Original Article

Effectiveness of Biofeedback Therapy versus Traditional Therapy on Dysphagia: A Randomized Control Trial

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ABSTRACT

Objective: To determine the effectiveness of biofeedback on the severity of dysphagia in Parkinson's patients.
Study Design: A randomized control trial study
Place and Duration of Study: This study was conducted at the Fauji Foundation Hospital Islamabad from 1st January 2024 to 30th June, 2024.
Methods: A randomized control trial was conducted in Fauji Foundation Hospital, Islamabad. A sample of n=12 was recruited by utilizing convenient sampling technique. Parkinson's patients with oropharyngeal dysphagia without cognitive impairment was included and patients with NG tube were excluded. Randomization was done to divide the participants into Control group (n=6) which received traditional exercises and Experimental group (n=6) which received biofeedback strengthening using tongueometer. Each group underwent twelve sessions of exercises after a baseline evaluation and received therapy for 30 minutes, having four sessions per week. FOIS was used for pre & post evaluation of patients. Analysis of the data was done using SPSS 22.0.
Results: Mann-Whitney test results, FOIS scores showed significant improvement ($p = 0.02$) in the biofeedback group (6 ± 0) as compared to the control group (5 ± 1), thus indicating decreased severity of dysphagia. The biofeedback group showed significantly higher tongue strength and tongue endurance compared to the control group in independent t-test results. The results showed that there was difference in FOIS in terms of severity among Experimental group and control group. The severity was significantly lower in experimental group than the control group after post assessment (MR = 8.67 vs 4.33). Additionally, repeated measures ANOVA for within-group analysis confirmed significant improvements. which indicated that the null hypothesis is rejected.
Conclusion: The study concludes that biofeedback tool is effective and have potential benefits of incorporating it into therapeutic interventions for clients with dysphagia as compared to traditional exercises.
Key Words: Biofeedback tool, Dysphagia, Functional Oral Intake Scale, Parkinson, Tongueometer, Traditional Exercises.

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INTRODUCTION

The term "Dysphagia" refers to a condition of difficulty in swallowing due to the dysfunction in mouth, pharynx, or esophagus thus, can be classified into oropharyngeal and esophageal types[1].

Parkinson's disease is a progressive neurological disorder which caused by the degeneration of neurons which leads to motor symptoms[2].

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About 80% of Parkinson's patients develop dysphagia and the severity increases as disease progresses. Studies have shown that its prevalence is more frequent in older adults especially with age over 65[4,5]. In Parkinson's disease patients, dysphagia occurs usually as a result of pharyngoesophageal motor abilities. Literature reveals a very high prevalence of Parkinson disease of 38.6% in Asia[6].

Common symptoms include difficulty eating, fatigue, fear of choking, communication issues, and sleep disturbances. The swallowing is compromised by muscle coordination issues, causing swallowing delays and complications, requiring management[7].

Swallowing is a complex process with three main phases: oral, pharyngeal, and esophageal. The complicated process can be explained through two classic models; the four-stage model which explains liquid swallowing, on the other hand, the process model describes eating solid foods. The process of swallowing can be divided into three major phases. These phases involve actions which are voluntary and involuntary,

sensory feedback and different coordination among cranial nerves and brain regions to guarantee safe swallowing.

Management of dysphagia in Parkinson's disease can be done by a multidisciplinary team approach including evaluations like FEES, VFSS and interventions by speech-language pathologists[8]. Management focuses on swallowing therapy, altering the food consistency, swallowing exercises, body positioning, personalized exercises and medication. However, combined approach integrating biofeedback and similar technologies is also used[9,10].

Previous studies highlighted the positive impact of tongue-strengthening exercises in strengthening swallowing safety and improving swallowing[11,12]. However, challenges involve inconsistent exercise protocols, fewer evidence on ideal intensity and difficulty to maintain adherence outside clinical environment. Visual biofeedback tools, such as the tongueometer and Iowa Oral Performance Instrument helps in enhancing exercise accuracy and adherence by delivering real-time feedback[13]. One of the previous research conducted on 84 volunteers revealed that biofeedback significantly improved tongue strength, which proposed its use for treatment of dysphagia in Parkinson's patients[14].

Keeping in view the high prevalence of oropharyngeal dysphagia in Parkinson's patients in developing countries, limited literature on effectiveness of biofeedback tools such as tongueometer on dysphagia in Parkinson's, current study was conducted to determine the effectiveness of biofeedback on the severity of dysphagia in Parkinson's client using a Randomized Control Trial design to compare biofeedback therapy using tongueometer versus conventional therapy. This study is of significant importance because it will add the gap in existing literature and will offer perspectives of combining traditional and modern techniques to improve swallowing in Parkinson's patients.

METHODS

The Randomized Control Trial (RCT) was conducted at Fauji Foundation Hospital Islamabad from 1st January 2024 to 30th June, 2024 after obtaining ethical approval of research from 2nd October 2023 with #RIPHAH/FR&AHS Letter 014251.

A sample of n=12 Parkinson's patients with oropharyngeal dysphagia was recruited by utilizing convenient sampling technique. Sample size was calculated through G*power and randomized into Control group (n=6) and Experimental group (n=6) by lottery method.

Sample included adult participants of both genders with Parkinson's disease and oropharyngeal dysphagia and patients with cognitive impairments were excluded from this study (3). Among them 2 participants were lost to follow up.

- **Tools:**

This study used the Montreal Cognitive Assessment (MoCA) for screening cognitive impairments, the biofeedback tool Tongueometer for enhancing tongue strength and endurance and also provide their real-time biofeedback, additionally, the Functional Oral Intake Scale (FOIS) to evaluate modifications in functional oral intake of liquid and food among dysphagia patients (17-19).

- **Data Collection Procedure and intervention protocols:**

The biofeedback tool was used for the experimental group for tongue isometric pressure exercises (Protocol A), whereas, control group performed traditional tongue strengthening exercises (Protocol B). FOIS and biofeedback tools were used to determine tongue strength and severity of dysphagia during baseline, and post-intervention assessments. Twelve sessions (four sessions per week) were conducted and each session comprised 30-minute therapy duration

Protocol A: The biofeedback device(tongueometer) was used which provided real-time data to monitor progress and adherence. Sixty tongue presses divided into six sets of ten repetitions each. Participants pressed and held the bulb against their palate for 10 seconds, followed by a 30-second rest between sets. Training intensity at week 1 was 60% of maximum strength, increased by 10% each week, at week 3 reaching 80%.

Protocol B: The traditional isometric tongue strengthening exercises were performed. Thirty tongue presses divided into 3 sets of 10 repetitions each. Three sets of 10 repetitions of lateral lingual movements were performed. Patient pressed and held tongue for 10 seconds followed by 30 seconds break between each set.

Data Analysis: SPSS version 22.0 was used for demographic and descriptive analyses. An independent T-test was conducted to determine the effect of biofeedback tool and traditional exercises on severity of Dysphagia in Parkinson's Clients. Mann Whitney Test was applied for between group analysis of FOIS scores to determine severity of dysphagia.

RESULTS

This randomized controlled trial (RCT) evaluated the impact of biofeedback device by using tongueometer in comparison with the traditional tongue-strengthening exercises on severity of dysphagia among individuals suffering from Parkinson's disease.

Demographics and Baseline attributes

Gender distribution of study participants revealed that most of the participants were males n=8 (66.5%) and female n=4 (33.3%). The mean age of the participants of the experimental group was 68.4 ± 3.8, while the mean age of the participants of control group was 67.4

± 4.4. The mean score of the Montreal cognitive assessment of experimental group was 26 ± 0.5, while the mean score of the Montreal cognitive assessment of control group was 27 ± 1.

After the interventions, the experimental group displayed significantly increased tongue strength (11.33 ±3.36) than control group (2.36 ± 2.08) with a statistically significant difference of (p = 0.00). Similarly, experimental group tongue endurance was significantly greater (4.00 ± 0.89) than control group (1.33 ± 0.82) with significant statistical difference (p = 0.00) as presented in table 2.

As normality of the FOIS scores was not assumed, Mann Whitney U test was applied to check the differences b/w the means of the groups. No significant difference in FOIS scores between the two groups (p > 0.05) was recorded during baseline assessment (table 2). After 12 sessions, there was significant improvement in FOIS scores of experimental groups as compared to the control group (p = 0.023). Greater improvement in FOIS scores of experimental groups was observed, increasing from 4 ± 1 at baseline to 6 ± 0 at post-assessment. Alternatively, the control group score remains at 5 ± 1. The severity was significantly lower in experimental group than the control group after post assessment (MR = 8.67 vs 4.33). Thus the null hypothesis was rejected.

Table No.1: Comparison of Endurance and Strength between Groups

Variable	Group	Mean ± SD	P value
Strength	Experimental	11.33 ± 3.36	.000
	Control	2.36 ± 2.08	
Endurance	Experimental	4.00 ± .894	.000
	Control	1.33 ± .816	

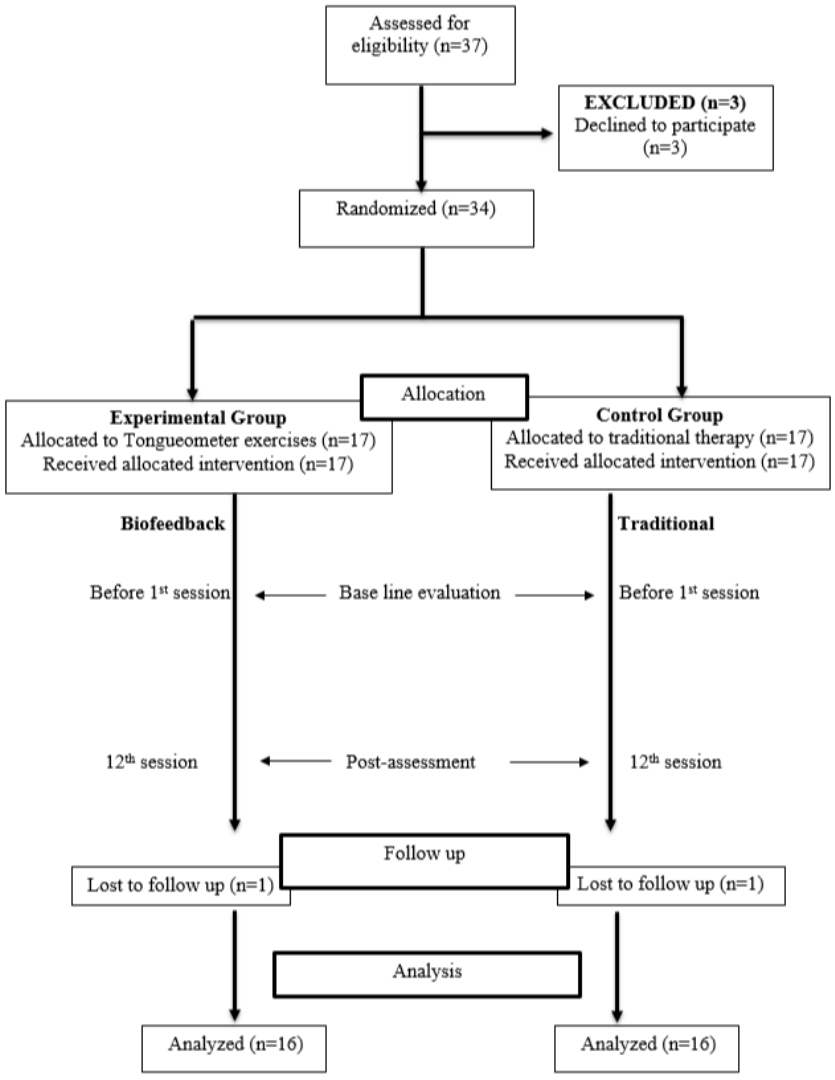

Figure No.1: CONSORT Diagram

Table No.2: Mann Whitney Test (Severity of Dysphagia)

Variable	Time of collection	Group	Mean ± SD	MR	p- value	IQR
FOIS	Baseline	Experimental	4 ± 1	5.50	.269	1
		Control	5 ± 1	7.50		
FOIS	Post Assessment Score	Experimental	6 ± 0	8.67	.023	1
		Control	5 ± 1	4.33		

DISCUSSION

This research assessed the effect of biofeedback therapy on the severity of dysphagia, specifically functional oral intake and strength of the tongue. The results show that biofeedback significantly improves swallowing function, as indicated by FOIS scores and strength of the tongue measurements.

The biofeedback group showed considerable improvement in FOIS scores after the intervention (mean = 6 ± 0) compared to the control group (mean = 5 ± 1) with a p-value of 0.02. This is in support of earlier studies in which biofeedback interventions showed significant improvements in swallowing function. Similarly. a study results found a clinically significant FOIS score improvements in chronic stroke patients after surface electromyography (sEMG) biofeedback training, from median scores of 1 to 6 ($p < 0.01$).

The biofeedback group also demonstrated significantly greater tongue strength and endurance than the control group, as measured by independent t-tests. These findings are in agreement with studies using the Iowa Oral Performance Instrument (IOPI) for tongue-pressure training that have reported that biofeedback-supported exercises can enhance tongue strength and pressure-generation accuracy in patients with dysphagia[18].

The measured median ranks (MR = 8.67 for the experimental group versus 4.33 for the control group) reflect a noteworthy decrease in the severity of dysphagia in the biofeedback group.[19]

This is confirmed by studies showing that biofeedback therapy can result in enhanced swallowing safety and pharyngeal clearance among post-stroke dysphagia patients[19].

CONCLUSION

In conclusion, this study highlighted the significant advantages of biofeedback tools such as Tongueometer over traditional therapy for managing dysphagia in Parkinson's clients, mainly by improving tongue strength, endurance and functional swallowing. These findings also highlighted the potential for biofeedback tools, such as Tongueometer to be integrated in the dysphagia management practices.

Author's Contribution:

Concept & Design or acquisition of analysis or interpretation of data:	Gulalai Shafique Khan, Maryam Nadir Kiyani
Drafting or Revising Critically:	Tehreem Ijaz, Tahira Yousaf, Sidra Imran
Final Approval of version:	All the above authors
Agreement to accountable for all aspects of work:	All the above authors

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