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Effect of shakers exercise with kinesio taping in subjects with gastroesophageal reflux disease: A randomized controlled trial

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ABSTRACT

The prevalence of GERD in India ranges from 8-20% according to recently conducted studies based on different case definitions and study methodology. Although GERD is rarely life-threatening, it can severely limit daily activities and productivity. The principal goal for GERD treatment is relief of symptoms. Hence the aim of this study was to compare the effect of Shakers Exercise with kinesio taping and medical management over only medical management of GERD on severity of the disease and functional limitation. 30 participants clinically diagnosed with GERD were recruited.15 participants were allocated to control group (CMED) where only medical management was given and other 15 were allocated to intervention group (SKT)where shakers exercise, kinesio taping and medical management were given. Frequency Scale for the Symptoms of GERD was the outcome measure. Paired and unpaired t-test was used to test the significance of difference between mean values of two groups (CMED) and (SKT). Statistically significant improvement was observed in both the groups when compared before and after intervention. However, the SKT showed to be better than CMED group post intervention. It was concluded that Shakers exercise and Kinesio Taping should be incorporated along with medical management in the treatment of patients with GERD on routine basis.

Key words: GERD, Kinesio taping, Shakers exercise, Medical management

INTRODUCTION

During normal digestion, food goes down the esophagus through a muscle or valve known as the lower esophageal sphincter (LES) and into the stomach. The main function of the LES is to serve as a barrier to protect the esophageal mucosa and more proximal structures from potentially damaging substances in the stomach including gastric acid, pepsin, and bile salts. [1]Incompetence in some form of the LES is the predominant determinant of Gastro-Esophageal Reflux disease (GERD). It results from backward flow of the stomach contents into the esophagus and causes trouble symptoms. [2-4]

Roughly one half of the adult population in industrialized countries has experience of reflux symptoms and 20%-30% suffer from disease. The traditional belief is that GERD occurs less frequently in Asia than in Western countries. However, there is an emerging suggestion that prevalence of GERD may be on the rise in Asia.[5]There is paucity of data regarding the magnitude of the problem in India. A recent study has shown the prevalence of GERD to be 16.2% among the employees of a large tertiary hospital in North India. [6]

Causes of gastroesophageal reflux in adults include an increased number of transient lower esophageal sphincter relaxations, ineffective esophageal mobility, and reduced lower esophageal sphincter tone.[7]Risk factors for

gastroesophageal reflux disease include obesity. One of the most probable mechanisms is the increase in mechanical stress imposed on the gastroesophageal junction (GOJ) and the predisposition to hiatus hernia other factors are use of estrogens, nitrates, anticholinergics, and tobacco products. [8]Symptoms associated with GERD include heartburn, acid regurgitation, and belching, sore throat and chest pain as well as "extra-oesophageal" manifestations such as nausea, chronic coughing, asthma and hoarseness. All the symptoms may compromise the health-related quality of life. [9]

Diagnosis of GERD is done by traditional diagnostic modalities such as barium swallow and endoscopy have a sensitivity of 10% to 50% and 30% to 50% respectively. [10]Endoscopy is the most widely used method to diagnose esophagitis and follow up GERD. It is also useful in diagnosis and management of the complications of GERD. There are several classification systems for grading the endoscopic severity of erosive reflux esophagitis and associated complications. Currently the most commonly used systems are Los Angeles classification. Grade description:- A- One(or more) mucosal break no longer than 5mm that does not extend between the tops of 2 mucosal folds, B- One(or more) mucosal break more than 5mm that does not extend between tops of 2 mucosal folds, C- One(or more) mucosal break that is continuous between the tops of 2 or more mucosal folds but that involves less than 75% of the circumference, D- One(or more) mucosal break that involves at least 75% of esophageal circumference. [10]

Symptom-focused questionnaires have an important role in clinical trials of GERD management. A patient's self-report on symptom status is now believed to be more reliable than a physician's assessment. [11] Frequency Scale for Symptoms of GERD (FSSG) scoring is widely used as it can evaluate not only the acid-reflux related symptoms but also the dyspeptic symptoms; the FSSG showed a sensitivity of 62%, a specificity of 59% and accuracy of 60%. The score obtained using the questionnaire correlated well with the extent of endoscopic improvement in patients with mild or severe GERD. This questionnaire was suggested by the authors as useful for the objective evaluation of symptoms in GERD patients.[12]

Management of GERD is usually medical approach which includes life-style modifications and drug therapy. As per the American College of Gastroenterology (ACG) guidelines, acid suppression is the mainstay of therapy for symptom relief in GERD in both the acute and long-term treatment of the disease. Proton pump inhibitors (PPIs) remain the mainstay of treatment which provides most rapid symptom relief and heal esophagitis in the highest proportion of patients. It is recommended for both moderate and severe GERD and its complications. Pooled results from clinical trials on H2RA demonstrate a 50 to 75% rate of symptom control and mucosal healing. [13] However it is less effective in patients with moderate to severe erosive disease, with response rates of nearly 80% in grade I to II esophagitis, but only 30 to 50% in grade III to IV disease. [13-15] A study done on pathophysiology and pharmacological treatment of GERD reported that an uncomplicated GERD may be treated by medications along with modification of life style and eating habits in an early stage of GERD. [16]Hence there is a need for allied health treatment to be added as an adjunct to the medical management. The allied or complementary treatments can be in the form of exercises, massage, myofascial therapy, taping, chiropractic etc.

Kinesiology taping (KT) was developed by Japanaese Chiropractor Dr.KenzoKasein the 1970's. It is a therapeutic tool developed with the intention to alleviate pain and improve the healing in soft tissues and has become increasingly popular within the sporting arena. [17]There are many proposed benefits to KT, including: proprioceptive facilitation; reduced muscle fatigue; muscle facilitation; reduced delayed-onset muscle soreness; pain inhibition; enhanced healing, such as reducing edema, and improvement of lymphatic drainage and blood flow. [17]Kinesiotaping is suggested by the chiro-practitioners for management of Indigestion.[18]A case report is available in pediatric population in which Kinesio Taping is applied with the idea of maintaining corrected stomach position and stimulating proprioceptive response from the skin surrounding the upper abdominal area to decrease acid reflux. [19]But, there is scanty literature which can confirm effectiveness of kinesio taping in adult age group. Reza shaker, a gastroenterologist is the founder of Shaker's exercise. According to him, the exercises can help improve pharyngeal swallowing and dysphagia as the classic symptoms of GERD include heartburn, regurgitation & dysphagia. The effectiveness of Shaker's exercises has shown to be useful in subjects suffering from upper esophageal dysfunction, dysphagia and deglutition issues in adults & in elderly patients.[20-22]however, there are notrials done to study effect of Shaker's exercises on symptoms of GERD.

Hence, it was hypothesized that combination of K-taping with Shaker's exercises may have additive benefit on subjects with mild and moderate grades of GERD. Thus, the objective of the present study was to study the effects

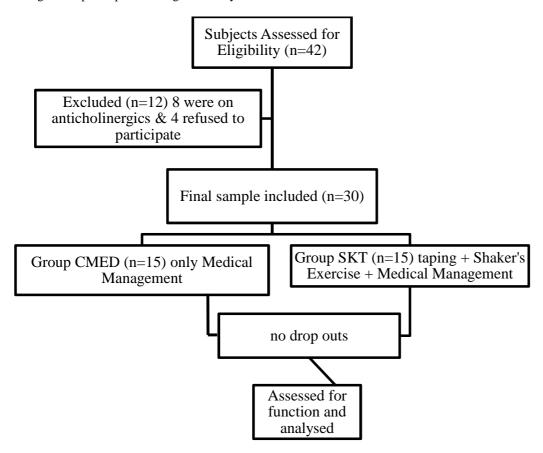
of Kinesio-taping and Shaker's exercises along with medical treatment and compare with subjects treated only with medical management on reduction of severity of symptoms of the disease.

MATERIALS AND METHODS

The study was a randomized controlled trial. The study was approved by the Institutional Ethical Board. Subjects were from the tertiary care hospital. Subjects were screened for inclusion and exclusion criteria and then included in the study. The inclusion criteria were: (1) subjects diagnosed with GERD by certified Gastroenterologist 2) both male and female subjects aged 18-55 years (2)Grades A & B GERD according to Los Angeles grading for GERD by Endoscopy (diagnosed by Gastroenterologist)(3) Patients willing to participate. The exclusion criteria were: (1)Past history of any pharyngeal surgery procedures (2)lack of cognition or comprehend commands (3)history of alcoholic neuropathy (4)patient who could not lift their head and flex the neck(5) individuals unable to exercise independently or with caregiver (6) currently using Anticholinergics or any drugs which cause GERD symptom (7) known dermatological condition (8) any contraindication to kinesio-taping. All participants gave written informed consent prior to this study.

The subjects were divided randomly into 2 groups as follows. (CMED): Control group-15 subjects received only medical management. Group (SKT): Experimental group-15 subjects received Shakers exercise and Kinesio taping along with medical management.

Flow diagram of participants through the study



Interventions: CMED (Control) & SKT (Experimental) group consisted of the standard medical management given by Gastroenterologist which by and large included the same group of medicines for all the participants. The participants in the SKT (Experimental) group in addition to medical management received supervised physical therapy treatment which consisted of Shaker's exercise (Figure 1) every day and KT tape (Figure 2) for 3 times in

the 10 days of treatment sessions. The exercises and taping was done by a certified physical therapist. The treatment session lasted for 10days for both the groups. All the participants were assessed for outcome measure on the 1st day pre-intervention and 10th day post intervention.

Medical intervention:

This included standard prescription of medications by certified Gastroenterologist. This included the following set of medications and dosages as per the requirement and severity of the subjects' symptoms.

- Antacids &/ H2 blockers and/ proton pump inhibitors
- Prokinetics

Figure: 1. Shaker's Exercise



Figure: 2. Application of Kinesio-tape



${\bf Procedure\ for\ Physiotherapy\ intervention:}$

Shaker's Exercise: the exercises are performed in two parts viz. Isometric hold contractions followed by isokinetic repeated contractions. Initially subjects performed sustained head lifts for the 1-min in the supine position with a 1-minute rest between lifts for 3 consecutive repetitions. This was then progressed by participants' tolerance to 30 consecutive repetitions of head raisings in supine position. For both sustained and repetitive head rising, volunteers were instructed to raise the head high enough to be able to observe their toes without raising their shoulders. Participants were instructed to stop the exercises right away if the they start to feel light headed, become short of breath or get a headache. They were also instructed not to hold breath with isometric holds. Participants were advised neck stretching exercises to help ease the soreness. [4, 23](Figure: 1)The exercise program consisted of a total of 5 sessions per week over two week period.

K-tape: This included use of two I-bands with blue color code. First I tape was put at the center of the stomach above the belly button with mild stretch at the center of the tape with no stretch applied at either ends. Second tape was applied across the first tape with mild stretch at the center and no stretch at the either ends. This taping was kept for 3 days and new taping was done on 4th day. The taping was done thrice in 10 days period. [18](Figure: 2)

Outcome Measure: The outcome measure was FSSG (Frequency Scale for the Symptoms of GERD). This was a questionnaire based assessment scale which is specifically used for gastro-esophageal reflux disease (GERD). It assesses the patient's symptomatology, assessment of symptom severity and frequency, assessment of health-related quality of life and for assessment of response to treatment. (Annexure-I)

RESULTS

Statistical analysis for the present study was done using (SPSS) version 21. To find the significance of categorical variables i.e. gender Fisher's Exact Test was performed. Chi square test was done for Endoscopy grading. Paired and Unpaired t-tests were used to test the significance of difference within and between group CMED and group SKT treatment. Probability values of <0.05 were considered as statistical significant.

The demographic data and baseline characteristics are described in Table:1. There were no significant differences in baseline demographic or clinical characteristics in the two groups.

CMED Parameters p value 35.33 ± 9.574 34.8 ± 10.234 0.884° Age (mean \pm SD) 0.264^{b} Gender (M/F) 11/4 7/8Height (mean \pm SD) 163.8 ± 8.213 164.00 ± 9.457 0.935a 62.73 ± 7.126 59.87 ± 8.219 0.316 Weight (mean ± SD) $BMI \, (mean \pm SD)$ 23.59 ± 3.459 22.53 ± 3.089 0.381 W/H ratio (mean \pm SD) 0.86 ± 0.145 0.76 ± 0.135 0.061° 9/6/0/0 Endoscopy (Grade A/B/C/D) [n] 8/7/0/0 0.390°

Table: 1. Characteristics of the Study Population

 $a\hbox{--} t \ test; \ b\hbox{--} F isher's \ Exact \ test; \ c\hbox{--} Chi\hbox{--} square \ test$

The within group analysis i.e. pre post treatment comparison showed significant improvement in the FSSG score in both CMED and SKT groups (p<0.05). Hence, both control (CMED) and Experimental (SKT) groups were effective in showing better functional improvement. However, the inter group comparison showed significant difference for the functional scores using FSSG scale. (p=0.012). Thus, it can be inferred that the Shaker's exercises with kinesio taping intervention group along with the conventional medicines (experimental) showed to be more beneficial than only medicines group (control).(Table: 2)

Table: 2. Inter group comparison for FSSG scores between CMED and SKT groups

	PRE TREATMENT		POST TREATMENT	
	Mean	SD	Mean	SD
CMED	19.67	8.58	6.80	3.028
SKT	19.47	6.82	10.40	4.205
p value	0.944		0.012*	

*statistically significant

DISCUSSION

The present randomized controlled trial was conducted to compare the effect of Shakers Exercise with kinesio taping and medical management over only medical management of GERD on severity of the disease and functional limitation. The common treatment given to both the groups was conventional medical management i.e. H2 antagonist and PPIs as these drugs increase gastric emptying.

The mean age of participants in the present study was 35 years of age. GERD is known to be common condition affecting adults in the age group of 30-70 years. [24]This is further supported by a study done on prevalence of heartburn and GERD in the urban Brazilian population. The average age of both men and women in the study were 36.9 ± 15.0 and 39.6 ± 15.2 respectively. The evidence showed prevalence of heartburn to be 11.9% and GERD 7.3%. [25, 26]In present study too the number of male participants was more than the female participants. The

studies have shown that along with progressing age, the male gender is at higher risk for GERD. A review states that frequency of heartburn increased with age and was more common in men (40.7%) than women (32.6%). He also suggested that the aggravating factors that included dietary factors, spicy foods and greasy rich food along with stress. [27]Abdominal obesity increases the risk of GERD. A study was done to find association between body mass index and occurrence of GERD comparing normal weight and overweight women. The authors concluded that BMI is associated with GERD symptoms and that even modest weight gain may exacerbate reflux symptoms. [28]In another study by Jennifer Kramer, the author demonstrated that Waist-to-Hip Ratio is associated with an increased risk of Barrett's esophagus in white men. More number of patients with BE had a higher Waist hip ratio. They also suggested that there was no association between BMI and Barrett'sesophagus. [29]However, the current study showed the participants had normal BMI with borderline values of WHR.

In the present study all the participants in control group who received only medications showed significant improvement in symptoms and functions. This is in accordance to many previous studies who suggest medical management to be a mainstay of treatment for milder to moderate forms of GERD.[13-15]The various agents that were used in the present study for treatment of GERD included combinations of antacids, proton pump inhibitors, H2 blockers and prokinetics depending upon their symptom severity and grades on endoscopy. This was according to the guidelines by American Society of Gastroenterology. The medications are said to effectively treat the symptoms for mild to moderate grades of GERDs. [13]Hence, the subjects included in the current study were with mild to moderate grades of GERD.

The present study showed significant improvement in patient's functional outcomes with Shaker's and Kinesiotaping along with medical management. Basically Shaker's exercises were developed and administered for subjects with upper esophageal dysfunctions. Pathophysiologically, gastroesophageal reflux in adults is attributed to increased number of transient lower esophageal sphincter relaxations, ineffective esophageal motility, and reduced lower esophageal sphincter tone. [7] In a review article on clinical disorders of the upper esophageal sphincter the author has stated that the majority of esophagopharyngeal regurgitation events occur in the erect posture and in very close association with gastroesophageal reflux events.[30]Also, there are common symptoms of GERD and Laryngo-esophageal reflux like heartburn, dysphagia, nausea, regurgitation, belching, sore throat etc. Thus, in the present study application of Shaker's exercises for GERD symptoms is reasonable and valid.

The results of the present study demonstrated improvement in their symptoms of GERD. Shaker's exercises have shown to cause an upward and forward movement of the hyolaryngeal structures resulting from the pull of the thyrohyoid, mylohyoid, geniohyoid and anterior belly of diagastric muscles. These improvements in the patients can be attributed to factors like strengthening of the muscles that facilitate UES opening, deglutitive muscles. Thus, the exercises aid to reduce dysphagia, reflux of the food, and avoid contents of stomach from being aspirated into the throat or larynx. [22]The strengthening effects of Shaker's exercises have been studied in a comparative experimental study done where the comparative effect of a head-raising exercise on swallow-induced UES opening and hypopharyngealintrabolus pressure was assessed in the elderlyby videofluoroscopy and manometry before and after exercises. The authors concluded that this approach may be helpful in patients with dysphagia due to disorders of deglutitive UES opening. They found that in normal elderly subjects, deglutitive UES opening is amenable to augmentation by exercise this is also accompanied by a significant decrease in hypopharyngealintrabolus pressure, indicating a decrease in pharyngeal outflow resistance. [22]In the present study, similar factors might have also contributed in reducing the symptoms of GERD. Another study was done by Reza Shaker(2002)on rehabilitation of swallowing by exercise in tube-fed patients with pharyngeal dysphagia secondary to abnormal UES opening. The author concluded that after shakers exercise i.e. suprahyoid muscle strengthening exercise program is effective in restoring oral feeding in some patients with deglutitive failure because of abnormal UES opening. [31]Yet another small clinical trial was done in the year 2009 that included patients who exhibited oropharyngeal dysphagia on videofluorography (VFG) involving the upper esophageal sphincter (UES) and who had a 3-month history of aspiration. All patients were randomized to either traditional swallowing therapy or the Shaker exercise for 6 weeks. Results showed that the Shaker patients exhibited a greater reduction in post swallow aspiration than traditional therapy. [20]Hence, the above evidences show findings that are similar to that of the present study.

Kinesio taping has been suggested to be effective in treatment of indigestion. This was used by chiropractitioners along with massage and chiropractic care in pediatric patients with reflux issues. Taping has shown to be effective in facilitation and inhibition of the affected areas. In case of GERD, there are two theories or principles on which taping is said to be effective. [17-19]Firstly it provides support and secondly it reduces edema and pain. The first

effect may be due to facilitatory effect of taping on the lower esophageal sphincter which is relaxed in subjects with GERD. Since there is relaxation of lower esophagus sphincter, a kinesio tape for facilitation and support was to be applied over the area of sphincter with relevance to surface landmark of LES. The second effect can be explained as, when kinesiology tape is applied to the skin over an inflamed area; the stretch in the tape gently lifts the skin, creating a space between the skin and the tissues below. This creates an area of negative pressure, allowing both blood vessels and lymphatic vessels to dilate (open), increasing the circulation of both fluids. In this study it was seen that patients suffered from epigastric pain pretreatment and that pain was reduced post treatment in SKT group. The principle of use of blue color tape is to calm high-energystructures and to lower muscle tonus. [17-19] Similar findings were reported in a case report in pediatric Reflux disease where taping was given in combination with chiropractic care. [19]In the present study, Shaker's exercise was given in combination with Kinesio taping. However, there are no previous studies where Shaker's exercises are given along with taping for GERD.

In the present study although both control and experimental groups showed significant improvement in the severity of symptoms of GERD, the experimental group(taping+exercises+medications) showed to have additive effects over only medications.

Limitations of the study:

According to The European Medicine Agency Guidelines, trial duration of 8 weeks will be regarded as the minimum requirement for the documentation of healing of reflux esophagitis.[32]Endoscopy would show changes in mucosal healing only after minimum of 8 weeks of medical management. Due to the time constraint of the present study and difficulty to follow up with patients, the study duration was decided for 10days. The outcome measure was only subjective as in the mild and moderate grades of GERD are assessed more based on symptoms. However, the objective of the present study was to measure subjective improvements.

Future scope:

The similar research should be tried on a larger sample size and with longer duration of treatment with follow up. Future research should incorporate more outcome measures and also include objective method of assessment. Studies also should be conducted where effects of Shaker's exercises and taping on biomechanics of lower esophageal sphincter function can be objectively measured incorporating endoscopic changes, videofluroscopy and manometry.

CONCLUSION

In the present study both the groups showed significant improvement but Shakers exercise and kinesio taping along with medical management showed better improvement when compared with only medicines group. Hence, based on the results of present study it can be concluded that shakers exercise and kinesio taping along with medical management should be incorporated in the treatment of patients with GERD. The gastroenterologists should incorporate reference to physiotherapy department for additional therapy including shakers exercise and kinesio taping along with medical management in the treatment of patients with GERD of mild to moderate grades on outpatient basis.

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