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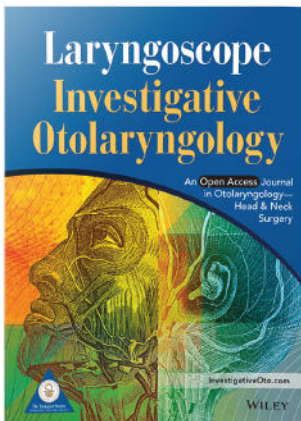


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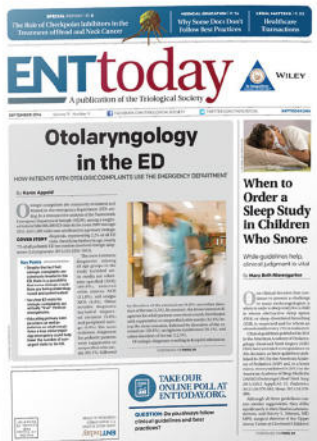


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ORIGINAL RESEARCH

# Treatment of horizontal canal BPPV—a randomized sham-controlled trial comparing two therapeutic maneuvers of different speeds

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## Abstract

**Objectives:** To compare the effect of a high-speed barbecue maneuver with the modified Lempert maneuver and sham in patients with benign paroxysmal positional vertigo (BPPV) of the horizontal canal.

**Methods:** Randomized sham-controlled, single blinded multicenter clinical trial in two university hospitals investigating consecutive patients with horizontal canal BPPV. Patients were randomly assigned to high-speed barbecue (HSB), modified Lempert maneuver (ML), or sham maneuver (SM). All treatments were performed in a biaxial rotational chair with weekly follow-up to a maximum of three treatment sessions. The final follow-up was 3 months after the last treatment.

**Results:** Primary outcome: 2-week recovery rate per protocol. Secondary outcome: Cumulative recovery rate and Dizziness Handicap Inventory (DHI) scores after 3 months per protocol (HSB and ML) and intention to treat (all groups). Fifty-four patients were analyzed after 2 weeks (HSB = 17; ML = 20; SM = 17). Two-week recovery rate was 14/17 after HSB, 11/20 after ML, and 4/17 after SM, with significantly better recovery in HSB [OR 15.17, 95% CI (1.85, 124.63),  $P = .001$ ] using sham as base level. Recovery rate after 3 months was 15/17 after HSB and 15/19 after ML. Cumulative recovery rate showed no significant differences between the two treatment groups [95% CI (0.30, 13.14),  $P = .46$ ] in cure rate DHI [95% CI (−16.56, 15.02),  $P = .92$ ]. No unexpected adverse events were observed.

**Conclusion:** Velocity change in horizontal canal BPPV treatment gives a faster initial recovery. Rapid recovery could reduce the disease burden.

**Trial Registration:** Clinicaltrials.gov. Identifier: NCT01905800.

**Level of Evidence:** 1b

## KEYWORDS

barbecue, benign positional vertigo, horizontal semicircular canal

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## 1 | INTRODUCTION

The effect of acceleration and deceleration during barbecue maneuvers for horizontal canal benign paroxysmal positional vertigo (HC-BPPV) has been debated.<sup>1-4</sup> is the most common cause of vertigo, and HC-BPPV is the second most common subtype,<sup>5,6</sup> with a prevalence ranging from 5% to 30% in patients with BPPV.<sup>7-9</sup>

The commonly accepted cause of BPPV is ectopic otoconia located within the lumen of the semicircular canals (canalolithiasis) or attached to the cupula (cupulolithiasis),<sup>10,11</sup> generating attacks of positional nystagmus and vertigo after certain head movements. BPPV is often a self-limiting condition,<sup>12,13</sup> but can be persistent or recurrent.<sup>14-17</sup> BPPV may cause considerable handicap for patients, restricting work as well as other activities of daily living. A rapid recovery is therefore important for both the patient and society in general. Treatment is based on effectively removing the displaced otoconia. HC-BPPV is typically treated with barbecue roll or Gufoni maneuvers.<sup>14,18</sup> HC-BPPV can be difficult to treat, and persistence of symptoms ranges from 5% to 61%,<sup>19-26</sup> with a lower recovery rate for apogeotropic HC-BPPV.<sup>21,27</sup> Recently, the use of particle repositioning chairs has become more common in the treatment of difficult BPPV cases.<sup>28</sup> Manual chairs give the possibility to perform the maneuvers with acceleration and brisk deceleration that may promote the removal of otolithic debris from the semicircular canal.<sup>29</sup> A mathematical model developed by Hain et al suggests that strong and prolonged accelerations could move otoconia a significant distance through a semicircular canal.<sup>30</sup> However, the important question of whether acceleration and deceleration adds an effect to treatment of HC-BPPV, has remained unanswered.

The aim of this study was to compare the effect of a high-speed barbecue maneuver with a modified Lempert maneuver in a sham-controlled randomized trial.

## 2 | MATERIALS AND METHODS

### 2.1 | Ethics

This study was approved in advance by the regional Committee for Medical and Health Research Ethics of Western Norway. Participation was based on written informed consent. The study was registered at clinicaltrials.gov (identifier: NCT01905800).

### 2.2 | Design and setting

This was a prospective randomized, single blinded multicenter trial, conducted at two university hospitals in Norway, including patients from August 2013 to August 2017. Data were reported according to

the CONSORT statement.<sup>31</sup> Participants were equally allocated (1:1:1) to the three interventions being compared.

### 2.3 | Participants

Consecutive patients referred with a history suggestive of BPPV were considered for inclusion, which was based on confirmed active HC-BPPV according to international diagnostic criteria.<sup>32</sup> In total, 647 patients with positional vertigo were screened (CONSORT flowchart Figure 1). The inclusion criteria were having HC-BPPV, symptomatic at the time of examination, with canal-specific positioning nystagmus under positional testing in a biaxial chair. The exclusion criteria were BPPV of the vertical canals identified during the diagnostic procedure, history of neurological disease including migraine or inner ear disease other than BPPV.

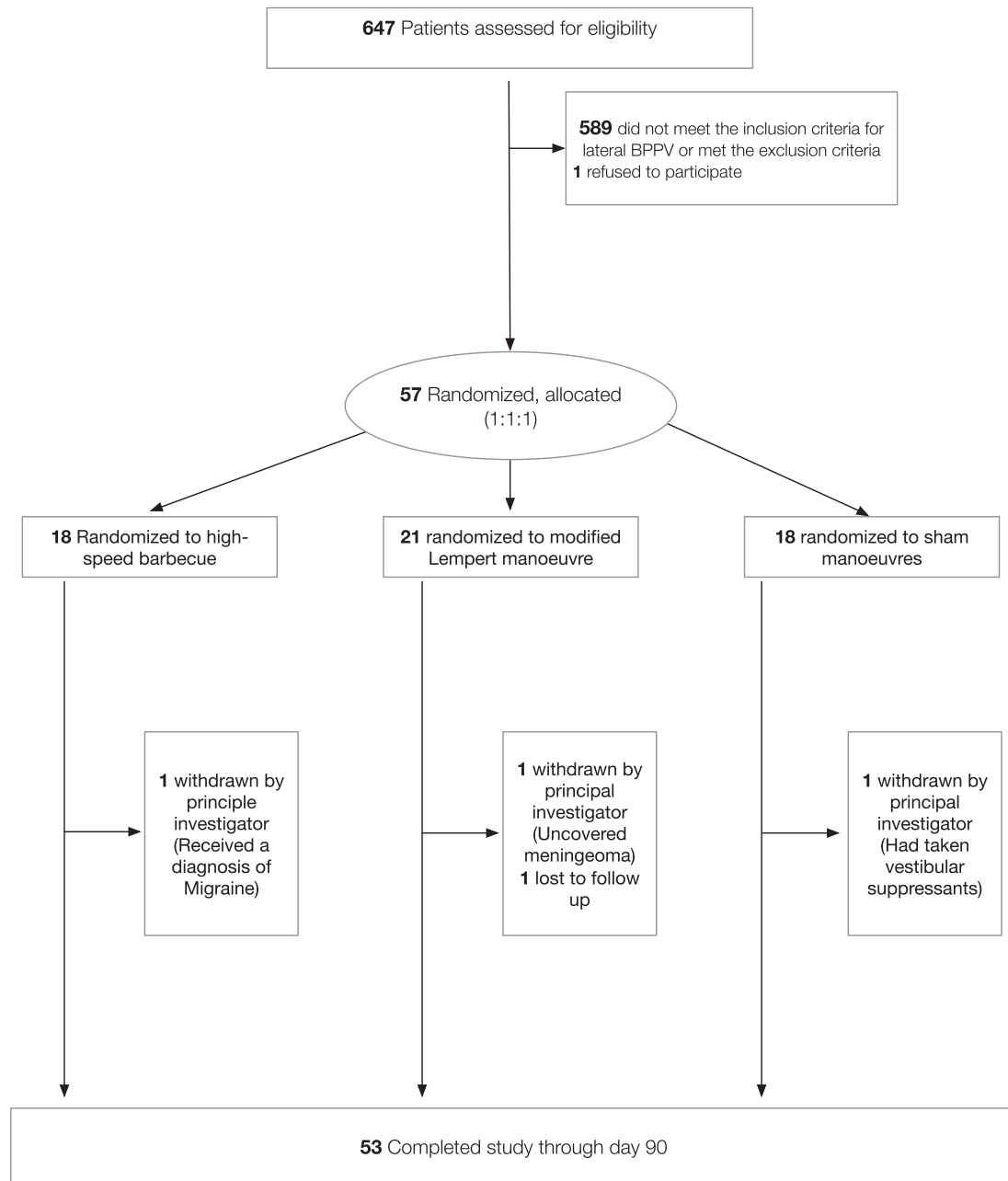
Magnetic resonance imaging (MRI) was ordered in case of severe imbalance or treatment failure. In some of the patients, MRI had been taken prior to referral. A total of 32 patients (56%) underwent head MRI.

A total of 57 patients were enrolled, 18 were assigned to receive the high-speed barbecue (HSB) maneuver, also called the dynamic barbecue by the manufacturer of the biaxial chair, 21 were assigned to the modified Lempert maneuver (ML), and 18 were assigned to receive the sham maneuver (SM). Three patients were excluded and one lost to follow-up. Reasons for exclusion was a diagnosis of migraine ( $n = 1$ ), meningioma ( $n = 1$ ), and use of vestibular suppressants ( $n = 1$ ). All audiograms for the included patients were within normal limits for age and gender<sup>33</sup> or showed symmetrical presbycusis. None of the included subjects had spontaneous nystagmus when fixating with the unrecorded eye or nystagmus during lateral gaze or after a 10-second headshake.

### 2.4 | Procedure and interventions

On the day of examination, the history was verified by interview, and symptom questionnaires were completed. The subjects underwent a physical examination as well as a standardized examination for positional nystagmus (roll test and Dix-Hallpike maneuver). Further assessment included a physical ear, nose and throat-examination, otoneurologic examination, videonystagmography, head impulse testing, and pure tone audiometry.

The diagnostic procedure started with mounting the patient in a biaxial chair (TRV, Synapsys, Marseille, France). The patient was secured to the chair with a four-point harness, with headrest, headband, and leg straps. The chair is operated manually and can be rotated so that each of the six semicircular canals is oriented in the earth-vertical position and rotated 360° in the plane of the canal.



**FIGURE 1** CONSORT flow diagram showing participant flow through the stages of the randomized sham-controlled trial

The Dix-Hallpike maneuver was performed toward both sides, starting on the symptomatic side as determined by the interview. Then, the roll test was performed to both sides and repeated as necessary to determine the side with strongest nystagmus.

HC-BPPV was diagnosed by the presence of positional vertigo in combination with horizontal geotropic paroxysmal or apogeotropic prolonged nystagmus provoked by the supine position test. Geotropic and apogeotropic nystagmus were defined respectively as nystagmus beating toward the lower and uppermost ear in both side-lying positions. The causative site of HC-BPPV was determined by using Ewald's second law. In geotropic HC-BPPV, nystagmus is most intense toward the affected ear, in apogeotropic HC-BPPV, nystagmus is

strongest on the side opposite to the affected ear. Dix-Hallpike right and left, supine position test, and bilateral roll test were performed. In cases where it was difficult to determine the affected ear using Ewald's second law, we used the "bow and lean test."<sup>34</sup>

The treatment procedure in each group followed standardized management depending on group allocation: HSB, ML, or SM.

The HSB maneuver with rapid acceleration and rapid deceleration started with the patient in the side-lying (lateral) position with the affected ear down.

Step 1: The patient was rotated  $8 \times 360^\circ$  in the axial plane toward the unaffected side. The rotations were performed manually with a speed of approximately  $180\text{--}240^\circ$  per second (velocity

measured by calculating average time per maneuver of 360°). Step 2: After the rotations, the patient was abruptly stopped and kept in a position with the unaffected ear down and the face directed 45° downwards toward the ground for 30 seconds. Step 1 was repeated, this time ending with the face directed downwards toward the ground. The patient was kept in this position for 60 seconds and returned to the upright position.

The ML started with the patient in the side-lying (lateral) position with the affected ear down. The patient was then rotated slowly 360° toward the unaffected ear. A 30 second stop was applied every 45°. After a pause of 1 minute, the procedure was repeated, and the patient was returned to the upright position.

The SM treatment consisted solely of the diagnostic maneuvers as described above, conducted in random order.

Patients were considered to have recovered when no positional vertigo or pathological positional nystagmus could be elicited by the diagnostic maneuvers as described above.

Video recordings of nystagmus were evaluated after the study by two of the authors blinded to the patients' symptoms and treatment allocation.

Treatment was given weekly until no symptoms or a maximum three times. Thereafter, the patients were given a new appointment for the last follow-up after 3 months. Patients in the SM group were transferred to active treatment (HSB) if still symptomatic after two SM. No home exercises were administered during the follow-up.

## 2.5 | Outcomes

The primary outcome was the 2-week recovery rate, and the secondary outcome was recovery rate and Dizziness Handicap Inventory (DHI) scores after 3 months. Patient-reported symptoms were collected by DHI questionnaires in conjunction with the screening visit and at the end of study. DHI scores range from 0 to 100 with higher scores indicating a greater disability. To correct for missing values, the mean score for the answered items was multiplied by the total number of questions (25) to obtain a corrected total score. In general, missing items were few. We used the DHI questionnaire adapted to Norwegian with verified internal reliability and validity.<sup>35,36</sup>

Changes with respect to grading of cure rate were done after trial commencement based on findings from our previous study on nystagmus in a normal population.<sup>37</sup> Complete recovery was defined as absence of positional vertigo and absence of pathological apogeotropic or geotropic nystagmus at positional tests. Pathological nystagmus was defined as 95% CI of 4°/s for horizontal nystagmus.<sup>37,38</sup> Treatment failure was defined as residual positional vertigo and pathologic positional nystagmus on positional tests. Recurrence of symptoms and positional nystagmus following complete recovery were considered to indicate BPPV recurrence.

Videonystagmography (VNG) was performed with light occluding goggles to avoid fixation during the positional maneuvers, and both nystagmus traces and videos were recorded for later analysis. Nystagmus intensity was defined as the maximum nystagmus slow-phase

velocity ( $SPV_{max}$ ), measured in degrees per second after each diagnostic maneuver. The VNG-files were imported into a LabVIEW program developed for this study. One of the authors conducted a blinded evaluation of the VNG-signals, selecting and measuring the area of the horizontal nystagmus with highest slow-phase velocity. If there were any doubts interpreting the nystagmus, the series were reviewed independently by three of the other authors.

The objective measurements of  $SPV_{max}$  of the horizontal component of the nystagmus elicited by supine roll left and right were quantified. Registrations were done the day of inclusion, at every post-treatment control, and at the end of the study, 3 months after last treatment.

## 2.6 | Cases with recurrence

If patients developed a new episode of BPPV after having been evaluated as recovered, the case was registered as a recurrence.

## 2.7 | Statistical analysis

The null hypothesis was that the two maneuvers would be equally effective with respect to primary and secondary outcomes. Power analysis showed that for chi-square tests with two degrees of freedom, power of 80%, and significance level of 0.05, the minimum detectable effect size would be  $w = 0.53$  with 17 participants in each group. Chi-square tests with  $3 \times 2$  tables and Fisher's exact tests were used to compare groups for primary and secondary outcomes. Non-parametric tests were used due to distribution of data. Multiple exposure levels were used to estimate odds ratios.

A multiple linear regression model was used to identify factors associated with change in dizziness-related quality of life using changes in DHI score as the dependent variable (continuous, ranging from 0 to 100) and treatment group and baseline DHI as factors. The significance level,  $P < .05$ , was corrected for multiple comparisons by the Bonferroni correction, (0.05/2), giving a value of  $P < .03$  for significant results. STATA version SE 15.1 was used for statistical evaluation.

## 3 | RESULTS

### 3.1 | Patients

The inclusion criteria were initially met in 57 patients. The mean age of the patients was  $57 \pm 12$  years (mean  $\pm$  SD, range: 27-78), and 68% (38) were female. Sixty percent (34) of the patients had apogeotropic nystagmus. The right side was involved in 53% (30). Table 1 shows the characteristics for each group of patients at baseline. Of the 57 patients, three discontinued the study and did not provide outcome data because of later findings uncovering exclusion criteria (Figure 1). The primary outcome was analyzed in 54 patients (17 in the HSB group, 20 in the ML group, and 17 in the SM group).

Of the 53 that completed the study, 17 completed in the HSB group, 19 in the ML group, and 17 in the SM group. One patient in the ML group was lost to follow-up. Recruitment and follow-up were from August 2013 to August 2017.

Two-weeks post-treatment, 29 patients had recovered (54%), 14 of 17 in the HSB group (82%), 11 of 20 in the ML group (55%), and four of 17 (24%) in the SM group. The recovery rate in the HSB group was significantly higher compared to the SM group [OR 15.17, 95% CI (1.85, 124.63),  $P = .001$ ] (Table 2).

The total recovery rate after 3 months was 75% (40 of 54 cases) (75%). At this time, there was no significant difference between the

HSB group (88%) and the ML group (80%) (Fisher's exact,  $P = .66$ ) (Table 3). The SM group was not analyzed at this point, since patients in this group that did not recover received active treatment.

In the group that did not recover, 10 out of 14 (77%) had cupulolithiasis. Eight patients had short recurrences of BPPV during the study, two patients in the HSB group and six patients in the ML group.

The mean DHI score before treatment was  $46.1 \pm 22.1$  (mean  $\pm$  SD, range: 0-96). After 3 months, the DHI score in the HSB group was  $22.6 \pm 23.3$  (mean  $\pm$  SD, range: 0-62) and in the ML group was  $22.5 \pm 23.3$  (mean  $\pm$  SD, range: 0-62.5). There were no significant

**TABLE 1** Baseline characteristics of patients with lateral canal BPPV (N = 57)

Characteristics	High-speed barbecue	Modified Lempert	Sham
	N = 18	N = 21	N = 18
Gender			
Female	14	13	12
Male	4	8	6
Age years (range)	36-78	34-71	27-74
Mean $\pm$ SD	$55.8 \pm 12.13$	$57.6 \pm 11.6$	$58.3 \pm 11.6$
Involved side			
Right	11	13	7
Left	7	8	11
Type			
Canalolithiasis	7	11	5
Cupulolithiasis	11	10	13
DHI score (range)	0-96	6-76	2-96
Mean $\pm$ SD	$47.6 \pm 23.6$	$48.1 \pm 20.6$	$46.5 \pm 25.5$
MRI			
Yes	10	10	12
No	8	11	6
Rec. BPPV			
Yes	10	12	10
No	8	9	8

Note: There were no significant differences between the groups in baseline characteristics. Chi-square, Fisher's exact for categorical variables, and ANOVA for continuous variables.

Abbreviations: BPPV, benign paroxysmal positional vertigo; DHI, Dizziness Handicap Inventory; Rec. BPPV, patients with earlier episodes of BPPV prior to inclusion in study.

**TABLE 2** Primary outcome (2-week recovery rate) according to treatment group

Intervention	Recovery after 2 weeks				Total N
	Yes		No		
	N	% within study group	N	% within study group	
High-speed barbecue	14	82.4	3	17.6	17
Modified Lempert maneuver	11	55	9	45	20
Sham maneuver	4	23.5	13	76.5	17
Total	29		25		54

Note: Chi-square = 11.85. Two degrees of freedom,  $P = .003$ . Fisher's exact  $P = .003$ .

**TABLE 3** Secondary outcome: Three-month recovery rate according to treatment group (sham excluded)

Intervention	Recovery after 3 months				Total N
	Yes		No		
	N	% within study group	N	% within study group	
High-speed barbecue	15	88.2	2	12.8	17
Modified Lempert maneuver	15	79.0	4	21.0	19
Total	30		6		36

Note: Chi-square = 0.56. One degree of freedom,  $P = .46$ . Fisher's exact,  $P = .66$ .

correlations between change in DHI and treatment group [95% CI (−16.56, 15.02),  $P = .92$ ].

### 3.2 | Adverse events

No serious adverse events were noted. Although discomfort during and immediately after maneuvers was not recorded as a part of the study protocol, it was the impression of the authors that the HSB maneuver was associated with a higher degree of immediate discomfort (dizziness, nausea, and vomiting) than the other maneuvers. One patient withdrew from the study due to anxiety related to treatment; this was from the ML group.

## 4 | DISCUSSION

This study found a higher 2-week recovery rate in patients with HC-BPPV treated with HSB compared to ML and sham. The difference between the two active treatments was not retained after 3 months. There was no significant difference in DHI between the treatment groups. The findings are of importance, since rapid clinical recovery is desirable.

Most studies recommend rapid position changing<sup>20,24,39</sup> to allow facilitation of otoconia, but the effect of acceleration or deceleration has not been established to date. Tian et al<sup>40</sup> showed, from their comparative study on the implication of the number of accelerations in the treatment of posterior canal BPPV, that more accelerations and smaller rotation angle improved effectiveness. Hwang et al<sup>1</sup> conducted a prospective randomized study to evaluate the effect of an accelerated Gufoni maneuver in 50 patients with apogeotropic HC-BPPV, and found that faster maneuvering added little benefit, but that the gravitational force may be a more important contributor to the treatment effect. However, no previous study has documented the effect of the HSB in a biaxial chair. Biaxial chairs facilitate the consistency of speed, angle, and amplitude of the diagnostic maneuvers.<sup>41,42</sup>

Another study by Shan et al<sup>4</sup> found that treatment for geotropic HC-BPPV with rotation at 120°/s succeeded by two slower rotations had a higher success rate compared to conventional barbecue. The study did not have a control group and bias of being treated in a biaxial chair compared to conventional treatment was not corrected for. The latter was also the case in a recent study by Wang et al<sup>43</sup> finding biaxial

chair treatment superior to manual treatment in HC-BPPV. The use of acceleration was not accounted for in this study.

Fourteen patients recovered after 2 weeks of treatment. The reason for this could be the need for repeated maneuvers in some cases or possibly due to spontaneous recovery.

Of the patients that did recover, 16/40 (40%) still had weak horizontal nystagmus. This finding is in agreement with our earlier study on positional nystagmus in healthy subjects, and may be explained by asymptomatic canal- or cupulolithiasis or even asymptomatic central vestibule-ocular reflex asymmetry.<sup>37</sup> It is doubtful whether total elimination of positional nystagmus is a relevant measure of therapeutic success in BPPV,<sup>44</sup> since infrared video-frenzel systems used today are highly sensitive, making it possible to detect positional nystagmus of low velocity in 88% of the normal population.<sup>37,38,45-47</sup>

Our DHI results are in line with Lee et al who found that patients with BPPV on average score  $45.9 \pm 8.8$  (mean  $\pm$  SD), a substantial improvement in DHI after successful maneuvers to  $19.8 \pm 7.2$  (mean  $\pm$  SD), but never reaching the level of healthy controls  $11.8 \pm 5.2$  (mean  $\pm$  SD).<sup>48</sup> In our study we found a pretreatment score of  $46.1 \pm 22.1$  (mean  $\pm$  SD) and a post-treatment score of  $25.6 \pm 24.7$  (mean  $\pm$  SD), indicating that subjective imbalance was improved but not completely resolved.<sup>48</sup> There was no significant difference in DHI between the treatment groups.

According to earlier reports, most cases of HC-BPPV resolve within  $3.7 \pm 3.9$  (mean  $\pm$  SD) days in patients with cupulolithiasis and  $6.7 \pm 4.1$  (mean  $\pm$  SD) days in patients with canalolithiasis.<sup>12</sup> However, BPPV persists in 30% of patients if left untreated,<sup>5</sup> and a recent study found that 61% of patients with persistent BPPV suffered from horizontal canal involvement.<sup>26</sup>

### 4.1 | Limitations and strengths of this study

The strengths of this study were its prospective design, use of a standardized mechanical chair, which ensured reproducible diagnostic maneuvers in preset positions, rigorous use of international diagnostic criteria for the BPPV subtypes, as well as the use of video documentation and computerized videonystagmography that facilitates the analysis of positional nystagmus. Biaxial chairs facilitate consistency of speed, angle, and amplitude of diagnostic maneuvers, which is critical when evaluating the latency and intensity of nystagmus,<sup>41,42</sup> and can be of valuable assistance in the sometimes challenging determination

of involved side in HC-BPPV.<sup>49</sup> Objective measurement of nystagmus, and diagnostic maneuvers with a biaxial chair make the diagnosis of BPPV more objective and gives the examination and treatment increased consistency.<sup>50</sup>

A possible limitation of the study was related to generalizability as we are a tertiary clinic and the patients may differentiate from patients seen in general practice or in emergency departments.

## 5 | CONCLUSION

To our knowledge, this is the first randomized sham-controlled study on treatment of HC-BPPV in a biaxial chair. The effects of the HSB maneuver were analyzed in comparison with the ML maneuver and SM, and the former treatment showed a higher 2-week recovery rate. After 3 months, there were no differences in recovery rate or dizziness handicap between treatment groups.

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## CONFLICT OF INTEREST

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#### SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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