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Long-term Comparative Effectiveness of Telemedicine in Providing Diabetic Retinopathy Screening Examinations: A Randomized Controlled Trial

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Abstract

IMPORTANCE—Minimal information exists regarding the long-term comparative effectiveness of telemedicine to provide diabetic retinopathy screening exams.

OBJECTIVE—To compare telemedicine to traditional eye examinations in their ability to provide diabetic retinopathy screening examinations.

DESIGN, SETTING, AND PARTICIPANTS—From August 1, 2006, through September 31, 2009, 567 participants with diabetes were randomized and followed up to 5 years of follow-up

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Trial Registration: The Comparative Effectiveness of Telemedicine to Detect Diabetic Retinopathy, NCT01364129, http://clinicaltrials.gov/ct2/show/NCT01364129.

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Design of the study: SLM, TMB, KW
Conduct of the study: SLM, KW, CS
Data collection: KW, SLM, CS, SD
Data management: SLM, CS, GB
Data analysis: SLM, SG, CS, GB
Data interpretation: SLM, SG, CS, SD, KW, TB, GB
Manuscript preparation: SLM, CS, GB
Manuscript review and approval: SLM, SG, CS, SD, KW, TB, GB

Conformity with Author Information: This research protocol was approved by the Internal Review Boards (IRBs) of Legacy Health (Portland, Oregon), Oregon Health and Science University (Portland, Oregon), and the Northwest Portland Area Indian Health Board (Portland, Oregon). Informed consent was obtained from all participants, and the study was conducted in accordance with the tenets of the Declaration of Helsinki for human subjects research.

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(last date of patient follow-up occurred on August 6, 2012) as part of a multicenter randomized clinical trial with an intent to treat analysis. We assigned participants to telemedicine with a nonmydriatic camera in a primary care medical clinic (n = 296) or traditional surveillance with an eye care professional (n = 271). Two years after enrollment, we offered telemedicine to all participants.

MAIN OUTCOMES AND MEASURES—1) percentage of participants receiving annual diabetic retinopathy screening exams; 2) percentage of eyes with worsening diabetic retinopathy during the follow-up period using a validated scale from Stage 0 (none) to Stage 4 (proliferative diabetic retinopathy); and 3) percentage of telemedicine participants who would require referral to an eye care provider for follow-up care using a cut-off of moderate diabetic retinopathy or worse, the presence of macular edema, or an 'unable to determine' result for either retinopathy or macular edema.

RESULTS—The telemedicine group was more likely to receive a diabetic retinopathy screening exam when compared to the traditional surveillance group during the 6-month or less (94.6% [280/296] vs 43.9% [119/271]; 95% CI, 46.6%-54.8%; P < .001) and greater than 6-month through 18-month (53.0% [157/296] vs 33.2% [90/271]; 95% CI, 16.5%-23.1%; P < .001) time bins. After we offered telemedicine to both groups, we could not identify a difference between the groups in the percentage of diabetic retinopathy screening examinations. Diabetic retinopathy worsened by 2 stages or more in 35 (8.5%) of 409 participants (95% CI, 5.8%-11.2%) and improved by 2 stages or more in 5 (1.2%) of 409 participants (95% CI, 0.1%-2.3%) over the 4 year time period. The percentage of telemedicine participants requiring referral ranged from 19.2 (52/271) to 27.9% (58/208) during the study period.

CONCLUSIONS AND RELEVANCE—Telemedicine increased the percentage of diabetic retinopathy screening exams; most participants did not require referral to an eye care provider; and diabetic retinopathy levels were generally stable over the study period. This suggests that primary care clinics can use telemedicine to screen for diabetic retinopathy and monitor for disease worsening over a long period of time.

Introduction

Research suggests the prevalence of diabetes in the U.S. adult population will increase from 14% in 2010 to approximately 33% by 2050.[1] Diagnosis and treatment of diabetic retinopathy is a key public health intervention because it can greatly reduce the likelihood of vision loss.[2,3] However, less than 50% of those with diabetes receive annual diabetic retinopathy screening examinations.[4–6]

Health clinics can use store-and-forward telemedicine with nonmydriatic cameras to acquire retinal images without dilation and send images for remote evaluation. Studies[7–9] show excellent diagnostic precision for diabetic retinopathy when compared to examinations with dilated pupils in eye care providers' offices. However, studies[10–17] have only evaluated the ability of telemedicine to provide diabetic retinopathy screening exams with short-term follow up.

The Tribal Vision Project[10] was designed to determine the comparative effectiveness of telemedicine versus traditional surveillance techniques (examinations with eye care

providers) for providing diabetic retinopathy screening exams using a multicenter, randomized controlled trial design. It addresses two recommendations from the Institute of Medicine's priority topics for comparative effectiveness research including decreasing health disparities in diabetes and comparing the effectiveness of new remote monitoring technologies.[18] We are unaware of any previous reports that have examined the long-term effectiveness of telemedicine in providing diabetic retinopathy screening. Researchers and primary care clinics can use this information to determine the long-term impact of using telemedicine to detect diabetic retinopathy.

Materials and Methods

Participants

We determined that a sample size of 194 participants (97 participants per group) was required to detect a 10% increase in the percentage of diabetic retinopathy screenings in the telemedicine group using an α level of .05 and a power of 0.80 in the 1-year and 2-year time bins. We consecutively enrolled more participants than required to allow for attrition during long-term follow-up (last date of patient follow-up occurred on August 6, 2012). From August 1, 2006, through September 31, 2009, we recruited adults from 2 primary care clinics that serve a large number of American Indian/Alaska Native patients with diabetes (Figure 1). Participants self-classified their race/ethnicity. We included people with diabetes aged 18 years or older who were scheduled to visit their primary care physician. Exclusion criteria were cognitive impairment that prevented the ability to give informed consent or a disability that would not allow camera imaging.[10] The Institutional Review Boards of Legacy Health, Oregon Health and Science University, and the Portland Area Indian Health Service reviewed and approved the study protocol (Supplement 1). All patients provided written informed consent, and the study was conducted in accordance with the tenets of the Declaration of Helsinki for human subjects research. We registered the study in the clinicaltrials.gov registry (*The Comparative Effectiveness of Telemedicine to Detect Diabetic Retinopathy*, NCT01364129; http://clinicaltrials.gov/ct2/show/NCT01364129).

Group Assignment and Staged Intervention

We used a random number generator to randomly assign participants to the telemedicine group or the traditional surveillance group. Tribal leadership wanted all participants to have access to telemedicine during the study, so we offered telemedicine screening to those in the traditional surveillance group after they had been enrolled in the study for 2 years. This staged-intervention design allowed us to examine the use of telemedicine when offered to participants who were originally assigned to traditional surveillance.

Telemedicine group—Participants in the telemedicine group received retinal imaging at their primary care clinic during a regular visit. While telemedicine with nonmydriatic cameras can screen for diabetic retinopathy, telemedicine cannot replace a comprehensive eye exam.[19] Therefore, the project staff encouraged all participants to see an eye care provider once per year for a comprehensive eye examination.

We describe our category 4 telemedicine program[19] in detail in a previous manuscript.[10] Briefly, we used a modified Diabetic Retinopathy Study protocol to capture six undilated, 1.5 megapixel, 45-degree fundus photographs of each eye including: a stereo pair of photos centered on the optic disc, a stereo pair centered on the macula, a single image centered on the superior temporal retina, and a single image centered on the inferior temporal retina.[20,21]

Devers Eye Institute created a telemedicine system to encrypt, compress, and securely transfer retinal images and participant data to a Health Insurance Portability and Accountability Act (HIPAA)-compliant database. The system automatically emailed a notification to the image reviewers when clinic staff uploaded new photos for evaluation. The reviewers (SD, SLM) graded images according to standard, scalable criteria (see Table 1).[22,23] The reviewers entered their findings into electronic forms within the telemedicine system, and the system automatically sent the evaluation reports to the clinics via email or facsimile. One can view the telemedicine imaging process, including a video demonstration of how the software works, at: http://www.youtube.com/watch?v=dpN1Sp-P074&feature=email.

Traditional surveillance group—Medical staff recommended annual eye exams to all participants during their primary care provider visits. If a participant did not already have an eye doctor, the primary care provider referred the participant to an eye care provider in the community. A study investigator (SLM) telephoned the community eye care providers to introduce the project and request their participation in completing the data collection forms for the study. Research staff sent eye care providers data entry forms containing the same diabetic retinopathy grading criteria as the telemedicine group (see Table 1). The eye care provider's office faxed or mailed the data entry form back to research staff for data entry. Research staff also reviewed participants' clinic medical charts at regular intervals to identify missing eye exams and contacted eye care providers for the results.

Data Analysis

All analyses were performed using the R statistical program (Available at: www.R-project.org, last accessed on March 1, 2013) or SPSS Version 19.0 (IBM Corp. Armonk, New York). We compared baseline characteristics (age, sex, primary race/ethnicity, blood pressure, HbA1c, and duration of diabetes) for the two groups using independent sample *t*-tests for continuous variables and Fisher's exact test for categorical variables. We calculated the percentage of patients who received diabetic retinopathy screening exams, the percentage of telemedicine exams requiring referral to an eye care provider, and the percentage of eyes that had higher, lower, or the same level of diabetic retinopathy.

Percentage of Patients Receiving Diabetic Retinopathy Screening Examinations

We created time bins based on number of days since enrollment to determine the percentage of participants who received a diabetic retinopathy screening examination. We defined enrollment as the date participants signed the consent form. We defined the time bins based on their latest time point: the 6-month or less time bin was 6 months before through 6 months after enrollment (−182 through 181 days); the greater than 6-month through 18-month time bin was greater than 6 through 18 months (182 through 546 days) after

enrollment; the greater than 18-month through 30-month time bin was greater than 18 through 30 months (547 through 911 days) after enrollment; the greater than 30-month through 42-month time bin was greater than 30 through 42 months (912 through 1276 days) after enrollment; and the greater than 42-month through 54-month time bin was greater than 42 through 54 months (1277 through 1641 days) after enrollment. We included 6 months before enrollment as part of the 6-month or less time bin to include examination results from participants who had recently completed an examination. We included participants in a time bin if they were active in the study for the entire length of time defined by the bin.

We defined a 'diabetic retinopathy screening exam' as any type of exam (traditional or telemedicine) within a time bin, but excluded exams that did not evaluate the retina (e.g., refractions or anterior chamber exams after cataract surgery). We compared the percentage of diabetic retinopathy screening examinations between the telemedicine and traditional surveillance groups for each time bin using a Fisher's exact test.

Percentage of Patients Requiring Referral with Telemedicine

We calculated the percentage of patients that would require referral to an eye care provider based on their telemedicine exam results. The criteria for referral were (1) a diabetic retinopathy grade of moderate nonproliferative diabetic retinopathy or worse, (2) the presence of clinically significant macular edema, or (3) an 'unable to determine' grade in either eye for either diabetic retinopathy or macular edema.[10, 24, 25] For this analysis, we identified the number of examinations per participant in each time bin and reported the highest (i.e. worse) level of diabetic retinopathy or macular edema (see Table 1) between eyes. An 'unable to determine' result was coded as the highest category for both diabetic retinopathy and macular edema. However, we allowed repeat testing for poor images. Therefore, the analysis used an 'unable to determine' result if all eligible tests were 'unable to determine' in this time bin.

Worsening of Diabetic Retinopathy

We determined the percentage of eyes with a change in the diabetic retinopathy stage during study follow-up. For this analysis, we used both exam types (traditional and telemedicine) and excluded all 'unable to determine' results. In this analysis, we evaluated each eye separately. We determined the baseline stage of diabetic retinopathy by selecting the *first* exam result within the 6-month or less time bin (−6 months through 6 months) that was not an unable-to-determine result. For the greater than 6-month through 18-month through greater than 42-month through 54-month time bins, we used the worst grade of retinopathy recorded within the bin. We then compared the stage of retinopathy in each time bin to the 6-month or less time bin to determine whether the stage of diabetic retinopathy had increased (worsened), remained stable, or decreased (improved).

Results

Demographics

We evaluated 646 people for eligibility; 567 (87.8%) were enrolled and 79 (12.2%) were not enrolled (78 declined participation and 1 was ineligible because he/she was not a health

clinic patient). We did not find differences in age, duration of diabetes, or HbA1c between those enrolled when compared to those who were not. However, females were more likely to enroll than males (52% (295/567) vs. 48% (272/567), *P*=.03).

Table 2 displays the demographic characteristics. A total of 411 participants (72.5%) reported a nonwhite primary, secondary, or tertiary race/ethnicity. The mean number of years since receiving a diagnosis of diabetes was 9.5 years, and participants had a mean HbA1c level of 8.3%. There were no differences in demographic and medical characteristics at enrollment between the telemedicine (n = 296) and traditional surveillance (n = 271) groups.

Percentage of Diabetic Retinopathy Screening Exams by Study Year

Figure 2 shows that the telemedicine group underwent a diabetic retinopathy screening examination more frequently than the traditional surveillance group in the 6-month or less time bin with a 50.7% difference (94.6% [280/296] vs 43.9% [119/271]; 95% CI, 46.6%-54.8%; P < .001) and the 6-month through 18-month time bin with a difference of 19.8% (53.0% [157/296] vs 33.2% [90/271]; 95% CI, 16.5%-23.1%; P < .001). After we offered telemedicine to both groups, the percentage of diabetic screening examinations was similar for subsequent years (>18-month through 30-month time bin: 131 [44.3%] of 296 vs 107 [39.5%] of 271; difference, 4.8%; 95% CI, 3.0%-6.6%; P = .27; >30-month through 42-month time bin: 127 [45.0] of 282 vs 121 [46.4%] of 261; difference, 1.4%; 95% CI, 0.4%-2.4%; P = .80; and >42-month through 54-month time bin: 115 [51.1%] of 225 vs 117 [56.0%] of 209; difference, 4.9%; 95% CI, 2.9%-6.9%; P = .34).

Figure 2 shows that the traditional surveillance group had an increase in the percentage of eye examinations starting at the greater than 18-month through 30-month time bin through the greater than 42-month through 54-month time bin, suggesting that the availability of telemedicine increased the percentage of participants receiving retinopathy screening examinations. A small percentage of participants in the traditional surveillance group continued to only use traditional examinations even after telemedicine was offered to them, with this percentage decreasing during the follow-up period. The percentage of patients receiving only telemedicine examinations vs patients receiving only traditional examinations in the traditional surveillance group was 40.5% vs 59.4% (P = .12), 61.0% vs 39.0% (P = .17), and 89.0% vs 11.0% (P < .01) in the greater than 18-month through 30-month, greater than 30-month through 42-month, and greater than 42-month through 54-month time bins, respectively. This finding suggests that, when onsite telemedicine and offsite traditional eye examinations were both an option, most participants eventually opted for telemedicine. In addition, when participants only received one type of examination, they were more likely to have a telemedicine exam.

For the 6-month or less through greater than 42-month through 54-month time bins, we could not identify a difference in the prevalence of any stage of diabetic retinopathy between those in the telemedicine group and those in the traditional surveillance group (eTable 1 and eTable 2 in Supplement 2). However, the telemedicine group had a higher percentage of unable-to-determine results for macular edema when compared with the traditional surveillance group during the 6-month or less and greater than 6-month through 18-month

time bins (≤6-month: 15.4% [43/280] vs 0% [0/119]; P < .001; >6-month through 18-month: 17.2% [27/157] vs 0% [0/90]; P < .001).

Referral Percentage for Telemedicine Examinations

Table 3 shows the percentage of patients receiving a telemedicine exam that would require referral to an eye care provider based on telemedicine exam results. The data show that the majority of participants did not need to be referred for follow-up. Table 3 also shows that an 'unable to determine' result for diabetic retinopathy or macular edema was a common reason for referral.

Worsening of Diabetic Retinopathy

Table 4 shows the changes in diabetic retinopathy stage throughout the duration of the trial. Over the course of the study, over 90% (range 90.4-94.1%) of eyes had their diabetic retinopathy stage within +/− 1 of their baseline diabetic retinopathy stage throughout the study. At the greater than 42-month through 54-month time bin, 35 (8.6%) of 409 participants (95% CI, 5.8%-11.2%) experienced worsening by 2 stages or more, and 5 (1.2%) of 409 (95% CI, 0.1%-2.3%) had an improvement in diabetic retinopathy by 2 stages or more. Overall, this suggests that levels of diabetic retinopathy were relatively stable over the study period.

Discussion

This project addressed the Institute of Medicine's recommendations for the escalating public health issue of diabetes and diabetic retinopathy[18] using a first quartile priority topic: "Compare the effectiveness of interventions to reduce health disparities in *diabetes…*"; and a second quartile priority topic: "Compare the effectiveness of new remote monitoring technologies (e.g., telemedicine) and usual care in managing chronic diseases, especially in rural settings." We found that telemedicine increased the percentage of participants who obtained diabetic retinopathy screening exams when compared to traditional surveillance. After all participants had access to telemedicine, the data show that telemedicine increased the percentage of participants receiving exams over the long-term. The severity of diabetic retinopathy remained relatively stable over the study period, and most telemedicine participants did not have levels of diabetic retinopathy that warranted referral to an eye care provider. Overall, these results suggest that primary care clinics could use telemedicine to triage and monitor patients for diabetic retinopathy over a long period of time.

Similar to previous studies,[10, 11, 26, 27] we found that telemedicine increased the percentage of participants that obtained diabetic retinopathy screening examinations at baseline when compared to traditional surveillance with eye care providers. However, when our study offered telemedicine to both groups after two years of enrollment, the percentages receiving screening exams became similar. When participants are offered both traditional and telemedicine diabetic screening examinations, approximately 30% of patients will utilize *only telemedicine* (Figure 2). Therefore, even when eye care providers are available, telemedicine will increase the percentage of diabetic retinopathy screening exams.

One advantage of screening for diabetic retinopathy with telemedicine is that it may decrease the societal burden of providing a full eye examination for every patient with diabetes. However, if most participants require subsequent referral, screening examinations would actually increase healthcare costs. Similar to previous studies,[24, 25] we used 'moderate diabetic retinopathy' or worse, 'macular edema', or an 'unable to determine' finding from a telemedicine exam as the cut-off for recommending further evaluation with an eye care provider. Using this cut-off, only a few participants would be referred to an eye care provider. We also found that most patients had stable levels of retinopathy over the course of the study.

We found that the percentage of annual diabetic screening examinations from greater than 18 months through 54 months was between 40% and 55% despite the availability of telemedicine to all participants. This percentage is below the National Committee for Quality Assurance's requirement of 60% for the Diabetes Recognition Program.[28] This finding suggests that while telemedicine has the potential to increase the percentage of patients receiving diabetic retinopathy screening exams, other barriers to obtaining exams exist. Sheppler and colleagues[29] found decreased adherence when participants (1) believed their medical insurance did not sufficiently cover the costs of diabetic eye exams, (2) had uncontrolled blood glucose, or (3) had a shorter duration of diabetes. Future studies should include multiple types of interventions, such as telemedicine with health education and promotion, to improve diabetic retinopathy screening percentages.

Poor quality images are a common reason for referral in a telemedicine diabetic retinopathy screening program[10] and in the current study. Poor quality nonmydriatic imaging may occur due to small pupil size or ocular media abnormalities (e.g., cataract). Future studies are needed to determine the best imaging method to decrease the percentage of unreadable images.

Our study has several important findings for researchers and clinicians proposing telemedicine as a tool to increase the percentage of patients screened for diabetic retinopathy. However, our study also has limitations. The study population included a high percentage of participants who had transient housing and moved in and out of the health care system. Consequently, communities that display more stable housing may actually observe higher percentages of patients receiving long-term follow-up. We developed a health belief questionnaire during the last year of the study and invited all active participants to complete the survey.[29] This may have increased the percentage of follow-up in both groups during this time because we offered a small monetary incentive ($25) for completing the questionnaire.

Overall, our findings suggest that primary care clinics can effectively use telemedicine to triage and monitor patients for diabetic retinopathy over a long period of time. While telemedicine with nonmydriatic cameras may detect many eye diseases, it may miss ocular hypertension or refractive error. Therefore, we encouraged all participants to see an eye care provider regardless of their group assignment. Future studies should evaluate whether patients require a comprehensive eye examination with an eye care provider if a telemedicine result does not meet referral criteria and participants have no symptoms of eye disease.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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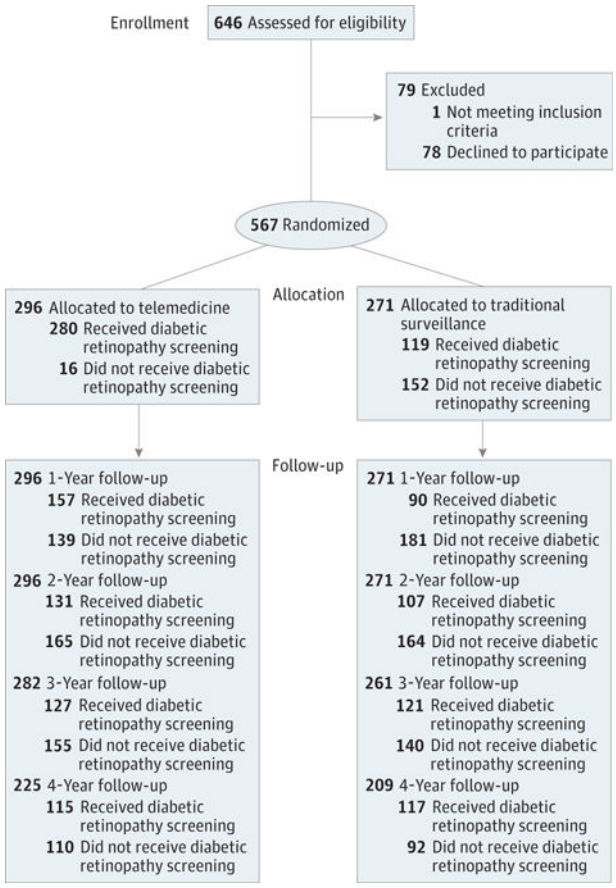

Figure 1.
Flowchart of the Study Protocol

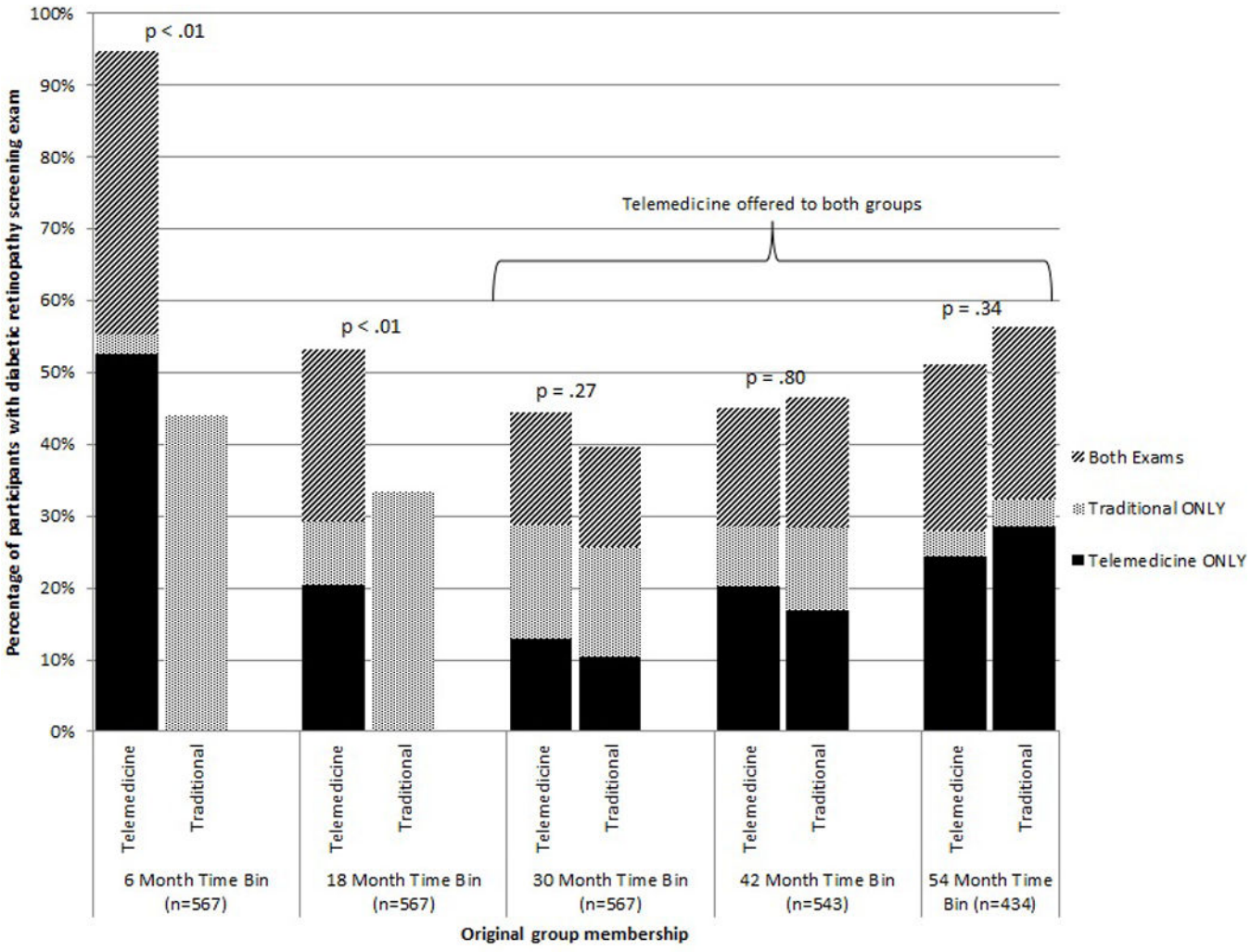

Figure 2.

Percent of individuals that received a diabetic retinopathy screening exam (<6 month through >42 month to 54 month time bin) compared by original group assignment (telemedicine, traditional) with type of exam (telemedicine, traditional, or both exams) noted.

Table 1

Description of stages of diabetic retinopathy * (NPDR = nonproliferative diabetic retinopathy; PDR=proliferative diabetic retinopathy) and macular edema. Tribal Vision Project 2014.

Stage	Description
Stage 0	No abnormalities
Stage 1-Mild NPDR	Microaneurysms only
Stage 2-Moderate NPDR	More than just microaneurysms (such as venous beading) but less than severe NPDR
Stage 3-Severe NPDR	Contains one of the three characteristics termed the 4:2:1 rule: 1) approximately 20 dot blot hemorrhages in all 4 midperipheral quadrants; 2) venous beading in 2 quadrants; 3) or severe intraretinal microvascular abnormalities in 1 quadrant without PDR
Stage 4-PDR	Neovascularization of the optic disc or elsewhere; vitreous hemorrhage associated with neovascularization of any part of the eye; or evidence of previous panretinal photocoagulation
Unable to Determine	Reader not able to clearly determine stage of diabetic retinopathy
Macular Edema	Retinal thickening within 500 microns of the fovea; exudates associated with retina thickening within 500 microns of the fovea; or retinal thickening of one disc area in size within one disc diameter of the fovea
Unable to Determine	Reader not able to clearly determine level of edema in the macula

* Adapted from proposed international clinical diabetic retinopathy and diabetic macular edema disease severity scales[17,18]

Table 2

Baseline demographic and medical variables. Data are presented in mean (standard deviation) unless otherwise specified. Tribal Vision Project 2014.

	Overall (n=567)	Telemedicine (n=296)	Traditional surveillance (n=271)	p[a]
Age, years	51.1 (11.8)	50.5 (12.3)	51.7 (11.3)	.23
Female gender, % (n)	51.7 (293)	52.0 (154)	51.3 (139)	.87
Primary Ethnicity (white vs. other), % (n)				.61
White	53.1 (301)	52.0 (154)	54.2 (147)	
American Indian/Alaska Native	16.8 (95)	18.6 (55)	14.8 (40)	
African American	18.0 (102)	16.9 (50)	19.2 (52)	
Hispanic/Latino	10.9 (62)	11.8 (35)	10.0 (27)	
Asian	1.2 (7)	0.7 (2)	1.8 (5)	
Other	0.0 (0)	0.0 (0)	0.0 (0)	
Secondary Ethnicity (white vs. other), % (n)				.73
White	6.0 (34)	6.4 (19)	5.5 (15)	
American Indian/Alaska Native	32.8 (186)	33.4 (99)	32.1 (87)	
African American	0.5 (3)	0.3 (1)	0.7 (2)	
Hispanic/Latino	1.8 (10)	2.0 (6)	1.5 (4)	
Asian	0.0 (0)	0.0 (0)	0.0 (0)	
Other	0.2 (1)	0.3 (1)	0.0 (0)	
No secondary ethnicity	58.7 (333)	57.4 (170)	60.1 (163)	
Diastolic blood pressure, mmHg	76.9 (12.2)	76.8 (12.4)	77.0 (12.0)	.85
Systolic blood pressure, mmHg	127.7 (19.8)	127.5 (19.8)	127.9 (19.7)	.82
Hemoglobin A1c, %	8.3 (2.4)	8.5 (2.4)	8.2 (2.4)	.18
Years since diagnosis at enrollment	9.5 (8.1)	9.5 (8.0)	9.6 (8.3)	.84

[a] p-value comparing telemedicine to the traditional surveillance group (independent sample t-test or Fisher's exact test, as applicable)

Table 3

Referral for diabetic retinopathy and macular edema in the eye with more advanced retinal disease based on telemedicine exams only. Tribal Vision Project 2014.

	<6 month time bin (n=271)	>6 month to 18 month time bin (n=130)	>18 month to 30 month time bin (n=149)	>30 month to 42 month time bin (n=208)	>42 month to 54 month time bin (n=261)
Stage of diabetic retinopathy, % (n)					
None	74.5 (202)	71.5 (93)	73.8 (110)	70.7 (147)	65.1 (170)
Mild NPDR[a]	13.3 (36)	16.2 (21)	10.1 (15)	9.6 (20)	16.9 (44)
Moderate NPDR[a]	3.0 (8)	1.5 (2)	4.0 (6)	3.8 (8)	3.4 (9)
Severe NPDR[a]	0.0 (0)	1.5 (2)	0.7 (1)	0.5 (1)	1.5 (4)
PDR[a]	1.1 (3)	6.2 (8)	4.0 (6)	4.8 (10)	5.4 (14)
Unable to Determine	8.1 (22)	3.1 (4)	7.4 (11)	10.6 (22)	7.7 (20)
Macular Edema, % (n)					
Not Present	83.4 (226)	76.2 (99)	83.2 (124)	78.4 (163)	83.9 (219)
Present	0.4 (1)	1.5 (2)	0.0 (0)	0.0 (0)	3.4 (9)
Unable to Determine	16.2 (44)	22.3 (29)	16.8 (25)	21.6 (45)	12.6 (33)
Requiring referral[b], % (n)	19.2 (52)	26.2 (34)	23.5 (35)	27.9 (58)	22.6 (59)

[a]NPDR= non-proliferative diabetic retinopathy; PDR= proliferative diabetic retinopathy

[b]Criteria for referral: (1) a diabetic retinopathy grade of Moderate NPDR or higher, (2) the presence of macular edema, or (3) an ‘unable to determine’ result for diabetic retinopathy or macular edema. Some participants met multiple referral criteria, so the total percentage requiring referral is not a simple sum of the percentages..

Table 4

Change in diabetic retinopathy stage using either the telemedicine or traditional examination results. Tribal Vision Project 2014.

	Change in diabetic retinopathy stage[a]	>6 month to 18 month time bin (n=402 eyes)	>18 month to 30 month time bin (n=385 eyes)	>30 month to 42 month time bin (n=394 eyes)	>42 month to 54 month time bin (n=409 eyes)
Decrease in Stage	−4	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	−3	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
	−2	2 (0.5%)	5 (1.3%)	2 (0.5%)	4 (1.0%)
	−1	32 (8.0%)	16 (4.2%)	24 (6.1%)	17 (4.2%)
No Change	0	300 (74.6%)	279 (72.5%)	300 (76.1%)	284 (69.4%)
Increase in Stage	+1	45 (11.2%)	62 (16.1%)	47 (11.9%)	68 (16.6%)
	+2	13 (3.2%)	13 (3.4%)	13 (3.3%)	19 (4.6%)
	+3	2 (0.5%)	5 (1.3%)	6 (1.5%)	7 (1.7%)
	+4	8 (2.0%)	5 (1.3%)	1 (0.3%)	9 (2.2%)

[a]Eyes without a baseline traditional or telemedicine examination or a result of “unable to determine” are not included. Minus (−) means a decrease or improvement in stage (e.g., from “moderate non-proliferative diabetic retinopathy (NPDR)” to “mild NPDR”); zero (0) means no change in stage; and plus (+) means increase or worsening in stage (e.g., from “Moderate NPDR” to “Severe NPDR”) as compared to the <6 month time bin.