Original Article

Arc Light as an Alternative Approach to Diagnose Diabetic Retinopathy (DR) At Grass Root Level of Health Care System

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Purpose: To compare Arc Light and Direct Ophthalmoscope in diagnosing patients with normal eyes, patients having signs of Diabetic retinopathy and patients with other eye diseases.

Study Design: Quasi Experimental study.

Place and Duration of Study: Basic Health Units in Nishtar Town, Lahore in collaboration with Eye Department Lahore General Hospital, Lahore from Sep 2017 to Nov 2017.

Material and Methods: A total of 552 examinations (276 examinations with Ophthalmoscope and 276 examinations by using Arclight) were performed on 46 patients. All patients were selected using purposive sampling. The patients were examined by the Optometrist, Medical Officers (MO) and Ophthalmologists in sequence and findings of the selected patients were noted using Arc light and Ophthalmoscope on the prescribed format.

Results: We found that findings of medical officers for right eye and left eye using Arc Light had 50% and 54.9% agreement respectively with findings of Consultant who was gold standard in this study and more technical person in eye care. When Optometrist findings were compared with Consultant, they were excellent in terms of accuracy and level of agreement in findings of both users. When Consultant findings using Arc light were compared with Ophthalmoscope findings only one case was misdiagnosed through Arc light. Sensitivity and specificity of Arc light was 100% in right eye but it was reduced to 94.4% in left eye.

Conclusions: Arc Light is nearly as efficient tool as an Ophthalmoscope and provides comparable results during diabetic retinopathy examination.

Key-words: Arc Light, Direct Ophthalmoscope, Diabetic Retinopathy.

Vision 2020 is the global initiative, launched in 1999 by the International Agency for the Prevention of Blindness (IAPB) and World Health Organization (WHO), with the aim of eliminating avoidable blindness. In Pakistan, the national survey done in 2006 showed prevalence of blindness to be 3.4% and severe visual impairment as 4.9% in patients who were 30 years or older[1]. Significant development has been noted in treatment and prevention options of anterior segment eye diseases like cataract and trachoma but a large proportion of avoidable blindness in developing countries of Asia is due to posterior segment diseases such as glaucoma and diabetic retinopathy[2]. Pakistan has 6th largest population in the world. Diabetic Association of Pakistan (DAP) and WHO showed an overall prevalence of diabetes as 11.47% (ranged from 6.39–16.5%)[3]. According to internal diabetic federation

(IDF), there were 6.9 million cases of diabetes in Pakistan in 2014 and prevalence of diabetes in adults of 20-79 years of age was 6.8%. However, the projected estimates of International Diabetic foundation (IDF) for 2035 shows an alarming situation and Pakistan with an estimated number of 12.8 million diabetics, will be ranked 8th among the world's top 10 countries having increased prevalence of diabetes[4]. Diabetic retinopathy is the most common micro-vascular complication of diabetes mellitus[5] and, globally, is the leading cause of avoidable blindness in working age group adults[6,7]. A 2014 review of worldwide POAG prevalence among people aged 40-80 years showed estimates of 2.31% in Asia, 3.65% in Latin America and the Caribbean, and 4.20% in Africa[8]. Although, no cure has been found yet for glaucoma or diabetic retinopathy, early diagnosis and management is the key to slow down progression of disease and improve visual prognosis[9,10]. In many Asian countries the *per capita* number of ophthalmologists and the prevalence of blindness are inversely related; majority of ophthalmologists are practising in urban areas and most of the patients are living in poorer rural regions[11,12]. In addition to this, the total numbers of eye health providers are less than the required. There is a great variation in the ratio of Ophthalmologists and the populations in different south Asian countries. On an average this ratio between Ophthalmologist and population is 1:22,000. Most of Ophthalmologists are located in urban areas, on the contrary around 70% of the population lives in rural areas, 50% of the ophthalmologists are surgically inactive and clinical ophthalmology is more in practice than community ophthalmology[13]. In Pakistan there are ten consultant ophthalmologists per million[14]. Therefore, most of the time patients with eye diseases are reviewed by general practitioners, opticians, and allied eye care personnel. These groups need access to equipment and sufficient training to enable them to examine and detect abnormality in the posterior segment of the eye. Standard direct ophthalmoscopes are expensive that ranges from USD $200 to 600 per instrument. The Arclight ophthalmoscope (Figure 1) is a low-cost alternate to standard direct ophthalmoscopes. It costs USD $7.50 when purchased in bulk. At one end it has a small direct ophthalmoscope while on the other end has an illuminating magnifying loupe (allowing examination of the anterior segment) and a detachable otoscope. Its weight is 18 grams, uses three LED light sources, and has an inbuilt battery which is rechargeable by either an integrated solar panel (useful for mobile clinics in Pakistan) or a USB port. Three different lenses are integrated on an adjustable lens slider which allows a rough correction of the patient's or examiner's refractive error. The device also consists of a small colour vision test, a near visual acuity chart, a ruler, and a pupil size gauge.

The rationale of this study was to find an alternative and cheaper approach to diagnose Diabetic Retinopathy (DR) at gross root level of health care system. The arc light has been shown to provide effective results and findings which are similar to an Ophthalmoscope; an available Gold standard in the market. So this study is focused on the comparison of Arc Light versus Ophthalmoscope in diagnosing patients with Normal eyes (DR Negative), patients having symptoms of Diabetic retinopathy (DR Positive) and patients with other eye diseases.

MATERIAL AND METHODS

A total of 552 examinations (276 examinations with Ophthalmoscope and 276 examinations by using Arclight) were performed on 46 patients at Basic Health Units in Nishtar Town, Lahore from Sep 2017 to Nov 2017. Sample size was calculated by following formula: $n= (Z_{\alpha/2} + Z_{\beta})^2 \times (p_1(1 - p_1) + p_2 (1 - p2)) / (p_1-p_2)^2$

The study was planned such that training was given to Medical Officers (MO's) at BHU level so that they could identify major eye diseases early at BHU level which could then be referred for treatment to tertiary care referral centre. MO's findings were compared with Consultant; Gold Standard in this study and Arc light findings were compared with Ophthalmoscope: another Gold standard tool of the study.

This quasi experimental study was planned to evaluate the effectiveness of training given to Medical Officers (MO) on arc light and Ophthalmoscope to diagnose DR positive and others eye diseases. Further efficiency of arc light was compared with Ophthalmoscope so that in future it would be used as replacement instrument of eye disease diagnosis. This study was an evidence based study including Medical officers, optometrist and consultant ophthalmologist. The study was started after approval from the ethical committee of the Lahore General Hospital (LGH) which was the tertiary care centre attached with the Basic Health Unit. Training was given to Medical Officers of Nishtar Town District Lahore at LGH before the start of the study.

The study included subjects having DR positive,

DR negative and others diseases. The patients were examined by these three persons systematically. They noted findings in right and left eyes of these subjects using Arc light and Ophthalmoscope. All patients who were un-cooperative or had media opacities were excluded from the study.

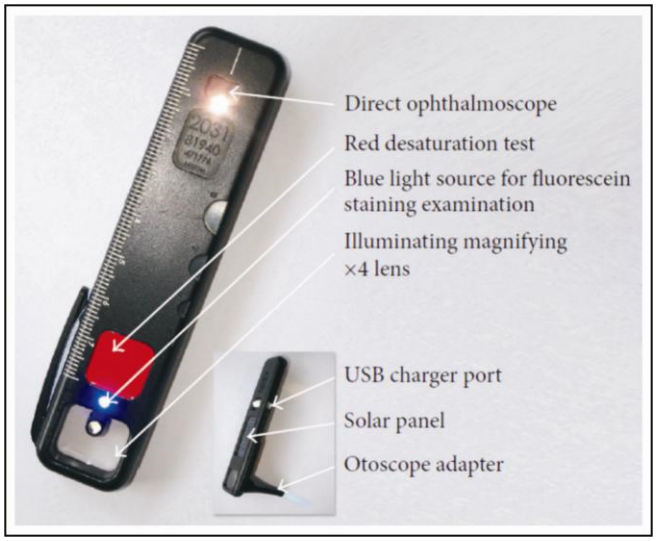

Fig. 1: Arc Light.

All patients were selected using MR number from Health Information Management System (HIMS) Olive Track through purposive sampling. First of all, patients were examined by the Optometrist of the project team and the finding of the selected patients were noted using Arc light and Ophthalmoscope on the prescribed format and also entered in the HIMS. Then all selected patients were referred to Medical Officers (MO's) on the same day for diagnosis by using Arc light and Ophthalmoscope. Findings of both were kept separate and they did not know about each other's findings. These selected patients were later examined by the visiting consultant ophthalmologist from LGH by using Arc light and ophthalmoscope for final evaluation and comparison of findings of the optometrist and medical officer. Consultant Ophthalmologist findings and Ophthalmoscope assessments were labeled as the Gold Standards in this study.

All these findings were added in HIMS by each person separately; MO's, optometrist and Consultants. This data was also added in SPSS version 20 by data manger. After that it was further analyzed by Consultant Researcher according to guidelines to produce an evidence based study. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and level of agreement were performed on this collected data. This analysis was used to make a decision about the efficiency of arc light in comparison with ophthalmoscope and also to evaluate the MO's training impact.

RESULTS

Results showed that the short term training of medical officers had only some impact on their skills for making a correct diagnosis using an arc light or an ophthalmoscope. But Optometrist produced exceptionally good results and matched with Consultant findings; Gold standard in this study. Afterwards the validity of arc light was assessed using sensitivity and specificity analysis. Findings showed that arc light produced excellent results or almost in parallel to Ophthalmoscope, another Gold standard tool, if it was used by Optometrist or Consultant Ophthalmologist.

Results of the right eye when observed through Arc light and Ophthalmoscope by Medical Officers and Consultant showed that there were 23 patients who were classified by Consultant as DR positive cases by using Arc light while only 11 patients out of 23 were rightly classified by Medical officers, Table 1. Remaining 12 subjects were misclassified into DR Negative and others. Similarly, 19 subjects were DR negative or diagnosed as normal by Consultant. Here only 2 cases out of 19 were wrongly classified into other categories. In the category of people having other diseases were rightly classified by MO. Chi-square test of association showed a strong relationship between these two types of observations. Further Kappa test had a value of 0.506 which showed that there was 50% level of agreement between Consultant and MO findings about Right eye through Arc Light.

Similarly, Optometrist findings were also compared with Consultant; Gold standard in this study. Their findings 100% matched with the consultant findings in case of RE diagnosis through Arc light, Table 2.

After observing right eye, Arc Light was used to assess the problems of LE by both; MO and Consultant. Almost similar findings were recorded for left eye. Here association results were also significant. Kappa test value shows that there was 54.9% agreement in both observers. Medical Officers (MO) were not good at diagnosing DR positive cases of Left eye as 10 out of 17 were wrongly classified, Table 3.

Table 1: MO Findings for RE with Arc light compared with Consultant's findings of RE.

		Consultant's findings for RE with Arc Light			Total	Chi-Square with p-value	Kappa
		DR Positive	DR Negative	Others			
MO findings for RE with Arc light	DR Positive	11	0	0	11	37.586 (.000)	.506
	DR Negative	11	17	0	28		
	Others	1	2	4	7		
Total		23	19	4	46		

Table 2: Optometrist findings for RE with Arc light compared with Consultant's findings.

		Consultant's findings for RE with Arc Light			Total	Chi-Square with p-value	Kappa
		DR Positive	DR Negative	Others			
Optometrist findings for RE with Arc Light	DR Positive	23	0	0	23	92.000 (.000)	1.000
	DR Negative	0	19	0	19		
	Others	0	0	4	4		
Total		23	19	4	46		

Table 3: MO Findings for LE with Arc light compared with Consultant's findings of LE.

		Consultant's findings for LE with Arc Light			Total	Chi-Square with p-value	Kappa
		DR Positive	DR Negative	Others			
MO findings for LE with Arc Light	DR Positive	7	0	0	7	41.776 (.000)	.549
	DR Negative	10	18	1	29		
	Others	0	2	8	10		
Total		17	20	9	46		

Table 4: Optometrist findings for LE with Arc light compared with Consultant's findings.

		Consultant's findings for LE with Arc Light			Total	Chi-Square with p-value	Kappa
		DR Positive	DR Negative	Others			
Optometrist findings for LE with Arc Light	DR Positive	17	0	1	18	84.617 (.000)	.966
	DR Negative	0	20	0	20		
	Others	0	0	8	8		
Total		17	20	9	46		

Findings of left eye diagnosed through Arc Light by optometrists were also analyzed. Here there was a small discrepancy as only 1 case out of 46 was misclassified by Optometrist. Their findings matched 96.6% with the consultant findings, table 4.

Table 5 depicts comparison of findings with Ophthalmoscope by MO and Consultant. Medical Officers classified the RE findings as DR positive cases identified by Consultant into three categories; positive, negative and others. Here level of agreement was 61.3% with strong association between these two users.

Table 6 shows findings of optometrist diagnosed through Ophthalmoscope compared with consultant's findings. Here, there was again 100% performance by Optometrist. Their findings 100% matched with the consultant findings.

Table 7 shows LE diagnosis by using Ophthalmoscope. Medical officers classified the DR positive cases identified by Consultant again into three categories; Positive, Negative and Others. They misclassified 8 DR positive cases into DR negative and others. All other cases having DR negative and other diseases were reasonably correctly classified. Here level of agreement was 62.1% with strong association between these two users.

Now, Left eye was diagnosed through Ophthalmoscope by Optometrists. Here, there was

Table 5: MO findings for RE with Ophthalmoscope compared with Consultant's findings.

		Consultant's findings for RE with Ophthalmoscope			Total	Chi-Square with p-value	Kappa
		DR Positive	DR Negative	Others			
MO findings for RE with Ophthalmoscope	**DR Positive**	14	0	0	14	40.447 (.000)	.613
	DR Negative	7	17	0	24		
	Others	2	2	4	8		
Total		23	19	4	46		

Table 6: Optometrist findings for RE with Ophthalmoscope compared with Consultant.

		Consultant's findings for RE with Ophthalmoscope			Total	Chi-Square with p-value	Kappa
		DR Positive	DR Negative	Others			
Optometrist findings for E with Ophthalmoscope	DR Positive	23	0	0	23	92.000 (.000)	1.000
	DR Negative	0	19	0	19		
	Others	0	0	4	4		
Total		23	19	4	46		

Table 7: MO findings for LE with Ophthalmoscope compared with Consultant's findings.

		Consultant's findings for LE with Ophthalmoscope			Total	Chi-Square with p-value	Kappa
		DR Positive	DR Negative	Others			
MO findings for LE with Ophthalmoscope	DR Positive	10	0	0	10	42.605 (.000)	.621
	DR Negative	7	18	1	26		
	Others	1	2	7	10		
Total		18	20	8	46		

Table 8: Optometrist findings for LE with Ophthalmoscope compared with Consultant.

		Consultant's findings for LE with Ophthalmoscope			Total	Chi-Square with p-value	Kappa
		DR Positive	DR Negative	Others			
Optometrist findings for LE with Ophthalmoscope	DR Positive	18	0	0	18	92.000 (.000)	1.000
	DR Negative	0	20	0	20		
	Others	0	0	8	8		
Total		18	20	8	46		

Table 9: Consultant's findings for RE with Arc Light and Ophthalmoscope.

		Consultant's findings for RE with Ophthalmoscope			Total	Chi-Square with p-value	Kappa
		DR Positive	DR Negative	Others			
Consultant's findings for RE with Arc Light	DR Positive	23	0	0	23	92.000 (.000)	1.000
	DR Negative	0	19	0	19		
	Others	0	0	4	4		
Total		23	19	4	46		

Table 10: Consultant's Findings for LE with Arc Light and Ophthalmoscope.

		Consultant's findings for LE with Ophthalmoscope			Total	Chi-Square with p-value	Kappa
		DR Positive	DR Negative	Others			
Consultant's findings for LE with Arc Light	DR Positive	17	0	0	17	84.617 (.000)	.966
	DR Negative	0	20	0	20		
	Others	1	0	8	9		
Total		18	20	8	46		

again 100% performance by Optometrist. Their findings matched 100% with the consultant findings, table 8.

The most important part of the study was to validate the Arc light as an efficient tool for diagnosis of DR cases and others. For this purpose, consultant findings on both, Arc light and Ophthalmoscope were compared and matched. Cross table and Bar chart analysis highlighted that both results matched 100%. It shows that Arc light can be an effective tool for diagnosis, table 8.

Now, same procedure was performed for Left eye by Consultant. In this case only one case out of 46 subjects was misclassified through Arc light. Performance analysis shows that there was 96.6% level of matching in the consultant findings through two different tools, table 9.

Validity analysis of the Arc light was done and compared its findings with Ophthalmoscope. In this case only DR positive and DR Negative cases of RE were compared through both diagnosing tools. Arc light produced 100% sensitivity, specificity, PPV, NPV and accuracy. In addition to these values, Confidence intervals were also given to see the range of accuracy and measurements, table 10.

Table 11: Validation parameters of RE.

Statistic	Formula	Value	95% CI
Sensitivity	$\frac{a}{a+b}$	100.00%	85.18% to 100.00%
Specificity	$\frac{d}{c+d}$	100.00 %	82.35% to 100.00%
Disease prevalence	$\frac{a+b}{a+b+c+d}$	54.76% (*)	38.67% to 70.15%
Positive Predictive Value	$\frac{a}{a+c}$	100.00% (*)	
Negative Predictive Value	$\frac{d}{b+d}$	100.00% (*)	
Accuracy	$\frac{a+d}{a+b+c+d}$	100.00% (*)	91.59% to 100.00%

These two tools were also applied on LE diagnosis by consultant. But when we validated the Arc light findings with Ophthalmoscope for DR positive and DR negative cases, one case was misdiagnosed by Arc light. So, here sensitivity, NPV and Accuracy reduced to 94.4%, 95.24% and 97.37% from 100% respectively, table 12 and 13.

Table 12: Validation parameters of LE.

Statistic	Formula	Value	95% CI
Sensitivity	$\frac{a}{a+b}$	94.44%	72.71% to 99.86%
Specificity	$\frac{d}{c+d}$	100.00 %	83.16% to 100.00%
Disease prevalence	$\frac{a+b}{a+b+c+d}$	47.37% (*)	30.98% to 64.18%
Positive Predictive Value	$\frac{a}{a+c}$	100.00% (*)	
Negative Predictive Value	$\frac{d}{b+d}$	95.24% (*)	74.86% to 99.26%
Accuracy	$\frac{a+d}{a+b+c+d}$	97.37% (*)	86.19% to 99.93%

DISCUSSION

The Arc light ophthalmoscope is emerging as a reliable, low-cost alternative to the standard direct ophthalmoscope. The cost of an Arclight ophthalmoscope is significantly lower than a direct ophthalmoscope or comparable instruments. Comparing the current price of Heine direct ophthalmoscope (USD $365), one can buy 48 Arclight ophthalmoscopes at their marketed bulk order price (USD $7.5). Arclight is the only direct ophthalmoscope that is specifically designed for low-income settings[15]. However, it would be useful in medical training and education across the globe by providing an affordable direct ophthalmoscope for medical students. In comparison to other low-cost direct ophthalmoscopes[16,17] the Arclight has an adjustable lens power with three power settings (+4, −3, and −6 diopters). These lenses will be sufficient for most of the patient and examiner refractive error. Arc Light also has an additional attachable otoscope which is helpful to examine ear problems (Figure 1).

We found that findings of medical officers for right eye and left eye using Arc Light had 50% and 54.9% agreement respectively with findings of Consultant who was gold standard in this study and more technical person in eye care. When the medical officer used the Ophthalmoscope for the assessment of same case's RE and LE, they got 61% and 62% agreement with consultant findings. In this study, more than one medical officer was involved and got training on both tools. So it was planned to see the individual findings and their agreement with consultant findings. When split analysis was performed it was observed that there was huge element of heterogeneity among MO's in the performance and accuracy. This detailed analysis showed that they were not at same level and Kappa test also reported 23.4% to 75% level of agreement for RE through ARC Light. For LE it was 39.4% to 76.5%. In both cases; RE and LE through arc light, MO's accuracy was 31.8% to 100% in different doctors when they used Ophthalmoscope for RE and similarly 45.5% to 100% for LE. Overall it can be seen that, MO's mostly got confused and gave wrong assessment when they diagnosed those patients who have DR positive status. In the case of DR negative and others diseases their accuracy was comparatively good. Lowe et al[18] in a similar study, in which examination was performed by final-year medical students, found no clinically significant difference between the Arclight ophthalmoscope and the Heine K180 direct ophthalmoscope in terms of accuracy of the vertical cup to disc ration (VCDR) measurement and with a similar proportion of examinations yielding a ≥ 0.2 difference in the VCDR compared to the reference standard for both the Arclight and Heine ophthalmoscopes. Importantly, 85% of Arclight examinations yielded VCDR estimation, compared to 61% with the Heine ophthalmoscope. Medical-students found that the Arclight was much easier to use than Heine ophthalmoscope. Moreover the study also found that the LED bulb used in the Arclight ophthalmoscope was better tolerated by the subjects during ocular examination, with considerably lower scores for both "glare" and "length of examination".

Arc light ophthalmoscope has a solar powered battery which makes it useful even in remote, rural areas with interrupted power supply and also cuts the cost of buying new batteries regularly. Our study assessed the accuracy of the Arc light ophthalmoscope in detecting pathologies in the retina and it could be used to detect diabetic retinopathy. With such a low cost, Arc light has the capacity to be much more widely available and will improve training opportunities and examination of the diabetic retinopathy by medical specialists in rural areas. Earlier detection and management of retinopathy will improve the prognosis of the patients with a less likelihood of progression to blindness.

Blundell R et al[19] compared Arclight with traditional direct ophthalmoscope to examine retinal diseases and found that Arclight was equally effective in terms of identification of clinical signs and making correct diagnosis and observers found more ease in using Arclight. Arc light could be helpful in better training of fundoscopy and easy access to direct ophthalmoscopes in low budget settings.

In another study by McComiskie et al[20] Panoptic versus conventional direct ophthalmoscope was compared in a group of 'naïve' first year medical students to determine which would be more suitable for non-ophthalmoligists. Their results showed that the medical students found the panoptic (PO) much easier to use, with accuracy of rating the VCDR similar to the conventional direct ophthalmoscope.

We also compared the findings of Optometrist with gold standard; Consultant. They had excellent accuracy and level of agreement with the findings of the consultant. Only one case was misdiagnosed by Optometrist out of 184 cases.

Comparison was also made between findings of the Consultant with Arc light and Ophthalmoscope. As a whole, only one case was misdiagnosed through Arc light. Validity of Arc Light versus Ophthalmoscope was evaluated using sensitivity and specificity analysis. Overall the Arc Light showed good results in its validity test. Sensitivity and specificity of Arc light were 100% in RE. But in LE its sensitivity reduced was to 94.4%. Overall Arc light produced excellent results. The Ophthalmoscope was used as a Gold standard versus the Arc Light in this analysis.

The limitation of the study was that it was done at two centres. We have planned to extend this study to other centers to increase the number of patients examined. Moreover medical students will also be included in the study to get another perspective.

CONCLUSION

We found that Medical officers had some difficulty in diagnosing DR positive cases with Arc light. While

Optometrists were better at diagnosis and using these two tools. Furthermore Arc Light is nearly as efficient tool as an Ophthalmoscope when used by the consultants. Arc light is easy to use and provides comparable results when examining diabetic retinopathy. It is capable of improving easy access to equipment in low-budget setups around the world and improvingfundoscopy skills in eye care workers and diagnosis of retinal diseases. On the basis of these findings we recommend that it is important to train the MO's before asking them to use the Arc light. As MO's are not proficient in eye care, therefore it is better to introduce Optometrists along with medical officers at BHU level on permanent basis where they can work in outpatients department. Arc light can be used as a replacement of Ophthalmoscope for diagnosing DR or other diseases as shown by the sensitivity and specificity analysis in this study.

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Conflict of Interests

None.

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