THE RELATIVE EFFECTIVENESS OF SEMONT'S AND EPLEY'S CANALITH REPOSITIONING MANEUVERS FOR TREATMENT OF POSTERIOR CANAL BPPV: A SYSTEMATIC REVIEW

(Rehabilitative Audiology)

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fulfilment for the Degree of Master of Science in Audiology

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September 2021

CERTIFICATE

This is to certify that this dissertation entitled **'The relative effectiveness of Semont's and Epley's canalith repositioning maneuvers for treatment of posterior canal BPPV: A systematic review'** is a bonafide work submitted as a part for the fulfilment for the degree of Master of Science (Audiology) of the student Registration Number: 19AUD003.This has been carried out under the guidance of the faculty of this institute and has not been submitted earlier to any other university for the award of any other Diploma or degree.

Mysuru
September 2021

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DECLARATION

This is to certify that this dissertation entitled **'The relative effectiveness of Semont's and Epley's canalith repositioning maneuvers for treatment of posterior canal BPPV: A systematic review'** the result of my own study under the guidance of Dr.Niraj Kumar Singh, Associate Professor, Department of Audiology, All India Institute of Speech and Hearing, Mysore and has not been submitted earlier to any other University for the award of any other Diploma or Degree.

Mysuru **Registration Number: 19AUD003**

September 2021

DEDICATED TO

MY

PARENTS

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ABSTRACT

Benign paroxysmal positional vertigo (BPPV) is considered as one of the most common disorder of peripheral vestibular system. Among different varieties of BPPV, posterior canal BPPV (PC-BPPV) is the most common type. Several maneuvers exist concurrently for the treatment of posterior canal with the Semont's and the Epley's maneuvers leading the popularity charts. Several Randomized control trials (RCT) have reported about the relative effectiveness of Semont's and Epley's maneuvers in alleviating the symptoms associated with the PC-BPPV. There are only few systematic reviews which have collated the outcomes of these RCTs to give a clear picture of one maneuver being superior to the other. So, the present study aimed at reviewing the recent studies comparing the effectiveness of Epley's and Semont's maneuver. Database search was done in Google scholar, PubMed, and Science direct. We selected only RCT studying adults with diagnosis of BPPV confirmed by the Dix-Hallpike test. The studies should have included both Epley's and Semont's. The main outcome was negative Dix-Hallpike test and the changes to subjective complaints. Articles found through the database search were entered into RAYYAN software. Duplicate removal, title screening, abstract screening and at the final stage full text screening was carried out. We could find 9 studies which followed the inclusion and exclusion criteria. Data was extracted from the selected studies. Selected RCT showed that the Epley's and Semont's maneuver are having good results on individuals with PC-BPPV. Most of the studies did not report of any complication after administering the maneuver. Comparing the relative effectiveness of a particular maneuver, Epley's maneuver was found as safe and effective individuals with PC BPPV.

Key word: Epley's maneuver, Semont's maneuver, Posterior canal BPPV

CHAPTER-1

INTRODUCTION

The inner ear is home to the cochlea as well as the vestibular system. The vestibular system is a sensory organ that provides information to the brain about balance, motion and location of the head and body with respect to the surroundings. The vestibular apparatus plays an important role in maintaining posture and equilibrium. This apparatus consists of three semi-circular canals and two otolith organs. The three semi-circular canals in each vestibular apparatus are placed at right angles to each other. This type of arrangement of the semi-circular canals represents the three axes of rotation: vertical, anteroposterior and transverse axes (Khan et al., 2013). The otolith organs help maintain balance during linear accelerations (Rabbitt et al., 2006).

Any pathology affecting the vestibular system results in a sensation of imbalance, swaying or vertigo. Vestibular neuritis, benign paroxysmal positional vertigo (BPPV), superior semi-circular canal dehiscence, Meniere's disease, and labyrinthitis are common disorders of the peripheral vestibular system. Among them, BPPV is the most common disorder of vertigo (Brevern et al., 2007).

BPPV was first reported by Barany (1920) as a brief, episodic, transient vertigo triggered by changes in the head position. BPPV is majorly found in isolation and termed "primary" or "idiopathic" BPPV. This type accounts for about 50%–70% of all cases of BPPV. BPPV can also occur as a sequel to other conditions such as presbystasis, cerebro-vascular disease, hypertension, vestibular neuritis, and migraine (Haripriya et al., 2018;

Hughes & Proctor, 1997; Zhu et al., 2019). Such a BPPV is termed as the "secondary" BPPV.

1.1 Incidence and Prevalence

BPPV is the most common peripheral vestibular disorder, accounting for 8% of the patients suffering from moderate to severe vertigo (Tirelli et al., 2017). The lifetime prevalence is around 2% (Brevern et al., 2007). The incidence of BPPV increases with increase in age. It is documented that 1year prevalence is 0.5% in 18-39 years of age and 3.4% among people over 60 years of age (Silva et al., 2015). The prevalence of BPPV was reported to be nearly twice as much in females than in males (3.2: 1.6) (Brevern et al., 2007).

1.2 Sign and symptoms

BPPV is induced by positional changes. Patients with BPPV report of brief and recurrent episodes of vertigo caused by changes in head position with respect to gravity, such as bending down, looking up, getting up or turning over in bed (Schuknecht, 1969). Symptoms last usually less than 20-30 seconds in one episode (Bhattacharyya et al., 2008; Dix & Hallpike, 1952; Instrum & Parnes, 2019). They may also experience nonspecific dizziness, postural instability, lightheadedness, nausea and vomiting sensation during BPPV episodes (Blatt et al., 2000). Nystagmus is also seen in them and the direction of nystagmus depends on the side of the lesion and type of BPPV (Dix & Hallpike, 1952). The severity of vertigo ranges from mild symptoms to severely disabling conditions that can affect the quality of life of an individual.

1.3 Pathophysiology of BPPV

In persons with BPPV, the otoconia are detached from their position from the utricle, rarely within the saccule, and they move into any one of the three semicircular canals (Schuknecht, 1962). When the head position is changed relative to the gravity, cause a movement of otoconial crystals which results in an abnormal endolymph flow in the affected ear. This fluid displacement sends a signal to the brain indicating that rotational movement is occurring. However, the vestibular apparatus in the unaffected ear will not be transmitting the same signal because there are no loose otoconia triggering the hair cells there. The resultant mismatch in signal coming from the right and left vestibular system leads to the sensation of vertigo. Vertigo associated with this condition is of short duration, even if the person with the condition stays in the provocative position, because the endolymph and otoconia will quickly come to a rest so the hair cells will no longer be displaced (Lee & Kim, 2010). This is true when the otoconia particles are freely floating within the semicircular canal. However, in a condition called cupulolithiasis (described in more details in the subsequent sections), the nystagmus and vertigo are persistent.

1.4 Canal involvement

According to the canal where the otoconia crystals are present, the pathology is classified as anterior, posterior or lateral canal BPPV (Parnes et al., 2003). Among the three major sub-types, the PC-BPPV is seen in nearly 90% of the cases, and lateral canal BPPV is seen in approximately 8% of the patients (Ibekwe et al., 2012). Anterior-canal BPPV (AC-BPPV) is considered the rarest form of semi-circular BPPV, with a postulated frequency of 1-2% (Von Brevern, 2013). The orientation of the posterior semi-circular canal (PC-BPPV) makes it most prevalent type of BPPV. The detached otoconia particles

from the utricular macula, rarely from the saccular macula, have a tendency to gravitate to the posterior canal, as this canal is the most pro-gravity oriented canal in the upright and supine positions. The presence of the otoconia particles in the semicircular canal makes the otherwise non-gravity sensitive canals pro-gravity by instigating fluid deflection / sensory cell deflection caused by their movement.

1.5 Types of BPPV

There are mainly 2 types of BPPV namely, canalolithiasis and cupulolithiasis. In canalolithiasis, the loose calcium carbonate particles can move freely in the fluid of the canal (Epley, 1980). In cupulolithiasis form, the otoconia particles cling on to the cupula. The canalolithiasis and cupulolithiasis are commonly evidenced in the lateral canals. However, it is possible to see them in any of the 6 semicircular canals.

The free floating otoconia particles in the posterior canal accumulate to form a critical mass in the dependent portion. They move from their position when the orientation of the semicircular canal is modified in the gravitational plane. Their movement stimulates the vestibular part of the vestibulocochlear nerve resulting in vertigo. In the head-hanging position, when the otoconia mass is present in the ampullary arm of the posterior canal, the otoconia mass moves away from the cupula which causes ampullar deflection in a way that it produces an excitatory response. This causes an abrupt up-beating torsional nystagmus with the torsional component beating towards the affected canal side. A completely reversed direction of nystagmus occurs for the canalolithiasis when the otoconia particles are lodged within the non-ampullary arm of the posterior semicircular canal. On the other hand, cupulolithiasis of posterior is a less common condition causing more intense and longer spells of vertigo (Ichijo, 2013). This condition was first proposed by Schuknecht

(1969) by staining masses attached to the posterior canal cupula in patients who had BPPV symptoms. He assumed that the masses were detached utricular otoliths which were removed by decalcification in preparation. The cupulolithiasis of the posterior canal causes similar nystagmus patterns to the canalolithiasis of the ampullary arm of the same canal, except that cupulolithiasis produces vertigo and nystagmus of longer duration and the nystagmus starts immediately after the position is assumed (i.e., does not have a latency period) (Moriarty et al.,1992).

1.6 Diagnosis of BPPV

Movement of head in specific position is required in Dix-Hallpike or Roll Tests, results in the migration of the detached otoconia crystals due to gravity and induce vertigo during the assessment (Dix & Hallpike, 1952). While doing with a VNG with specific magnification, enables the clinician for a proper diagnosis.

The Dix-Hallpike maneuver is the widely used tool for the diagnosis of the PC-BPPV. Individuals with BPPV of the posterior canal show a positive result in Dix-Hallpike test. In this test, the patient suspected with BPPV is seated upright with his/her head 45^{o} to one side. Holding this head and body relative position, the patient is brought to supine position such that there is an additional head extension by 20^{o}. In this position, assuming that we are encountering the most common type of the PC-BPPV (canalolithiasis of the ampullary arm), the free-floating otoconia particles in the posterior canal move away from the cupula. It activates the ipsilateral superior oblique and contralateral inferior rectus muscles via the vestibulo-ocular reflex (VOR) pathway. For more details on the VOR pathway, the readers are encouraged to go through the study by Fetter (2007). While holding the patient in this position, the clinician watches the patient's eyes for torsional and

up-beating nystagmus during the test procedure. Typically, vertigo starts after a latency period of about 5-20 seconds after positioning the patient in this position. The vertigo so initiated, usually resolves within about 60 seconds. This confirms the presence of a PC-BPPV (Dix & Hallpike, 1952). If the nystagmus and vertigo start with virtually no latency, a suspicion of cupulolithiasis is made times (Schuknecht,1964). In case, the clinician observes down-beating torsional nystagmus, the non-ampullary arm's canalolithiasis of the posterior canal can be suspected which requires a differential diagnosis from the anterior canal's ampullary arm's canalolithiasis (Califano et al., 2014). After ascertaining the position of the otoconia crystals, the maneuver required to remove the crystals would be decided (Helminski et al., 2010).

1.7 Management of BPPV

There are several approaches to treat BPPV. These include vestibular habituation exercises, vestibular sedatives, destructive surgeries, and repositioning maneuvers (Gans & Harrington-Gans, 2002). Literature says that the canalith repositioning maneuvers are more effective than other treatment strategies. As BPPV is a physical disorder caused by displacement of otoconial debris, the mainstay of treatment involves a repositioning of these particles back to their original position.

The first effective treatment of BPPV was proposed by Brandt and Daroff (1980), called the Brandt-Daroff exercise. Here the individual is asked to sit upright. In the second step, he/she is brought to lying position on one side with the head turned at a 45^{o} angle in the opposite direction. Following a brief interval, he/she is brought back to the sitting position. The same steps are repeated for the other side. The belief is that the repeated

provocations of vertigo will cause the brain to get habituated of receiving variable signal from two sides, allowing it to ignore the discrepancy.

In 1988, Semont et al introduced a liberatory maneuver popularly known as the Semont's maneuver, as an alternative to the Brandt-Daroff exercise. To carry out this, the patient is seated in an upright position with head turned 45^{o} away from the affected ear. In step 2, he/she is quickly brought to a lying down position towards the affected side and held in this position until the symptoms of vertigo and nystagmus dissipate. In the next step, the patient is briskly moved to a lying down position on the opposite side, creating a rainbow-like path of the head (via sitting position) from lying down on one side to the other. As a final step, the patient is brought back to the original sitting position slowly. According to the cupulolithiasis theory, the otoconia are attached to cupula and they break from their positions during the Semont's maneuver.

Arguably, the most popular treatment form for the PC-BPPV is the Epley's maneuver, which is based on the canalithiasis theory (Epley, 1992). In the Epley's maneuver, the patient is seated on the edge of the bed. His/her head is turned 45^{o} towards the affected side. Maintaining this relative position of the head and body, he/she is brought to a supine position such that in this position his/her head is extended by 20^{o}-30^{o}. This position is held until the vertigo and nystagmus completely subside. Holding the supine body position, his/her head is tuned by 90^{o} to the opposite side, and this position is held for as long as the nystagmus and vertigo remain. Upon cessation of nystagmus and vertigo, he/she is turned to a lateral position on the unaffected side. In this position, his/her nose faces directly to the ground. Finally, he/she is brought back to sitting position while still maintaining the relative position

of the head and body of the previous position. This step by step rotation of head causes the otoconial crystals in the canal to move out of the canal and fall back into the utricle.

Roberts et al. in 2006 introduced the Gans' repositioning maneuver as an alternative for Semont's and Epley's maneuvers. The principal of Gans' maneuver is similar to the Semont's procedure. The individual is seated with the head turned 45^{o} away from the affected ear. From here, the patient is moved into a side-lying position on the involved side. The difference in the Gans' maneuver from the Semont's maneuver begins at this step where, instead of making a rainbow kind of movement, the subject is rolled from the involved side to the uninvolved side. Otolith debris moves to common crus with this movement. After this step, the patient instructed to shake head side-to-side three or four times. Finally, the patient is brought to an upright, seated position with head turned forward to central position. This is believed to facilitate the entry of the otolith debris in the utricle.

Need for the study

Studies have shown that the canalith repositioning procedures remain an efficient and long lasting non-invasive treatment of BPPV (Fife & Fitzgerald, 2005). The three treatment maneuvers described above are Epley's maneuver, Semont's maneuver and Gan's maneuver. Gan's maneuver has been found less efficacious than the Epley's maneuver (Saberi et al., 2017) or has been shown to be equally effective to Epley's maneuver or Semont's maneuver (Dispenza et al., 2012; Omara et al., 2017). However, the Gan's maneuver has execution difficulties, especially when handling heavy weight individuals, which possibly makes it less popular than the Epley's and Semont's maneuvers.

The effectiveness of Epley's maneuver for resolving BPPV ranged from 89% to 93% (Fife et al., 2008; Prokopakis et al., 2005; Richard et al., 2005;). Similarly, the Semont's maneuver was found to be effective in resolving the BPPV symptoms in 73%-90.3% of the patients across the studies (Levrat et al., 2003; Perez-Vazquez et al., 2018; Vaz Garcia, 2005). However, these studies did not compare the two techniques.

The efficacy of both Semont's and Epley's maneuvers are well established. A number of randomized controlled trials (RCTs) have been conducted comparing these two techniques (Gans et al., 2002; Moreno & Renaud, 2000; Okhovat et al., 2003).Some RCTs have found the Epley's maneuver better than the Semont's maneuver (Lee , 2014), a number of the RCTs also found both techniques equally effective (Ajayan et al.,2017; Mazoor & Niazi, 2011). However, a systematic review of RCTs comparing these two techniques is missing. Therefore, there is a need to review the concurrent literature to gain better understanding of the relative effectiveness of the Semont's and Epley's maneuvers in resolving the symptoms of the PC-BPPV.

Aim and Objectives

The above discussion points towards several publications using the RCT (RCT) to compare Semont's and Epley's maneuvers for their effectiveness in the treatment of PC-BPPV. However, a systematic review with updated studies is missing from the concurrent literature. Hence, the present study aims to conduct a systematic review of the studies using the RCT design to compare the effectiveness of Semont's and Epley's maneuvers.

CHAPTER-2

METHODS

The present study aimed to carry out a systematic review of the randomized clinical trials that compared the efficacy of Epley's and Semont's treatment maneuvers used for the PC-BPPV. The steps followed to accomplish this aim are delineated in the sub-sections that follow.

2.1 Databases and Search Strategy

An electronic database search was carried out. For this, the search engines used were PubMed, Google Scholar, and Science Direct. We used search words such as 'benign paroxysmal positional vertigo', 'BPPV', 'PC-BPPV', 'PC-BPPV', 'pc-BPPV', 'Epley's maneuver', 'Semont's maneuver', 'liberatory maneuver', 'particle repositioning maneuver', and 'canalith repositioning maneuver'. These search words were entered into different databases in different combinations using the Boolean operators 'AND', 'OR', and 'NOT'. Articles published in 2016 or later were considered. Table 2.1.1 shows various search strings used in the present study. These search strategies were entered into different databases to ensure comprehensive literature. Reference lists of all eligible studies were also reviewed to identify other potentially relevant studies.

Table 2.1.1.

Search strings used for literature search in different databases

SI. No.	Search engine	Search string	No of articles obtained
1.	Pubmed	((("Benign Paroxysmal Positional Vertigo"[Mesh] AND "BPPV"[tw] AND "PC-BPPV"[tw] OR "Posterior canal-BPPV") OR (Epley maneuver)) OR (Semont maneuver)) OR (Liberatory maneuver)	57
2.	Pubmed	((("Benign Paroxysmal Positional Vertigo"[Mesh] OR "BPPV"[tw] OR "PC-BPPV"[tw] OR "Posterior canal-BPPV") AND (Epley maneuver)) AND (Semont maneuver)) AND (Liberatory maneuver)	5
3.	Pubmed	((Canalith repositioning maneuvers) AND (Epley maneuver)) AND (Semont maneuver)	15
4.	Google scholar	PC-BPPV and Epley maneuver and semont maneuver	167
5.	Google scholar	Epley maneuver and Liberatory maneuver	126
6.	Science direct	Epley maneuver and semonts maneuver	220
7.	Science direct	Epley maneuver or semonts maneuver or liberatory maneuver	75
8.	Science direct	PC-BPPV and PC BPPV and Epley maneuver or semonts maneuver or liberatory maneuver	13

2.2 Article Selection Criteria

The inclusion and exclusion criteria used for selection of the articles in this systematic review are mentioned below:

2.2.1 Inclusion criteria

1. Articles comparing Semont's maneuver and Epley's maneuver for the treatment of PC-BPPV.
2. The diagnosis of PC-BPPV using the Dix-Hallpike positional test.
3. Expected post-maneuver outcomes include the negative result in the Dix-Hallpike test and subjective reports.
4. Randomized controlled trial design for comparison between the maneuvers.
5. Articles published in English language.
6. Studies on human subjects.

2.2.2 Exclusion criteria

1. Cohort, retrospective case control, or single case study designs
2. Studies using atypical forms of BPPV.
3. Presence of other peripheral vertigos like Meniere's disease, labyrinthitis, vestibular neuronitis, superior semicircular canal dehiscence.
4. Studies where the outcome of one/or both of these treatment maneuvers is compared with placebo, no treatment or any other medical treatment (Betahistine, surgery etc.), but not with each other.
5. Studies where treatment maneuvers other than Epley's and Semont's maneuvers are reported.
6. Studies using any form of modification of the original Epley's or Semont's maneuvers.

2.3 Screening Procedure

The studies were obtained from multiple search engines using different combinations of keyword. Total articles identified from different database were 458. These articles were converted into RIS (Research Information Systems) format and uploaded into Rayyan Software. Rayyan software was used to remove the risk of bias while screening and selecting the studies. It is a free web-tool developed by Qatar Computing Research Institute for systematic reviews and other knowledge synthesis projects, for speeding up of the screening process. Rayyan software allows the reviewer to add the studies into the software, and each reviewer can screen the articles independently. The decisions of one reviewer is not visible to the other. So, it helps remove the risk of bias while screening. The discrepancies between the two reviewers at various stages of the review process was resolved through discussion, and in case of unresolved decisions a third reviewer pitched-in to resolve the conflict between two reviewers.

Duplicate detection was done for the uploaded articles. Total number of duplicates detected was 137. Among the duplicates, 52 were detected as exact matches by the software and 55 were marked duplicates and deleted by the first reviewer. A total of 18 articles that were initially not resolved by the software, were found to be not duplicates during manual verification and thus retained. Both reviewers identified an additional 12 articles as duplicates that were missed by the software. These 12 articles were also deleted. After the removal of duplicates, the remaining 321 articles were used for title screening. Two review authors screened the titles and abstracts independently. The reviewer bias was overcome by involving two independent reviewers at each stage of screening and disagreements between them was dealt through discussions between the two reviewers. In case the

discussion did not yield conclusive decision, the decision of a third reviewer was used for inclusion or exclusion of these articles. During the title screening, the first author included 185 articles and excluded 136 articles whereas the second author included 232 articles and excluded 89 articles. There was a conflict for 47 articles. This was resolved by the third reviewer. One hundred and thirty-eight articles were selected after the removal of conflict in title screening and 183 articles were excluded. In a similar way, the abstract screening was carried out. After abstract screening, the first author included 38 articles and excluded 100 articles, whereas the second author included 79 articles and excluded 59 articles. There was a conflict for 41 articles. This was resolved by the third reviewer. A total of 57 articles were selected after the removal of conflict at this stage and 81 articles were excluded. Full text screening was carried out after the abstract screening. After the full text screening, the first author included 10 articles and excluded 47 articles whereas the second author included 20 articles and excluded 37 articles. There was a conflict for 10 articles. This was resolved by the third reviewer. A total of 9 articles were selected after the removal of conflict in the full text screening and 48 articles were excluded. Reasons for excluding the article were documented and reported at this phase in accordance with the PRISMA standards. Summary of the screening procedure is shown in PRISMA Diagram in Figure 2.3.1.

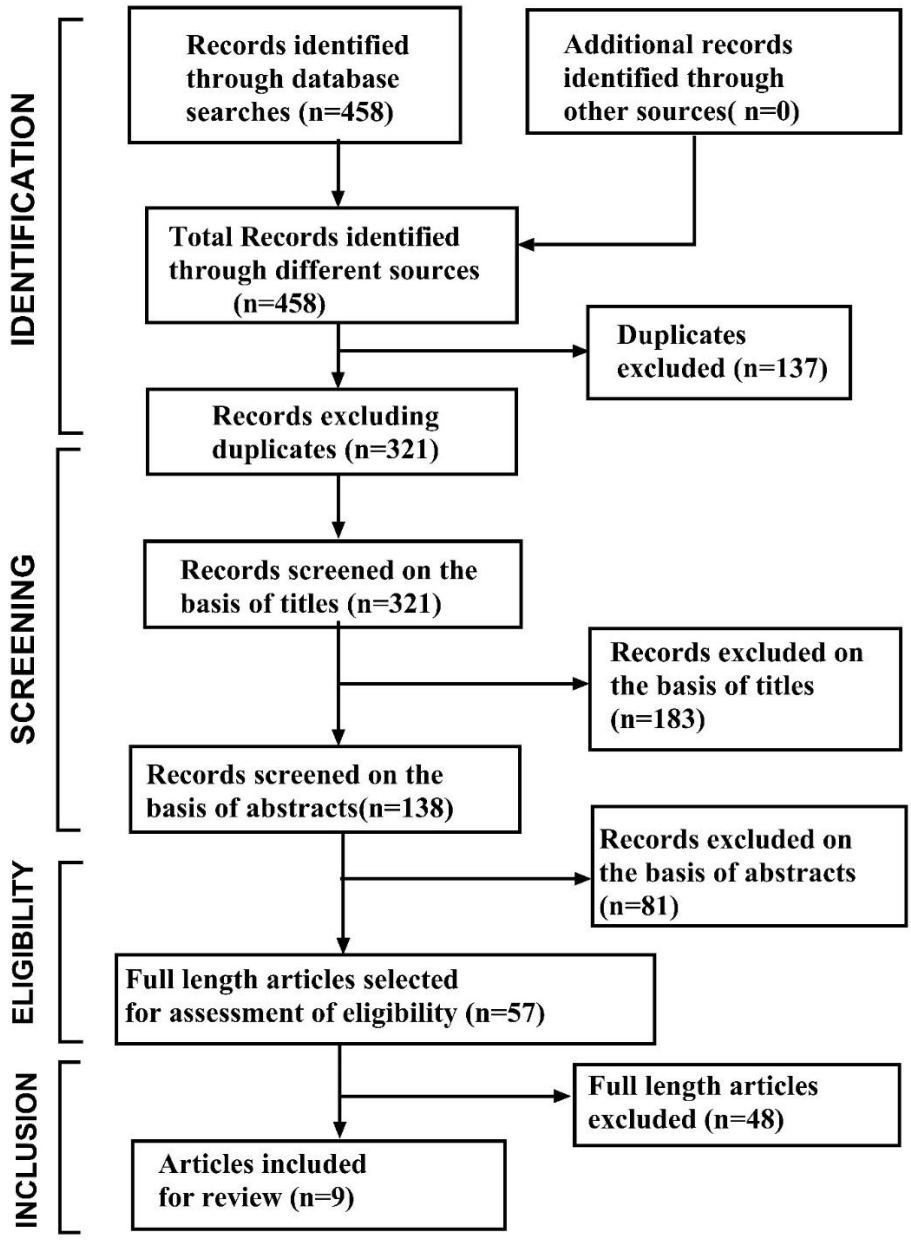

***Figure 2.3.1**:*

PRISMA chart showing different screening phases of systematic review

2.4 Data extraction

The data available in the articles were extracted, including study characteristics, sample demographic information, diagnosis, and management procedures used. The following data were extracted from each study: (1) Study characteristics: first author, study region, sample size, publication year, and study design (RCT or quasi RCT); (2) Sample demographic information: gender, age (mean ± SD), (3) diagnostic indicators: the test used for diagnosis (4) management options: treatment procedures used, recovery criteria defined, intervention outcomes, statistics, evaluation time and follow-up.

2.5 Quality analysis

The Quality appraisal of the selected studies was assessed using Critical Appraisal Skills Programme (CASP) tool. It is a checklist which allows each paper to be appraised by the researchers to determine risk of bias of studies. The CASP tool has eleven questions covering different areas. The questions are divided into 4 sections; A, B, C, and D. There are 3 questions in section A, which ask about the validity of study design. Section B is to assess whether or not the study was methodologically sound. The section C and D assess the results and the external validity of study. The author has to answer the question in 'yes', 'no', or 'can't tell'. All the studies were rated by two reviewers to remove the risk of bias. Each reviewer had to rate every article with a final rating as 'yes', 'no', or 'can't tell' and it was planned to approach a third reviewer if there were discrepancies between the results of the reviewers. However, there were no differences between the ratings of initial two reviewers and thus a third review for risk of bias was not required. The studies were classified as weak when the scores were below 5 and strong when the scores were more than 7. The studies with scores ≥ 5 and ≤ 7 were considered as moderate.

CHAPTER-3

RESULTS

The present study aimed to carry out a systematic review of the randomized clinical trials that compared the efficacy of Epley's and Semont's treatment maneuvers used for the PC-BPPV. The summary and findings obtained from the selected articles are explained below.

3.1 Study selection and characteristics

A total of 458 studies were identified through the database search. After gradually excluding 458 articles through various screening stages, a total of nine articles were included for the systematic review. The details of article selection and stages of exclusion were mentioned in the PRISMA analysis chart in Chapter 2 (Figure 2.3.1).

3.2 General characteristics of the study

The descriptions of the selected studies (Abdelatief & Yehia, 2017; Ajayan et al. 2017; Demirbilek, 2019; Gupta et al. 2019; Prathap & Rajamma 2016; Sen et al., 2016; Sinsamutpadung, & Kulthaveesup, 2021) included in this review are shown in Table 3.2.1

Table 3.2.1.

Description of the selected study features

SI. No.	Title	Author	Year	Country	Management gone	No. of subjects	Type of study
1	Comparative Efficacy of Epley and Semont Maneuver in Benign Paroxysmal Positional Vertigo: A Prospective Randomized Double blind study	Sen et. al.	2021	India	Epley's and Semont's maneuver	60	Randomized and prospective double blind study
2.	Combined Epley and Semont Maneuver in Benign Paroxysmal Positional Vertigo	Demirbilek	2019	Turkey	Epley's and Semont's maneuver	196	Prospective Randomized controlled trial
3.	Effect of Epley maneuver versus Semont maneuver on vertigo in postmenopausal Women	Abdelatief & Yehia	2017	Egypt	Epley's and Semont's maneuver	60	RCT

4.	Effect of Epley, Semont Maneuvers and Brandt–Daroff Exercise on Quality of Life in Patients with Posterior Semicircular Canal Benign Paroxysmal Positional Vertigo (PSCBPPV)	Gupta et al.	2019	India	Epley's and Semont's maneuver	90	RCT
5.	Effect of Particle Repositioning Maneuver Epleys versus Semonts in the Treatment of Idiopathic Benign Paroxysmal Positional Vertigo of the Posterior Semicircular Canal	Prathap and Rajamma	2016	India	Epley's and Semont's maneuver	116	RCT
6.	Epley's maneuver versus Semont's maneuver in treatment of posterior canal benign positional paroxysmal vertigo	Ajayan et al.	2017	India	Epley's and Semont's maneuver	90	RCT

7.	Switch to Semont maneuver is no better than repetition of Epley maneuver in treating refractory BPPV	Oh et al.	2017	Germany	Epley's and Semont's maneuver	506	RCT
8.	Comparison of outcomes of the Epley and Semont maneuvers in PC-BPPV: A randomized controlled trial	Sinsamutpadung & Kulthaveesup	2021	Thailand	Epley's and Semont's maneuver	80	RCT
9.	Effectiveness of positional maneuvers in management of Posterior canal benign positional paroxysmal vertigo- a Controlled trial	Makhdoomi et al.	2019	India	Epley's and Semont's maneuver	101	RCT

3.2.1 Design

All the studies included in the review used a randomized controlled trial research design. The participants of the study were randomly allocated to any of the treatment groups and they were blinded to the treatment given to them. Individuals who were allocated into different groups were given either Epley's maneuver or Semont's maneuver.

3.2.2 Sample size

The total sample size including all selected studies was 1124. The sample sizes were generally large for all studies. The minimum number of participants were 60 in the study by Sen et al (2016). The maximum number of participants (506) were in the study by Oh et al. (2017).

3.2.3 Setting

All studies were conducted in secondary or tertiary care in otolaryngology departments. Some studies were also conducted in the neurotology departments.

3.2.4 Intervention

Participants were divided into 2 treatments groups, Epley's or Semont's maneuver, in all these studies. The study by Gupta et al. (2019) considered 3 treatments maneuvers namely, Epley's maneuver, Semont's maneuver and Brandt-Daroff exercises. But the data from the Epley's and Semont's maneuver were extracted and used in the present systematic review.

3.2.5 Outcome

The effectiveness of a particular maneuver was compared by administering the Dix Hallpike maneuver before and after the treatments. The participants were also asked to make follow up visits after intervals of 1 week, 1 month, 4 months, or 6 months in different studies. The subjective report of recovery from symptoms was also considered to be a parameter for assessing the recovery from BPPV. In the study by Gupta et al. (2017), the Vestibular Activities and Participation (VAP) Scale, which is based on the International Classification of Functioning, was administered before and after these maneuvers to compare the effectiveness of the maneuvers. In addition, the study by Sinsamutpadung and Kulthaveesup (2021) considered the Visual Analog Scale (VAS) and the Dizziness Handicap Inventory (DHI) to assess the severity of dizziness before and after the maneuvers.

3.3 Levels of Evidence

Among 9 studies, 5 studies (Demirbilek, 2019; Oh et al., 2017; Ajayan et al., 2017; Makhdoomi, 2019; Abdelatief & Yehia, 2017) were registered randomized controlled trials. Although the other 4 studies were not registered as RCT (Gupta et al., 2019; Prathap & Rajamma, 2016; Sinsamutpadung & Kulthaveesup., 2021; Sen et al., 2021), considering the randomization of subjects mentioned in the study, they were also categorized as randomized controlled trials in this review. The evidence level was decided based on the rank order of level of evidence pyramid. The level of evidence of these studies is mentioned in Table 3.3.1

Table 3.3.1.

Level of evidence rating based on the research pyramid

Author and year	**Hierarchy**	**Level of evidence**
Demirbilek (2019)	RCT (R)	2
Oh et al.(2017)	RCT (R)	2
Ajayan et al., (2017)	RCT (R)	2
Abdelatief & Yehia, (2017)	RCT (R)	2
Gupta et al., (2019)	RCT	2
Sen et. al., (2021)	RCT	2
Makhdoomi, (2019)	RCT (R)	2
Prathap & Rajamma, (2016)	RCT	2
Sinsamutpadung and Kulthaveesup, (2021)	RCT	2

Note: The 'registered randomized controlled trials' (R) were registered as this design whereas the 'randomized controlled trials' were decided by the authors of this review as adhering to this research design.

3.4 Quality analysis

CASP quality analysis checklist was administered to assess the quality of articles selected for the review. It assessed the validity of the basic study design, methodology, results and generalization of research findings. The quality of the assessed studies showed

that all articles had 80% and above scores. Table 3.4.1 shows the responses for quality analysis questionnaire.

Table 3.4.1

CASP quality appraisal scores for included studies

	Section A			Section B			Section C			Section D		Total
	Q1	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	**Q9**	**Q10**	**Q11**	
Sen et al. (2021)	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	10
Demirbilek (2019)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	10
Abdelatief & Yehia. (2017)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	9
Gupta et al.(2019)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11
Prathap & Rajamma. (2016)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	10
Oh et al. (2017)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11
Sinsamutpadung & Kulthaveesup. (2021)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11
Makhdoomi. (2019)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	10

3.5 Data extraction

A total of 9 studies were selected for this systematic review (Abdelatief & Yehia, 2017; Ajayan et al. 2017; Demirbilek, 2019; Gupta, et al. 2019; Prathap, & Rajamma, 2016; Sen et al., 2016; Sinsamutpadung, & Kulthaveesup, 2021). Table 3.5.1 shows the summary of the included studies based on the PICOT (Patient population, Intervention, outcome, timing) format. All the selected studies used both Epley's and Semont's maneuver and their outcomes were compared by using transition from positive to negative Dix-Hallpike test result and self- reported reduction in symptoms by patients. A few studies also used scales such the Dizziness Handicap Inventory (DHI) and the Visual Analog scale (VAS) to assess the recovery after administration of a maneuver.

Table 3.5.1

Summary table of the included studies based on PICOT

Sl. No	Author	Population	Assessment Tools	Interventions	Comparison and outcome
1.	Sen et al. (2016)	Group 1: 50.07±10.53yrs Group 2 : 44.87±12.44yrs	Dix Hallpike test during follow up at 1st week, 4th week and 6th week.	Group 1- Epley's maneuver- administered in 30 subjects Group 2 –Semont's maneuver- Administered in 30 subjects	Group 1 had showed greater reduction in vertigo and other symptoms (54%) when compared to group 2 (46%). During follow up at week 1, 4, and 6 there was no relapse of symptoms and the result were statistically significant (P = 0.01) between groups during follow-ups. So it showed that Epley's maneuver was superior to Semont's maneuver in the management of BPPV.

2.	Demirbilek (2019)	19 to 66 years Mean age: 52.6±8.5 years	Dix Hallpike test and Roll test together with VNG at 1st day , 1st week, 1st month	Group 1: Epley's maneuver administered in 62 subjects Group 2: Semont's maneuver in 49 subjects Group 3: Combined maneuver in 85 subjects	The success rate with the Epley's maneuver was reported as 69.35% on the first day, 75.80% after one week and 85.48% after one month. With the Semont's maneuver, the success rate was found to be 63.26% on the first day, 75.51% after one week and 81.63% after one month.
3.	Abdelatief & Yehia (2017)	45 to 60 years	Visual vertigo analogue scale, Dix Hallpike test	Group 1: Epley's maneuver Group 2: Semont's maneuver	Results revealed that there was significant difference between post treatment vertigo intensity both groups. Reduction in vertigo was more seen in Epley's group. But there was no statistically significant difference in nystagmus duration between 2 groups.

4	Gupta et al. (2019)	31 to 70 years, mean age: 49.96 ± 13.96 years	Dix–Hallpike test and Vestibular Activities and Participation (VAP) Scale	Group 1: Epley's maneuver Group 2: Semont's maneuver Group 3: Brandt-Daroff maneuver	A total of 90% of individuals treated with Epley's maneuver recovered from symptoms of BPPV and 73.33% patients recovered using Semont's maneuver. Maximum mean score improvement was observed in Epley's group than Semont's group.
5.	Prathap & Rajamma (2016)	40-59 years	Dix Hallpike maneuver	Group 1: Epley's maneuver Group2: Semont's maneuver	In the first follow up 92% of subjects showed recovery from vertigo in Epley's maneuver group. In Semont's maneuver the subjects showed 73.2% recovery rate. Subjects exposed to Epley's maneuver had greater reduction in vertigo when compared to Semont's maneuver.
6.	Ajayan et al. (2017)	19 to 75 years Mean age: 46 years.	Dix Hallpike test and subjective report of symptoms	Group 1: Epley's maneuver Group2: Semont's maneuver	A total of 83% of the patients who underwent Epley's maneuver showed negative results in Dix- Hallpike test. During follow up at 1st week 94% and at 3 months 95% individual showed negative results.

					A total of 74% of the patients who underwent Semont's maneuver showed negative results in Dix- Hallpike test. During follow up at 1st week 89% and at 3 months 94% individual showed negative results.
7.	Oh et al. (2017)	144 subjects Mean age: 64 ± 12 (22–87) years	Dix Hallpike maneuver	Group 1: Epley's maneuver Group 2: Semont's manuever	A total of 38.6% of patients showed an improvement with Epley's maneuver and 27.0% with Semont's maneuver. No significant difference was seen between 2 groups in terms of resolution of symptoms or resolution of nystagmus.
8.	Makhdoomi et al. (2019)	101 subjects in the age range of 18 years to 77 years.	Dix Hallpike test	Group 1: Epley's maneuver Group 2: Semont's manuever	A total of 84% of the patients who underwent Epley's maneuver showed negative results in Dix- Hallpike test. During follow up at 1 months 92% and at 3 months 95% individual showed negative results. A total of 82% of the patients who underwent Semont's maneuver showed

					negative results in Dix- Hallpike test. During follow up at 1 months 84% and at 3 months 94% individual showed negative results.
9.	Sinsamutpadung & Kulthaveesup. (2021)	Epley's maneuver Group: Age range of 22-84 years (Mean age: 60.43) Semont's maneuver Group: age range of 27-79 years (Mean age: 61.73 years)	Dix Hallpike test , DHI, VAS)	Group 1: Epley's maneuver Group 2: Semont's manuever	No significant difference was seen in the 2 groups in the VAS scores and Dix Hallpike test. The severity of dizziness measure using the questionnaire showed a statistically significant reduction in dizziness severity in Epley's maneuver (P = .009).

3.6 Effect of intervention

3.6.1 Positive to negative Dix Hallpike test (Resolution of nystagmus and vertigo)

In all studies there was a statistically significant difference in the conversion from a positive to a negative Dix-Hallpike test after the treatment in both the treatment groups. The percentage of recovery rate was calculated. Most studies have reported Epley's maneuver as more effective than Semont's maneuver in individuals with PC-BPPV (Demirbilek, 2019; Gupta et al., 2019; Prathap & Rajamma, 2016; Sen et al., 2016; Ajayan. et al., 2017; Abdelatief & Yehia, 2017; Makhdoomi et.al., 2019). The percentage of recovery rate was more for Epley's maneuver and it was statistically significant. However, study done by Sinsamutpadung & Kulthaveesup (2021) reported no significant difference in the percentage of recovery between the two treatment groups. Oh et al. (2017) also reported equal effectiveness for Epley's and Semont's maneuver.

3.6.2 Subjective report of recovery from symptoms

The changes reported by most of the subjects were reduction in severity of vertigo, duration of vertigo, vomiting sensation. All studies reported that the reduction in vertigo was mostly seen in individuals who had undergone Epley's maneuver. Recurrence of symptoms were assessed by asking the subjects to come for follow up visit at certain intervals and their symptoms were assessed again by the clinician. The recurrence rate of symptoms was also reported to be lesser for individuals who underwent Epley's maneuver. In a study by Sinsamutpadung & Kulthaveesup (2021), the authors reported significantly larger reduction in VAS score after Epley's maneuver than the Semont's maneuver. But the patients who received the Epley's maneuver reported significantly less dizziness than did those who received the Semont's maneuver. Severity of dizziness after treatment was less in Epley's maneuver group.

3.6.3 Complications after administration of a maneuver

BPPV is seen mostly in the older adults. So administration of maneuvers becomes difficult as there are complication with faster neck and head movements in particular angles. The complications after administration of a particular maneuver involves neck pain, back pain, joint pain etc. The study done Sen et al. (2019) has considered this as a criterion for exclusion for candidates for administering a particular maneuver. In a study done by Demirbilek et al. in 2019, one of the patients reported of lower back pain after undergoing Epley's maneuver for the treatment of PC-BPPV.

CHAPTER-4

DISCUSSION

Posterior canal BPPV is the most common form of BPPV (Ibekwe et al., 2012). The etiology of BPPV is the dislodgment of otoconia crystal from the utricle and saccule to any of the 3 semicircular canals (Schuknecht, 1962). The dislodged otoconia crystals move freely inside the semicircular canal under the influence of gravity. This makes the semicircular that has the crystals gravity dependent whereas the other canal with no crystals remain gravity independent. The movement of the otoconia crystals cause depolarization or hyperpolarization of the SCC with crystal which does not match with its paired SCC on the opposite side. Hence the brain receives conflicting signals from a SCC pair. So patients with BPPV report persistent dizziness and imbalance, and aggravation of their symptoms occurs with position change. The treatment of BPPV is accomplished by moving the otoconia back from the semicircular canal to the utricle. There are few maneuvers proposed by different researchers to treat the posterior canal BPPV. Epley's and Semont's maneuvers are the most popular among them. This systematic review aimed to compare the effectiveness of these 2 most popular maneuvers for the treatment of posterior canal BPPV.

4.1 Findings from selected studies (Comparison of the Epley's maneuver with the Semont's maneuver)

The studies reviewed in this systematic review showed a reduction in vertigo after undergoing either of the two maneuvers in patients with a PC-BPPV. However, majority of these studies (Abdelatief & Yehia, 2017; Ajayan et al. 2017; Demirbilek, 2019; Gupta, et al. 2019; Prathap, & Rajamma, 2016; Sen et al., 2016; Sinsamutpadung, & Kulthaveesup, 2021) has reported that Epley's maneuver is more safe and effective treatment for PC-BPPV. The range of

positive outcomes after an Epley's maneuver was reported to be 38.6%-92.9% whereas the range of positive outcomes was reported to be 27%-90%. Among them, only two studies reported equivalent outcomes for both the treatment groups (Ajayan et al., 2017; Sinsamutpadung & Kulthaveesup, 2021). All the other remaining studies found Epley's maneuver to yield more positive outcomes than the Semont's maneuver. The differences between the set of studies could be caused by the differences in the clinical settings (primary Vs tertiary care settings, or specialty care Vs general hospital). Additional factors contributing to the differences could be pre-treatment severity, duration since the onset of BPPV, and the criteria of success (only negative Dix-Hallpike after treatment Vs patient becoming asymptomatic along with a negative result on post-treatment Dix-Hallpike test) (Sinsamutpadung & Kulthaveesup, 2021).

4.2 Comparison with previous literature

In a systematic review of studies comparing the effectiveness of the Epley's maneuver with the Semont's maneuver, Hilton and Pinder (2014) found that the former is more effective in making a participant asymptomatic than the later. However, the two treatment maneuvers were comparable on the rate of negative Dix-Hallpike after the treatment. While the findings in the present review are similar to the ones reported by Hilton and Pinder (2014) for conversion to asymptomatic stage, the difference lies in the negative Dix-Hallpike after the treatment. Studies other than Barring and Oh et al (2017) and Sinsamutpadung and Kulthaveesup (2021), all other studies after the year 2016 found the Epley's maneuver to yield more negative post-treatment outcomes than the Semont's maneuver. The differences from Hilton and Pinder (2014) could be the period of review and the differences in settings in which the selected studies were carried out. The studies included in the present review were RCTs conducted in 2016 or later whereas, Hilton and Pinder (2014) included studies conducted up to 2014. Further, the present study included a

majority of studies conducted in the tertiary care hospitals or neuro-otology set-ups whereas Hilton and Pinder (2014) also included studies conducted in primary care or non-specialty set-ups.

Another systematic review of the randomized controlled trials by Yun Liu et al (2015) reported that the Epley's maneuver was similar to the Semont's maneuver were similar in terms of effectiveness and safety for PC-BPPV for a short period of time, but both maneuver were better than sham-controlled treatment. The findings of the present systematic review, however, showed higher efficacy of the Epley's maneuver than the Semont's maneuver. As stated before, the differences from Yun Liu et al (2015) could be the differences in the period of review and the differences in settings in which the selected studies were carried out. The studies included in the present review were RCTs conducted in 2016 or later whereas Yun Liu et al (2015) included studies conducted up to 2015. Further, the present study included a majority of studies conducted in the tertiary care hospitals or neuro-otology set-ups whereas Yun Liu et al (2015) also included studies conducted in primary care or non-specialty set-ups.

Few studies used subjective report of recovery from symptoms, Dizziness Handicap Inventory (DHI), Visual Analog Scale(VAS), Vestibular Activities and Participation (VAP) Scale as an outcome measure (Abdelatief & Yehia, 2017; Gupta et al. 2019; Sinsamutpadung, & Kulthaveesup, 2021). They also reported that in individuals who have undergone Epley's maneuver reported of having lesser degrees of dizziness when compared to those treated with the Semont's maneuver.

4.3 Possible justification for the stated findings:

Most of the studies do not report of any possible reason for why Epley's maneuver is better than Semont's maneuver. The possible reason for that could be the way which they are administered. In a study by Faldon. and Bronstein (2007), the authors described the movements of

otoconia crystals during the positioning maneuvers. They evaluated the movement during Epley's and Semont's maneuver and they could find that Epley's and Semont's maneuvers approximated to stepwise, 360°, backward movement of otoconia particles in the plane of the targeted posterior canal. The trapped particles are able to move afar from the canal's closed end and into the utricle due to the rotation orientation. This reveals the similarities between both the maneuvers. However, the success rate is lesser for Semont's maneuver when compared to Epley's maneuver.

The efficacy of the Semont's maneuver for BPPV is relies mainly on the speed of the 180° whole-body swing (Radtke et al., 2004). During the Semont's maneuver, the patients head is rotated 90° in the backward direction, which causes the particles to fall away from their trapped position. In the second stage the whole body will be rotated 180°in the opposite direction. If this 180° swing is performed slowly, then the particles will just reverse direction and return to the trapped position. The SCC accelerates centripetally towards the center of rotation throughout the whole-body swing. The amount of this centripetal acceleration is determined by the velocity of the head. The centripetal acceleration operates downwards at the swing's center, where the there is maximum velocity of head, in the opposite direction of gravity's acceleration. So, if the 180° swing is carried out with adequate speed, then it equates a slow backward rotation on the posterior canal. If the movement speed is not fast enough, the particles will not pass, causing the failure of Semont's maneuver.

In contrast, Epley's maneuver failure does not adversely affect the treatment outcome, indicating that the interlaced propagation particles during the maneuver through the posterior canal is more robust in terms of minor deviations from the treatment instructions. Along with that, adequate neck extension and flexibility is required for a successful Epley's treatment. The maintenance of horizontal plane during the roll across the other side is important while carrying

out Epley's maneuver or else there is chance of debris moving back towards the cupula. So it is crucial to maintain the position for effective treatment (Viirre et al.,2005). But this is not a common problem. Whereas to determine the adequate amount head velocity during Semont's maneuver is common issue if it is not an experienced clinician. So it causes failure of the Semont's maneuver. This could be the possible reason for reduced success rate of Semont's maneuver.

CHAPTER-5

SUMMARY AND CONCLUSIONS

BPPV is seen in nearly 8% of the people with moderate or severe dizziness, with predominance for the posterior canal variety. BPPV causes sudden vertigo, nausea and vomiting. Along with this it may affect the person's day-to-day activities. A significant amount of people with BPPV avoid leaving their home or give-up on physical activities that may induce vertigo. In fact, a study reported significant association between BPPV and the psychophysical behaviors of a person (Hagr, 2009). So a proper care and treatment has to be given to patients with BPPV.

An effective treatment will be helpful in the fast recovery, preventing the relapse of symptom, increasing the quality of life, and ensuring long term benefits. Several maneuvers exist concurrently for the treatment of posterior canal BPPV, with the Semont's and the Epley's maneuvers leading the popularity charts. Also, several RCT have reported about the relative effectiveness of the Semont's and the Epley's maneuvers in alleviating the symptoms associated with the posterior canal BPPV. However, a clinician's trust on one over the other is dependent upon the study he/she has read. There are only two systematic reviews which have collated the outcomes of these RCTs to give a clear picture of one maneuver being superior to the other. However, the last of them by Yun Liu et al (2015) was published 6 years ago. Several RCTs on this line have been subsequently published; nonetheless, their findings have not been collated and published. So, the outcomes of this study will give a clear picture on the comparative effectiveness of these two popular treatment techniques for PC-BPPV.

A database search was done using different key words such as 'benign paroxysmal positional vertigo', 'BPPV', 'posterior canal BPPV', 'PC-BPPV', 'pc-BPPV', 'Epley's maneuver',

‘Semont’s maneuver’, ‘liberatory maneuver’, ‘particle repositioning maneuver’. These search words were entered into different databases in different combinations using the Boolean operators ‘AND’, ‘OR’, and ‘NOT’. For this, the databases used were PubMed, Google Scholar and Science Direct. The articles fulfilling the inclusion and exclusion criteria mentioned above were selected. Duplicate removal, title screening, abstract screening and full text screening was carried out. A total of 9 articles were selected after the final stage of full text screening. Data was extracted from these selected studies.

The randomized controlled trials provided strong evidence that the Epley’s and Semont’s maneuver are effective in treating individuals with posterior canal BPPV. Also from this study, it is found that the Epley’s maneuver is more effective than the Semont’s maneuver. The reason could be mainly the way in which it is administered. Speed of rotation is critical for the success for the Semont’s maneuver and adequate neck extension is important for success of Epley’s maneuver. Hence the clinician treating the patient should be having knowledge about the way they are administered. In subjects where the Epley’s maneuver cannot be performed due to lower back pain and neck pain, the Semont’s maneuver can be used as an alternative method. Therefore, both these maneuvers have a place in the routine clinical setting.

5.1 Clinical implication:

Epley’s maneuver and Semont’s maneuver are effective in managing individual with posterior canal BPPV. But the success rate is more for Epley’s maneuver. The possible reason for the reduced success rate in Semont’s maneuver could be issues with amount of velocity applied during the repositioning maneuver. If it is very slow it causes failure of the maneuver. The rotation speed is crucial for the Semont’s maneuver’s effectiveness. Whereas, appropriate neck extension and flexibility is needed for an effective Epley’s treatment (Viirre et al., 2005). Therefore

Clinicians should therefore be informative well enough about both the maneuvers; a young obese patient with good neck mobility might be better treated with an Epley's procedure, whereas a lightweight elderly patient with poor neck mobility would be better treated with a Semont's maneuver. To say in other words, the Semont's maneuver can be used as an alternative treatment strategy when the patient is having spinal cord disorder.

5.2 Limitations of the study

This systematic review aimed to compare the effectiveness of Epley's and Semont's maneuver for the treatment of PC-BPPV using articles published on the same. The article search was limited to 3 databases as the other databases such as Scopus, Embase, Cochrane etc. were not accessible from the institute. Articles published in languages other than English were also removed. There might be additional articles and information present on the same topic which could not be used for review due to lack of availability of resources due non-English language.

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APPENDIX I

Critical appraisal skill programme

Randomised Controlled Trial Standard Checklist

Study and citation: …….

Section A: Is the basic study design valid for a randomised controlled trial?			
1. Did the study address a clearly focused research question? CONSIDER: Was the study designed to assess the outcomes of an intervention? Is the research question 'focused' in terms of: • Population studied • Intervention given • Comparator chosen • Outcomes measured?	**Yes**	**No**	**Can't tell**
2. Was the assignment of participants to interventions randomised? CONSIDER: • How was randomisation carried out? Was the method appropriate? • Was randomisation sufficient to eliminate systematic bias? • Was the allocation sequence concealed from investigators and participants?	**Yes**	**No**	**Can't tell**
3. Were all participants who entered the study accounted for at its conclusion?	**Yes**	**No**	**Can't tell**

CONSIDER: • Were losses to follow-up and exclusions after randomisation accounted for? • Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)? • Was the study stopped early? If so, what was the reason?			
Section B: Was the study methodologically sound?			
4. Were the participants 'blind' to intervention they were given? • Were the investigators 'blind' to the intervention they were giving to participants? • Were the people assessing or analysing outcome/s 'blinded'?	**Yes**	**No**	**Can't tell**
5. Were the study groups similar at the start of the randomised controlled trial? CONSIDER: • Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out? • Were there any differences between the study groups that could affect the outcome/s?	**Yes**	**No**	**Can't tell**
6. Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)? CONSIDER: • Was there a clearly defined study protocol? • If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups? • Were the follow-up intervals the same for each study group?	**Yes**	**No**	**Can't tell**
Section C: What are the results?			
7. Were the effects of intervention reported comprehensively?	**Yes**	**No**	**Can't tell**

CONSIDER: • What outcomes were measured, and were they clearly specified? • How were the results expressed? For binary outcomes, were relative and absolute effects reported? • Were the results reported for each outcome in each study group at each follow-up interval? • Was there any missing or incomplete data? • Was there differential drop-out between the study groups that could affect the results? • Were potential sources of bias identified? • Which statistical tests were used? • Were p values reported?			
8. Was the precision of the estimate of the intervention or treatment effect reported? CONSIDER: • Were confidence intervals (CIs) reported?	**Yes**	**No**	**Can't tell**
9. Do the benefits of the experimental intervention outweigh the harms and costs? CONSIDER: • What was the size of the intervention or treatment effect? • Were harms or unintended effects reported for each study group? • Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)	**Yes**	**No**	**Can't tell**
Section D: Will the results help locally?			
10. Can the results be applied to your local population/in your context?	**Yes**	**No**	**Can't tell**

<table>
<tr><td>CONSIDER:
• Are the study participants similar to the people in your care?
• Would any differences between your population and the study participants alter the outcomes reported in the study?
• Are the outcomes important to your population?
• Are there any outcomes you would have wanted information on that have not been studied or reported?
• Are there any limitations of the study that would affect your decision?</td><td colspan="3"></td></tr>
<tr><td rowspan="2">11. Would the experimental intervention provide greater value to the people in your care than any of the existing interventions?
CONSIDER:
• What resources are needed to introduce this intervention taking into account time,finances, and skills development or training needs?
• Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?</td><td>Yes</td><td>No</td><td>Can’t tell</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="4">APPRAISAL SUMMARY: Record key points from your critical appraisal in this box.

What is your conclusion about the paper? Would you use it to change your practice or to recommend changes to care/interventions used by your organisation? Could you judiciously implement this intervention without delay?</td></tr>
</table>