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Can kinesio taping be a novel treatment option for Emesis Gravidarum? A randomized preliminary study

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ABSTRACT

This prospective, randomized study included 77 women divided randomly into two groups. To investigate the effect of Kinesio taping on nausea and vomiting in women with Emesis Gravidarum.
The study group received standard medications as metaclopramide(10 mg) twice in a day and vitamin B6(30 mg) single dose in a day and was performed Kinesio taping on the stomach region over the abdomen, while the control group received only the standard medications for treatment of emesis gravidarum. The degree of nausea and vomiting was evaluated by a 10-cm visual analogue scale (VAS) and Pregnancy unique quantification of emesis (PUQE) scoring.
There was no statistically significant difference between the two groups regarding mean of age, gravidity, parity, body mass index, gestational weeks at admission. Both groups showed a significant reduction in nausea and vomiting after the treatments. However, when considering the decrease in PUQE scores and VAS scores in groups from baseline at admission to the fifth day of treatment, the Kinesio tape group was significantly superior than the control group (p=0.048). This randomized, preliminary study demonstrates that Kinesio taping can be a useful and novel treatment option as supplement to the standard medication in the management of emesis gravidarum.

Key Words: Kinesio taping, emesis gravidarum, nausea, vomiting, pregnancy

Introduction

Nausea and vomiting during pregnancy are commonly seen complaints starting in early first trimester. The prevelance of nausea is reported to be from 50 to 80% and for vomiting it is 50% (1). It is also called as Emesis Gravidarum (EG) which is usually eperienced in morning and cause a significant impact on the quality of life of women and their partners (2). However, if these symptoms persists and cause the loss of >5 % of original body weight, dehydration, electrolyte imbalance, acidosis or ketosis during pregnancy, it is then called as Hyperemesis Gravidarum (HG) (2). This disorder is less common and affecting between 0.3% and 3% of pregnant women (3). These patients are usually hospitalised and rehydration therapy with pharmacological drugs are used for controlling this ominous condition which may be life threatening in some circumtances like electrolyte imbalance, encephalopaty, ketonaemia and weight loss (4). The exact etiology of EG and HG is not well-established and believed to be multi-factorial involving hormonal, immunological and psychosocial factors (5).

Although, the complaints of EG during early pregnancy are mild and sometimes, patients do not need and wish to take any treatment because of fearing to give harm to their baby and the feeling of themselves as guilty. However, it is reported that the emesis gravidarum negatively affected the patients' relationship with their partners and their partner's daily life and indeed their social life including worklife. Therefore it is important to treat this disorder. The treatment options including pharmacological and non-pharmacological options (1). Drug treatment is composed of different molecules including antiemetics, which includes anticholinergics, antihistamines (H1 receptor antagonists), dopamine agonists such as metoclopramide and domperidone, selective 5-hydroxytryptamine receptor antagonist (ondansetron) or any combination of these agents. In case of HG, due to the patients cannot take oral medications, these drugs are administered parenterally with rehydration (1).

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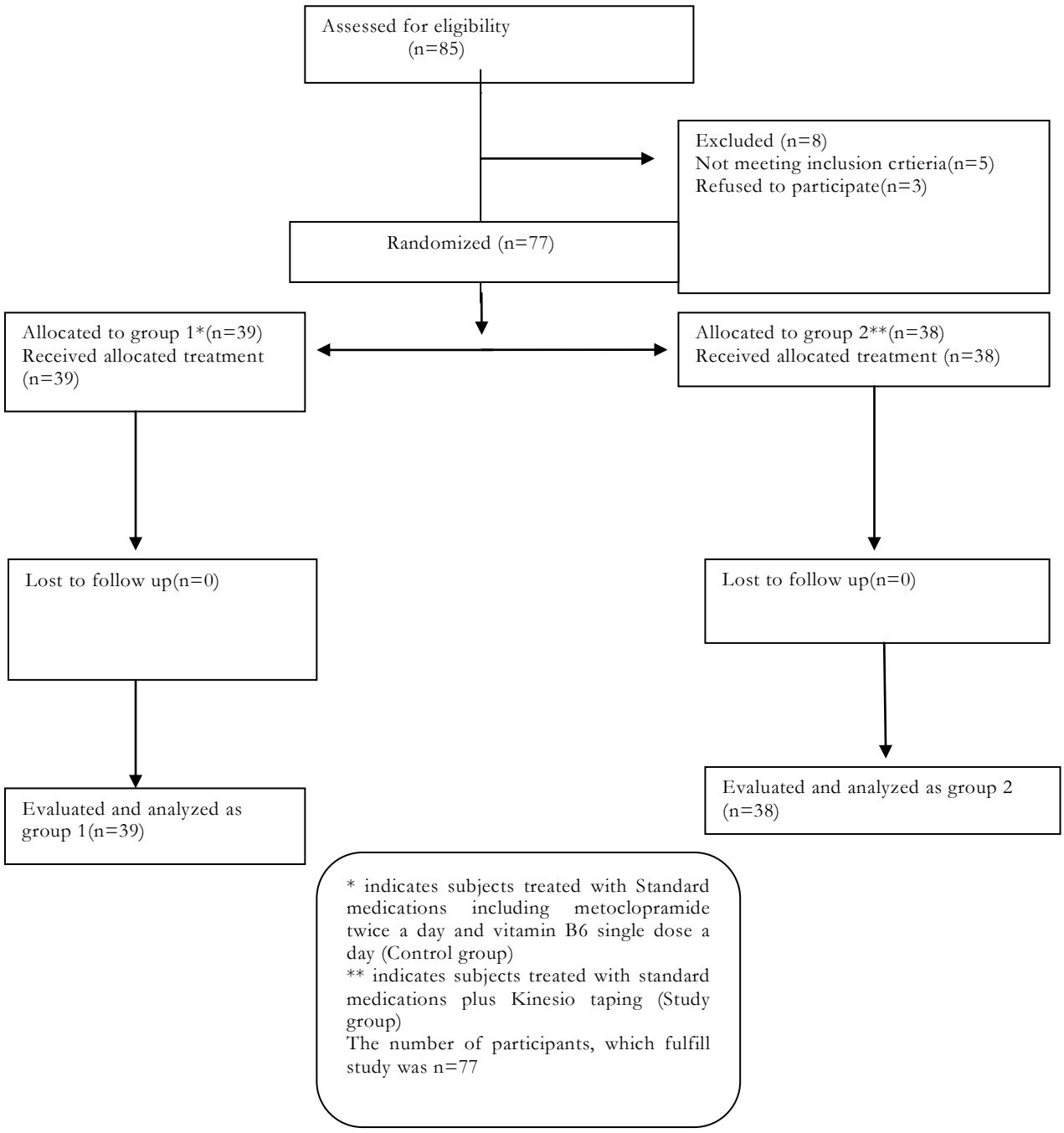

Fig. 1. The progress of subjects throughout the study

Women with EG fears from the use of these drugs and the possible teratogenic effect and side effects such as drowsiness, sedation, arrhythmia, poor efficacy of pharmaceutical medications used in the past leads to difficulty in the treatment of nausea and vomiting during pregnancy (6). Non-pharmacological option has been proposed to be effective in the treatment of both EG and HG. These include hypnosis, acustimulation, tactile massage and psychotherapy (7,8). These alternative and complementary therapy options have been studied before.

Kinesio tape is a drug-free and an elastic therapeutic tape used for treating various musculoskeletal problems such as injury, pain, and dysfunction and a variety of other disorders (9). The kinesiotaping was found to be effective in stimulation of large and small intestinal peristaltism and treated constipation in a case report (10). Kinesio taping applications were created by a Japanese chiropractor, Dr Kenso Kase, in the 1970s. Although the exact mechanisms of the effects are not yet clear, some investigators claimed that Kinesio taping has multiple functions. The inventor stated that the

Fig. 2. The application of Tape

tape should be applied from origin to insertion to inhibit muscle function (10,11). The vomiting is characterised by the retrograd peristaltism (movement) of gastrointestinal smooth muscle function. So the hypothesis of our study is based on the inhibition of retrograd peristaltism of gastrointestinal system by applying the kinesiotape from origin (from top to bottom where the stomach is placed on the abdominal region) to insertion (alongside the gastric curvature) so as to decrease the vomiting and maybe nause which is predominately induced by the central nervous system.

In this preliminary study, we aimed to investigate and evaluate whether the Kinesio taping on the stomach region can be effective to decrease the nausea and vomiting in EG patients as a non-pharamacological and safe treatment option.

Materials and Methods

This prospective randomized preliminary study was conducted in the Department of Obstetric and Gynecology and Department of Sports Medicine at a university hospital between December 2015 and September 2016. The ethics committee of the Medical Faculty of the University approved the study and informed patient consent was obtained from all patients (protocol number: 02, approved 18/12/2015). Experimental procedures followed the ethical standards for experimentation on humans declared by the 1975 Declaration of Helsinki.

Any patients with complaints of nausea and vomiting at 6-12 weeks gestation who were diagnosed as emesis gravidarum (EG) were invited to participate into the study. The patients were selected from the cohort of our hospital and also, we called the other hospitals' physicians to inform their patients with EG about the trial and to redirect them to our clinic. We applied strict exclusion criteria because of the possible confounding variables may arise in the study and affect the results. These exclusion criteria were as follows: any patient who did not accept to participate, patients with already known gastrointestinal diseae including inflammatory bowel disease, gastric ulcer and esophagitis, patients who had already the diagnosis of hyperemesis gravidarum (HG), women with multiple pregnancy and patients with chronic medical illnesses. The diagnosis of emesis gravidarum was done by nausea and vomiting in a pregnant woman who had no underlying another pathology and had no need for hospitalisation in case of hyperemesis gravidarum (HG) as described before in which more complicated treatment options should be given.

During the study period, eighty-five pregnant women were assessed for eligibility; eight were excluded from the study: one with twin pregnancy, two with known gastric ulcer and two with severe symptoms that anticipated to progress to HG. Three patients declined to participate the study because of the preliminary nature of the intervention. No patients were lost to follow-up (Figure 1). The remaining 77 patients were randomly divided into two groups through a computer generated randomisation number sequence. Thirty-nine pregnant women were randomized to a control group in whom receiving metoclopramide twice in a day (10 mg) and vitamin B6 single dose in a day (30 mg) for five days as a routine management of emesis gravidarum. The second (study) group consisted of thirty-eight patients receiving the routine medications as metoclopramide twice in day and vitamin B6 single dose in day plus the kinesiotaping intervention for five days.

Intervention: Kinesiotape was prepared, cut and applied to the study group by the same physician. The patient was standed on upright position. The physician instructed the patient about the steps of application and the tape that will not harm to her baby. The tape was placed from the sub-xyphoid region to the bottom of the right lower quadrant through the projection of gastric curvature. One I bands with a width of 5 cm and thickness of 0.5 mm were used (Kinesio tape, Libor, Turkey). The tape was placed for five days and then removed (Figure 2).

The patients were assessed for the severity of symptoms and the effectiveness of therapies. For this, two different clinical scores, Pregnancy

unique quantification of emesis (PUQE) (range 3-15) and a visual analog scale (VAS) (range 0-10), were employed to check daily the intensity of symptoms and the sense of wellbeing: higher scores indicate worse symptoms (17). The primary outcomes were checked and compared between two groups during the first admission and fifth day after treatment.

Statistical Analysis: Descriptive statistics for studied variables (characteristics) were presented as Mean, Standard Deviation values. Continuous variables were compared among the two groups using Students T-Test. Chi-Square test was used to examine the association between categorical variables. Statistical significance levels were considered as 5%. The SPSS (Version 20.0 - IBM Corp. Released 2011. IBM SPSS Statistics for Windows. Armonk, NY: IBM Corp.) statistical program was used for all statistical computations.

Results

A total of 77 patients were included in the present study and randomly assigned two groups, as shown in Figure 1. Kinesiotaping on the stomach was applied to the study group (n=38) with receiving antiemetic medications and the control group (n=39) received only the antiemetic medications. The mean age of study group and control group were as 26.24±5.30 and 25.49±5.69 which was not statistically different (p=0.552). Table 1 shows the demographic data regarding the two groups. There was no statistically significant difference between two groups regarding mean of gravidity, parity, body mass index, gestational weeks at admission and history for emesis (p>0.05).

When analyzing the education level of patients, in both groups, the majority of patients were illiterate in the study and control group (31.6% vs 38.5%, respectively). Working status of patients did not show any difference between two groups in which significant number of patients were non-working in both groups (92.1% vs 92.3%, respectively). The mean VAS scores of the study and control groups at admission regarding nausea and vomiting were not statistically different (8.09±0.81 vs 7.90±0.72, p=0.275 respectively). In each groups, the VAS score statistically significantly decreased and significant improvement was observed after treatment but this was seen statistically higher in study group (1.68±1.33 vs 2.41±1.04 p=0.009).

When evaluating the PUQE scores in the two groups, the mean PUQE score of study group was 10.97±1.88 and for control group was 10.28±1.61 at admission before treatment, which was not statistically different. In both the groups, the PUQE scores were significantly reduced at fifth day of treatment compared with baseline (10.97±1.88 vs 4.16±1.39 in study group and 10.28±1.61 vs 4.77±1.29 in control group, p<0.05). However, when considering the decrease in PUQE scores in groups from baseline at admission to the fifth day of treatment, the Kinesio tape group was significantly superior than the control group (p=0.048).

Discussion

In this randomised preliminary study, we found that kinesiotaping on the stomach region plus standard medications is more effective in reducing the nausea and vomiting in EG patients when compared to standard medications alone. Nausea and vomiting during early pregnancy have a profound effect on the quality of life of a woman. As long as the etiology and underlined mechanism is not well-known, there is a lack of evidence-based medical and caring treatments for emesis gravidarum. It is estimated that about 10% of women will require pharmacotherapy for alleviating the syptoms of nausea and vomiting during pregnancy (12). Hyperemesis gravidarum is a serious form of emesis gravidarum which leads to weight loss, electrolyte imbalance and metabolic instability and these patients are usually hospitalized and intravenous rehydration plus medications are strongly required. Although emesis gravidarum is a mild form, it also have serious impact on the pregnant woman's business life and family life so it is mandatory to treat these undesired complaints. In the current study, we evaluated the first trimester pregnant women with emesis gravidarum who managed primarily in outpatient clinic while allowing them to take the standart baseline treatment in both groups in order to eliminate the confounding variables regarding HG metabolic instability and various medications. The first line medicine used for EG that recommended by the The American Congress of Obstetricians and Gynecologists (ACOG) is that a combination of oral pyridoxine hydrochloride (vitaminB6, 25 mg) and doxylamine succinate (antihistamine, 12.5mg) (13). The other medical options for EG is antihistamines (H1 receptor antagonists), dopamine agonists such as metoclopramide and domperidone, selective 5-hydroxytryptamine receptor antagonist (ondansetron) or any combination of these agents.

Table 1	Kinesiotape (-) (n:39)	Kinesiotape (+) (n:38)	p
Maternal age	25.49±5.69	26.24±5.30	0.552*
Gravidity	2.36±1.33	2.29±1.63	0.838*
Parity	1.13±1.28	1.11±1.49	0.941*
BMI	23.32±3.39	23.97±3.75	0.427*
Education			
Illiterate	15 (38.5%)	12 (31.6%)	
Primary school	6 (15.4%)	8 (21.1%)	
Secondary school	9 (23.1%)	10 (26.3%)	0.945#
High school	6 (15.4%)	5 (13.2%)	
University	3 (7.7%)	3 (7.9%)	
Working status			
Not working	36 (92.3%)	35 (92.1%)	0.974#
Working	3 (7.7%)	3 (7.9%)	
History of emesis gravidarum	17 (43.6%)	15 (39.5%)	0.714#
Gestational week	10.82±1.57	10.23±1.55	0.105*
VAS- score 1	7.90±0.72	8.09±0.81	0.275*
VAS- score 2	2.41±1.04	1.68±1.33	0.009*
PUQE- score 1	10.28±1.61	10.97±1.88	0.086*
PUQE- score 2	4.77±1.29	4.16±1.39	0.048*

* : Students T-Test was used for comparing continuous variables

: Chi-Square Test was used for comparing categorical variables

VAS: Visual analog scale, PUQE: Pregnancy unique quantification of emesis

Because of the possible side effects of this anti-emetic drugs such as antihistaminic effect or drowsiness and extrapyramidal effects and also, the fear of using a medication due to the historical concerns and feeling guilty for a pregnant woman from the aspect of teratogenicity lead to the investigation of non-pharmacological caring and treatment options. These included tactile massages, accupressure, moxibustion procedure, herbal medicines (ginger, chamomile, peppermint, raspberry leaf), hypnotherapy, dietary interventions, activity interventions and emotional support (1).

Studies showed that physicians believe that these treatment options as 'natural' and therefore safe or lower risk than medications, and also patients easily accept to use (14). To our knowledge, no study has evaluated the effect of kinesiotape on the emesis gravidarum yet. As a preliminary study, our hyphotesis based on the physciological mechanisn of vomiting in which a retrograd gastrointestinal peristaltism occurs. And also, as a mechanical view, the Kinesio taping of an origin (the bottom of stomach) to insertion (the top of stomach) in case of vomiting may inhibit this retrograd peristaltism of stomach so as to decrease the vomiting. As an another complementary and non-pharmacological approach, acupressure is a type of acupuncture that apply a constant pressure on the P6 (or Neigun point) point and suggested to treat nausea and vomiting (15). Shin SH et al studied on the acupressure and found that Nei-Guan point acupressure is a useful treatment for relieving symptoms experienced by women with hyperemesis gravidarum (15). In the cochrane review about interventions for nausea and vomiting in early pregnancy stated that there is a lack of high-quality evidence to support any particular intervention (1). As an alternative medical approach, tactile massage was used to treat severe nausea and vomiting during pregnancy and the study concluded that tactile massage is a good alternative and complement to traditional treatment of severe nausea and vomiting (8).

The psychological theories have also been proposed to explain the etiology of HG and hypnosis as one of the psychodynamic therapy has been reported in a review that to be encouraging the positive outcomes (16). But the current evidence is not sufficient to establish the effectivity of hypnosis in the treatment of emesis gravidarum. However, the exact mechanism of these complementary approaches are not well-known. Based on these data, in this preliminary study, we thought that as a non-pharmacological

method, it was rational to study Kinesio taping on the EG patients to treat the nausea and vomiting.

Kinesiotape has been used for many various clinical condition especially for pain management such as low back pain, rotator cuff impingement or tendonitis and scoliosis (11). Like these, in a case report by Pyszora A reported a 62-year-old woman with malignancy suffering from chronic constipation and abdominal pain probably due to the lengthy immobilization and low peristaltism of small and large intestines (10). This case was treated succesfully with spiral application of Kinesio taping on the abdomen that imitate the direction of intestinal movements. So in our study, for the first time, Kinesio taping on the stomach region was studied on the patients with emesis gravidarum and it is found that this novel intervention decreases the degree of nausea and vomiting in EG patients as an outpatient procedure in addition to the use of standard medications.

On the other hand, our study had some limitations regarding the placebo effect of procedure that can not be ignored. And also, psychosocial factors that may affect the severity of emesis gravidarum and the treatment outcomes was another limitation factor. Another limitation is the subjective assessment of nausea and vomiting with VAS and PUQE scoring system, even though these are widely accepted methods to evaluate the nausea and vomiting and no other objective parameter like laboratory assessments is available for emesis gravidarum patients in which ketonuria and electrolyte imbalance are not expected in the laboratory analysis. The main strength of our study is that it was designed as a randomized study. The sample size in both groups was enough to interpret the results of the study and the patients were regularly followed up throughout the treatment period.

In conclusion, to the best of our knowledge, this is the first study to evaluate effect of kinesio taping on the nausea and vomiting during early pregnancy. Based on our preliminary results, our findings indicate that, as used, Kinesio taping is an efficacious and well tolerated non-pharmacological treatment option for emesis gravidarum. When compared with standard medications alone, combined kinesiotaping and standard medications therapy seems to be more effective to decrease nausea and vomiting in pregnant women with emesis gravidarum. Kinesio taping intervention is an easliy applicable, non-invasive and non-pharmacological method that can be be used as a complementary treatment option to decrease nausea and vomiting in women with emesis gravidarum. However, our findings should be supported with further randomised studies with different settings including hyperemesis gravidarum patients, better metodological quality and larger sample groups.

Declaration of interest.

The authors report no declarations of interest.

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