Efficacy of a New Home Treatment Device for Benign Paroxysmal Positional Vertigo

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Objective: To prospectively test the efficacy of a device for the home treatment of benign paroxysmal positional vertigo (BPPV).

Design: Multicenter prospective cohort study.

Setting: Community and tertiary care clinic offices and patient homes.

Patients: Forty patients with active BPPV.

Interventions: Training on and treatment with a home treatment device (The DizzyFIX) as their primary therapy technique.

Main Outcome Measure: The Dix-Hallpike maneuver at 1 week after treatment.

Results: Patients using the home treatment device had no evidence of nystagmus in posttreatment Dix-Hallpike maneuvers at 1 week in 88% of cases (n=40). This rate was comparable to standard treatment. There were no significant complications.

Conclusion: The use of this device enables patients with an established diagnosis of posterior canal BPPV to safely conduct an effective particle repositioning maneuver and achieve success rates similar to those found with the standard Epley maneuver.


Benign paroxysmal positional vertigo (BPPV) is the most frequent cause of peripheral vertigo.1 Though it typically resolves over several months without any treatment, a clinician-guided maneuver can expedite the process. The 2 fundamental maneuver variations are based on the techniques of Semont et al2 and Epley.3 Following either, the condition is highly recurrent.2,4

The current understanding of BPPV is that it occurs when otoconia become dislodged from the macula of the utricle and migrate down into the most gravity-dependent long arm of the posterior semicircular canal. Short-lived nystagmus with associated vertigo results from gravity-induced movement of these particles. The nystagmus that occurs during posterior canal BPPV has characteristic upbeating and torsional components causing the superior pole of the eye to rotate toward the affected side in the head-hanging position. By contrast, horizontal BPPV has only horizontal nystagmus, which is either geotropic (fast component toward the ground) or apogeotropic (fast component away from the ground), depending on the variant. Superior canal BPPV, although rare, has downbeating vertical nystagmus.5 While BPPV itself tends to resolve over weeks to months, the associated morbidity is high due to depression, anxiety, injury from falls, and occupational hazard.6-10

The incidence of BPPV increases with age and has been estimated at greater than 10% to 20% beyond the sixth decade of life.11-13 Reported recurrence rates vary widely and are dependent on the duration of follow-up. However, recurrence has been reported in as many as 30% to 50% of patients who undergo treatment by repositioning.3,4

In the 1980s, Brandt and Daroff14 and Brandt et al15 described a series of exercises that led to a more rapid resolution of symptoms. However, these exercises required the regular induction of vertigo. After the description of new repositioning maneuvers by Semont et al2 in 1988 and Epley3 in 1992, effective treatments for most patients became available (Figure 1). At our institution, we use a variation of the Epley maneuver that we call the particle repositioning maneuver (PRM).16 Beyond repositioning manu-

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vers, there is no effective nonsurgical treatment for BPPV. Both singular neurectomy and posterior semicircular canal occlusion are highly effective surgical procedures, though the latter is easier and carries less risk.17,18

Some authors have suggested that home self-treatment may be an alternative to clinician-guided repositioning.19,20 It has further been proposed that home self-treatment become an accepted part of the otolaryngologist’s management of recurrent BPPV.19 We believe that patients, community clinicians, and allied health care workers could be easily educated about this maneuver. However, it has also been our experience that the maneuver, while easy to perform, is somewhat difficult for patients to remember correctly. Studies have also demonstrated that even new medical graduates are not well versed in the maneuver.21 The effectiveness of home therapy has been studied, but the efficacy of an incorrect maneuver is unclear.20,22 Certainly, an incorrectly performed Dix-Hallpike maneuver will be diagnostically misleading. Finally, an incorrectly performed PRM is unlikely to be therapeutic. The use of a device to assist in the performance of a modified Epley maneuver for the treatment of posterior BPPV may improve access to effective treatment, increase success, reduce the rate of recurrent disease, and reduce costs by moving treatment into the home.

Our research group23 has described a novel device (DizzyFIX; Clearwater Clinical Limited, Calgary, Alberta, Canada) that can assist patients in the treatment of posterior BPPV at home. We determined that use of this device had a positive impact on the performance of the PRM compared with written instructions alone. Herein, we report our findings of a prospective evaluation of the real short-term efficacy of the home treatment device in patients with active BPPV.

**METHODS**

Ethical approval for this study was obtained from the Lawson Health Research Institute’s clinical research impact committee (certificate No. 11547). The DizzyFIX device has been approved by the US Food and Drug Administration (K No. 081602) for the home treatment of BPPV and provides visual feedback to guide a patient or assistant in the performance of the PRM for the treatment of posterior canal BPPV (Figure 2). Details of the design of the device have been published elsewhere; it is based on the canalithiasis theory of BPPV. In essence, it is an analogue of the PRM rather than an analogue of the semicircular canals (Figure 3). The device consists of a plastic tube attached to a hat in such a way that the tube is visible to the person wearing the hat. The tube is filled with a viscous fluid and contains a particle. As the user moves his or her head, the particle within the tube also moves, giving the user simple visual feedback that in one sense indirectly resembles the movement of otoconia within the vestibular canals. It should be noted that the tube shape was designed to enable accurate replication of the Epley maneuver and has little resemblance to the shape of vestibular canals. In the event of an incorrect maneuver, the particle, by nature of the shape of the tube, will not move ahead, indicating that a correction must be made. In this fashion, the device directs the user in the correct performance of the maneuver.

Our primary end point was the rate of posttreatment resolution as measured by the Dix-Hallpike maneuver 1 week after dispensing the home treatment device. Forty patients were recruited into the prospective cohort.

The study was conducted by 4 clinicians in their community and tertiary care clinic offices. Patients with documented symptoms consistent with BPPV were identified, and those aged between 18 and 75 years who reported active symptoms were included. Patients who were non-English speaking or had a clinically significant physical disability were excluded. Informed consent was obtained from each patient. All patients initially underwent a standard clinical examination, including a Dix-Hallpike Maneuver.
Not all patients with histories consistent with BPPV had typical nystagmus in the Dix-Hallpike head-hanging position. Only those patients with this objective finding diagnostic of BPPV were invited to continue in the trial. Following a return to the sitting position, they were given a home treatment device, a manual of typewritten instructions, and an instructional video. At home they then watched the instructional video and reviewed the manual. This video detailed the use of the device and how the floating ball within the device represented the offending otoconia in BPPV. These patients then performed a PRM guided only by the device. They were instructed to repeat the maneuver twice a day for 1 week or until they stopped having symptoms. Patients then returned for follow-up at 1 week to be evaluated for BPPV.

RESULTS

In total, we recruited 40 patients, 25 women (63%) (mean age, 55 years), and 15 men (37%) (mean age, 57 years). The average age of the participants overall was 55 years with a range of 34 to 75 years.

One participant had a pretreatment positive finding on Dix-Hallpike testing on both sides, and after 1 week of using the device was found to have been successfully treated on both sides. In addition, 34 others of the 40 total patients (34 of 40, 88%) were successfully treated in that they tested negative on the Dix-Hallpike at 1 week. Among the 5 who still tested positive on the Dix-Hallpike, 2 reported some subjective improvement of their symptoms. There were no adverse effects from the use of the device, and it was easily tolerated by users. No instances of conversion to lateral canal BPPV were reported. Nausea was reported in several cases.

The efficacy of the home treatment device for BPPV in this prospective clinical trial was 88% (35 of 40), measured by objective end point (Dix-Hallpike test). The spontaneous resolution rate of BPPV expected within 1 week is 15%. Success rates for the Epley maneuver have been reported as high as 90%. In aggregate, the home treatment device appears to be effective and, based on these data, may be as effective as expert-guided PRM in the treatment of BPPV.

Although the present study design demonstrated efficacy well, the lack of a control group was not ideal for comparative purposes. Direct statistical comparison was not performed owing to the lack of a matched prospective control group. We were aware of this and sought only to perform a preliminary assessment of the efficacy of the DizzyFIX-guided PRM. A subgroup analysis based on BPPV causes such as virus or trauma would be interesting.

Our experience suggests that unguided home treatments are plagued by incorrect maneuvers, which are thought to be the most common cause of failure of home treatment. Studies have also demonstrated that assistive visual feedback devices are superior to written instructions and in-office training. A natural extension of the present study would be to directly compare the efficacy of the different available unguided home maneuvers with those guided by the home treatment device. A blinded prospective study with larger numbers and subgroup analysis would help to resolve these issues.

Conversion to lateral canal BPPV has been reported as a rare complication of canal repositioning. No instances of conversion were reported in the present study group. Users with limited neck range of motion may have difficulty with the maneuver and hence be unable to use the device without assistance, but this was not encountered during our study. Aside from associated nausea, the main difficulty in both groups was treatment failure. In addition, recurrence rates have previously been reported as high as 50%. The true recurrence rate of BPPV is difficult to quantify because many published reports include differing or incomplete follow-up.

The resolution rate in our prospective cohort resulted from a week-long trial of the device and instructions to the patients to repeat the maneuver daily as required. By contrast, a single repositioning maneuver is often all that is possible in the office setting. In fact, it is undesirable to rapidly repeat the maneuver until there is a negative Dix-Hallpike response because maneuver repetition creates uncertainty whether the response is abolished because of a truly successful maneuver or because of a fatigued response.

We deliberately did not restrict home users to a single maneuver, both for compliance reasons and because the efficacy of a single, device-guided maneuver would be of little practical interest. The intention of home treatment is to enable patients diagnosed as having BPPV to repeat the maneuver as often as needed. The intention of this part of our study was to compare the treatments realistically available to patients: a single maneuver in the office vs home treatment where the chance to conveniently repeat the maneuver can help compensate for lack of direct expert supervision. While it remains unclear how far a person can vary from a perfectly correct maneuver without affecting outcome, it has been demonstrated that repetition increases the likelihood of success. The repeated nature of the home maneuver may account for the slightly higher resolution rate in our patients. In future trials, we will instruct patients to formally record the number of repetitions of the maneuver required for symptom resolution, and first-use efficacy will be a secondary outcome.

The design of an entirely new medical device proved challenging. Results from our group’s earlier study demonstrated that the PRM is nonintuitive to both medical and lay persons. It is possible, however, to improve on the performance of the maneuver with the use of the repositioning device. A definitive diagnosis of BPPV must be made and other central disease ruled out prior to initiation of home therapy. It is not anticipated that patients with single episodes of BPPV who have access to tertiary neurovestibular care will benefit greatly from home treatment. Furthermore, it is not suggested that clinicians delay in-office treatment in favor of home treatment. Patients with recurrent symptoms who have been diagnosed with posterior BPPV by a clinician stand to benefit greatly. This benefit may apply to as many as 30% to 50% of patients with BPPV. Furthermore, patients who currently perform home Brandt-Daroff maneuvers could also benefit from the increased efficacy offered by Epley...
maneuvers at home. Home treatment allows those physi-
cians who rarely perform the Epley maneuver to pre-
sent the patient with an additional treatment option.

The PRM is not intuitive. Our group’s earlier publi-
ished results indicate that the use of a home treat-
ment device has better results than the unassisted per-
formance of the PRM despite clinician and written training
of control subjects. Other authors cite an inappropri-
ately performed maneuver as the main reason for home
treatment failure. Based on the present study, the use
of home repositioning maneuvers assisted by a treat-
ment device as the primary form of treatment appears
to be effective in patients with active BPPV. The ability
to repeat the maneuver at home also may increase the
success rate of patients using the device. The chronic
nature of BPPV makes home treatment a useful solution
for those who experience repeated episodes. Furthermore,
the use of a treatment device provides patients without
access to specialist care the ability to perform the most
effective treatment maneuver. The present findings also
suggest that home treatment is efficacious. The manage-
ment of BPPV has improved and evolved as our understand-
ing of its mechanism has matured. Home treatment devices
offer the potential to help safely and effectively manage
BPPV primarily in the community or at home.

Submitted for Publication: October 9, 2009; final revi-
sion received January 2, 2010; accepted February 8, 2010.
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important intellectual content: Hughes, Raymond, Suker-
man, and Parnes. Statistical analysis: Bromwich. Admin-
istrative, technical, and material support: Bromwich. Study
supervision: Hughes, Raymond, Sukerman, and Parnes.

Financial Disclosure: Subsequent to the initiation of this
research, Dr Bromwich developed a financial interest in
Clearwater Clinical Limited, the manufacturer of DizzyFIX.
Dr Parnes has no stock or share financial interest but re-
ceives a stipend from Clearwater as an advisory board
member.

Funding/Sponsor: Funding and support for this project
came from the Department of Otolaryngology, Univer-
sity of Western Ontario.

Previous Presentation: This research was presented at
the American Academy of Otolaryngology–Head and Neck
Surgery Annual Meeting; September 22, 2008, Chicago,
Illinois.

Additional Contributions: Karen Findlater, BSc, was in-
strumental in this research.

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