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Double-blind randomized trial on the efficacy in a short-time follow-up of the "Quick Liberatory Rotation" maneuver in treating posterior canal BPPV

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Abstract

This double-blind randomized study evaluates the efficiency of the Quick Liberatory Rotation maneuver (QLR) in solving signs and symptoms of Posterior Canal BPPV in a short time follow-up comparing the efficiency of QLR vs. a sham maneuver ("Fake QLR").The study was performed at an input-output tertiary center for balance disorders. From January to September 2012, 200 patients with signs and symptoms of Posterior Canal BPPV respected the inclusion criteria in the study. The diagnosis was based on observation with binocular infrared videonystagmoscopy of the paroxysmal torsional and upbeat nystagmus evoked through the Dix-Hallpike test (DHT). Patients were divided in two groups, 100 in the group treated by QLR (Group 1) and 100 in the control group treated by "Fake QLR" (Group 2). Before the treatment, they self-evaluated a Visual Analogue Score on their vertiginous complaints (V-VAS). Patients were controlled one hour after the treatment by a blinded examiner about the first phase of the study through DHT, the Straight head-hanging positioning test and the Head Roll test in supine position and assessed again with V-VAS. Patients with a persisting positive Dix- Hallpike test were subsequently treated through QLR.

The main outcome measure is the number of patients treated through QLR or "Fake QLR" with a negative DHT one hour after the first treatment. At the post-procedure check, 79 patients from Group 1 presented a negative DHT with little or no subjective symptoms, whereas all the patients of Group 2 presented persistence of a positive DHT. The presence of the secondary nystagmus during QLR ("liberatory" nystagmus) was significantly correlated with a negative DHT at the post-procedure control. In Group 1 pre- and post-treatment V-VAS differences were significant; post-treatment V-VAS differences were significant in Group 1 vs. Group 2. In a short time follow-up QLR is an effective treatment for Posterior Canal BPPV when compared to a sham maneuver.

Running title: Double-blind randomized trial on QLR

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Introduction.

Benign Paroxysmal Positional Vertigo (BPPV) is the most common vertiginous syndrome.

Adler [1] first described it; Barany reported a case citing his assistant Carlefors [2]. The concept of positional vertigo was finally introduced into the clinical practice by Dix and Hallpike: *"Two things are quite clear. Firstly, the pathological process, wherever or whatever it is, is essentially a benign or self-limiting one. Secondly, the lesion, whatever its nature, is limited to the vestibular apparatus and here the term "vestibular" is used in its widest sense, to include the labyrinth, vestibular nerve and its central connexions"*[3].

The pathogenetic mechanism was postulated by Shucknecht [4] who first described the presence of basophile elements (otoliths) adhering to the cupula of the posterior semicircular canal in individuals who had suffered from this disease. From this observation the word "cupulolithiasis" was born.

In 1979 Hall[5] hypothesized the mechanism of "canalolithiasis"; in 1985 Pagnini[6] and McClure[7] described, individually, lateral canal BPPV.

In 1980 Brandt and Daroff [8] introduced a therapeutic maneuver for BPPV based on repetitive lateral positioning of the body passing each time from the sitting position and Epley [9] formulated the Canalith Repositioning Procedure for Posterior Canal BPPV[10]; in 1988 Semont introduced his maneuver for Posterior Canal BPPV [11]; in 1989 Toupet [12] optimized the Semont Maneuver (SM).

Epley Maneuver (EM) and SM allow an effective treatment, sometimes in a single session, of Posterior Canal BPPV, thus affirming the concept of "liberatory therapy"; both EM and MS are widespread, since they are very effective, easy to perform, with minor side effects compared to therapeutic benefits.

Furthermore, in most cases BPPV evolves towards a spontaneous resolution in few days or weeks [13]; therefore, at least a part of the successes attributed to therapeutic maneuvers could be effects of the natural benign evolution of the disease.

In 1992 Guyat [14] introduced the concept of "Evidence Based Medicine" (EBM): any treatment should be evaluated on the basis of clinical evidence by the comparison with other treatments, with placebo and with no treatment regimen; clinical evidence is classified in a grade system as "levels of evidence" [15].

The Cochrane Collaboration, an international network which collaborates to help healthcare providers, policy-makers, patients, their advocates and carers, prepares the largest collection of records of randomized controlled trials in the world, published as part of *The Cochrane Library*.

Cochrane reviews stressed that EM and SM were often not analyzed through studies that reflect the EBM criteria for the validation of such treatments; the last

review [16] analyzed only five trials involving 292 participants for EM. It concludes that "*There is evidence that Epley maneuver is a safe, effective treatment for posterior canal BPPV, based on the results of five mostly small randomized controlled trials with relatively short follow-up*".

A recent double-blind randomized trial on short-term efficacy of SM [17], on the intentions of the authors, has brought the level of effectiveness rating of SM for posterior canalolithiasis to level B, defined as evidence based on "*randomized controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies*" [15].

In 2003 we proposed the "Quick Liberatory Rotation Maneuver" [18] (QLR) for treating posterior canal BPPV; QLR uses the speed of execution of SM but performs the movement in the frontal plane, as in EM (Fig.1). In a comparative study of efficacy in the short and medium term between QLR, Parnes maneuver[19] and SM, we demonstrated the equal clinical efficacy of these treatments [18]. Our maneuver, based on a quick rotation of the head and the body of the patient, has been replicated by other Authors: "hybrid approach through Gans maneuver" [20], "hybrid maneuver" [21]. Our original paper is not cited in these articles.

Objectives.

The aim of the present study is to evaluate through a controlled, randomized, double-blind study the short-term (one hour) efficacy of QLR compared with a "fake QLR" which does not cause a significant shift of otoliths from the position in which they are located after the Dix-Hallpike Test (DHT): therefore, the "fake-QLR" (Fig.2) can be considered a sham-maneuver with a possible placebo effect.

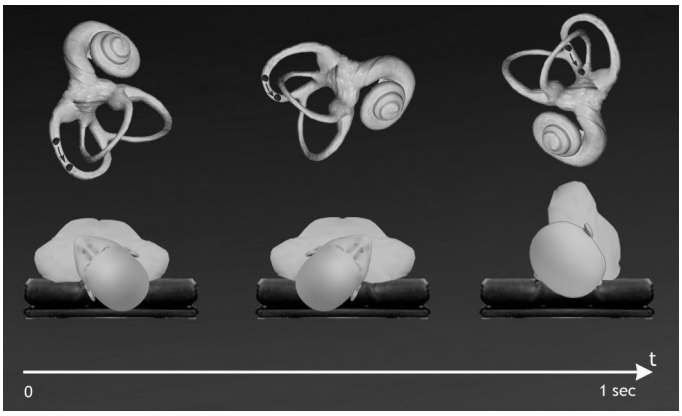

Fig. 1. The "Quick Liberatory Rotation" maneuver for left posterior canal BPPV

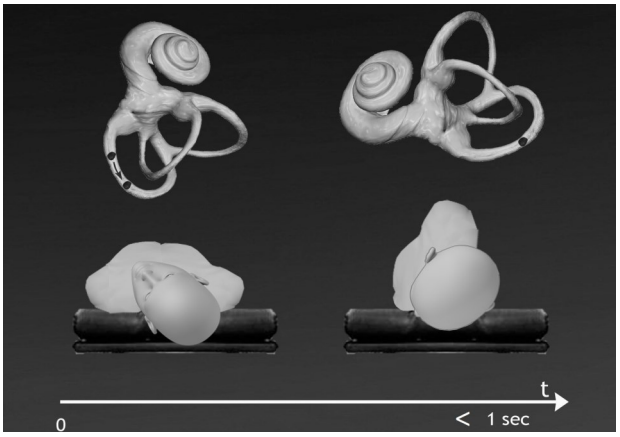

Fig. 2. The "Fake-QLR" maneuver for left posterior canal BPPV

Outcomes were evaluated one hour after the treatment with QLR or "fake QLR":

1. Primary outcome: conversion of a positive DHT into a negative DHT by each maneuver.
2. Secondary outcome: reduction of subjective

complaints during the post-treatment DHT, assessed by a Visual Analogue Score of Vertigo (V-VAS), administered before and after treatments with QLR or "fake QLR".

In a putative way, the primary outcome at one hour evaluates the efficacy of both maneuvers in moving otoliths from the ampullary arm of the posterior semicircular canal into the utricle; the secondary outcome evaluates the reduction or disappearance of subjective symptoms on which, however, extra-labyrintine factors, such as anxiety or fear of vertigo, can also interfere. We included in the study only patients with no prior history of BPPV to minimize these factors, which may already be structured in patients with previous, similar experiences.

Patients and methods

From January to September 2012, 298 patients with a diagnosis of Posterior Canal BPPV were observed.

The clinical examination consisted of the execution of a "vestibular bed-side examination" in search of spontaneous nystagmus or nystagmus evoked by the Gaze test, Head Shaking test, Vibratory test, Hyperventilation test, DHT, Straight head-hanging positioning test and Head-Roll Test in supine position. Observations were carried out by infrared videonystagmoscopy. After the execution of the diagnostic tests and before the treatment, patients assessed their subjective symptoms through a 0 to 10 V-VAS, where 10 was the worst.

QLR was performed through a quick movement (about 1 second) of the head and of the body in a supine position from the diagnostic Dix-Hallpike position, triggering signs and symptoms of posterior canal BPPV, to a contralateral 45° nose-down position. After three minutes, the patient returned to the sitting position.

The sham maneuver (Fake-QLR) consisted of the rapid rotation of the head by about 90° in the supine position from the Dix-Hallpike position triggering signs and symptoms of posterior canal BPPV to an ipsilateral nose-down position in less than 1 second.

The inclusion criteria were:

1. Patients at least 18 years old;
2. No prior history of BPPV;
3. Absence of neurological diseases (eg. cancer, degenerative diseases, demyelinating diseases, recent stroke);
4. Acquisition of an informed consent about BPPV, its therapy and evolution, objectives and mode of the experimentation.

Out of 237 eligible patients, 200 patients were included in the study, whereas 37 refused the consent.

Patients were assigned to two groups based on a list of random numbers supplied by a Lehmer generator. To ensure double blinding, the randomization list was prepared by a Healthcare professional not involved in the clinical respects of the study (M.C.). Each group contained 100 patients; "Group 1" was treated with QLR

whereas "Group 2" (the control group) received the "Fake QLR" maneuver. Patients were not informed which treatment group they were in.

One hour after the treatment, patients were re-tested via DHT, Straight head-hanging positioning Test and Head-Roll Test and again assessed their subjective complaints through the V-VAS. The clinical testing was performed by a blinded examiner about the first phase of the examination.

As primary outcome, a negative post-treatment DHT was considered a successful treatment, and a positive post-treatment DHT was considered a failure. As secondary outcome, assessed through the V-VAS, a reduction in the intensity of the subjective vertigo was considered a successful treatment, whereas the absence of symptom reduction or its increase were considered a failure.

After the post-treatment check, patients were informed which maneuver they had received and, in cases of persisting positive DHT, QLR was performed.

All patients were invited to further check-ups every two days until a negative DHT was observed and thirty days after the last maneuver, but these points are not included in the objectives of the present study.

The statistical analysis was conducted using the Wilcoxon test and the Pearson's chi-square Test [22] via SPSS software.

Results 112 women and 88 men, mean age 58.7 ± 9.76 years, were included in the study.

There were no significant differences between the two groups in mean age (p = 0.2), gender (p = 0.569), involvement of the right or left posterior semicircular canal (p = 0.776) or associated diseases, in particular recent cranial trauma, diabetes, cardiovascular disease, autoimmune diseases. Idiopathic forms of BPPV accounted for 63% in Group 1, 69% in Group 2 (p = 0.37).

The mean pre-treatment V-VAS was 8.1 ± 0.92 in Group 1, 8.3 ± 0.91 in Group 2 (p = 0.65).

Clinical data are summarized in Table I.

Phase I: Therapy

Group 1. 100 patients were treated with a single session

TABLE I. Patients' clinical data

	M	F	Mean age	Recent cranial trauma	Diabetes	Cardiovascular diseases	Thyroiditis	R.P. BPPV	L.P. BPPV	Mean VAS of Vertigo
Group 1	42	58	58.4 ys	4	10	21	2	56	44	8.1 ±1.05
Group 2	46	54	58.9 ys.	5	8	18	0	54	46	8.3 ±1.10

Legend. M: Males; F: Females; R.P. BPPV: Right posterior canal BPPV; L.P. BPPV: Left posterior canal BPPV

VAS: Visual Analogue Score

of QLR. During the maneuver, in 78 cases a secondary nystagmus was observed with the same direction as the diagnostic one in either the nose-down position contralateral to the affected side (74 cases) or in coming back to the sitting position (4 cases).

Group 2. 100 patients were treated with the "fake QLR". During the maneuver, a secondary nystagmus in the final supine position (nose-down ipsilateral to the affected side) was never observed whereas in 82 cases in coming back to the sitting position a direction-reversed nystagmus was observed.

Patients of both groups were then placed in a sitting position, remaining still for one hour.

Phase II: Control

After one hour, all patients of both groups were tested again through DHT, the Straight head-hanging positioning Test and the Head-Roll Test by a "blinded examiner" and they assessed again their subjective complaints through V-VAS.

Group 1. 79 patients presented a negative DHT with little or no subjective symptoms. Among them, 73 were in the group of 78 patients (93.6%) who presented the secondary nystagmus during the execution of QLR and 6 were in the group of 22 patients who did not present it (27.3%). 21 patients presented a still positive DHT with acute vertiginous symptoms: during the execution of QLR 5 of these had presented the secondary nystagmus and 16 did not. No patient presented signs of either lateral or anterior canal BPPV.

The difference of the primary outcome among patients who presented or did not present the secondary nystagmus during QLR was statistically significant, in the sense that patients with secondary nystagmus resulted disease-free more frequently than those who did not (χ^2=45.49, df=1, p <0.0001) (Table II).

The post-treatment mean value of V-VAS in the whole Group 1 was of 3.5 ± 2.74, more precisely 2.2±1.1 for the 79 patients with negative Dix-Hallpike test, 8.3 ± 0.84 for the 21 patients with positive DHT; V-VAS differences were statistically significant before treatment vs. after treatment (p <0.0001) and, after the treatment, in patients with DHT still positive vs. those with negative control test (p <0.0001).

Group 2. All patients presented a persistent positive DHT

TABLE II. Correlations between secondary nystagmus and Dix-Hallpike control test in the Group 1

	Positive DHT	Negative DHT
Secondary nystagmus present	5/78 (6.4%)	73/78 (93.6%)
Secondary nystagmus absent	16/22 (72.7%)	6/22 (27.3%)
Overall	21/100	79/100

Legenda. DH: Dix-Hallpike test p<0.0001

and reported acute vertiginous symptoms. No patient presented signs of lateral or anterior canal BPPV. The mean value of V-VAS was 8 ± 1.07, not significantly different if compared to the pre-treatment value (p = 0.56).

Comparing the two groups, the primary outcome is statistically significant (χ^2=130.58, df=1, p <0.0001) in patients treated with QLR (DHT negative in 79%) vs. those treated with "Fake QLR" (no negative DHT); the post-treatment V-VAS difference is also significant (p <0.0001) in patients treated with QLR (3.5 ± 2.74) vs. those treated with "Fake QLR" (8 ± 1.07).

121 patients with vertigo and nystagmus still evoked by DHT, 21 in Group 1 and 100 in Group 2, were treated through QLR and controlled again two to three days after.

Discussion

BPPV is the most frequent vertiginous syndrome, with a life-time prevalence of 2.4% [23].

Conventional studies [18,23-29], meta-analyses [30-34], case-control studies [15] and cohort studies [35] have reported that treatment with SM, QLR, and EM are very effective in curing Posterior Canal BPPV with no significant side effects.

The literature emphasizes how early physical therapy reduces the costs related to the management of patients affected by BPPV [36], decreases relapses and reduces the fear of vertigo, which often influences the quality of life of dizzy patients [37].

The main objection made to the majority of the existing clinical trials is that they usually do not compare the treatment to other ones, to a placebo treatment or to a no treatment regimen. Although BPPV frequently tends to a spontaneous resolution [13], the success rate of therapeutic maneuvers is much higher than the effects of the spontaneous resolution[32]. Bhattacharyya et al. [15], analyzing few Class B studies (Randomized Clinical Trials), stated that posterior canal BPPV could be treated with EM, which presents good evidence of effectiveness when compared to control groups, both in the resolution of subjective symptoms and in negative DHT results. In a Cochrane review, Hilton[16] reported evidence of efficacy of EM in the treatment of BPPV in a short-term follow-up. A randomized multicenter double-blind study showed the short-term efficacy, from 1 to 24 hours, of SM compared with a sham maneuver, showing that the presence of "liberatory nystagmus" is a valid prognostic indicator of effectiveness [17].

Our double-blind randomized study tested the effectiveness of QLR vs a "fake QLR" in a very short term follow-up. It was our intention to show, via the primary outcome at one hour evaluated through a positive or a negative DHT, the capacity of each maneuver to clean the posterior semicircular canal from otoliths, whereas the secondary outcome valuates the connections between a negative or a positive DHT and the subjective complaints of patients.

In 79/100 patients, QLR was effective in converting DHT from positive to negative, whereas the "fake QLR" was never effective, with a statistical significance in the outcomes of the two procedures ($p < 0.0001$).

73 of 78 patients (93.6%) who presented the secondary nystagmus during QLR, and only 6 of the 22 patients (27.3%) who did not, presented a negative post-treatment DHT ($p < 0.0001$). This justifies the terminology of "liberatory nystagmus" to indicate a secondary nystagmus which has the same direction as that observed during the execution of the diagnostic test, in a similar way as shown in MS [17]. Moreover, QLR improved subjective symptoms, evaluated through V-VAS, when compared to the group treated through "fake QLR" in which, instead, subjective symptoms were largely unchanged.

After QLR, in 79% of cases we observed the resolution of signs and symptoms in a one-hour follow-up, a time frame in which a spontaneous resolution is extremely unlikely, especially considering that patients remained in a locked sitting position for the entire time between treatment and control.

Our study showed the effectiveness of QLR in solving signs and symptoms of Posterior Canal BPPV in a high rate of cases when compared to a sham maneuver: it is our belief that the study provides a Class B evidence of efficiency of QLR in treating Posterior Canal BPPV.

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