Healing criteria: how should be defined an episode of benign paroxistic positional vertigo of posterior semicircular canal´s resolution? Prospective observational study

Running title: Healing criteria for the resolution of benign paroxysmal positional vertigo of the posterior canal.

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Abstract

Objectives: To compare the outcome of the Epley maneuver (EM) in benign paroxysmal positional vertigo of the posterior canal (CSP-BPPV) depending on the definition used for recovery.

Design: Multicenter observational prospective study.

Setting: Otoneurology Units of five tertiary reference hospitals.

Participants: All patients presenting with unilateral CSP-BPPV assisted for one-year period.

Exclusion criteria: Spontaneous nystagmus, positive McClure-Pagnini maneuver, positive bilateral Dix-Hallpike maneuver (DHM), positive DHM for vertigo but negative for nystagmus and atypical nystagmus.

Main outcome measures: Response to EM was measured after 7 days in three different outcomes: disappearance of nystagmus during the DHM in the follow-up visit, disappearance of vertigo during the DHM and general status during daily life activities.

Results: 234 patients were recruited (68 male / 166 female, mean age 62 years). After the EM, nystagmus disappeared in 67% of them, vertigo in 54% and 36% were asymptomatic in their daily life. These outcomes were strongly correlated, but they were not concordant in all cases; only the 26% of patients met all of them. The healing process follows the next sequence: negativization of positional nystagmus, then disappearance of positional vertigo and, finally, improvement of general status during daily life activities.

Conclusion: Nowadays, healing criteria for the resolution of CSP-BPPV have not been defined yet. In absence of other otoneurological disorders, the next resolution criterion is proposed: absence of nystagmus and absence of vertigo during control DHM and disappearance of symptoms during daily life activities.

Keywords: BPPV, Epley maneuver, nystagmus, positional nystagmus, positional vertigo.

Introduction

Benign paroxysmal positional vertigo (BPPV) is the most frequent vestibular disorder, with a prevalence between 10.7 and 64 cases per 100,000 people[1,2]. It is the leading cause of patient referral to the Otoneurology clinics[3], where it generates 20-30% of visits[4–7]. Most cases affects to posterior semicircular canal (PSC).

PSC-BPPV is diagnosed through the Dix-Hallpike maneuver (DHM) and the treatment consists in a particle-repositioning maneuver, which promotes the ampullofugal movement of otoconia into the utricle. The most frequently used repositioning maneuver in PSC-BPPV is the Epley Maneuver (EM)[14], which have a variable success rate, described between 75-89%[14].

The diagnostic criteria for BPPV have been defined by the Bárány Society[15]. However, standardized criteria for recovery from a BPPV episode have not been specifically established. Therefore there is not a unanimous definition of episode recovery among authors: recovery is usually defined as the disappearance of nystagmus on the control DHM, but disappearance of vertigo during DHM and changes in general status (GS) in daily life activities reported by patients at follow-up are also important results. Often resolution criteria are usually not specified or there is no consensus between authors among CSP-PBBV literature[21-28].

The objective of our study was to compare the outcome of the EM in patients with unilateral PSC-BPPV according to the definition used for episode recovery and discuss in detail what should be the most suitable criterion to consider that a patient has recovered from an episode.

Material and method

Ethical Considerations. The study received the relevant approval from all participant hospitals Care Ethics Committee. Prior to inclusion in the study, each patient was duly informed and their signed informed consent obtained. Personal data were appropriately treated.

Sample and design. All patients presenting with unilateral PSC-BPPV of the Otoneurology Units of five tertiary reference hospitals were prospectively recruited for a one-year period. Table 1 shows inclusion and exclusion criteria. Medical history and a complete systematic otoneurological examination were recorded for all included patients, including a DHM with naked eyes. After informed consent, patients underwent the EM and were recommended to sleep with 30º elevated head of bed that night. They were appointed for a follow-up visit 7 days later where response to the EM was documented regarding to nystagmus, positional vertigo and daily life general status:

- Nystagmus on the DHM at the follow-up visit, expressed as a dichotomous variable (nystagmus is present or not) and an ordinal variable (no nystagmus, mild (<5 nystagmus), moderate (>5 nystagmus, evident ocular movement) or intense nystagmus (>5 nystagmus, severe ocular movement)).

- Positional vertigo triggered by the DHM at the follow-up visit, expressed as a dichotomous variable (symptoms present or not) and an ordinal variable-none, slight (lower intensity than habitual episodes), mild (similar to episodes) or severe (worse than episodes).

- General status during daily life activities as reported by patients at the follow-up visit, which was evaluated through the following question: "In general, how does the patient report they feel one week after the EM?" expressed through an ordinal variable with four possible answers (asymptomatic, better, the same, worse) and a dichotomous variable (asymptomatic or symptomatic).

Statistical analysis. The concordance degree between categorical qualitative outcome variables was measured with the Kappa (κ) concordance index, assuming moderate concordance strength for κ>0.41. Differences between ordinal qualitative variables were evaluated with the Kruskal-Wallis (K-W) test for multiple comparisons. Hypothesis contrast was considered significant for p values lower than 0.05.

Results

Patients were recruited between April 1st 2015 and March 31st 2016. During that period, the data from a total of 688 potential participants were collected. Five of them were excluded due to spontaneous nystagmus and 13 because they presented a Pagnini-McClure maneuver outcome compatible with horizontal semicircular canal involvement; 312 patients were excluded because they did not present nystagmus in any of the DHM; 58 because they presented nystagmus in both maneuvers and 31 because they presented nystagmus, which was not compatible with canalithiasic involvement of the posterior canal, either due to atypical morphology (17 patients) or duration longer than 60 seconds (14 patients). One patient did not give consent for the EM and was consequently excluded. Finally, 25 patients were excluded in follow-up because they failed to attend the appointed visit and 9 patients because they closed their eyes during the DHM so that the presence or absence of nystagmus could not be observed.

The final sample included 234 patients: 68 men and 166 women of 62 years old on average. In the follow-up visit 36% of patients reported being asymptomatic in their daily life. After the DHM, absence of nystagmus was found for 67% and absence of vertigo for 54% of patients. However, when fulfillment of several conditions was considered to define recovery from the BPPV episode, absence of nystagmus and vertigo in the DHM was found for 48% of patients while absence of symptoms in daily life, vertigo and nystagmus in the DHM was found only for 26% of them.

Figure 1 summarizes the relationships among the outcome variables: GS was related to the appearance of nystagmus and vertigo during the follow-up DHM, so that the proportion of patients with positional vertigo and nystagmus on the DHM was higher among those reporting symptoms in daily life at the follow-up visit and vice versa (figure 1 A and B). Appearance of positional nystagmus and vertigo on the DHM were also positively related (figure 1, C).

Although differences were statistically significant, concordance did not reach 100%: there was a clinically significant group of patients, where such associations were not observed: 18% of asymptomatic patients presented positional nystagmus (figure 1A *central*); 15% of patients with positional vertigo on the DHM reported to be asymptomatic in daily life (figure 1B right); 10% of patients without positional vertigo showed nystagmus (figure 1C *central*); 29% of patients without nystagmus experienced positional vertigo on the follow-up DHM (figure 1C right).

Changes in GS, intensity of nystagmus and positional vertigo triggered by the DHM at the follow-up visit were related in a way that asymptomatic patients showed absence or lower intensity of positional vertigo and nystagmus as compared with patients who still reported symptoms (K-W general status-nystagmus *p<0.001; GS-vertigo p= 0.003).* However, no significant differences were found in positional vertigo or nystagmus intensity among patients who reported symptoms (better, the same, worse).

Figure 2 shows the percentage of recovery from BPPV with its upper and lower limits (95% confidence interval) per GS group, according to the used diagnostic criterion (disappearance of vertigo –V– or nystagmus negativization –N-). In both cases, statistically significant differences were found between asymptomatic and symptomatic-better patients, whereas no differences were found for other groups (*K-W –N-, p= 0.003; K-W –V-, p< 0.001).* Also, recovery rate defined through disappearance of positional vertigo during control DHM or nystagmus negativization tend to behave similarly

excepting “worse” one, reducing its percentage of resolution in all groups, with a 21% lower percentage on average in posicional vertigo criteria, following the sequence of positional nystagmus negativization, then positional vertigo disappearance as GS group improves, and finally general status.

Discussion

Is the standardization of criteria for recovery of a BPPV episode necessary?

In practice, most otoneurologists assess the outcome of an EM on a visit scheduled some days after the maneuver, on the basis of patient-reported symptoms plus assessment of the disappearance of positional nystagmus and vertigo on the DHM. In case symptoms or nystagmus persist, maneuver repetition is considered. However, there is no consensus on recovery: authors such as Oh and Soto-Varela consider in their studies that the maneuver has been successful when patient-reported vertiginous symptoms disappear and the DHM becomes negative, without specifying whether it should be negative for symptoms during daily life or nystagmus during DHM[21,22]. Babac considers success for negative DHM also without specifying whether if negative maneuver is referred to symptoms or just nystagmus[23]; Oliveira for negative nystagmus regardless of patient-reported symptoms or positional vertigo on the DHM[24]. Most authors, like Pérez-Fernández, Pérez and López-Escámez, consider recovery from an episode when no positional nystagmus or vertigo on the DHM[25–28] is observed, without taking into account the persistence of symptoms in daily life. In other studies, resolution criteria is not specifically defined, assuming that negativization of nystagmus is used.

From a research point of view, variability in the time elapsed between the EM and the follow-up visit, as well as the heterogeneity in the recovery criteria hinder the comparison of results from different patients or therapeutic interventions. From a clinical point of view, a recovery criterion based only on nystagmus disappearance could sometimes lead to persistence of low otolith load BPPV. Unification and systematization of the recovery criteria and the time between the EM and the follow-up DHM could enhance healthcare aimed at preventing persistence and recurrence. From a research point of view, systematization would additionally facilitate the comparison of results from different patients, researchers and therapeutic actions.

Why do symptoms during daily life or positional vertigo could persist after nystagmus negativization?

Several authors have documented persistence of vestibular symptoms after nystagmus negativization in patients with BPPV treated with repositioning maneuvers[25,29,30]. Seok *et al* conducted a prospective study on 49 patients with BPPV of all the semicircular canals, who had been treated with repositioning maneuvers; after vertigo and nystagmus disappearance on the control DHM, persistence of symptoms such as continuous or intermittent dizziness was recorded; 61% of patients showed symptoms after the DHM negativization (similar to the 57% in our series, figure 1A) with an average duration of 16±18 days; all of them were asymptomatic three months afterwards[25].

In our series, the GS was related to the appearance of nystagmus on the follow-up DHM and the intensity of positional nystagmus and vertigo were related to one another and to the GS, so that worse GS corresponded to more intense positional vertigo and nystagmus. However, concordance did not reach 100%: a significant group of patients reported symptoms during daily life and/or positional vertigo even after positional nystagmus had become negative (figure 1).

There are four possible reasons that had been postulated for symptom persistence after the EM in nystagmus-negative control DHM:

1) Since the BPPV is a disorder related to the utricle macula, which is in charge of spatial orientation, alterations at this level due to particle movement could produce transient symptoms[31,32].

2) The occurrence of a non-identified concomitant vestibular disorder: a study demonstrated that the persistence of unspecific dizziness was significantly higher among BPPV patients with other concomitant central or peripheral vestibular disorders[33].

3) Recovery delay could be due to prolonged central adaptation time after particle repositioning[25].

4) The most supported hypothesis attributes symptoms to otoconial particles remaining in the semicircular canal, which although not enough to produce positional nystagmus and/or vertigo, but enough to produce mild symptoms[17]. Such canalithiasis without positional nystagmus may be controversial but it has been proposed in several studies, based on the evidence of patients with a typical BPPV history and negative DHM, who show clinical improvement after repositioning maneuvers[18–20,34]. In fact, it was first recognized by Haynes and later by other authors under the name of subjective BPPV[18,19,35] and it is currently included in the consensus document of the Bárány Society[15] and

recognized by the Committee for Standards in Diagnosis of the Japan Society for Equilibrium Research[36] in the category of *probable VPPB*, assuming that it is conceivable that the number of otoconia in the PSC in such cases may be enough to evocate subjective symptoms though not to stimulate the vestibule-ocular reflex[16,17] and produce the typical positional nystagmus. The same reasoning can be applied when the response to the EM of a patient with BPPV is evaluated: reduction of the otolithic load first leads to disappearance of nystagmus, followed by positional vertigo, while the capacity to produce milder symptoms persists for longer time. Accordingly, figure 2 shows that the recovery rate defined through disappearance of vertigo tends to behave similarly to recovery defined through nystagmus negativization, although with an average 21% lower values (minimum 1.2 in "asymptomatic", maximum 50 in "worse"), following the sequence: disappearance of positional nystagmus, then positional vertigo and finally general symptoms.

How to observe the eyes during the DHM?

The detection of nystagmus is conditioned to the method of observation of the eyes. Videonystagmography (VNG) and Frenzel glasses may detect nystagmus that could not be detected with naked eye; therefore, these tools offer a higher sensibility for VPPB diagnosis. According to the Consensus document of the Committee for the Classification of Vestibular Disorders of the Bárány Society[15], <<VNG or Frenzel glasses are helpful to detect positional nystagmus, particularly if it is weak or momentary; however, in most cases nystagmus can be seen clinically without any special equipment>>. In our sample, these observation method could explain why some patients with symptomatic GS and vertigo in DHM did not show nystagmus. Despite of this limitation, our data indicates that the disappearance of vertigo in DHM-follow up visit occurs before general symptoms. Also, since DHM was positive for nystagmus in all patients to make the diagnosis, our data show as well that nystagmus negativization (or at least intensity reduction if VNG or Frenzel glasses had been used) take place before vertigo in DHM and GS disappearance in most patients (figure 2). Under these considerations we should repeat EM in patients with symptoms during daily life or vertigo in DHM even though nystagmus negativization in DHM.

When to carry out the follow-up?

The period of time between the EM and the subsequent follow-up also varies widely among studies. Although some authors examine the patients 24-72 hours after the maneuver[25,26], most physicians do it 8-10 days afterwards[24,27]. On the one hand, some authors have considered examining the patients on the same day, after a short rest[24], and to repeat the EM if necessary[37]: this method is based on the idea that repeated EMs per session in a few sessions are more effective than a single EM per session, over several sessions[38]. However, was found that repeating the EM in the same session is no more efficient and may even worsen the symptoms perceived in the following five days[37]. It was also found that re-evaluating the EM outcome by immediately repeating the DHM is not advisable due to the so-called fatigability of nystagmus phenomenon, which may lead to false negative results[26,39]. On the other hand, delayed follow-up may lead to mistake spontaneous recovery for recovery due to the intervention. Therefore, a one-week period seems appropriate to evaluate EM outcomes both from the clinical and research points of view. However, there is no consensus between authors and controlled studies specifically designed to study this issue are necessary.

Proposed criteria for recovery from a BPPV episode

Although the diagnosis and treatment criteria for this disorder are well defined[15], the criteria to consider the recovery of a BPPV episode have not been systematically established. According to the data in our study, the plausibility of the otolithic load hypothesis[16,17] and the evidences of clinical improvement – subjective and of positional vertigo – after a repositioning maneuver in patients with BPPV symptoms without positional nystagmus[18–20], it seems reasonable to evaluate not only nystagmus disappearance but also positional vertigo and patient-reported symptoms-changing during daily life to consider that a BPPV episode is solved. Therefore, provided that concomitant vestibular disorders have been ruled out, the following criteria for recovery from a BPPV episode are proposed: disappearance of positional nystagmus and vertigo on the follow-up DHM and absence of symptoms during daily life. According to these criteria, recovery from posterior semicircular canal BPPV one week after an EM reached only a 26%. Systematization of these criteria would probably reduce persistences and recurrences and, from a research point of view, it would improve result comparability.

Conclusions

The GS and the intensity of positional vertigo and nystagmus on the follow-up DHM are related, although concordance does not reach 100%. Provided that other otoneurological disorders have been ruled out, disappearance of positional nystagmus and vertigo on the follow-up DHM and absence of symptoms during daily life are proposed as recovery criteria for of a BPPV episode.

Disclosure Statement

Authors declare not having any conflict of interest or funding.

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Tables

Tabla 1. Inclusion and exclusion criteria

Figure legends

Figure 1. Relationship between outcome variables on follow-up 7 days after the EM. Concordance between patient-reported GS and appearance of nystagmus on the control DHM (A): asymptomatic patients showed lower nystagmus proportion than symptomatic ones (18% vs 41%, *A central*); proportion of symptomatic patients was larger among patients with nystagmus than among patients without it (81% vs 57%, *A right*); patients with nystagmus presented positional vertigo in a higher proportion (83%) than patients without nystagmus (29%). Two patients were not able to evaluate vertigo during control –DHM. GS: general status during daily life, Asx: asymptomatic, Sx: symptomatic, T: total, N: negative, P: positive, DHM: Dix-Hallpike Manouver.

Figure 2. Resolution´s percentage by general status during daily life (GS) depending of resolution´s criteria: nystagmus negativization (N) or positional vertigo (V) presence trigerred by the control DHM, statiscally significant for both criteria. Resolution´s percentage falls dramatically between "asymptomatic" and "better" groups, beying this reduction less marked between next GS´s cathegories. Re-

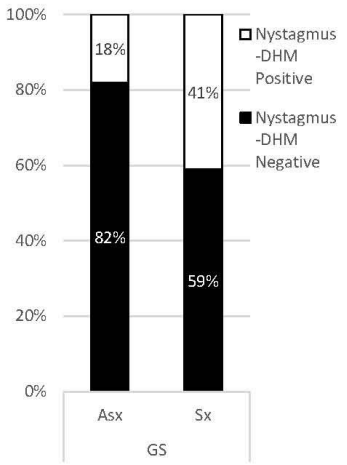
covery rate tend to behave similarly although with an average 21% lower percentage in posicional vertigo criteria (percentage difference between both criteria: 1.2% in “asymptomatic”, 12% in “better”, 14% in “the same” and 50% in “worse”).

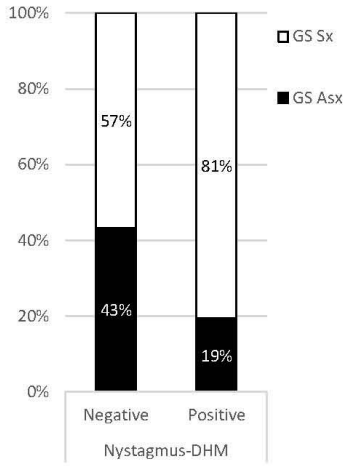
Inclusion criteria	Exclusion criteria
a) Complaining of short vértigo episodes triggered by head movements b) Instability and history of vertigo compatible with BPPV c) PSC-BPPV incidentally diagnosed during examination	a) Spontaneous nystagmus b) Positive McClure-Pagnini test c) Bilateral positive DHM, atypical nystagmus in DHM, posicional vertigo without nystagmus in HM d) Patients not giving consent to the EM

A

		GS		
		Asx	Sx	T
Nystagmus-DHM	N	68	89	157
	P	15	62	77
Total		83	151	234

κ=0.2, p<0.0001

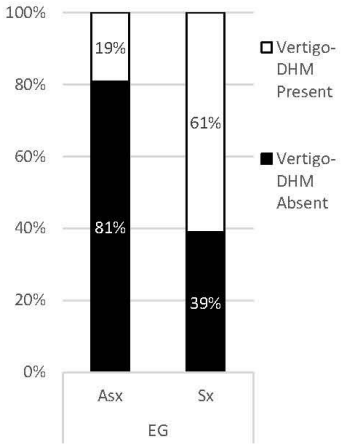


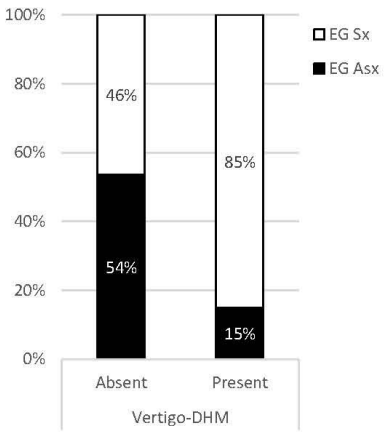


B

		GS		T
		Asx	Sx	
Vertigo-DHM	Absent	67	58	125
	Present	16	91	107
Total		83	149	232

κ=0.4, p<0.0001

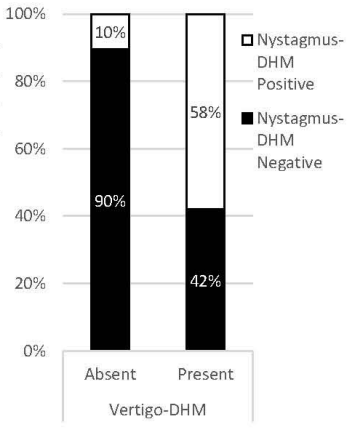


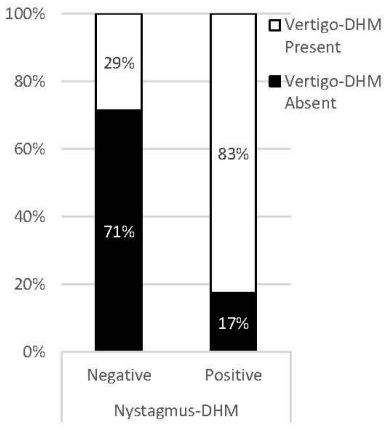


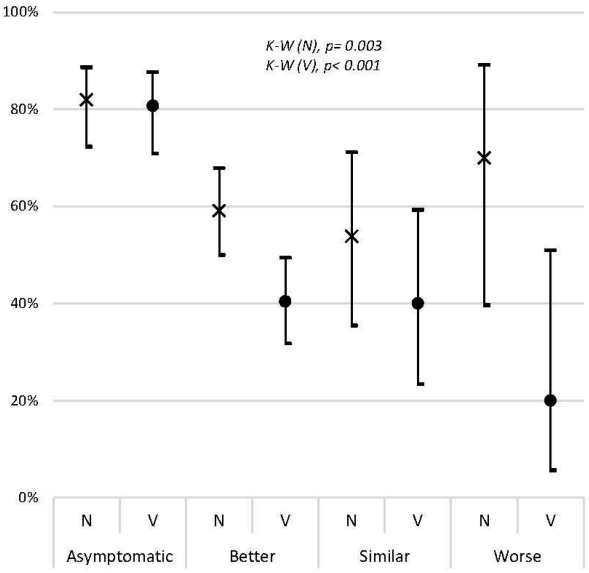
C

		Vertigo-DHM		T
		Absent	Present	
Nystagmus-DHM	N	112	45	157
	P	13	62	75
Total		125	107	232

κ=0.5, p<0.0001







_ Upper limit; confidence interval 95%
x Resolution percentage defined by nystagmus negativization
• Resolution percetage defined by vertigo abscence in control DHM
- Lower limit; confidence interval 95%