balanceback

intuitive Videonystagmography (iVNG)

Clinical Trials Data Report

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SECTIONS

I. Intuitive Videonystagmography (VNG) Protocol

Patient Preparation

Each patient was seated in a chair centered approximately 4.5 feet from the projected image. Goggles were placed securely on the patient's head to eliminate light from entering in from the sides during vision denied conditions. Adjustments were made as needed to the lenses so the eyes were viewable in the eye display boxes. The eyes were zoomed to fill most of the display box. Slider bars beside the eye display boxes were used to adjust (center) the images. Adjustment of the threshold bars was accomplished by moving to the lowest level and then gradually raising the threshold bar until the crosshairs were centered over the pupil.

Calibration

All patients were instructed to follow the target using only their eyes and not moving their head. As each calibration point was accepted the target was automatically moved to the next point until calibration was completed. If a calibration point did not advance, it was because that calibration point was not accepted. If a patient was not successfully calibrated, then a default calibration was used. The default calibration was based on a ± 15 degree stimulus amplitude.

Saccades

The patient was instructed to follow the stimulus using only their eyes and to not move their head as the stimulus moved randomly across the projected area. Patients were encouraged not to anticipate stimulus movement by moving their eyes prior to movement of the stimulus. If the eye movement tracing deviated consistently from the stimulus tracing, a problem with calibration was suspected and the patient was recalibrated and retested.

Smooth Pursuit

The patient was instructed to follow the stimulus using only the eyes and not move the head as the stimulus moved back and forth across the projected area. As for Saccades, the patient was instructed to avoid anticipation of stimulus movement. Smooth eye movement was encouraged when following the stimulus. Data were obtained for a 0.2 Hz and a 0.4 Hz stimulus.

Optokinetics

Patients were instructed to keep their head still and watch the checkerboard pattern on the projected area. If a patient had difficulty producing an optokinetic nystagmus with this instruction then the patient was asked to watch each of the black blocks move past the center. A final option was to ask the patient to count the blocks in one row as they moved past the center. 1 Over-instructing the patient was avoided as this is known to contaminate Optokinetic results. It is noted that for patients who experienced dizziness or nausea after viewing the stimulus, it was sometimes necessary to allow the patient to recover before proceeding to the next test. No patients with a reported history of epilepsy and/or seizure disorders were administered this iVNG subtest.

Gaze with Vision-Denied

This test was completed with the cover placed over the goggles. In the vision-denied condition, the patient was instructed to keep their head still and look center or look straight ahead. For eccentric gaze testing, the patient was instructed to look toward each direction (i.e., "look to the right, look to the left ... "). The eyes of the patient were returned to the center eye position after each eccentric gaze position. Each position was held for 15-20 sec to allow for adequate recording of eye movements.

Gaze with Vision-Enabled

If gaze nystagmus was observed during the vision-denied condition, the patient performed the same gaze task (which elicited the nystagmus) with a visual stimulus projected onto the viewing surface. For example, if nystagmus was elicited in vision denied, right eccentric gaze testing, then right eccentric gaze testing with vision enabled was performed. In this case, the patient was simply instructed to follow the stimulus with only their eyes while keeping the head still.

High-Frequency Headshake

Prior to this test, each patient was instructed that a tone would be presented to assist with the appropriate speed to shake his or her head. It some cases, it was helpful to demonstrate headshake maneuver. This test was completed with the cover placed over the goggles. The patient was instructed to look straight ahead until the tone was heard at which time they should begin shaking their head in the horizontal plane synchronous with the tone. The tone stopped at the end of 20 s and the patient was instructed to keep their eyes open and their head still until the test was complete. It is noted that if the patient experienced dizziness or nausea, time was allowed for the patient to recover before proceeding to the next test.

Hallpikes

These tests were performed with vision, as any pathological nystagmus cannot be suppressed in cases of true benign paroxysmal positional vertigo (BPPV). A vertebral artery screening test was performed on all patients prior to positioning.

Two procedures were used to test during Hallpikes, Modified Hallpike or Side-lying. Modified Hallpike was appropriate for most patients, while Side-lying was used for patients with cervical spine issues, vertebrobasilar insufficiency issues, cervical range of motion issues, etc.

Instructions for Modified Hallpike

Each patient was instructed that they might experience dizziness during the test, but if they had BPPV, it would only have a brief duration. The patient was also instructed that their head would be off the table and supported by the examiner. It was necessary that the patient allow the examiner to fully support the head of the patient so that appropriate extension of the neck would be maintained to provoke any BPPV. It was also important for the patient to keep their eyes open during the procedure so that nystagmus could be visualized and recorded. Upon returning to the seated position, the patients were instructed that they may experience dizziness.

Modified Hallpike Procedure - Each patient was seated on the exam table with their back to the examiner and legs resting comfortably on the table. The patient was positioned on the table so when supine, the head was off the table. The patient crossed their arms over their chest and turned their head 45° toward the side to be tested (i.e., right side then left side). The examiner stood behind the patient and supported the head and neck of the seated patient. Slowly and comfortably, the patient was laid down. The examiner moved down with the patient to a seated position. The examiner continued to support the head by holding the neck of the patient. The patient's neck was hyperextended when the head was off the table. The patient remained in this position for approximately 30 s if there was a negative finding or until the nystagmus or vertigo subsided in conjunction with a positive finding. If the nystagmus and vertigo persisted beyond 1 min, the patient was moved out of the provoking position. The patient was asked to return to a seated position and the procedure was repeated for the opposite ear. The examiner always maintained supportive contact with the patient as provocation of symptoms was always possible on return to the seated position.

Instructions for Side-lying:

Each patient was instructed that they might experience dizziness during this test, but if symptoms of BPPV were provoked, the duration of the symptoms would be brief. The patient was also instructed to keep their head in the appropriate position (turned to the left when testing the right ear and turned to the right when testing the left ear). The patient was reminded to remain on their side and not to roll to their back. It was also important for the patient: to keep their eyes open during the procedure so that nystagmus could be visualized and recorded. Upon returning to the seated position, the patient was told that they may experience dizziness.

Side-lying Procedure - This procedure was used for evaluation of patients with cervical spine, hip, or other issues that would preclude testing using Modified Hallpike. The patient was centered on the side of the exam table in a seated position. To test the right ear, the examiner was positioned to the patient's right. The patient was instructed to cross their arms over their chest and tum their head away from the test ear (to the left when testing the right ear). The patient was positioned on the right side, swinging their legs onto the table. The examiner prompted the patient's legs during this maneuver. The patient was then looking up at the ceiling. The patient remained in this position for approximately 30 s if there was a negative finding or until the nystagmus or vertigo subsided in conjunction with a positive finding. If the nystagmus and vertigo persisted beyond 1 min, the patient was moved out of the provoking position. Then the patient was returned to a seated position. This procedure was repeated for the left ear. The patient was instructed to sit up independently from the Side-lying position while the examiner provided supportive guidance as patients may provoke on return to the seated position. If the patient experienced dizziness or nausea it was sometimes necessary to allow the patient to recover before proceeding to the next test.

If a rotary-torsional nystagmus was present, this was indicated appropriately using the iVNG pop up box. If subjective vertigo was reported, this was also indicated appropriately using the pop up box. Vertigo was qualified as transient or persistent when prompted by the program.

Positionals - Vision denied

The patient was instructed about and assisted into each of the test positions under the vision-denied condition initially. For this portion of testing, the patient was instructed to keep their head still and look center or look straight ahead. The cover was placed over the goggles. The patient was instructed about and assisted into each of the test positions. All patients were tested in supine, head right, and head left conditions. If nystagmus was present in a given head position, then it was essential to re-test that position with vision enabled. If the patient could not provide enough rotation of the head due to limited range of motion, the examiner used body right and body left testing instead of head right and head left. If there was no positional nystagmus, the examiner continued to the next subtest (Calories).

Positionals - Vision enabled

If nystagmus was observed in the vision-denied condition, the patient was subsequently tested with vision enabled in the provoking position(s). During the conditions with vision, the patient was instructed to stare at the fixation light that came on during the trial. Eye movement was recorded for 20 s.

Body Right/Body Left Headshake

This test was performed in the vision denied condition. The patient was instructed to lie on their side. Prior to the test, the patient was instructed that a tone would be presented that would assist them with the appropriate speed to shake their head (2 Hz). In some cases, it was helpful to demonstrate the headshake to the patient. The cover was placed over the goggles. The patient was instructed to look straight ahead until the tone was heard at which time they began shaking their head side to side synchronized with the tone. When the tone stopped at the end of the 20 s, the patient had to keep their eyes open and their head still until the test was complete. If the patient experienced dizziness or nausea it was necessary to allow the patient to recover before proceeding to the next test.

Caloric Test

Each patient was tested in a vision-denied condition. The patient was instructed that they would hear and feel air going into each ear separately for 60 s. The patient was told to keep their eyes open (blink normally) so that any eye movements could be recorded. Patients were also instructed that it was possible they may feel subjectively dizzy, but this would only last for approximately one minute after the air stimulation was discontinued. The fixation light was presented in the goggles 100 s after the start of the recording. Patients were instructed to fixate on this target.

The caloric tests were performed with the patient reclined in a supine position, with the head e elevated by 30^{o}. The examiner determined if there was any spontaneous nystagmus present in the caloric testing position. If nystagmus was present, an exam note was placed in the quantified caloric data window. The right ear of the patient was irrigated with a warm air stimulus (50° C). This stimulus was presented for 60 s and the eye movements of the patient were recorded. Throughout the recording period, it was important for the patient to maintain the appropriate head position.

Following a 2-5 min waiting period to allow the temperature of the inner ear to return to normal, the warm stimulus was presented to the left ear. A cool air stimulus (24° C) was used to irrigate the ears after another waiting period. Mental tasking was sometimes necessary to keep certain patients from suppressing the nystagmus. If a given patient experienced dizziness or nausea it was sometimes necessary to allow the patient to recover before proceeding to the next irrigation.

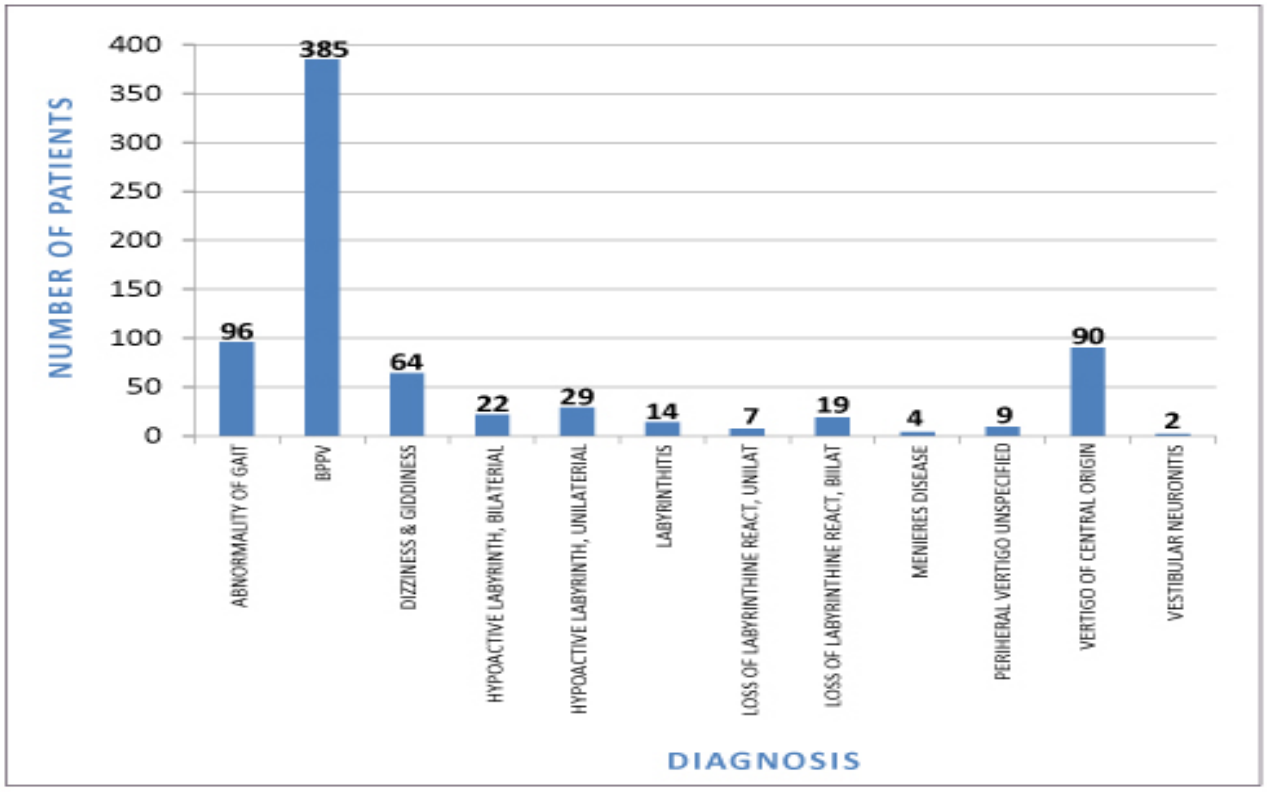
II. Use of iVNG as an Adjunct to Diagnosis

During the period of time from March to September 2006, 741 patients were seen at The American Institute of Balance for vestibular and equilibrium evaluation. These patients all underwent assessment using the balanceback iVNG system. Information from the iVNG was an integral part of each evaluation. These diagnostic results were combined with information using the balanceback integrated case history forms to determine the origin of each patient's symptoms.

Benign Paroxysmal Positional Vertigo

Please see Figure 1 for a breakdown of diagnoses. By far, the majority of patients had benign paroxysmal positional vertigo (BPPV). This diagnosis was made in 385 (52%) of the patients. BPPV is diagnosed by a positive finding on Hallpike or Side-lying testing. This testing is conducted during Positionals which is a key component of the iVNG test battery. The data in this report compares well with a report by Bath et al. (2000) which indicated that 243 out of 565 (43%) of their patients with vestibular causes of dizziness had BPPV. Importantly, the iVNG was also used during the treatment of these patients with BPPV. The iVNG was used at the post-treatment follow-up appointment to ensure that no otoconial debris had migrated to any adjacent semicircular canals during treatment.

Figure 1



Central Nervous System Involvement

The second most common diagnosis was Abnormality of Gait representing 96 (13%) of the overall diagnoses. 90 (12%) of the diagnoses were for Vertigo of Central Origin. Dizziness and Giddiness was diagnosed in 64 (9%) of patients. All of these diagnoses are associated more with central nervous system involvement rather than peripheral vestibular involvement. The oculomotor subtests of the iVNG battery (Saccades, Smooth Pursuit, and Optokinetics) are all sensitive to central nervous system involvement. Gaze and Positional testing are also sensitive to central nervous system involvement, depending on specific results. For example, patients with persistent ageotropic positionally provoked nystagmus and no subjective sensation of dizziness often have a central origin. Our results are in agreement with Bath et al. (2000) who report that 66 of 812 patients (8.1%) had central nervous system-based dizziness, along with another 4.9% of patients that were diagnosed with mixed peripheral and central pathology.

Peripheral Vestibular Involvement

The remaining diagnoses were mostly related to a peripheral vestibular origin. These accounted for less than 30% each. Gaze, Positional, IDgh Frequency Headshake, and Caloric tests are all sensitive to these types of lesions. For example, a patient may present with a direction-fixed right beating nystagmus during Gaze and Positional Vision-denied testing that suppresses with vision. This nystagrpus may also enhance after High Frequency Headshake and a left unilateral weakness might be observed during Calories. This is all consistent with a left peripheral vestibulopathy. Again, the data compares well with the results of Bath et al. (2000).

III. Side Effects Associated with Use of Ivng

Significant Side Effects

There are no known significant side effects associated with the use of the iVNG. The infrared light sources for the cameras emits at an acceptable level. Infrared cameras have been used in other VNG systems for approximately 8 years and there has been no report of damage from this type of instrumentation.

Minor Side Effects

At various points during the iVNG test battery, some patients may become nauseated. This is most likely to occur during calories or in some patients with BPPV. This was a rare occurrence in our 741 patients. In fact, for most cases where nausea was present, this was able to be controlled using sensory integration techniques. These techniques included ice packs applied to the back of the neck, top of the head, and between the wrists. At most, two of the 741 patients became emetic as a result of the iVNG test protocol. These patients both felt fine after resting comfortably for a few hours in their homes.

IV. Conclusions

Over a nine month period of time, The American Institute of Balance evaluated 741 patients using the balanceback iVNG. The American Institute of Balance utilizes VNG systems from three different manufacturers (GN Otometrics, Interacoustics, and Synapsys) allowing ample opportunity for comparison among VNG instrumentation. We conclude that the balanceback iVNG is a highly useful clinical tool for assessment of patients with dizziness and balance disorders. No negative contraindications for use of the iVNG were observed.

V. Notarization Sheet

Please find the accompanying Clinical Trials Report on the balanceback intuitive Videonystagmography (VNG) system. Respectfully Submitted October 9, 2006

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Pursuant to s. 117.05(14),
Florida Statutes.

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Sworn to before me this 10th day of October, 2006, by Richard A. Roberts, Ph.D. and Richard E. Gans, Ph.D., and subscribed by Patricia Ann Gans at the direction of and in the presence of Richard A. Roberts, Ph.D. and Richard E. Gans, Ph.D., and in the presence of these witnesses.

Notary Public State of Florida
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Expires 06/09/2009

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☒ Personally Known, OR ☐ Produced Identification
Type of Identification Produced_____