduction

THE prevalence and incidence of diabetes mellitus are rapidly increasing in the United States and worldwide. Diabetes mellitus with its cardiovascular complications is one of the leading causes of death and disability in the United States.[1] Over 20 million Americans have been diagnosed with diabetes mellitus and it is estimated that more than six million Americans still have undiagnosed diabetes mellitus.[2] One of the complications of diabetes mellitus is diabetic retinopathy (DR), which, if untreated or delayed in treatment, can lead to blindness. In fact, DR is the leading cause of legal blindness in the working age population in the United States. Large scale population based annual screening for diabetic retinopathy is the recommendation for the detection of the early signs of the disease by the American Diabetes Association (ADA). Clinical guidelines recommend that the diabetic population is screened annually, and more frequent retinal evaluations are required to identify patients with evidence of vision-threatening stages of disease so they may be treated in an optimal time frame and manner. Appropriate detection and treatment can reduce risk to 5%.[3] Due to various factors, including geographic constraints, socioeconomic barriers (eg, income level, inadequate health insurance, and time away from work), education/cultural barriers (eg, education level, health illiteracy, and competing nontraditional medical healing), and lack of symptoms in early stages of DR, many patients do not seek an eye examination on a regular annual basis as recommended by the ADA.[4,5] Roughly 50% of all diabetic patients in the U.S. receive the recommended annual screening for DR under the traditional approach to detecting diabetic eye disease by fundus ophthalmoscopy by an eye care provider (ophthalmologist/retina specialist) separate from the primary care visits, and this number decreases to 10% to 12% in the underserved and minority populations.[6,7]

The development and use of portable digital equipment has allowed a profound change in the screening process in a variety of medical specialties. The combination of telemedicine and digital retinal imaging technology provide the potential to have the diabetic population evaluated by an ophthalmologist remotely for the screening for diabetic retinopathy. Retinal images can be easily acquired by a trained technician or provider at a primary care site using a digital nonmydriatic fundus camera. The retinal images are then transfer to the secured central server, which can be reviewed by a retinal specialist at a later time. It has been demonstrated in various settings that telemedicine is highly sensitive in detecting DR and is portable as well. This supports its use as a tool to evaluate DR.[8] The retinal images have the advantage of providing a permanent medical record for documentation and to follow the progression of diabetic retinopathy or response to treatments.[9] Although the digital retinal imaging technology has been widely used to screen diabetic retinopathy in the UK and Australia, it is used less frequently in the US.[10]

In this study, we designed and conducted a telemedicine-based screening program in large multi-site Federally Qualified Health Center (FQHC), Community Health Center, Inc (CHCI), the largest network of health centers in the state of Connecticut, serving 130,000 patients. Over 60% of CHCI patients are racial/ethnic minorities; over 90% are at /below 200% Federal Poverty Level; 60% are on Medicaid or state/public insurance; and 22% are uninsured (CHCI UDS Data 2009). Based on DR prevalence data, this is a population at high risk for DR. This study presented the results of cost benefit analysis using digital retinal imaging with review by a remote retinal specialist compared to a conventional fundus examination for the assessment of DR. The study findings suggest that this technology should be further explored and expanded as a means to screen and identify subjects with diabetic retinopathy. This technology may provide better access to patients while also reducing cost per patient. This will be crucial in the United States, and worldwide, as the cost of healthcare and in particular that related to patients with diabetes will be a growing national issue.

Methods

The telemedicine system was designed to acquire retinal images of diabetic patients, gather database information, merge digital images of the retina into the database and make the merged sets available in a central location from which a retina specialist can perform a follow-up evaluation at his/her convenience.[11] The Yale Eye Center (YEC) supports the CHCI health centers. In this system, a telemedicine coordinator at CHCI oversees all aspects of the program, including training of technicians, patient appointments and follow-ups. All telemedicine technicians (CHCI medical assistants) participating in this program underwent a comprehensive training and certification process led by a team proficient in the use of the camera and familiar with the specific EyePACS® imaging protocol. This training includes photography instruction, operation of a computer and software, general medical knowledge, and patient education.

All diabetic patients were offered the option of telemedicine evaluation following or in conjunction with their primary care visit. The digital retina photography

with a Canon CR-1 nonmydriatic fundus camera was performed by trained CHCI technicians. The images were compressed and encrypted into a single password-protected file. This file, with the retina images and related medical history and medications, was then uploaded onto a secure, password-protected Web server with broadband Internet access. Users of EyePACS, such as managers, technicians, and physicians were assigned IDs and passwords that provide access to the patient database for their particular clinic. A consultation report with patient data and diagnosis, treatment, and follow-up recommendations, including anticipated diagnostic testing when necessary, were transmitted to the referring primary care providers electronically through the EyePACS Web site by the Yale specialists. An alternative, the standard ophthalmologic examination is achieved by the diabetic patients first referred by a CHCI primary care provider to an ophthalmologist, an appointment made, and the patient evaluated by the ophthalmologist in the office several weeks to months later. The costs related to consumables of the two methods were investigated according to Medicaid reimbursement in 2009. This study was approved by the IRB at Community Health Center, Inc.

Cost of Telemedicine-Based Digital Fundus Imaging Examination

The process of the telemedicine-based diagnostic system for diabetic retinopathy is based on a take-store-forward-visualize structure. The digital fundus imaging system is comprised of a nonmydriatic fundus camera, a laptop computer, and software designed for managing the digitized patient information. The data were then put into the EyePACS system which can accommodate digital retinal images from a variety of camera sources. Our system used the Canon CR-DGi or Canon CR-1 nonmydriatic cameras in conjunction with the EyePACS Web server.[12] The digital fundus imaging was then visualized by a retinal specialist on a regular computer monitor and the diagnosis and recommendations were sent back to the CHCI sites. Initial costs for telemedicine used for diabetic retinopathy evaluation included cost for equipment, training, and overhead. Annual costs for telemedicine include expenses for human resources, device maintenance, and overhead.[8] The equipment was assumed to have a depreciation rate of 3%. The equipment and training costs (initial cost) were converted into an annual capital cost. The annual maintenance cost was set to 10% of the equipment investment. The equation NPV= E?(P/F, 10 years, 3%) is used to calculate the equivalent annual cost, where NPV is net present value of the devices, P/F, 10 years, 3% is the annuity factor for 10 years at the rate of interest of 3% (equal to 8.5302), and E represents the equivalent annual cost for devices.[13] A transportation fee was also considered because the patients need to be transferred to the CHCs from their homes. The transportation fee for the dependents to send the patients to CHCs was not included. In reference to the standard bus fee, the transportation fee was $2.50 per person for round trips. There were 611 diabetic patients screened at the multiple CHCI sites in our research period between July 1, 2009 to June 30, 2010. A subsequent conventional fundus ophthalmoscopy evaluation needed to be performed in the patients who were screened positive on the telemedicine evaluation.

Cost of Conventional Digital Fundus Imaging Examination

The total costs of conventional fundus ophthalmoscopy and imaging examination also included the transportation cost for the visiting eye specialist. The transportation cost was calculated by using the average consumption of gas per mile, and applied to the number of mean miles of the patient to the local CHCs. The ophthalmologic care was based on current Medicaid reimbursement to a hospital-based system for an outpatient dilated eye examination. Current Medicaid reimbursement was used to account the conventional cost. Loss of income and productivity of patients was not included in the study. This was for practical reasons, as it was difficult to identify from our database whether there is an actual loss of income and productivity.

Results

Six hundred-eleven patients with diabetes mellitus were evaluated using the teleophthalmology digital retinal screening during the first year of the program, and the demographics of this population of patients is described elsewhere (Cite our pending paper here-reference is below). Of these patients, 439 (72%) screened negative and were advised to be rescreened using the teleophthalmology system in one year. One hundred and sixty-six patients (27.2%) were evaluated as screening positive with evidence of DR. Seventy-five (12.3%) of the patients with DR were referred for further retina ophthalmological examination within one month due to clinically significant disease. The median age of the screened patients was 53.0 years old (ranges 28–77). There were slightly more males (53%) than females (47%). The known duration of diabetes mellitus with diabetic retinopathy was six to 10 years in 44 cases, 11–15 years in 36 cases, 16–20 years in 29 cases, 21 years and over in 20 cases.

Eye Care Insurance Coverage

Of the 166 patients who were evaluated and screened positive, 126 (75.9%) had healthcare insurance: 102 (61.4%) had Medicare, Medicaid, or both; 15 patients (9.0%) had a commercial insurance only; and the other nine (5.4%) had a combination of health insurance coverage.

Cost of Telemedicine-Based Digital Fundus Imaging Examination

The primary direct cost of the telemedicine was the staff cost, as well as the computer hardware and software that were used. It was estimated that, on average, about 10 minutes were spent on one patient by an ophthalmologist and a nurse. Assuming the ophthalmologist and nurse spend 48 weeks per year (four weeks of sick and vacation leave) and 35 hours per week working (remaining fivehours for breaks, attending meetings, etc), we used the midpoint salary on the federal pay to calculate the cost of a nurse ($3.80 per patient) and an ophthalmologist ($15.00 per patient). Depreciation of the initial cost at 3% rate of equipment and training ($14,995) was $1,757.9 ($17.6 per patient). The maintenance cost (10.0% rate) is a total of $1,499. Assuming the equipment life is 10 years, the cost of maintenance was $1.5 per patient. The transportation fee was $2.50 per person for round trips. The total cost in the telemedicine-based examination was $40.40 for the patients who needed to follow-up one year later (Table 1). One hundred and sixty-six patients (27.4%) were evaluated as screened positive and were further referred for conventional ophthalmological examination within one month.

Table 1.—Costs of Telemedicine-based Digital Retinal Imaging Examination (Per patient)

Items	Cost($)
Capital cost (Equipment + Training)	$17.60
Annual maintenance	1.50
Staff labor cost	
Ophthalmologist	15.00
Medical assistant	3.80
Transportation fee	2.50
Total	**$40.40**

Cost of Conventional Fundus Ophthalmoloscopy Examination

All costs of conventional digital fundus examination were classified into two categories: the transportation and current Medicaid reimbursements cost. We assumed that the average consumption of gas per 23 mile per gallon and the average of 35 miles for a roundtrip from home to the YEC ophthalmologic consultation visit. The total roundtrip transportation cost was $8.70. Current Medicaid reimbursements cost included cost of outpatient clinic visit and personnel. The cost of outpatient clinic visit is composed of the cost of exanimation, diagnosis, and the fundus imaging. The 2009 national Medicaid Physician Fee Schedule allowable for bilateral eye examination is $65.30. The amount is adjusted in each area by local indices. At the meanwhile, a nurse needs to spend 10 minutes on one patient and the salary was estimated to be $3.80 in the process. Income cost was not included for the conventional method of screening. Therefore, the total costs of conventional fundus examination were at least $77.80. Actually, 75 patients (12.3%) were required to undergo a subsequent examination. The cost of subsequent examination for the telemedicine-based fundus imaging option needed to be included in the total cost, which was an additional $9.55. If the cost of subsequent examination was added, the total cost of telemedicine-based digital fundus imaging was $49.95.

Discussion

Diabetic eye disease remains a major cause of blindness in the United States and around the world. It is the leading cause of irreversible blindness in the working age population. It has been demonstrated that vision loss secondary to DR is preventable with proper glucose control, routine screening and timely treatment of clinically significant disease. The identification of patients that have progressed from early, non vision-threatening microvascular changes to the more serious clinically significant changes that occur in more advanced disease is ideally accomplished with annual dilated retinal examination, which is recommended as the standard of care.[4,10,14] Early laser photocoagulation can significantly reduce the risk of vision loss and blindness in patients with advanced eye complications.[15] With digital retinal screening, patients with asymptomatic DR can be identified and triaged to further ophthalmic care, laser photocoagulation and other therapeutic modalities to slow or halt the disease progression. Unfortunately, despite its high level of patient convenience, clinical effectiveness, and low cost, telemedicine screening for diabetic eye disease remains a highly underutilized technology. A review by Mukamel et al[16] shows that, less than half of the diabetic patients received a recommended annual eye examination in the United States. Presently, the primary barriers to implementation of teleophthalmology in the primary care setting are the costs of the screening (no reimbursement in some states), initial investment of the nonmydriatic retina camera, and collaboration with retina specialists to review the digital images.

In our study, of the 611 total patients screened, 166 patients were evaluated as screen positive, 75 patients referred for additional ophthalmologic evaluation, 40 people (24.1%) had no healthcare insurance; 15 patients (9.0%) had a commercial insurance; nine patients (5.4%) had a combination of health insurance coverage; and only 102 patients (61.4%) had Medicare, Medicaid, or both. Uninsured Americans with diabetes mellitus aged 40 to 64 years are at risk for vision loss due to DR

(source?). Studies have shown that providing healthcare and screening to this population may greatly improve their health outcomes and the initial cost would be offset by a reduction in future healthcare and Medicare costs.[17–19] From the perspective of the healthcare provider, telemedicine targeting uninsured or underinsured adults without health insurance might be more beneficial if they focused on those at highest risk for serious vision loss. Telemedicine also offers individuals with diabetes mellitus the convenience of access to ancillary care by team members in one single location to improve access and compliance, serving as resources and providing specialist feedback and support. In our study, we used cost analysis of telemedicine-based digital retinal imaging technology to evaluate the new medical procedure. The present study shows it significantly lower cost to provide telemedicine than conventional retinal examinations for diabetes mellitus. The benefits of telemedicine were primarily savings from the cost of equipment, the visit to an ophthalmologist, and travel. The image acquisition of telemedicine was located in the primary care office ensuring convenience and compliance with annual diabetes screening. The total cost of a telemedicine-based examination for the diabetes mellitus patients was $40.40 with majority of the costs of telemedicine-based fundus imaging spent on equipment, and the evaluation by an ophthalmologist. Meanwhile, the total cost of conventional fundus examination was $77.80 and most of the costs were spent on the visit to the ophthalmologist and travel. In the present study, the administrative costs in both groups were similar and were not included.

Telemedicine-based fundus examination decreases the number of visits to the specialist's office as well as cost to health care system overall, while increasing the ability of a specialist to directly care for and refer for treatment expediently. Seventy-five patients (12.3%) were required to undergo a subsequent examination in the present study. The cost of subsequent examination for the telemedicine-based fundus imaging option needs to be included in the total cost, which was $9.55 (spread over all the patients in the study). Therefore, the total cost of telemedicine-based digital fundus imaging was $49.95, which is significantly lower than the cost of conventional ophthalmologic examination of $77.80. The overall calculation of this study is highly conservative since the telemedicine cost is compared to the Medicaid reimbursement as compared to private insurance carriers. More widespread use of telemedicine would also further reduce the contract prices and would place the breakeven point at a lower workload.[20] In addition, depreciation of initial and maintain cost per patient would further help to reduced the cost with greater use of the equipment in the future.

The results of our study were based on the data from 2009 to 2010. Approximately 20% of CHCI's patients with diabetes were screened because it was the first year for telemedicine consultation. With the expected increase of diabetes mellitus patients and decreasing cost of telemedicine, we affirm that the results at present would be even more favorable for the use of telemedicine.[13]

Although this experience validates the role of telemedicine for ophthalmology care in a resource-restricted setting, this is a model that is more widely applicable. Telemedicine is increasingly applied in pathology, dermatology, and even radiology.[21–23] In developing countries, telemedicine has a vital role in providing access to care in rural areas. In the United States, telemedicine also provides a potential mechanism for subspecialty care in areas with shortages of or limited access to ophthalmologists and other specialists.

There are limitations inherent in present study. First, there were factors we did not incorporate in the cost analysis data due to a lack of information in the published literature. Regional differences in clinic operations may exist within the United States and could account for significant variations in practice costs. Second, our results can be applicable only for the telemedicine project in the northeast region of the United States due to the source of local data.

In summary, teleophthalmology for diabetic retinopathy screening has the potential to provide an alternative method for remote and underserved populations, including uninsured patients, and can improve compliance and access. For the care of diabetes mellitus, teleophthalmology for evaluation of DR will become a necessity and likely a mainstay of diabetic eye care in the United States and around the world. With the expected increased prevalence of diabetes mellitus and financial limitations of the health care system, the decreasing cost of telemedicine and the our findings favor the use of telemedicine. The near-term focus should be on the development of quality image-acquisition and low-cost devices, and the long-term focus should be on the research of unique prognostic features on retinal images and automated image analysis. Also, widespread adoption of teleophthalmology should be encouraged in remote areas as a means toward providing improved access to specialist care.

REFERENCES

1. National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics. http://diabetes.niddk.nih.gov/dm/pubs/ statistics/ index.htm#12.
2. Centers for Disease Control and Prevention. National Diabetes Fact Sheet: General Information and National Estimates on Diabetes in the United States. Atlanta, GA, U.S. Department of Health and Human Services, 2005. Available from http://www. cdc.gov/diabetes/pubs/factsheet05.htm.

3. Ferris FL III, Davis MD, Aiello LM: Treatment of diabetic retinopathy. *N Engl J Med* 1999; 341:667–78.
4. Fong DS, Aiello L, Gardner TW, et al: The American Diabetes Association: Retinopathy in diabetes (Position statement). *Diabetes Care* 2004; 27(Suppl.1):S84–7.
5. Mukamel DB, Bresnick GH, Wang Q, Dicky CF: Barriers to compliance with screening guidelines for diabetic retinopathy. *Ophthalmic Epidemiol* 1999; 6(1):61–72.
6. National Committee for Quality Assurance. The State of Health Care Quality 2007.NCQAwebsite 2007. Availableat:http://www. ncqa.org/Portals/0/Publications/Resource%20Library/SOHC/SOHC_07.pdf.
7. Lee PP, Feldman ZW, Ostermann J, et al: Longitudinal rates of annual eye examinations of persons with diabetes and chronic eye diseases. *Ophthalmology* 2003; 110:1952–9.
8. Aoki N, Dunn K, Fukui T, et al: Cost-effectiveness analysis of telemedicine to evaluate diabetic retinopathy in a prison population. *Diabetes Care* 2004; 27:1095–101.
9. Al Sabti K, Raizada S, Wani VB, et al: Efficacy and reliability of fundus image digital camera as screening tool for diabetic retinopathy in Kuwait. *J Diabetes Complications* 2003; 17(4):229–33.
10. Taylor CR, Merin LM, Salunga AM, et al: Improving diabetic retinopathy screening ratios using telemedicine-based digital retinal imaging technology: The Vine Hill study. *Diabetes Care* 2007; 30(3):574–8.
11. Wilson RR, Silowash R, Anthony L, et al: Telemedicine process used to implement an effective and functional screening program for diabetic retinopathy. *J Diabetes Sci Technol* 2008; 2(5):785–91.
12. Jorge Cuadros, George Bresnick. EyePACS: An Adaptable Telemedicine System for Diabetic Retinopathy Screening. *J Diabetes Sci Technol* 2009;3(3):509–15.
13. Gomez-Ulla F, Alonso F, Aibar B, Gonzalez F: A comparative cost analysis of digital fundus imaging and direct fundus examination for assessment of diabetic retinopathy. *Telemedicine e-Health* 2008;14(9):912-918.
14. Health Employer Data and Information Set. Version 3.0. Washington, DC: National Committee for Quality Assurance; 1997:2.
15. Early treatment of diabetic retinopathy study research group. Early photocoagulation for diabetic retinopathy: ETDRS report number 9. *Ophthalmology* 1991; 98(suppl 5):766–85.
16. Mukamel DB, Bresnick GH, Wang Q, Dickey CF: Barriers to compliance with screening guidelines for diabetic retinopathy. *Ophthalmic Epidemiol* 1999; 6:61–72.
17. McWilliams JM, Zaslavsky AM, Meara E, Ayanian JZ: Health insurance coverage and mortality among the near-elderly. *Health Aff* (Millwood). 2004; 23(4):223–33.
18. McWilliams JM, Meara E, Zaslavsky AM, Ayanian JZ: Use of health services by previously uninsured Medicare beneficiaries. *N Engl J Med* 2007; 357(2):143–53.
19. Zhang X, Lee PP, Thompson TJ, et al: Health insurance coverage and use of eye care services. *Arch Ophthalmol* 2008; 126(8):1121–6.
20. BjØrvig S, Johansen MA, Fossen K: An economic analysis of screening for diabetic retinopathy. *J Telemedicine Telecare* 2002; 8:32–5.
21. Bergmo TS: An economic analysis of teleradiology *vs* a visiting radiology service. *J Telemed Telecare* 1996; 2:136–42.
22. Weinstein RS, Bloom KJ, Rozek LS: Telepathology and the networking of pathology diagnostic services. *Arch Pathol Lab Med* 1987; 111:646–52.
23. Olayiwola JN, Sobieraj DM, Kulowski K, et al: Improving diabetic retinopathy screening through a statewide telemedicine program at a large federally qualified health center. *J Health Care Poor Undeserved* (In press, August 2011).