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Efficacy of Swallowing Resistance Exercise Programs on Swallowing Function and Head Posture in Diabetic Older Adults with Cervicogenic Dysphagia. Randomized Controlled Study

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ABSTRACT

Background: The coupled effects of age advance and type 2diabetes mellitus (T2DM)is profoundly impacting the swallowing function (SF).

Purpose: To investigate the effectiveness of swallowing resistance exercises programs on the swallowing function (SF) and the forward head position (FHP) in diabetic older adults with cervicogenic dysphagia (CD).

Methods: 70elderly patients (age 60-75 years) with T2DM and CD, participated in this randomized controlled study, were randomly allocated to the study group-I (n=23), study group-II (n=23), and the control group (n=24). The SF(using the swallow difficulty questionnaire "SDQ") and the forward head position (FHP) (through the craniovertebral angle "CVA")were evaluated pre-and post-study. Participants of the study groups received 3 sessions per week for 8 successive weeks. The study group-I received the "swallowing resisting" exercise program, the study group-II received the resisted "chin tuck-in" exercise program,while the control group did not participate any training programs.

Results: In the study group-I,there was significant decrease in the SDQ scores (by -100.74%, P=0.00), but non-significant increases in the CVA(by 1.67%, P=0.30). Also, in study group-II; there was significant decrease in the SDQ score (by -232.51%, P=0.00), significant increases in the CVA (by 10.67%, P=0.00). While in the control group; there wasnon-significant decrease in the SDQ score (by -0.86%, P=0.74), and non-significant increases in the CVA (by 0.52%, P=0.61).There were significant differences in the SDQ scores (P=0.00) and theCVA (P=63-6) between-groups, in favor of the study group-II.

Conclusion: Swallowing resistance exercise programs can effectively improve the SF and FHP in diabetic older adults with CD.

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INTRODUCTION

The world is going through a huge demographic transition in which people older than 60 will constitute more than one-fifth of total world population by 2050.[1]Aging negatively and progressively impacts the swallowing function and lingular pressure gradient even in a symptomatic elderly.[2]A large proportion of the elderly admitted to hospital,[3] or those live independently,[4,5] are affected with swallowing difficulty and are predisposed to increased mortality and morbidity.[6]The predicted ongoing increase in the percentage of the elderly magnifies the demand for elderly-related healthcare services especially with presence of the non-communicable diseases as diabetes, obesity and cardiovascular diseases.[7]

Swallowing represents a complex sensorimotor process produced by different muscles and integrated movements.[8]Swallowing is basically composed of the volitional oral, then the reflexively-mediated pharyngeal, and finally, the coordinated esophageal anatomic phases.

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[9]Successful swallowing process includes harmonized and effortlessly volitional passage of the food or fluid bolus from the oral cavity towards the esophagus, followed by reflexive passage through the aerodigestive tract.[10]

Swallowing difficulty, defined as dysphagia is a serious, under-diagnosed health concern,[11]affecting about 68% of the elderly nursing home residents,[12]affecting about 30-40% of subjects older than 65 years,[13]with the oropharyngeal dysphagia is considered as a geriatric syndrome,[14]especiallywith existence of the age-related frailty and sarcopenia.[15]Although swallowingdifficulty is common among elderly with diabetes, but favorable results can be obtained through the rehabilitation programs.[16]Weakness of the oropharyngeal musculatures predisposes to swallowing difficulty and dysphagia,[17]that is anatomically classified into oropharyngeal or esophageal dysphagia.[18]Dysphagia is also classified according to the pathophysiology into either structural/ organic cause or physiological alternations and modifications.[19]

Disturbed cervical curvature is commonly associated with swallowing difficulty and dysphagia,[20]this is in part due to close proximity of the oropharynx and esophagus to the cervical spine.[21]Cervical abnormality and malalignment can indirectly alter the laryngeal closure pattern through direct compression on the esophagus,[22]disturbing the pharyngeal function,[23]ending in disturbed swallowing maneuver and is usually associated with abnormally increased score in the swallowing disturbance questionnaire (SDQ) more than 12.5 cut-off value which is considered a strong indicator for detecting swallowing difficulty and dysphagia.[24]

Early management of dysphagia and swallowing difficulty is important to prevent the associated complications and to alleviate the related economic burden.[25]Despite the obvious achievements in the dysphagia management, but still, more researches are warranted to fully understand the effects of different conservative rehabilitation approaches.[21]The goal of this study was to investigate the efficacy of the resistance training programs on the swallowing function, and the head posture in the elderly patients with diabetes and swallowing difficulty.

METHODS

Study Design

The study followed the randomized controlled, pre-test post-test study design.

Participants

Recruitment and Sample Size

Elderly patients with diabetes and swallowing difficulties were recruited via social media and face-to-face recruitment methods. The sample size was calculatedconsidering the swallowing difficulties prevalence among patients with diabetes mellitus is about 17.5%, [16]the power of 0.9, effect size of 0.45, and 0.05 alpha value, yielded that the total sample size for the 3 groups was 66, required to provide significant results. Extra 4 participants were included to anticipate any suspected withdrawals, so the total participants number was 70 participants of both genders (45 men and 25 women).

Inclusion and exclusion criteria

Patients with type 2 diabetes mellitus (T2DM) and difficulty of swallowing, oropharyngeal dysphagia, age 60-75 years,with craniovertebral angle (CVA≤ 49^O; describes as forward head posture(FHP), and signed written consent were included in this study.

Patients younger than 40 or older than 60 years, with type-1 diabetes, with esophageal dysphagia,on another exercise training program, with recent operations, or cardiovascular instability, with active inflammatory or infectious disorders, or who cannot follow the study instructions or did not provide a signed written consent were excluded from the study.

Randomization

110older adults with T2DM, complaining of swallowing difficulty were initially screened, but only 70 patients (45 men and 25 women) met the inclusion criteria and were randomly distributed through the randomizer software(https://www.randomizer.org/) to study group-I (n=23), study group-II (n=23), and the control group (n=24)(Figure-1; flow chart). The study group-I received the swallowing resistance exercise program-1 (SREP-I), The study group-II received the SREP-II, while the control group did not participate any SREP. Participants in all groups were encouraged to stabilize their pharmacological treatment throughout the study.

All participants received detailed orientation about the study procedures, assessment and treatment steps, and provided a written informed consent, approving volunteer participation and publication of the study results.

The nature of the study did not allow full blinding, participants get oriented about the provided treatment, therapist were aware about the therapeutic maneuvers, only assessors became blind to the provided treatments and groups' allocation. The swallowing function (SF) was the primary outcome (evaluated using the swallow difficulty questionnaire “SDQ”), while the FHP (evaluated through measuring the craniovertebral angle “CVA”) was the secondary outcome, and were evaluated pre-study, and after 8-weeks (post-study) in all participants.

Evaluations

Participants’ demographic characteristics

Participants age (in year), weight (in kg), height (in meter), body mass index (in kg/m^2) were assessed using standard weight and height scale (Detecto scale, USA). The diabetes statuswas confirmed via the laboratory assessment of the fasting blood glucose (FBG; in mg/dl) level and the glycosylated hemoglobin (HbA1c%).The resting heart rate and blood pressure (using BTL CardioPoint ABPM, USA) were also evaluated.

Assessment of the craniovertebral angle (the forward head position)

The forward head posture was evaluated via measuring the craniovertebral angle (CVA^O). The CVA was measured between the line extending from the ear tragus to the 7^{th} cervical vertebra (C7) spine and the horizontal line crossing the C7, and was evaluated according to the previously described

procedure.[26]

The CVA was evaluated through the digital imaging technique. After localization of the ear tragus and the C7 spinous process points by adhesive small circular tapes, the participant was directed to stand quietly with the body weight equally distributed over both lower limbs, looking straight forward on a mirror placed in front, with left shoulder facing the camera (Canon Vlogging digital camera)placed 200 cm away from the participant's left shoulder, at the level of participant's neck area. A three-lateral view photographs were then taken, and analyzed using the Photoshop software (Version 11.4.162, Adobe Systems Inc., USA), the average value was recorded for analysis. The CVA lesser than 49 ^{O} was indicative of the FHP.[27]

Assessment of the swallowing function (via the swallowing disturbance questionnaire; SDQ)

The swallowing disturbance was ensured if the swallowing disturbance questionnaire (SDQ) score was 12.5 or more. The SDQ constitutes 15-items, the first 5-questions are concerned with swallowing oral phase evaluation, while the following 10-questions are evaluating the pharyngeal phase. The 4-points rating scale (from 0 to 3) was used to respond to the first 14-questions, with "0" indicates no disturbance, "1" indicates disturbance occurring once or less a month, "2" indicating disturbance occurring 1-7 times per week, "3" indicates disturbance encountered more than 7-times per week. The SDQ 15thQuestion scoredas (yes: weighted as 2.5) or (no: weighted as 0.5).[24]

Interventions

Participants in both study groups were instructed to stabilize their medications, daily activities and dietary habits during the study period.The intervention programs for group I and II were applied in the form of day-after-day sessions (3 sessions/ week) for 8 successive weeks. Participants in the group I and II received the resistance exercise program-Iand II respectively in addition to the prescribed pharmacological treatment, while the control group received only the prescribed medications.

The resistance exercise program-I (The swallow resisting exercise program)

Participants in group I received the swallow resistance exercise program previously described by Agrawal et al.,with introducing minor modification to the Agrawal et al.,protocol; the gradually increasing resistance was applied to resist the anterior and superior laryngeal movements using a pressure monitoring instrument, (Rossmax - GB102 Aneroid Monitor, China) through an inflatable bladder (cuff)positioned on the anterior neck aspect on the laryngeal cartilage and secured by a surrounding strap. While the patient sits comfortably, the applied pressure was controlled via a pressure gauge and was gradually increased until it reached the target value usinga hand pump connected to the inflatable bag by a flexible catheter.[28]All participants in the group-I were managed byqualified Physiotherapist, the resistancewas gradually increased over the 8-week study period, resistance started as 20 mmHg during the first 2 weeks, progressed to 30 mmHg during the following 3 weeks, and reached 40 mmHg during the last 3 weeks. The swallow resistance training program was applied by asking the patient to perform 5 sets of 6 repetitions of slowly performed resisted saliva swallows, with 15 seconds of rest between sets.

The resistance exercise program-II (Resisted Chin tuck-in exercise)

Participants in group-II underwent evaluation of the maximum chin tuck strength (MCTS) by expert speech and language therapist. Then each participant assumed a relaxed setting position, and was directed to exert maximum force while performing 3 trials of 5 seconds eah, of chin tuck against suitable-size, air-filled bladder (cuff) secured below patient's ching, connected to a pressure gauge with a flexible catheter. (Rossmax - GB102 Aneroid Monitor, China) The best trial reading was reported to determine the participant's safe submaximal "target training intensity"which was set at 30% of the MCTS.[29]

Slightly modifying the protocol described by Smithard et al.,[29]and Yoon et al.,[30],each participant assumed relaxed setting position, and thriugh using the a pressure monitoring instrument (Rossmax - GB102 Aneroid Monitor, China), each particpant in group-II performed chin-tuck exercise against resistance applied by positioning a suitable-sizeair-filled bladder (cuff) under the chin, connected to a pressure gauge via a flexible catheter to monitor the produced pressure when the patient tucked his/her chin-in.Each particpant was directed to adjust his/ her effort to maintain the "target training intensity" which equals to 30% of the MCTS.The resistance training program was applied by asking the patient to perform 2 sets of 3 repetitions of chin tuck resisted exercise, one-minute duration for each repetition, with 15 seconds of rest after each repetition.

Statistical analysis

The statistical analysis was done using the SPSS software, version-20for windows (SPSS Inc, Chicago). Data were represented as mean ± SD. Changes in the SDQ mean scores, and the CVAmean values were compared within-groups by the student t-test and between-groups by the one-way ANOVA. $P < 0.05$ was considered the significance cut-off value.

RESULTS

Seventy participants were voluntary participated in this study, no serious events or drops-out were reported during the study.

The demographic characteristics of the participants in both groups are reported in (Table 1). No significant differences existed between-groups in the demographiccharacrtistics including age (P=0.98), height (P=0.94), weight (P=0.98), BMI (P=0.99), systolic blood pressure (P=0.99), diastolic blood pressure (P=0.68), resting heart rate (P=0.33), gender distribution (P=0.98), dysphagia duration (P=0.87), diabetes duration (P=0.9), fasting blood glucose level (P=0.89), and the glycosylated hemoglobin level (P=0.23)

No significant differences exist between-groups at the beginning of the study in the forward head position (the CVA mean values; P=0.82), or in the swallowing function (SDQ mean scores; P= 0.098). There were significant post-study differences between groups in the CVA ($P=63^{-6}$), and the SDQ (P=0.00) in favor of the study group II.

Within the study group I; there werenon-significant increase in the CVA mean value (by1.06%; P=0.3), significant decrease in the SDQ mean value (by -100.74%; P=0.00).Within the study group II; there were significant increase in the CVA mean value (by 10.67%; P=0.00), and significant decrease in the SDQ mean value (by -232.51%; P=0.00).Within the control group; there wasnon-significant increase in the CVA mean value (by 0.52%; P=0.61), and non-significant decrease in the SDQ mean value (by -0.86%; P=0.74) (Table 2).

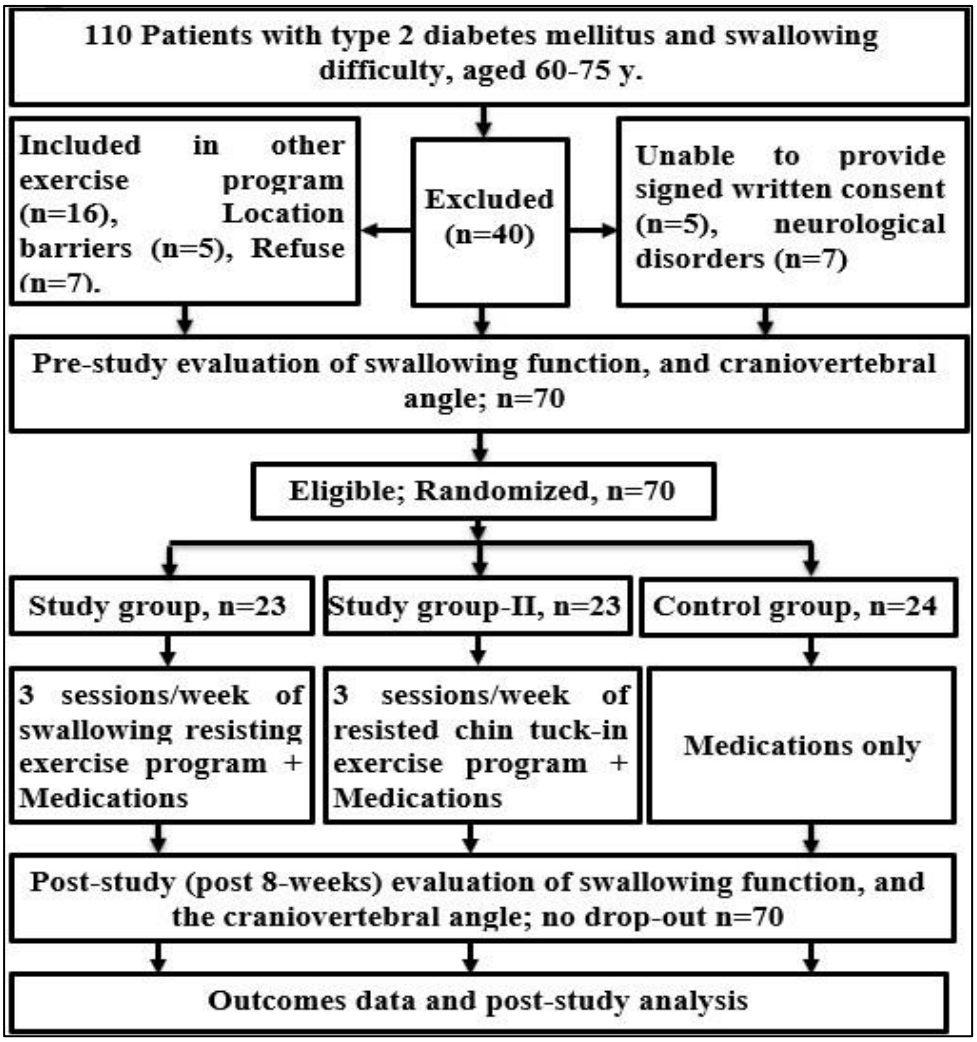

Figure 1. Patients' flow chart.

Table 1. The demographic participants' characteristics in all groups

Variables	Study group-I (n=23)	Study group-II (n=23)	Control group (n=24)	P value✡
Age (year)	67.22±3.94	67.04±3.17	67.21±3.04	0.98**
Weight (kg)	74.22±9.74	73.61±11.19	73.83±6.47	0.98**
Height (m)	1.64±0.05	1.64±0.04	1.64±0.03	0.94**
Body mass index (Kg/m^2)	27.48±3.43	27.43±4.51	27.42±2.35	0.99**
Cervicogenic dysphagia duration (year)	2.94 ± 0.46	3 ± 0.62	3.02 ± 0.67	0.87**
Diabetes duration (year)	11 ± 1.45	11 ± 1.86	10.79 ± 2.02	0.9**
Fasting blood glucose level (mg/dl)	167.48 ± 9.67	168.65 ± 8.71	167.88 ± 7.32	0.89**
Glycosylated hemoglobin %	8.43 ± 0.26	8.25 ± 0.42	8.28 ± 0.43	0.23**
Systolic blood pressure (mmHg)	140.91 ± 4.14	140.78 ± 4.47	140.71 ± 3.79	0.99**

Diastolic blood pressure (mmHg)	85.78 ± 2.95	85.35 ± 3.3	85.04 ± 2.46	0.68**
Resting heart rate (beat/min)	77.78 ± 5.1	77.91 ± 9.63	75.04 ± 6.7	0.33**
Gender (Men: Women)	15(65.2%):8 (34.8%)	15(65.2%):8 (34.8%)	15 (62.5%): 9 (37.5%)	0.98**

☼ =Level of significance at P<0.05. * = significant ** = non-significant

DISCUSSION

Dysphagia in the elderly became an alarming healthcare concept, with continuously increasing cost. Varity of training maneuvers are available for rehabilitation of patients with dysphagia, but little is known about the optimal training parameters in terms of frequency and treatment duration.[31]More researches are required to clarify the effects of different rehabilitation programs in patients with different dysphagia types.[32]

Table 2. Within and between-groups comparisons of swallowing function, and craniovertebral angle mean values in all groups.

Variables		**Study group-I (n=23)**	**Study group-II (n=23)**	**Control group (n=24)**	**P value☼**
Swallowing function (SDQ) score	Pre-intervention	17.57 ±3.25	17.65 ±3.33	17.5 ±3.5	0.98**
	Post-intervention	9.35 ±3.05	06.39 ±2.97	17.42 ±3.61	0.00*
T, P value		15.41, 0.00*	29.36, 0.00*	0.34, 0.74**	
Forward head position (CVA^{O})	Pre-intervention	36 ±4.09	35.39 ±3.38	35.5 ±2.77	0.82**
	Post-intervention	36.44 ±2.95	39.04 ±2.57	35.63 ±2.16	63^{-6}*
T, P value		-1.06, 0.302**	-12.22, 0.00*	-0.51, 0.612**	

☼ =Level of significance at P<0.05. * = significant ** = non-significant, **SDQ:** The swallow difficulty questionnaire**, CVA:** The craniovertebral angle.

Although the exercise training proved its effectiveness in alleviating dysphagia and improving the deglutition function, but still no standard practical procedure to follow while applying the exercise training for elderly with dysphagia, the treatment goals should be personalized to ascertain individual benefits.[31]results of the training-comparative studies can provide clues and guidelines to be administered during dysphagia rehabilitation programs.

This study investigated the effectiveness of the swallow resisting exercise program and the resisted chin tuck-in exercise program on the SF and the FHP in diabetic older adults with CD. Results concluded that the resisted chin tuck-in exercise program was effective in improving the SF and the FHP, compared with the swallow resisting exercise program that was effective in improving the SF only.

The current study conclusions clarified that the SF improvement can be achieved even without improvement in the FHP in diabetic elderly patients with CD. These conclusions were further supported by Aslam and Vaezi findings stated that aging adversely affects the SF, with the majority of the elderly with dysphagia can benefit from the dysphagia- targeting rehabilitation programs, even though the underlying pathology is not responding to treatment.[31]

The swallowing difficulty encountered in the elderly with diabetes can be explained on the basis that the age-related decrease in the muscular properties and connective tissues elasticity that predisposed the elderly to the decline in muscle strength and range of motion, that negatively impacted the swallowing process in the elderly.[33, 34] Furthermore; the cervical kyphosis and the FHP are usually associated with deep cervical flexors weakness and dysfunction, which is associated with disturbed cervical stability and pharyngeal dysfunctions during swallowing,[35]and finally predisposing for CD.[25]

The mal-aligned cervical spine can negatively affect the cervical and oral structures functions,[40]disturbs the laryngeal position and swallowing muscles function, and results in oropharyngeal dysphagia.[21]Additionally; the abnormally encountered FHP limits the cervical extension and the occiput-C2 angle, ending in deteriorated oropharyngeal space and arising of swallowing difficulties.[36]

Accordingly; it is assumed that modulating and improving these properties can significantly and positively impact the SF in elderly subjects with diabetes. Encountered swallowing difficulties and gastrointestinal disturbances can be significantly improved following segmental re-alignment training programs of the cervical spine.[37, 38]Additionally, variety of neck pathologies-associated symptoms can be effectively improved after providing strength training programs for cervical muscles.[39]

Many studies previously reported the effects of the cervical resistance exercise training in patients with dysphagia. Shaker et al., reported that cervical strengthening training increased cervical stability and significantly controlled the dysphagia impacts.[32]even short training period of 2-weeks can improve the

dysphagia severity in patients with maladjusted cervical spine.[20] Furthermore; cervical alignment and swallowing function respond favorably to the cervical isometric exercise training in patients with neurological insults.[40]

Limitations

The limited blinding procedure is the main concern. Future researches with larger sample sizes, many interventions, and longer durations should be conducted to evaluate the short as well as the long-term effects of the dysphagia-targeting interventions.

CONCLUSION

Swallowing resistance exercise programs can effectively improve the SF and FHP in diabetic older adults with cervicogenic dysphagia (CD).The resisted chin tuck-in exercise training is more effective than the swallow resisting exercise training in enhancing the swallowing function (SF) and the forward head position (FHP) in elderly patients with diabetes and CD.

Data Availability

Data will be provided upon request.

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Ethical Approval

This study procedures adhered to the Helsinki Declaration 1975, revised in 2000, was approved by the institutional ethical committee (Approval No. HAPO-02-K-012-2023-01-1956), and was conducted at Umm Al-Qura University, Saudi Arabia.

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None.

Conflict of interest

None

Informed Consent

each participant in this study provided a signed written informed consent at the beginning of the study, approving volunteer participation and publication of the study results.

Authorship contribution

The author contributed fullyto all the three categories established by the International Committee of Medical Journal Editors 1) conception and design, acquisition, analysis and interpretation of data; 2) drafting the article, revising it critically for important intellectual content; and 3) final approval of the version to be published.

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