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Feasibility of Non-Mydriatic Ocular Fundus Photography in the Emergency Department: Phase I of the FOTO-ED Study

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Abstract

Objectives—Examination of the ocular fundus is imperative in many acute medical and neurologic conditions, but direct ophthalmoscopy by non-ophthalmologists is underutilized, poorly performed, and difficult without pharmacologic pupillary dilation. The objective was to examine the feasibility of non-mydriatic fundus photography as a clinical alternative to direct ophthalmoscopy by emergency physicians (EPs).

Methods—Adult patients presenting to the emergency department (ED) with headache, acute focal neurologic deficit, diastolic blood pressure ≥ 120 mmHg, or acute visual change had ocular fundus photographs taken by nurse practitioners using a non-mydriatic fundus camera. Photographs were reviewed by a neuro-ophthalmologist within 24 hours for findings relevant to acute ED patient care. Nurse practitioners and patients rated ease, comfort, and speed of non-mydriatic fundus photography on a 10-point Likert scale (10 best). Timing of visit and photography were recorded by automated electronic systems.

Results—Three hundred fifty patients were enrolled. There were 1,734 photographs taken during 230 nurse practitioner shifts. Eighty-three percent of the 350 patients had at least one eye with a high quality photograph, while only 3% of patients had no photographs of diagnostic value. Mean ratings were ≥ 8.7 (standard deviation [SD] ≤ 1.9) for all measures. The median photography session lasted 1.9 minutes (interquartile range [IQR] 1.3 to 2.9 minutes), typically accounting for less that 0.5% of the patient’s total ED visit.

Conclusions—Non-mydriatic fundus photography taken by nurse practitioners is a feasible alternative to direct ophthalmoscopy in the ED. It is performed well by non-physician staff, is well-received by staff and patients, and requires a trivial amount of time to perform.

INTRODUCTION

Consider the following true case scenario: a young woman presents to multiple physician offices and emergency departments (EDs) complaining of severe headache. Repeat brain imaging is normal. Only a few physicians attempt direct ophthalmoscopy, and those who do, document that the optic disc is “difficult to visualize but likely normal.” When she presents
to an ophthalmologist several weeks later, chronic papilledema has caused irreversible visual loss. She remains legally blind from unrecognized intracranial hypertension, and several of the physicians involved in her earlier care are now parties to a medical malpractice lawsuit.

Imagine instead, that during this same patient’s initial assessments, the ED staff obtained not only vital signs, but photographs of the ocular fundus without pharmacologic dilation of the patient’s pupils; these photographs clearly revealed the patient’s papilledema (Figure 1), resulting in prompt diagnosis and management prior to irreversible visual loss.

The Fundus Photography vs. Ophthalmoscopy Trial Outcomes in the Emergency Department (FOTO-ED) has found that over 80% of previously unknown findings that were potentially relevant to acute ED patient management were missed by emergency physicians (EPs) and identified only by non-mydriatic fundus photography. Our objective in this article is to examine non-mydriatic ocular fundus photography as a feasible and promising alternative to direct ophthalmoscopy, particularly in the ED where limited training in the use of the direct ophthalmoscope, increasing demands on physicians’ time, and an under-appreciation of the prognostic value of ocular fundus examination sometimes places patients at risk for poor ophthalmologic, neurologic, and systemic outcomes, and exposes their caregivers to substantial medico-legal liability.

METHODS

Study Design

The FOTO-ED two-phase study is a sequential trial designed to compare the routine clinical use of direct ophthalmoscopy performed by EPs (in phase I) to the routine clinical use of non-mydriatic ocular fundus photography interpreted by EPs (in phase II). In both phases, non-mydriatic ocular fundus photography interpreted by neuro-ophthalmologists served as the reference standard. This article reports results from a planned interim analysis following the first phase of the FOTO-ED study. The study was approved by our institutional review board, and registered with Clinical Trials.gov (NCT00873613). Written informed consent was obtained from all subjects.

Study Setting and Population

A convenience sample of adult patients who presented to our university hospital ED with chief complaints felt to be at high risk for ophthalmologic findings (headache, acute focal neurologic deficit, acute visual changes, or a diastolic blood pressure $\geq 120$ mmHg) were eligible. To be included, the patients had to be medically stable, able to sit up, and provide informed written consent.

Study Protocol

Photographs of the posterior pole of the ocular fundus (optic disc, macula, and major retinal vessels) were obtained from both eyes of enrolled patients using a commercially available, Food and Drug Administration approved, non-mydriatic ocular fundus camera (Kowa $\alpha$-D, Torrence, CA) by nurse practitioners. Training of the nurse practitioners consisted of written materials, 15 to 30 minutes of training on the use of the camera, and observation by a member of the study team until the nurse practitioner felt comfortable obtaining photographs on his or her own. Photographs were taken in the ED under ambient light conditions by using a custom hood over the camera and the patient’s head and shoulders. Nurse practitioners took photographs between 7 am and 10 pm, seven days a week. Patients who presented to the ED who met the inclusion criteria outside of these hours could be included if they were still present in the ED during these hours.
Emergency physicians were not provided the photographs, were masked to the results of the photographs during their care of these patients, and were asked to proceed with their routine evaluation of patients, which may have included direct ophthalmoscopy or ophthalmological consultation. EP performance and outcome of direct ophthalmoscopy was prospectively recorded. Nurse practitioners and patients recorded their impressions of the ease, speed, and comfort of the fundus photography encounter on a 10-point Likert scale (10 best). Total patient ED length of stay, timing of evaluation by ED clinician, and length of photography sessions were recorded by automated electronic systems.

Outcome Measures

The primary outcome measure was the detection rate for funduscopic findings relevant to acute patient care in the ED (i.e., that would have changed acute management in the ED or patient disposition). Relevant ocular fundus abnormalities were defined as optic disc edema, optic disc pallor, retinal vascular occlusion, intraocular hemorrhages, and grade III/IV hypertensive retinopathy (Figure 2).

Analysis of photographs—Two neuro-ophthalmologists reviewed the photographs for the presence or absence of relevant ocular fundus abnormalities within 24 hours. EPs were notified to arrange appropriate follow-up for any relevant findings not identified during their routine care. In the case of disagreement, a third neuro-ophthalmologist made the determination of whether an abnormality was present or absent. In any case in which there remained diagnostic uncertainty, the patient was examined in-person in the ophthalmology clinic.

Quality of fundus photographs was rated with a novel five-point rating scale, developed by the investigators (1=inadequate for any diagnostic purpose, 2=unable to exclude all emergent findings, 3=only able to exclude emergent findings, 4=not ideal but still able to exclude subtle findings, 5=ideal quality). Frequency of high-quality images (grade 4 or 5) and those of no diagnostic value (grade 1) was determined. Timing of the photographs was determined by digital time stamps applied at the time of photography.

The medical records of included patients were reviewed for demographics and clinical characteristics. Triage logs were reviewed daily for patients who were potentially eligible for inclusion based on their chief complaints or blood pressure, but were not enrolled. A random sample (generated by a pseudorandom number generator) of 100 of these non-included patients was retrospectively reviewed for documentation of funduscopic examination.

Data Analysis

Statistical analysis was performed with R: A language and environment for statistical computing (R Foundation for Statistical Computing, http://www.R-project.org). Means and standard deviations (±SD) are reported for continuous, normally distributed data, and medians and interquartile ranges (IQR) are reported otherwise. Proportions were calculated with 95% confidence intervals (CI) by the exact binomial method.

RESULTS

Three hundred and fifty patients were enrolled in phase one of the FOTO-ED study. The median age was 44.5 years (IQR 31 to 59 years), and 220 (63%) were women (Table 1). There were 1,734 photographs taken during 230 nurse practitioner shifts.
Eighty-three percent of the 350 patients had at least one eye with a high quality photograph, while only 3% of patients had photographs of no diagnostic value. Mean ratings for ease, comfort, and speed by nurse practitioners and patients were ≥ 8.7 on a 10-point (10 best) Likert scale (Table 2).

The median length of ED stay was 7.5 hours (IQR 4.2 to 17.5 hours). Patients were first seen by an ED clinician at a median of 44 minutes (IQR 25 to 90 minutes). The median photography session lasted 1.9 minutes (IQR 1.3 to 2.9 minutes), typically accounting for less than 0.5% of the patient’s total ED visit.

As we have reported previously, headache was a presenting complaint in 228 patients (65%), focal neurological deficit in 100 (29%), elevated diastolic blood pressure in 21 (6%), and visual complaints in 92 (26%); note that these sum to more than 100% because patients were allowed to meet more than one inclusion criteria. (Table 1) Among the 350 patients enrolled, only 48 (14%, 95% CI = 10% to 18%) had direct ophthalmoscopy performed by an EP. In 46 of these 48 cases, documentation indicated a normal fundus examination by the EP. In the other two cases, the patients presented to the ED with a fundus finding diagnosed prior to presentation, about which the EP was aware. Forty-four of the 350 enrolled patients (12.6%, 95% CI = 9.3% to 16.5%) had relevant funduscopic findings identified on non-mydriatic fundus photography (Figure 2, Table 3). Eleven of the findings were known before ED presentation. Of the remaining 33 relevant findings, six were identified by ED ophthalmology consultation. Twenty-seven relevant findings were identified solely by fundus photography, representing 7.7% (95% CI = 5.1% to 11%) of all enrolled patients, 61% (95% CI = 45% to 76%) of all 44 relevant findings, and 82% (95% CI = 65% to 93%) of the 33 relevant findings that were not known prior to presentation in the ED.

Among the potentially eligible patients not included in the study, 100 were randomly selected to determine if they had documentation of funduscopic examination. Only four out of these 100 patients (4%, 95% CI = 1% to 10%) had documentation that direct ophthalmoscopy had been performed by EPs.

**DISCUSSION**

This first phase of the FOTO-ED study found that direct ophthalmoscopy was rarely and inadequately performed by EPs in a large academic medical center. Only 14% of patients with complaints and conditions in which ocular fundus examination is considered important had direct ophthalmoscopy performed by EPs. Furthermore, 12.6% of patients presenting with these complaints and associated acute medical or neurological conditions had a finding that would potentially alter the course of their ED management and disposition. Non-mydriatic fundus photography identified over 80% of the previously unknown relevant findings that were missed during routine ED evaluations, even with the 24-hour availability of ophthalmology consultation in our tertiary center ED. In several cases, non-mydriatic fundus photography resulted in recall of the patient back to the ED and admission to the hospital (e.g., recall of a patient to the ED with headache who had been discharged with papilledema that was later discovered on review of the fundus photographs, and the admission of patients with otherwise undetected malignant hypertension).

We showed that non-mydriatic fundus photography is superior at detecting clinically important pathology when compared to direct ophthalmoscopy by EPs. In addition, it was performed by non-physician staff with quality comparable to images obtained by trained ophthalmic photographers, only required a trivial amount of the patients’ time spent in the ED, and was well-received by patients and staff. This suggests that non-mydriatic fundus photography may be an ideal technique for improving the care of patients in the ED.
Even with the rapid progress that has been made in various diagnostic medical technologies such as neuroimaging, visualization of the ocular fundus often remains the only diagnostic clue to the identification of potentially serious medical conditions. For example, one study of patients with acute ischemic stroke found that 3% had urgent ophthalmoscopic findings when they were systematically evaluated with mydriatic fundus photography as part of a clinical pathway. In the ED, fundus examination should be routine in the evaluation of acute visual loss (e.g., central retinal artery occlusion), in the detection of warning signs of impending visual loss from a host of neurological conditions (e.g., papilledema), and in determining the severity of certain medical conditions (e.g., hypertensive emergency). Disturbingly, however, two previous studies of headache management in the ED found documentation of ophthalmoscopy in only 37% to 48% of cases, likely an overestimate assuming that the ED physicians knew they were being observed as part of a study. The underperformance of funduscopy is likely due to several factors: 1) limited training in use of the ophthalmoscope, 2) reluctance to perform pharmacologic pupillary dilation in the ED, 3) limited experience in recognizing important ophthalmoscopic findings, and 4) increasing demands on physicians’ time.

Studies including tens of thousands of patients have demonstrated the validity and utility of fundus photography in the detection of ocular and systemic diseases in various non-ED and research settings. Based on these findings, some have proposed overcoming the inherent barriers to adequate ocular fundus examination through the use of teleophthalmology services in the care of ED patients. However, none of these investigations were specifically directed at the systematic evaluation of non-ophtalmic patients at risk for ocular fundus findings relevant to the diagnosis and management of acute medical and neurological diseases in a general ED. Indeed, one of these other studies was based in a specialized, ophthalmic ED, and all of these studies were limited to patients with acute ophthalmic conditions. Additionally, all of these studies relied on the use of a camera mounted on a slit lamp, which requires pharmacologic dilation of the pupils and significant training to achieve adequate visualization of the ocular fundus.

Non-mydriatic fundus photography, as in our study, could overcome many of the barriers to an adequate, routine funduscopic examination in the ED. Indeed, not only is it easier to look at a photograph than to visualize the ocular fundus with direct ophthalmoscopy, but the field of view is much larger with a non-mydriatic camera than with most direct ophthalmoscopes (Figure 3). While the use of non-mydriatic fundus photography is already gaining momentum for the screening of diabetic retinopathy in primary care settings, it has not, to our knowledge, been applied to the routine evaluation of ED patients. Its potential for use in the ED setting is substantial, especially considering that the time required for adequate pupillary dilation would disrupt patient flow in the ED, clinical monitoring of pupil reactivity is important in neurologic patient care, and most patients prefer not to have their pupils dilated. In addition, non-mydriatic photographs can be taken with very little training by non-physician staff, reducing the burdens on limited physician time, an important consideration in the ED. Ultimately, this technique may offer acute telemedical ophthalmological consultation for rural and underserved areas, and provide opportunities for earlier patient identification and recruitment for therapeutic clinical trials of emergent neuro-ophthalmic diseases.

We acknowledge that some may be skeptical that yet another relatively expensive piece of equipment should be added to the diagnostic armamentarium of the ED. However, the cost of a camera is comparable to a basic diagnostic ultrasound or electrocardiogram machine, and costs will likely decrease with more widespread deployment. With appropriate interpretation, existing billing codes for fundus photography can be used. However, the
primary cost savings would most likely be gained through improved diagnosis, thereby decreasing medical and medico-legal costs.

While some might suggest that efforts be directed to improve education in direct ophthalmoscopy, evidence suggests otherwise. Two longitudinal studies by Lippa et al. found that despite a sustained, multi-year ophthalmology curriculum, the long-term application of funduscopy by medical students was minimal. For example, while there was initially a 46% documentation rate of ophthalmoscopy in one of their third year rotations, there were no documented funduscopic examinations during their fourth year internal medicine clerkship. In addition, only 23% of the students had purchased an ophthalmoscope by completion of medical school. Of concern, 13% to 16% of students stated that a direct ophthalmoscope was not important for clinical duties, and 5% to 6% stated that there was a “dearth of opportunities” for its use in clinical encounters.

Combining training in the interpretation of fundus photography with the systematic use of non-mydriatic fundus photography in indicated scenarios would likely be more successful in affecting patient care than current efforts directed at improving ophthalmoscopy skills in the ED, although the cost-benefit of this technique warrants specific studies. One small study has suggested that medical practitioners are already substantially more skilled at identifying abnormalities on fundus photographs than by direct ophthalmoscopy.

We are currently enrolling patients in phase II of the FOTO-ED study in which the clinical application of this modality by EPs will be investigated. The EPs are provided the fundus photographs that they may choose to use or not, during their routine patient evaluations. We hope to determine if there is superior detection of relevant findings by EPs with access to non-mydriatic fundus photographs during their routine patient care than there was in the first phase of the FOTO-ED study with physician access only to direct ophthalmoscopy.

**LIMITATIONS**

The primary limitation of this study is that it represents a convenience sample from an academic medical center in which a relatively high proportion of high acuity medical and neurological patients are seen. Therefore, further study is needed to determine the generalizability of the results. The convenience sample covered 15 hours of each day during which the majority of patients are seen. We were unable to enroll all patients eligible during these times, primarily because of time constraints created by obtaining informed consent in a busy ED setting (a situation that would not exist in routine clinical practice).

We retrospectively reviewed 100 eligible patients who were not enrolled in the study, and found direct ophthalmoscopy documented in only 4% of these patients, compared to 14% of enrolled patients. While we recognize that the quality of this retrospective data is not directly comparable to our prospective recording of direct ophthalmoscopy, the more frequent performance of direct ophthalmoscopy among enrolled patients may be due to the Hawthorne effect (improved performance when one is observed). This suggests that the routine rate of direct ophthalmoscopy in our ED may actually be lower than seen in this study. Furthermore, we do not believe that the included patients were more likely to have relevant fundus findings than those not included. On the contrary, it seems more likely that patients who were too ill to be approached with informed consent or to undergo the photography would have relevant findings, given the seriousness of their disorders. Finally, this study was not designed to detect false positive findings on fundus photography (i.e., specificity). However, this design allowed us to determine the frequency with which EPs routinely performed direct ophthalmoscopy while focusing on the more important issue of missed diagnosis (i.e., sensitivity).
CONCLUSIONS

We have shown that non-mydriatic fundus photography taken by non-physician ED staff is a feasible alternative to direct ophthalmoscopy by emergency physicians. It is performed well by non-physician staff, is well-received by staff and patients, requires a trivial amount of time to perform, and detects relevant findings important in routine ED care.

Acknowledgments

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References


Figure 1.
Obvious severe bilateral papilledema from intracranial hypertension. (Photographs taken using the non-mydriatic fundus camera used for the FOTO-ED study).
Figure 2.
Pie chart showing the distribution of the 44 relevant findings observed among 350 patients.
The photographs in each slice were taken during the study.
Figure 3. Comparison of the single field of view for conventional direct ophthalmoscopy (enlarged inset) and non-mydriatic fundus photography (large photo). The most commonly used conventional direct ophthalmoscope only shows part of the optic disc, and requires active exploration of the fundus by the examiner, whereas a photograph taken with a non-mydriatic fundus camera allows visualization of the entire posterior pole of the ocular fundus, including the optic nerve, the macula, and the major retinal vessels.
Table 1

Summary of patient characteristics, n=350

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Median or count</th>
<th>IQR or %</th>
</tr>
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<tbody>
<tr>
<td>Age, years</td>
<td>44.5</td>
<td>31–59</td>
</tr>
<tr>
<td>Women</td>
<td>220</td>
<td>63</td>
</tr>
<tr>
<td>Inclusion criteria*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>228</td>
<td>65</td>
</tr>
<tr>
<td>Focal neurological deficit</td>
<td>100</td>
<td>29</td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td>21</td>
<td>6</td>
</tr>
<tr>
<td>Acute visual loss</td>
<td>92</td>
<td>26</td>
</tr>
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</table>

IQR = interquartile range

* patients were able to meet more than one inclusion criteria
Table 2
Summary of nurse practitioner rating of ease and speed and patient ratings of ease, speed, and comfort on a 10-point (10 best) Likert scale

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD)</th>
<th>% = 10</th>
<th>% ≥7</th>
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<tr>
<td>Nurse practitioners</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ease</td>
<td>8.7 (±1.9)</td>
<td>55</td>
<td>85</td>
</tr>
<tr>
<td>Speed</td>
<td>8.9 (±1.8)</td>
<td>56</td>
<td>86</td>
</tr>
<tr>
<td>Patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ease</td>
<td>9.3 (±1.6)</td>
<td>72</td>
<td>92</td>
</tr>
<tr>
<td>Speed</td>
<td>9.2 (±1.6)</td>
<td>67</td>
<td>90</td>
</tr>
<tr>
<td>Comfort</td>
<td>8.8 (±1.8)</td>
<td>54</td>
<td>87</td>
</tr>
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Table 3

Cross tabulation of relevant abnormalities by inclusion criteria

<table>
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<tr>
<th>Inclusion criteria</th>
<th>Grade III/IV hypertensive retinopathy</th>
<th>Optic disc edema</th>
<th>Intra-ocular hemorrhage</th>
<th>Retinal vascular occlusion</th>
<th>Optic disc pallor</th>
<th>TOTAL</th>
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</thead>
<tbody>
<tr>
<td>Headache (H/A)</td>
<td>1</td>
<td>4</td>
<td>5</td>
<td>-</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>Acute focal neurologic (neuro)</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Elevated dBP (dBP)</td>
<td>4</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td>Acute visual change (visual)</td>
<td>1</td>
<td>6</td>
<td>3</td>
<td>4</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>H/A + neuro</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>H/A + dBP</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>H/A + visual</td>
<td>-</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>Neuro + visual</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>10</td>
<td>13</td>
<td>13</td>
<td>4</td>
<td>4</td>
<td>44</td>
</tr>
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dBP = diastolic blood pressure