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# Use of a handheld fundus camera as a screening tool for diabetic retinopathy

## *Uso de retinógrafo portátil como ferramenta no rastreamento de retinopatia diabética*

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## *ABSTRACT*

***Purpose:*** *Determine the effectiveness of the use a portable handheld fundus camera as a screening method for diabetic retinopathy, compared to regular digital retinography.* ***Methods:*** *This is a cross-sectional, observer-masked study, evaluating 100 eyes of 51 diabetic patients undergoing a routine dilated retinography for diabetic retinopathy. Fundus images pre and post-dilation we captured by Pictor Plus (Volk Optical Inc., Mentor, USA), followed by routine digital retinography by IMAGEnet (Topcon Medical Systems, New Jersey, USA). All exams were performed by a trained technician on the same occasion. The images were analyzed and graded by a masked retina specialist and classified as normal, presence of diabetic macular edema, nonproliferative diabetic retinopathy (initial, moderate and severe) and proliferative diabetic retinopathy. The ungradable images were recorded and excluded from analyses. The agreement between results obtained by the three methods was evaluated via Kappa coefficient. Sensitivity, specificity, positive and negative predictive values in relation to IMAGEnet images were also determined.* ***Results:*** *Images were gradable in 89% of pre-dilation photos. Pictor Plus pre-dilation images had high sensitivity and specificity in identifying normal eyes (92.9% and 93.4%) and in vision-threatening DR (82.9% and 97.9%) both when compared to IMAGEnet results.* ***Conclusion:*** *Pictor can capture retinal images of sufficient quality to screen for DR with and without dilation. Single retinal images obtained using Pictor can identify eyes with vision-threatening DR with high sensitivity and specificity compared to routine IMAGEnet images.*

***Keywords:*** *Diabetic retinopathy; Vision screening; Pictor plus; Portable Fundus camera; Blindness; Telemedicine*

## RESUMO

**Objetivo:** Determinar a concordância do retinógrafo portátil Pictor Plus, na ausência de midríase, com a retinografia digital e avaliar a sua acurácia como método de rastreio da retinopatia diabética (RD). **Métodos:** Estudo transversal, mascarado para o observador, avaliando 100 olhos de 51 pacientes diabéticos. Foram realizadas retinografias com o Pictor Plus com e sem midríase, seguidos de retinografia convencional com o retinógrafo IMAGEnet por técnico treinado. As imagens obtidas foram analisadas por oftalmologista especialista em retina e classificadas normais, presença de edema macular diabético, retinopatia não proliferativa (inicial, moderada e grave) e retinopatia proliferativa, além de análise inviável. A concordância entre os resultados foi avaliada via coeficiente Kappa. As imagens foram agrupadas em normais e alteradas e estas em RD de alto risco e RD de baixo risco. Avaliou-se ainda a sensibilidade, especificidade, valores preditivos positivos e negativos, em relação à retinografia convencional. **Resultados:** Oitenta e nove por cento das imagens foram consideradas viáveis para classificação. Pouco mais de 31% dos olhos avaliados foram considerados como normais pelas três tecnologias. O exame com Pictor na ausência de midríase apresentou altos índices de sensibilidade e especificidade para a classificação normal (92,9% e 93,4%) e RD de alto risco (82,9% e 97,9%) e bons resultados para RD de baixo risco (75,0% e 87,0%). **Conclusão:** O Pictor Plus apresentou altos níveis de concordância com a retinografia digital ao discriminar exames normais de alterados e portadores de RD de baixo e alto risco. Foram verificadas ainda altas sensibilidade e especificidade desta ferramenta, se comparados à retinografia padrão.

**Descritores:** Retinopatia diabética; Seleção visual; Cegueira; Retinógrafo portátil; Telemedicina

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## Introduction

Diabetic retinopathy (DR) is the leading cause of blindness among working-age adults and is estimated to be the cause of blindness among 2.38% of the 37 million blind people worldwide.[1] Population studies have estimated the prevalence of any stage of retinopathy in diabetics at about 35% (approximately 93 million people worldwide) and by 2035 this number could reach 600 million people affected. [2,3]

Studies have shown that the risk of DR blindness can be reduced to less than 5% when diagnosis is made in a timely manner and primary treatment (blood pressure and glycemic control) and/or secondary treatment (laser photocoagulation and anti-angiogenic injection) treatment are performed correctly before irreversible changes can take place. [3-4]

Brazilian epidemiological studies published in 2018 evaluated the prevalence of diabetic retinopathy in patients with type I diabetes. The average Brazilian prevalence was approximately 35.7%. The Brazilian regions with the highest prevalence rates were the South, in which 42.9% of the patients had some degree of diabetic retinopathy, and the Midwest, with 41.7%. The North and Northeast regions had the lowest prevalence (29.9%), but had the highest rates of high HbA1c (9.3 ± 2.3%), a factor frequently associated with diabetic retinopathy. Other most associated factors were the long duration of diabetes and elevated serum uric acid. Economic reality was another variable shown in the study. In the North and Northeast, patients with medium and high economic level had 80% lower prevalence of proliferative diabetic retinopathy in relation to the population. [5-7]

Retina Specialist Societies around the world have recommended eye follow-up with annual, half-yearly and even monthly examinations depending on the severity of diabetic retinopathy presented by the patient, as this population is at risk for other ophthalmic pathologies such as cataract and glaucoma. [5,7,8]

However, adherence to these recommendations has been hampered. Studies conducted by the American Academy of Ophthalmology have found that only 30% of diabetics meet the recommended eye monitoring regimen. [9] The reasons for this low adherence to specialized care include lack of knowledge about DR, as well as the difficulty of patient access to ophthalmologic examinations, due to poor distribution of ophthalmologists and geographical factors, as well as, in Brazil, due to lack of retina specialists outside major centers and within the SUS. [10,11]

Thus, some non-mydriatic handheld fundus cameras, such as Pictor Plus, have the advantage that they do not require the use of pupil dilating eye drops that may have side effects ranging from transient worsening of visual acuity to ocular hypertensive crisis. and its consequences. With no need for pupillary dilation, retinograms can be obtained by general practitioners or even technologists or health agents in more remote locations. This device allows you to view a field of 40or of the fundus with a low intensity flash and with the ability to record and store video images. [12,13]

Using this technology as an initial part of a broader telemedicine program could change the landscape of blindness and visual impairment, due to diabetic retinopathy, in a cost-effectively way and could even be incorporated into existing health promotion programs in the diabetic population, data is even more relevant if we consider the rapid growth in the global prevalence of DM. However, despite the significant advances in portable technology, it is necessary to determine the agreement of their findings in relation to the reference examination, digital retinography under mydriasis, which is the object of this study.

## Objective

To determine the agreement of the Pictor Plus handheld fundus camera in the absence of drug mydriasis with traditional digital retinography and to evaluate its accuracy as a screening method for diabetic retinopathy.

## Methods

This is a cross-sectional study, masked to the observer, whose participating population was 51 diabetic patients (100 eyes), previously scheduled for retinography, by medical request.

We excluded from this study patients who did not have diabetes, who were under 18 years of age, who had no indication for documented retinography and who did not agree with the Informed Consent Form (ICF).

The fundus images were initially captured by digital retinography with Pictor Plus, with macular fixation, in the absence of drug mydriasis, in a scotopic environment. Then, pupillary dilation was performed with 1% tropicamide and 10% phenylephrine eye drops. After mydriasis, the images were again captured with a Pictor Plus fundus camera and then with an IMAGEnet digital fundus camera following the department routine. All images were taken by an experienced technologist trained in the manual of the device, having already performed about 40 exams previously, in a pilot study.

The images obtained in the exams were classified as normal (without retinographic changes compatible with active diabetic retinopathy), presence of diabetic macular edema (DME), proliferative diabetic retinopathy (PDR), early, moderate, severe nonproliferative diabetic retinopathy (NPDR). and still unfeasible examination, either under mydriasis (Pictor M) or in the absence of it (Pictor NM). All images were graded by experienced retinal specialist based on retinographic findings (Table 1).

Additionally, for each level of the classification, the sensitivity, specificity and positive and negative predictive values were evaluated, considering that obtained by IMAGEnet (traditional digital retinography) as a reference standard. Values of $p \leq 0.05$ were considered significant.

## Results

Information from 100 eyes of 51 patients was analyzed. Of these, 11% of the images belonging to the Pictor NM group were considered unviable for fundus evaluation and were excluded from the analysis.

Table 2 apresents the classification by retinography technology. It can be noted that in the three forms of assessment, just a little over 31.0% of the eyes were considered to be normal.

Good agreement (k 0.707 to 0.847) was observed between the results of Pictor N and Pictor NM and IMAGEnet for the types 1, 2 and 3 classifications, and particularly for the normal classification,

**Table 1**
**Classification of retinographic images and their characteristics DR: diabetic retinopathy**

| CLASSIFICATION | CARACTERISTICS |
|---|---|
| NORMAL | Image shows no findings of DR. |
| DIABETIC MACULAR EDEMA | 1. Presence or not of retinal thickening less than 500 microns from center of fovea.<br>2. Presence or not of exudates at 500 microns from center of fovea with adjacent retinal thickening.<br>3. Retinal thickening measuring at least one disc diameter in size and less than one disc diameter at the center of the fovea. |
| PROLIFERATIVE DR | Presence of neovascularization in the optic disc or any retinal location and/or presence of vitreous hemorrhage. |
| INITIAL NON-PROLIFERATIVE DR | Presence of microaneurysms in small number. |
| MODERATE NO-NPROLIFERATIVE DR | Presence of focal infarct areas, cotton wool exudates and haemorrhagic spots in addition to microaneurysms. |
| SEVERE NON-PROLIFERATIVE DR | Presence of intraretinal hemorrhages in the four quadrants of the fundus, two with venous segmental dilation or one with intraretinal microvascular abnormalities. |

Adapted from American Academy of Ophthalmology. How to classify the diabetic eye [Internet]. [cited 2018 Nov 19]. Available from: https://www.aao.org/young-ophthalmologists/yo-info/article/how-to-classify-diabetic-eye. [14]
The images obtained were classified and further grouped into high risk (severe NPDR, PDR and DME) and low risk (unchanged examination, early and moderate NPDR) for screening for cases with higher potential for low visual acuity or blindness (Figure 1).
The time limit for image capture was 5 minutes per eye. If no images obtained were considered satisfactory for evaluation (showing shadows, reflections that occluded much of the fundus or other artifacts), they were described as unfeasible
The collected data was stored in a Microsoft Excel spreadsheet.
The agreement between the results of the different retinography technologies was evaluated via Kappa coefficient also in the Microsoft Excel spreadsheet, considering values from 0 to 0.19 as poor agreement; 0.2 to 0.39 as reasonable agreement; 0.4 to 0.59 as moderate agreement; 0.6 to 0.79 as strong agreement and 0.8 to 1.0 as excellent agreement. [15]

the Pictor NM showed a strong agreement. with IMAGEnet (k = 0.847, p <0.001), as shown in table 3.

Optimal concordance of the handheld fundus camera with IMAGEnet was also observed for high risk DR images, requiring priority referral (k = 0.817 and k = 0.840, respectively Pictor NM and Pictor M) and DME (k = 0.847 and k = 0.849, respectively). Pictor NM and Pictor M). (Table 3)

In addition, where DME was not observed (does not include normal eye), substantial agreement was found between handheld and IMAGEnet fundus cameras (k = 0.703 and k = 0.604 for Pictor NM and Pictor M, respectively).

In contrast, for the classification of eyes without priority (excluding eyes considered normal), the concordances of the IMAGEnet portable retinographs were moderate (k = 0.579 and k = 0.497 for Pictor NM and Pictor M, respectively).

In order to evaluate the accuracy of the results of handheld fundus cameras, the IMAGEnet classifications were considered as reference standard. Thus, Pictor NM has high (over 75%) sensitivities and specificities for all classifications (Table 4).

Similar pattern was observed for Pictor M. Excellent positive and negative predictive values were also observed for both Pictor NM and Pictor M (Table 4).

## Discussion

Telemedicine has been used as an important tool in the screening of various retinal pathologies, especially DR. [2,10,16] The

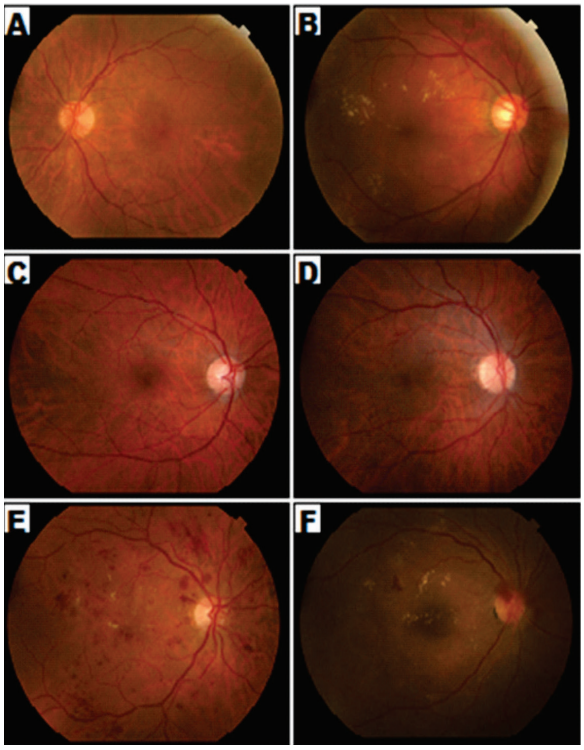


**Figure 1: A:** Normal; **B:** DME; **C:** Initial NPDR; **D:** Moderate NPDR; **E:** severe NPDR **F:** DME + PDR (images taken with IMAGEnet)

**Table 2**
**Distribution of classification by retinography technology**

| | Retinography Technologies | | |
|---|---|---|---|
| | IMAGENET | PICTOR NM | PICTOR M |
| ***Diabetic retinopathy classification - disaggregated*** | | | |
| Normal | 28/89 (31.5) | 30/89 (33.7) | 28/89 (31.5) |
| DME | 1/89 (1.1) | 8/89 (9.0) | 1/89 (1.1) |
| PDR | 3/89 (3.4) | 5/89 (5.6) | 5/89 (5.6) |
| Initial NPDR | 17/89 (19.1) | 22/89 (24.7) | 23/89 (25.8) |
| Moderate NPDR | 3/89 (3.4) | 2/89 (2.2) | 2/89 (2.2) |
| Severe NPDR | 7/89 (7.9) | 3/89 (3.4) | 2/89 (2.2) |
| DME + PDR | 6/89 (6.7) | 3/89 (3.4) | 1/89 (1.1) |
| DME + initial NPDR | 6/89 (6.7) | 6/89 (6.7) | 12/89 (13.5) |
| Moderate DME + NPDR | 10/89 (11.2) | 6/89 (6.7) | 10/89 (11.2) |
| DME + severe NPDR | 8/89 (9.0) | 4/89 (4.5) | 5/89 (5.6) |
| ***Rating 1*** | | | |
| Normal | 28/89 (31.5) | 30/89 (33.7) | 28/89 (31.5) |
| Priority | 41/89 (46.1) | 35/89 (39.3) | 36/89 (40.4) |
| Non priority | 20/89 (22.5) | 24/89 (27.0) | 25/89 (28.1) |
| ***Rating 2*** | | | |
| DME | 31/89 (34.8) | 27/89 (30.3) | 29/89 (32.6) |
| Non DME | 30/89 (33.7) | 32/89 (36.0) | 32/89 (36.0) |
| Normal | 28/89 (31.5) | 30/89 (33.7) | 28/89 (31.5) |
| ***Rating 3*** | | | |
| Normal | 28/89 (31.5) | 30/89 (33.7) | 28/89 (31.5) |
| Altered | 61/89 (68.5) | 59/89 (66.3) | 61/89 (68.5) |

Source: research data

use of digital retinographs under mydriasis to identify and classify diabetic retinopathy and referral of high-risk cases may contribute to the prevention of vision loss, due to their similar sensitivity and specificity indices. regarding the clinical examination. [17.18]

According to Mead and Davey, in a UK screening study, retinographic images taken in the presence and absence of mydriasis have very satisfactory sensitivity levels (excluding unviable images), around 86%, higher than recommended in screening for diabetic retinopathy in that country. [19]

The examinations can be performed by trained technicians and images sent to diagnostic centers where they will be classified by retinal specialists who will indicate the appropriate conduct,

**Table 3**
**Kappa coefficients for diabetic retinopathy classification**

| | Kappa (κ) | Standard Error | z | P value | Observed agreement% | Expected agreement% |
|---|---|---|---|---|---|---|
| ***Classification 1 (Priority, Non Priority, Normal)*** | | | | | | |
| IMAGENET x PICTOR NM | 0.759 | 0.075 | 10.07 | <0.001 | 84.3 | 34.8 |
| IMAGENET x PICTOR M | 0.707 | 0.075 | 9.38 | <0.001 | 80.9 | 34.8 |
| ***Classification 2 (DME, Non-DME, and Normal)*** | | | | | | |
| IMAGENET x PICTOR NM | 0.798 | 0.075 | 10.67 | <0.001 | 86.5 | 33.3 |
| IMAGENET x PICTOR M | 0.730 | 0.075 | 9.75 | <0.001 | 82.0 | 33.4 |
| ***Classification 3 (Normal and Altered)*** | | | | | | |
| IMAGENET x PICTOR NM | 0.847 | 0.106 | 8.00 | <0.001 | 93.3 | 56.0 |
| IMAGENET x PICTOR M | 0.739 | 0.106 | 6.98 | <0.001 | 88.8 | 56.9 |
| ***Priority*** | | | | | | |
| IMAGENET x PICTOR NM | 0.817 | 0.105 | 7.78 | <0.001 | 91.0 | 50.8 |
| IMAGENET x PICTOR M | 0.840 | 0.105 | 7.98 | <0.001 | 92.1 | 50.8 |
| ***Non Priority*** | | | | | | |
| IMAGENET x PICTOR NM | 0.579 | 0.105 | 5.50 | <0.001 | 84.3 | 62.7 |
| IMAGENET x PICTOR M | 0.497 | 0.105 | 4.74 | <0.001 | 80.9 | 62.1 |
| DME | | | | | | |
| IMAGENET x PICTOR NM | 0.847 | 0.105 | 8.03 | <0.001 | 93.3 | 56.0 |
| IMAGENET x PICTOR M | 0.849 | 0.106 | 8.02 | <0.001 | 93.3 | 55.3 |
| ***Non DME*** | | | | | | |
| IMAGENET x PICTOR NM | 0.703 | 0.106 | 6.64 | <0.001 | 86.5 | 54.6 |
| IMAGENET x PICTOR M | 0.604 | 0.106 | 5.71 | <0.001 | 82.0 | 54.6 |

be it periodic observation or immediate referral for treatment. This has been considered a good strategy for screening diabetic retinopathy in several countries.[10,17,20] However, the advent of portable retinography technologies may further broaden the scope of screeening programs.

The aim of this study was to determine the agreement of the Pictor Plus handheld fundus camera in the absence of drug mydriasis with traditional digital retinography and to evaluate its accuracy as a screening method for diabetic retinopathy, thus enabling its possible use in screening programs with special attention to high risk of blindness and visual impairment, thus favoring the priority referral of patients at risk to appropriate treatment.

We were able to demonstrate in our work that Pictor Plus, without the aid of mydriasis, was able to obtain satisfactory results for diabetic retinopathy screening compared to standard digital retinography.

**Table 4**
**Sensitivity, specificity, positive and negative predictive values and respective 95% confidence intervals**

| Classifications | Sensitivity (%) | Specificity (%) | Predictive Value | |
|---|---|---|---|---|
| | | | Positive | Negative |
| ***PICTOR NM*** | | | | |
| Normal | 92.9 (76.5 - 99.1) | 93.4 (84.1 - 98.2) | 86.7 (69.3 - 96.2) | 96.6 (88.3 - 99.6) |
| Priority | 82.9 (67.9 - 92.8) | 97.9 (88.9 - 99.9) | 97.1 (85.1 - 99.9) | 87.0 (75.1 - 94.6) |
| Non Priority | 75.0 (50.9 - 91.3) | 87.0 (76.7 - 93.9) | 62.5 (40.6 - 81.2) | 92.3 (83.0 - 97.5) |
| DME | 83.9 (66.3 - 94.5) | 98.3 (90.8 - 100.0) | 96.3 (81.0 - 99.9) | 91.9 (82.2 - 97.3) |
| Non DME | 83.3 (65.3 - 94.4) | 88.1 (77.1 - 95.1) | 78.1 (60.0 - 90.7) | 91.2 (80.7 - 97.1) |
| ***PICTOR M*** | | | | |
| Normal | 82.1 (63.1 - 93.9) | 91.8 (81.9 - 97.3) | 82.1 (63.1 - 93.9) | 91.8 (81.9 - 97.3) |
| Priority | 85.4 (70.8 - 94.4) | 97.9 (88.9 - 99.9) | 97.2 (85.5 - 99.9) | 88.7 (77.0 - 95.7) |
| Non Priority | 70.0 (45.7 - 88.1) | 84.1 (73.3 - 91.8) | 56.0 (34.9 - 75.6) | 90.6 (80.7 - 96.5) |
| DME | 87.1 (70.2 - 96.4) | 96.6 (88.1 - 99.6) | 93.1 (77.2 - 99.2) | 93.3 (83.8 - 98.2) |
| Non DME | 76.7 (57.7 - 90.1) | 84.7 (73.0 - 92.8) | 71.9 (53.3 - 86.3) | 87.7 (76.3 - 94.9) |

In our study, it was possible to determine agreement between IMAGEnet and Pictor NM in discriminating normal patients with some degree of diabetic retinopathy, evidenced both by Kappa coefficient and in the high sensitivity and specificity of Pictor NM and Pictor M. Both technologies were also evidenced in the identification of high risk conditions (patients with severe nonproliferative diabetic retinopathy, diabetic macular edema and proliferative diabetic retinopathy).

Although the ETDRS protocol is considered the gold standard for the classification of diabetic retinopathy, it requires, in its implementation, greater knowledge and technical skill on the part of the operator, as well as the need to obtain images of 7 different fundus fields that would require a much longer time. [21]

Thus, we chose a more simplified classification, since the clinical objective would be to track down the critically ill patient, facilitating their access to the specialized service where a more detailed assessment of the patient's ophthalmic and clinical picture would be performed.

Our study showed, in agreement with the findings of Zhang and colleagues using the same technology, that the strategy of obtaining only a representative fundus image captured by Pictor Plus was able to discriminate between high-risk and low-risk patients, similar to that found. when non-portable non-mydriatic retinographs were used.[13] This strategy, besides being efficient for the purpose of screening, allows greater comfort and convenience to the diabetic patient, noting the absence of risks inherent to the use of mydriatic eye drops, allowing its implementation in places. lack of medical-ophthalmic care.

Portable retinal scans, even based on smartphones, have been shown to be easy-to-use tools for documenting the optic nerve and retina in situations where ophthalmic services are lacking. Despite the lower cost compared to Pictor Plus, most of them require pupillary dilation to acquire better quality images, as well as the need for validation of these emerging technologies so that they can be definitively deployed in broader teleophthalmology services. [12,22–24]

Despite its portability and lower cost one of the limitations of the device is its inability to capture images of the peripheral retina. However, in the present study, this fact did not translate into a decrease in the efficiency in detecting the alterations of high risk diabetic retinopathy, in particular diabetic maculopathy.

Performing portable retinography in the absence of mydriasis requires specialized training in order to obtain artifact-free images. Images were obtained and classified by experienced retina specialist technologist and ophthalmologist. This fact may have been determinant of the high level of agreement found between the studied technologies, besides the high sensitivity and specificity found in our sample. This aspect has been considered relevant as shown by Mudiyanselage and contributors in a recent and extensive systematic review on the subject. [25]

Our study had some limitations: the patients' pupillary diameter, age, as well as the presence or absence of cataract or other opacity of means were not determined, impairing a possible inference about the causes of unfeasible examinations (11% of the total). We did not analyze "red-free" images, which could have facilitated the classification of DR and raised the levels of agreement, sensitivity and specificity in the sample studied.

Nevertheless, the data found here, despite the limited sample, suggest the potential use of this technology in DR screening programs. Larger studies using this tool, coupled with specialized training of non-medical personnel to capture good quality images, may contribute to the fight against blindness and visual impairment in DR patients.

## Conclusion

Pictor Plus, in the absence of mydriasis, may be considered a useful tool for screening diabetic retinopathy compared to digital retinography under mydriasis. The use of this portable technology was able to identify patients at high risk of blindness and visual impairment with good sensitivity, favoring their referral for appropriate treatment.

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