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Saudi Journal of Ophthalmology

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ORIGINAL ARTICLE

Validation of patient symptom diary in acute posterior vitreous detachment

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Received 29 November 2010; revised 16 January 2011; accepted 22 January 2011 Available online 28 January 2011

KEYWORDS

Cohen's kappa; Inter-rater agreement statistics; Krippendorff's alpha; Posterior vitreous detachment; Symptom diary; Validation **Abstract** *Purpose:* The purpose of the study is to determine the validity of an original patient symptom diary in recording symptoms of posterior vitreous detachment (PVD). *Methods:* In this prospective cohort study, all patients presenting to the Hotel Dieu hospital emergency eye clinic between September 2008 and July 2009 diagnosed with acute PVD were offered

emergency eye clinic between September 2008 and July 2009 diagnosed with actile PVD were offered enrollment in the study. Patients were given the Queen's University posterior vitreous detachment patient diary at the initial visit after detailed eye examination, assessment of risk factors for retinal tears and detachments and a thorough explanation of their presenting complaints to record their symptoms related to PVD. At a random point during their six-week follow up, the patients were verbally asked the same questions being recorded in the diary over the phone. At the six-week follow up visit, the diaries were collected and the verbal results were compared with the written results. *Results:* There was substantial to near perfect agreement between the verbal questions and written

Results: There was substantial to near perfect agreement between the verbal questions and written answers. Cohen's kappa scores for flash frequency, flash intensity, floater frequency, and floater type were 0.6229, 0.6389, 0.6495, and 0.8603, respectively.

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Peer review under responsibility of King Saud University. doi:10.1016/j.sjopt.2011.01.007

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Conclusions: The Queen's University posterior vitreous detachment patient diary is a useful tool for investigating the quantity, quality and change in symptoms of patients presenting with PVD in the first 6 weeks of initial presentation.

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1. Introduction

A posterior vitreous detachment (PVD) is a common age-related condition among patients aged 45 years or older. The vitreous cortex separates from the internal limiting lamina layer of retina, producing symptoms of flashing lights and floaters (Hikichi and Trempe, 1994). The main complications associated with PVDs are retinal detachments or breaks either at the initial presentation or at a later date (Hollands et al., 2009; Novak and Welch, 1984). A recent study estimated that 1.8% of symptomatic PVDs progress to delayed retinal breaks (Coffee et al., 2007). Therefore, all patients presenting with flashes or floaters are typically examined using slit lamp biomicroscopy, indirect ophthalmoscopy, and scleral indentation both at initial presentation and during a six-week follow up visit. Due to the high incidence of PVDs in the general population and the requirement for multiple eye examinations, the management of PVDs consumes significant amounts of resources (van Overdam et al., 2001).

There is considerable interest in identifying symptoms that can predict the later development of retinal detachments or breaks so that follow up visits can be reserved for patients with serious risk factors. A recent paper by van Overdam et al. (2005) suggested that among patients with isolated PVDs, only those with multiple floaters, a curtain or cloud, vitreous hemorrhages, or retinal hemorrhages at initial presentation need to be rescheduled for a follow up visit. All other patients can be instructed to return if the number of floaters increases.

In order to determine whether a change in symptoms related to PVD can predict these potentially devastating complications of delayed retinal tear or detachment, and to use this information to determine who requires follow up for PVD, an accurate method of recording patient symptoms is required. The purpose of the study is to determine the validity of the Queen's University posterior vitreous detachment patient diary in recording symptoms of PVD.

2. Methods

2.1. Study population

Study design was approved by the Queen's University Research Ethics Review Board. The research followed the tenets of the declaration of Helsinki, and informed consent was obtained from all the patients after explanation of the nature and possible consequences of the study. All patients presenting to The Hotel Dieu hospital eye urgent eye clinic diagnosed with acute PVD were offered enrollment in the study. The urgent eye clinic is a tertiary care centre accepting urgent referrals from ophthalmologists, optometrists and medical doctors in Kingston and surrounding areas of southern Ontario. Patients found to have retinal breaks or retinal detachments at the initial examination were not eligible for enrollment. Further exclusion criteria of the study included prior diagnosis of ocular disease, patients under the age of 40 years of age or who had symptoms for longer than 1 month, and an identified history of blunt trauma to the eye or ocular surgery. Patients who had undergone uncomplicated phacoemulsification cataract extraction with in the bag IOL insertion without posterior capsular rupture or vitreous loss were included. Over the course of the study, two patients offered enrollment declined participation due to an inability to keep the six-week follow up visit.

All patients were questioned regarding risk factors for retinal tears and underwent a full ophthalmologic examination including slitlamp biomicroscopy, indirect ophthalmoscopy, and scleral indentation. Goldmann 3-mirror examination was used as required based on clinical examination. All patients were seen by a Queen's University ophthalmology resident as well as an attending staff physician, vitreoretinal fellow or vitreoretinal surgeon.

Upon completion of the examination and a thorough explanation of the nature of the diagnosis, enrollment and consent was obtained. Each patient was provided a Queen's University posterior vitreous detachment patient diary. Each diary contains an instructions sheet (Fig. 1) and a sample sheet of how to fill out the diary. Patient demographic information, visual acuity and risk factors for retinal tears were recorded in the diary. Symptoms from the first day were recorded by the examining physician with the patient's input to ensure proper understanding. Patients were asked to fill out the diary daily just before going to bed.

A total of 58 patients who were given a Queen's University posterior vitreous detachment patient diary were contacted by phone once on a randomly selected day between their initial presentation and their six-week follow up. One investigator called all the selected patients and asked the same questions found in the patient diary. The phone call took place between 6:00 pm and 7:00 pm. Patients were asked about their symptoms from that particular day only and were requested to answer the questions without looking at their diary. If patients could not recall the floater groups, they were allowed to look only at the instructions page (Fig. 1) where they could find images of the floater groups.

Every patient enrolled in the study received a follow up appointment at two and six weeks if serious risk factors were found on examination (retinal or vitreal hemorrhage, or pigment visualized in the anterior vitreous). An appointment at six weeks was given without the above risk factors. A full examination was repeated at each visit and the NEI VFQ-25 was repeated at the six-week follow up visit. At every visit, the patient was reminded to return to clinic immediately if they noticed increasing photopsias, an increased number of floaters, or a visual field defect. All diaries were collected at the six-week visit and then the verbal answers were compared with the written answers.

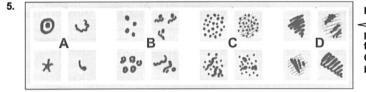
Instructions

This diary is an important component of your care for posterior vitreous detachment (PVD). Following these instructions carefully and filling out the diary on a daily basis will give your ophthalmologist insight into your condition and allow him or her to offer you the best possible care.

This diary is meant to be filled out at the end of EVERY day until your follow-up appointment for PVD. Take a few minutes with the diary each evening to recollect and record your experiences during the day.

- First, find the correct day of the week. If it is a new week, circle the week number at the top of the page. Record the date of every Monday.
- Ask yourself the question "how often did I notice or experience FLASHES today?" The first grey box for each day has several options: every minute; every hour; every 6 hours; every 18 hours; and never. Circle ONE option that best describes how regularly you noticed flashes.
- 3. Next, ask yourself "how intense were the flashes I noticed today?" To help with this, imagine a scale of 1 to 10 where 1 represents barely perceivable flashes of light and 10 represents flashes so brilliant they seem blinding. Circle the ONE number that you would rate the intensity of your flashes.
- 4. For floaters, ask yourself the same question you first asked about flashes: "how often did I notice or experience floaters today?" Circle ONE of the responses in the grey box.





Look at the legend of floaters provided (to the left). Pick the group of pictures that most accurately represents the floaters you experienced throughout the day. Circle the ONE letter of the group in the grey box.

- 6. Record any other visual symptoms or experiences on the line provided.
- 7. If you need help, use the example on the next page to help you fill out the diary. Someone will help you fill out the first day while in the clinic. Make sure you bring your completed diary with you to your 6-week follow-up.

Figure 1 Instructions sheet outlining the procedure for recording symptoms of posterior vitreous detachment with the Queen's University posterior vitreous detachment patient diary.

2.2. Instrument used

The PVD diary centers around the main symptoms of PVD including the frequency and quality of both photopsias and floaters, as well as any other symptoms the patient wishes to record (see Fig. 2a and b). This was requested to be completed each night before going to bed. The frequency of photopsias and floaters was recorded on a scale of having noticed each symptom individually every 18 h, 6 h, 1 h, 1 min, or never. The intensity of the photopsias was graded on a scale of 1 through 10, 1 meaning 'barely visible' and 10 meaning 'bright like the sun'.

The quality of floaters was recorded by using an established system developed by van Overdam et al. (2001, 2005). In this system, patients with isolated posterior vitreous detachment drew pictures of their floaters. The pictures were then grouped according to the number of floaters, with group A having 1–3 floaters, group B having 3–10 floaters, group C having >10 floaters, and group D representing a cloud or curtain (van Overdam et al., 2001, 2005).

2.3. Statistical analysis

Two inter-rater statistical measures – the Cohen's kappa (kappa) score and the Krippendorff alpha (alpha) score – were used to quantify the level of agreement between the information gathered in the phone call and the data from the PVD diary. We chose the kappa statistic because it is commonly used in the medical literature, it has published categorizations of values, and it admits a simple statistical test to rule out chance agreement (Viera and Garret, 2005). Landis and Koch published arbitrary categorizations for kappa scores: < 0.00 is poor agreement, 0.0-0.20 is slight agreement, 0.21-0.40 is fair agreement, 0.41-0.60 is moderate agreement, 0.61-0.80 is substantial agreement, and 0.81-1.00 is almost perfect agreement (Landis and Koch, 1977).

The alpha score was also used because it is robust with regards to missing data and is designed for both nominal and ordinal data (Landis and Koch, 1977). Alpha scores range from 0 to 1, with 0 indicating no agreement and 1 indicating perfect agreement.

3. Results

A total of 58 patients were enrolled in the study and verbally questioned in regards to their patient diary recordings. The study included 39 females (mean age = 62 ± 6 years) and 19 males (mean age = 63 ± 7 years). There were 58 valid responses for flash frequency and floater frequency. There were 55 and 13 valid responses for floater group and flash intensity, respectively. The 45 patients who did not chose a valid response to the question about flash intensity reported never seeing a flash that day. Their response was coded as "not applicable".

Kappa scores for flash frequency, flash intensity, floater frequency, and floater group were 0.6229, 0.6389, 0.6495, and

Name:	Legend: Groups of floaters
Week: 1 / 2 / 3 / 4 / 5 / 6 / 7	0 3 : * 0 0 4 4
At the end of every day, please circle one response in each blue box (4 boxes each day) If you need help, please read the instructions at the beginning of the diary.	А В С D * • 80 % % % % %
Episodes of Flashes	Episodes of Floaters
Monday (Date:)	
Flashes every: never / 18 hrs / 6 hrs / hour / minute	Floaters every: never / 18 hrs / 6 hrs / hour / minute
On a scale of 1 to 10 (1 = barely noticed; 10 = blinding)	Most like group A / B / C / D of the legend
Average intensity: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10	Other symptoms:
Tuesday	
Flashes every: never / 18 hrs / 6 hrs / hour / minute	Floaters every: never / 18 hrs / 6 hrs / hour / minute
On a scale of 1 to 10 (1 = barely noticed; 10 = blinding)	Most like group A / B / C / D of the legend
Average intensity: 1/2/3/4/5/6/7/8/9/10	Other symptoms:
Wednesday	
Flashes every: never / 18 hrs / 6 hrs / hour / minute	Floaters every: never / 18 hrs / 6 hrs / hour / minute
On a scale of 1 to 10 (1 = barely noticed; 10 = blinding)	Most like group A / B / C / D of the legend
Average intensity: 1/2/3/4/5/6/7/8/9/10	Other symptoms:

Figure 2a Daily recording pages for PVD symptoms. These pages were duplicated to provide enough daily records to record symptoms until the follow up visit six weeks after the initial visit.

Episodes of Flashes	Episodes of Floaters
Thursday	
Flashes every: never / 18 hrs / 6 hrs / hour / minute	Floaters every: never / 18 hrs / 6 hrs / hour / minute
On a scale of 1 to 10 (1 = barely noticed; 10 = blinding)	Most like group A / B / C / D of the legend
Average intensity: 1/2/3/4/5/6/7/8/9/10	Other symptoms:
Friday	
Flashes every: never / 18 hrs / 6 hrs / hour / minute	Floaters every: never / 18 hrs / 6 hrs / hour / minute
On a scale of 1 to 10 (1 = barely noticed; 10 = blinding)	Most like group A / B / C / D of the legend
Average intensity: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10	Other symptoms:
Saturday	
Flashes every: never / 18 hrs / 6 hrs / hour / minute	Floaters every: never / 18 hrs / 6 hrs / hour / minute
On a scale of 1 to 10 (1 = barely noticed; 10 = blinding)	Most like group A / B / C / D of the legend
Average intensity: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10	Other symptoms:
Sunday	
Flashes every: never / 18 hrs / 6 hrs / hour / minute	Floaters every: never / 18 hrs / 6 hrs / hour / minute
On a scale of 1 to 10 (1 = barely noticed; 10 = blinding)	Most like group A / B / C / D of the legend
Average intensity: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10	Other symptoms:

Figure 2b Daily recording pages for PVD symptoms. These pages were duplicated to provide enough daily records to record symptoms until the follow up visit six weeks after the initial visit.

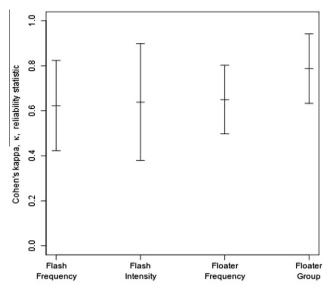


Figure 3 Kappa score of agreement between data gathered from phone call and patient diary for four symptoms: flash frequency, flash intensity, floater frequency, and floater group. Error bars represent 95% confidence intervals. A higher score denotes greater agreement.

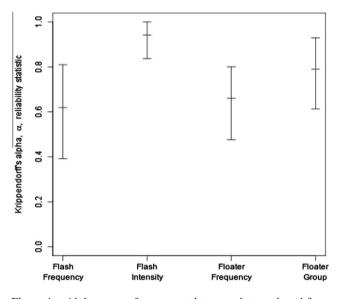


Figure 4 Alpha score of agreement between data gathered from phone call and patient diary for four symptoms: flash frequency, flash intensity, floater frequency, and floater group. Error bars represent 95% confidence intervals. A higher score denotes greater agreement.

0.8603, respectively (Fig. 3). Statistical tests found that the agreements reported by the kappa was higher than expected by chance (all *p*-values < 0.0001). The mean kappa score was 0.7094. The alpha scores for flash frequency, flash intensity, floater frequency, and floater group were 0.6201, 0.9422, 0.6510, and 0.7892, respectively (Fig. 4). The mean alpha score was 0.7526. None of the confidence intervals for alpha scores overlapped 0.

4. Discussion

PVD is a common ocular condition, representing a large component of presentations to eye care specialists. The need for a six-week follow up visit in uncomplicated patients with PVD has been questioned in the recent literature. Considering the diagnosis is associated with the possibility of serious complications, the follow up visits must not be taken lightly. The Queen's University posterior vitreous detachment patient diary has been designed to record patient's symptoms in acute presentation of PVD and can be utilized to determine whether symptoms are predictive of the consequences associated with posterior vitreous detachments in future studies.

Statistically, all kappa scores fall into the category of substantial agreement or near perfect agreement as described by Landis and Koch (Landis and Koch, 1977). For floater frequency and flash frequency, alpha and kappa scores are very similar confirming substantial agreement. The alpha score for flash intensity is markedly higher than the kappa score. Flash intensity was an ordinal variable which was coded as "not applicable" if the patient reported never seeing flashes that day. The alpha score is more robust to entries of "not applicable" than kappa and so it is likely to be a more accurate estimate of agreement than the kappa score.

One limitation of this study is that even though patients were instructed to not look at their diary while reporting their symptoms on the phone, a few individuals may still have recalled their verbal responses when they filled out the diary that night. Moreover, for some patients, there may have been a potential time lapse between the time of the phone call and the time the patient filled out the diary. However, the possible negative effects on our robust measures of correlation are likely minimal.

5. Conclusion

This study details an original patient diary useful for quantitatively and qualitatively recording the main symptoms of PVD, including photopsias and vitreous floaters. Our study supports our excellent experience with the diary, displaying substantial agreement between patients' verbal responses over the phone and the written record of their PVD symptoms. Informally speaking, no patient found the diary overly complicated or burdensome. The diary is a useful tool for investigating the symptoms of PVD within the first six weeks after initial presentation and likely beyond.

Disclosures

There are no conflicts of interest to report. The contents of this manuscript were presented in poster format during the 2010 annual Canadian Society for Epidemiology and Biostatistics National Students' Conference in Kingston, Ontario, Canada.

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