Original article

Influence of traditional Chinese medicine syndrome groups on quality of life in women with metabolic syndrome

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ABSTRACT

Traditional Chinese medicine (TCM; 中醫 zhōng yī) syndrome groups are based on the symptoms of human diseases and guide the use of Chinese herbs. The aim of this study was to examine the effects of TCM syndrome groups on biochemical characteristics and quality of life (QOL) in women with metabolic syndrome (MS). Among the 1080 registered female patients screened at our outpatient clinic, a total of 322 women aged between 18 and 65 years and meeting the requirements of MS were enrolled. All the patients were asked to fill out a questionnaire on metabolic TCM syndrome groups and a questionnaire on the QOL, the Medical Outcomes Study (MOS) Short Form-12 (SF-12). Data of biochemical characteristics were collected at the same time. The present study showed MS women in TCM syndrome groups had significantly lower physical and mental component scores in SF-12 compared with those not in TCM syndrome groups. We also found MS patients in TCM syndrome groups, except Kidney Deficiency syndrome, showed higher body mass indexes, waist circumference, and hip circumference. However, there was almost no difference in most biochemical characteristics between TCM syndrome groups. The MS patients diagnosed as belonging to TCM syndrome groups had poor QOL.
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1. Introduction

Metabolic syndrome (MS) represents a cluster of metabolic risk factors which can be defined when three or more metabolic disorders are present, namely, central obesity, hypertension and dyslipidemia, with either increased triglyceride levels or decreased high density lipoprotein cholesterol levels, and glucose intolerance.[1] Increasing obesity rates among adults are becoming more and more common. According to the Third National Health and Nutrition Examination Survey, the age-adjusted prevalence of MS among U.S. adults from 1999–2006 was 34.2%, which was a significant increase from 29.2% from 1988 to 1994. Further, the greatest increase in MS prevalence was observed in young women.[2]

Generally speaking, a person with MS is twice as likely to develop cardiovascular disease and five times as likely to develop diabetes compared to someone without MS.[3] In addition, MS has been linked to a growing list of other adverse events.[4,5] To improve the prognosis of MS, patients may seek traditional Chinese medicine (TCM; 中醫 zhōng yī) as an adjuvant treatment for controlling glucose and lipid metabolism.[6–8] According to TCM theory, physicians assess patients holistically; this consists of presenting the symptoms of illness as well as patients' emotional and psychological responses. Then, patients with different symptoms are classified into different syndrome groups. Differentiation of TCM syndrome groups is the key principle guiding the prescription of Chinese herbal formulae and is beneficial to the promotion of patient care. In the past studies, we developed a self-reported questionnaire on symptoms to facilitate classification of TCM syndrome groups and the six most common TCM syndrome groups of MS were defined.[9–11]

Some risk components of MS such as obesity, hypertension, and diabetes have been associated with impaired quality of life (QOL).[12–14] Many studies have shown that people with MS experience reduced QOL, and women with MS show even worse

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QOL.[15,16] However, few studies have addressed the association between TCM syndrome groups and QOL in MS. In our previous study, we developed a self-reported questionnaire of symptoms to facilitate the classification of different syndrome groups for different disease.[9—11] In this study, we examine the effects of TCM syndrome groups on biochemical characteristics and QOL in women with MS.

2. Methods

2.1. Study design and participants

This was a cross-sectional study conducted from January 2014 to December 2014 in Taipei City Hospital, Taiwan. We sent out invitation letters to 1696 female outpatients who were selected by a computerized simple-random sampling method. At first, 1080 females were willing to participate in this study after consulting and explanation of the program. Among the 1080 registered patients screened at our outpatient clinic, a total of 322 were enrolled. The inclusion criteria and exclusion criteria are shown in Table 1. In this study, MS was defined according to American Heart Association and the National Heart, Lung, and Blood Institute recommendations[5] and the National Cholesterol Education Program's Adult Treatment Panel III guidelines with the modification of waist circumference cutoff points for Asians.[17] The protocol was approved by the Human Ethics Committee of the Taipei City Hospital. Informed consent was obtained from all the enrolled patients.

2.2. TCM syndrome groups in MS

The enrolled patients were examined by TCM practitioners, and diagnoses were made on the basis of the examination; symptoms reported by the patients and according to the practitioner's experience. Based on TCM concepts, our clinical experience and related studies,[9—11] we designed a self-reported questionnaire on patient symptoms as a diagnostic tool and the six most common TCM syndrome groups of MS were defined. These groups were respectively characterized by "Stomach Heat syndrome (胃熱 wèi rè, SHS)", "Yin Deficiency syndrome (陰虛 yīn xū, YDS)", "Qi Deficiency syndrome (氣虛 qì xū, QDS)", "Kidney Deficiency syndrome (腎虛 shèn xū, KDS)", "Qi Stagnation syndrome (氣滯 qì zhì, QSS)", and "Spleen Deficiency syndrome (脾虛 pí xū, SDS)". Nine TCM physicians with clinical experience discussed and proposed three yes—no questions under each syndrome group for classification of MS patients. The questionnaire is shown in Table 2. MS patients were classified into a particular TCM syndrome group if they had more

Table 1
Inclusion and exclusion criteria.

Inclusion criteria
Female
Aged between 18—65 years old
Meeting the requirements of metabolic syndrome (having at least 3 out of 5 of the following):
1. Systolic blood pressure ≥130 mmHg and/or diastolic blood pressure ≥85 mmHg or taking antihypertensive medication
2. Fasting blood glucose ≥100 mg/dL or taking antihyperglycemic medication
3. Triglyceride ≥150 mg/dL
4. High Density Lipoprotein <50 mg/dL
5. Waist circumference ≥80 cm
Willing to participate in this study
Exclusion criteria
Abnormal liver function (Glutamate Pyruvate Transaminase >80 U/L)
Abnormal kidney function (serum creatinine >2.5 mg/dL)
Prolactin or pregnancy women and planned-to-pregnant women
Heart failure, acute myocardial infarction, stroke, and heavy injuries in 6 months
Any other conditions not suitable for trial as evaluated by the physician

Table 2
Classification Criteria for the diagnosis of TCM syndrome groups.

In the past week, did you often have the following symptoms?
(Often means more than 8 h per day and more than four days per week)
Stomach heat syndrome (胃熱 wèi rè)
Sore gums or Bad breath.
Swift digestion with frequent hunger.
Like to drink cold beverages.
Yin deficiency syndrome (陰虛 yīn xū)
Dry throat or mouth.
Night sweats.
Palm or face flushing sensation.
Qi deficiency syndrome (氣虛 qì xū)
Felt exhausted or lack of energy.
Did not feel like talking or talked in a low and weak voice.
Did not feel like moving about or did not have the strength to walk
Kidney deficiency syndrome (腎虛 shèn xū)
Felt backache easily.
Tinnitus and hard of hearing.
Frequent urination (more than 2 times in the night).
Qi stagnation syndrome (氣滯 qì zhì)
Chest tightness.
Palpitation.
Agitation and irritability.
Spleen deficiency syndrome (脾虛 pí xū)
Leg pitting edema.
Felt thirsty and like to drink water easily.
Anorexia.

Definition: Patients who have 2 of 3 or more of the criteria in the Stomach Heat, Yin Deficiency, Qi Deficiency, Kidney Deficiency, Qi Stagnation, Spleen Deficiency syndrome groups are compatible with that TCM syndrome; TCM, traditional Chinese medicine.

than two symptoms corresponding to each TCM syndrome in the questionnaire. Validation test results showed an alpha coefficient of 0.85 and a Cronbach's alpha coefficient of 0.78, which indicate the questionnaire has good reliability.

2.3. Quality of life

To measure QOL, we used the self-administered questionnaire of a medical outcomes study (MOS) Short Form-12 (SF-12) with 12 items. These 12 items estimate eight concepts: general health, physical functioning, role limitation due to physical problems, role limitation due to emotional problems, bodily pain, vitality, mental health, and social functioning. The responses of the questions were calculated and converted respectively into two scores, physical and mental component summaries (PCS-12 and MCS-12). The general population usually has a mean of 50 and a standard deviation of 10 in SF-12 MCS and PCS measure scores. Higher scores indicate a better health condition.[18]

2.4. Outcome measurements

The major outcome measurement was the difference in QOL scores between different TCM syndrome groups of women with MS. Other measurements included body mass index (BMI), waist circumference, hip circumference, blood pressure, insulin, and biochemical characteristics in the six TCM syndrome groups. Biochemical characteristics were composed of fasting blood sugar, triglyceride, total cholesterol, creatinine, and glutamate pyruvate transaminase (GPT).

Insulin and biochemical characteristics were measured in the morning after 8—9 h of fasting. The entire blood sample was drawn and centrifuged at 4 °C, with 1 ml of the was sample rapidly frozen at −80 °C for the subsequent radioimmunoassay concentration analysis. BioSource INS-IRMA Kits (BioSource Europe S.A., Nivelles, Belgium) were used to determine the level of insulin in the serum as previously reported.[19,20] Sampling was reported if a difference

SHS, Stomach Heat syndrome; YDS, Yin Deficiency syndrome; QDS, Qi Deficiency syndrome; KDS, Kidney Deficiency syndrome; QSS, Qi Stagnation syndrome; SDS, Spleen Deficiency syndrome
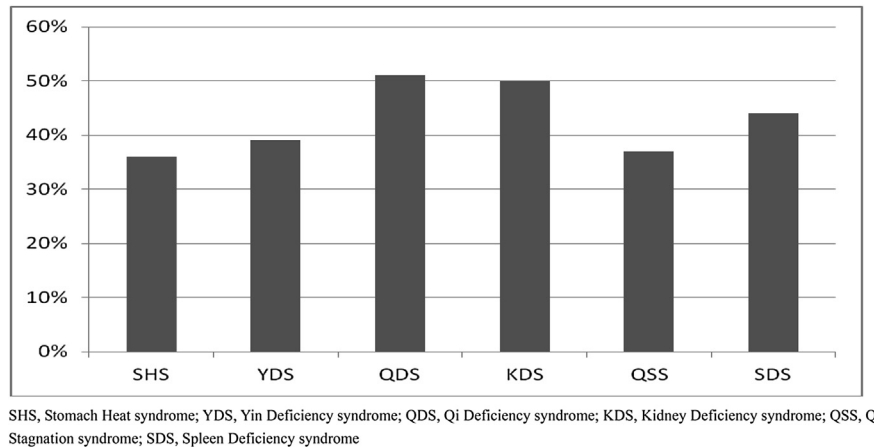
Fig. 1. Distribution of different traditional Chinese medicine syndrome groups among women with metabolic syndrome.

exceeding 10% of the coefficient of variation was found between duplicated results of the sample. Following the approach of Matthews, et al., we used homeostasis model assessment for insulin resistance (HOMA-IR) to estimate the insulin resistance of our subjects.[21]

2.5. Statistical analysis

All statistical analyses were performed using SPSS (version 19.0 for Windows, Chicago, IL, USA). A student t-test was employed to examine the main outcomes: demographic data, biochemical data, and score of QOL. All p values were two-tailed and the α level of significance was set at 0.05.

3. Results

3.1. Demographics and clinical features of subjects

Among the 1080 registered cancer patients screened at our outpatient clinic, a total of 322 met the inclusion and exclusion criteria. As shown in Fig. 1, QDS and KDS were the two most common TCM (中醫 zhōng yī) syndrome groups in the study. 52% and 50% of subjects had QDS and KDS, respectively. Table 3 lists the demographic and clinical features of the participants. As can be seen, the mean age, BMI, systolic/diastolic blood pressure, and fasting bold sugar of the subjects in our study were 48.0 ± 10.9 years, 29.5 ± 4.5 kg/m^2, 138.5 ± 17.7/82.8 ± 11.1 mmHg, and 121.7 ± 39.5 mg/dl, respectively. Average PCS and MCS scores in SF-12 of the participants were 45.0 ± 7.7 and 47.7 ± 9.7.

3.2. Comparison of basic data among different TCM syndrome groups

Table 4 displays the basic data differences among women with MS in the six TCM syndrome groups. As shown in the table, there were significant differences in BMI, waist circumference, and hip circumference between the patients with and without SHS, QDS, and SDS. The patients with YDS had significantly elevated levels of BMI and hip circumference compared to those without YDS. The patients with QSS also had significantly higher means of hip circumference compared to those without QSS. It seems that women with MS in TCM syndrome groups, except of KDS, were fatter than those not in the TCM syndrome groups. In addition, the patients with SHS and SDS were younger than the others.

3.3. Comparison of biochemical characteristics and insulin among different TCM syndrome groups

As seen in Table 4, there was no difference in most biochemical characteristics between TCM syndrome groups. The subjects with QDS had significantly higher GPT levels than those without QDS. On the other hand, the patients with KDS had higher insulin levels than those without KDS. However, no significant difference in HOMA-IR between those with and without TCM syndrome groups was seen.

3.4. Comparison of QOL among different TCM syndrome groups

Overall, in both physical and mental domains, the women with MS in TCM syndrome groups had lower scores in SF-12. As seen in Table 4, there were significant differences in both PCS-12 and MCS-12 scores between the patients with and without YDS, QDS, and QSS. The subjects with SHS and SDS had markedly lower MCS-12 scores than those without SHS and SDS. The difference in PCS-12 between those with and without KDS was also noted.

Table 3
Demographic, biochemical and quality-of-life characteristics of MetS women.

Variables	MetS (+) (n = 322)
Basic data	
Age, years	48.0 (10.9)
Body Mass Index, kg/m^2	29.5 (4.5)
Waist circumference, cm	93.9 (10.1)
Hip circumference, cm	105.5 (10.2)
Systolic Blood Pressure, mmHg	138.5 (17.7)
Diastolic Blood Pressure, mmHg	82.8 (11.1)
Biochemical data	
Fasting Blood Sugar, mg/dl	121.7 (39.5)
Triglyceride, mg/dL	184.8 (73.2)
Total Cholesterol, mg/dL	211.7 (36.2)
High Density Lipoprotein, mg/dL	44.0 (8.7)
Low Density Lipoprotein, mg/dL	132.3 (35.7)
Glutamate Pyruvate Transaminase, IU/L	36.6 (25.7)
Creatinine, mg/dL	0.7 (0.2)
Insulin, μIU/ml	17.4 (11.2)
HOMA-IR[b] index	5.1 (3.3)
SF-12	
PCS-12	45.0 (7.7)
MCS-12	47.7 (9.7)

The data are presented with mean (standard deviation).
MetS, Metabolic syndrome; HOMA-IR, Homeostasis model assessment for insulin resistance; SF, Short form; PCS, Physical condition score; MCS, Mental condition score.

Table 4
Difference in basic, biochemical and quality-of-life data among different traditional Chinese medicine syndrome groups with metabolic syndrome.

Variables	SHS		YDS		QDS		KDS		QSS		SDS	
	Yes (n = 117)	No (n = 205)	Yes (n = 125)	No (n = 197)	Yes (n = 165)	No (n = 157)	Yes (n = 161)	No (n = 161)	Yes (n = 120)	No (n = 202)	Yes (n = 143)	No (n = 179)
Basic data												
Age, years	44.7 (11.6)**	49.9 (10.1)**	47.2 (11.1)	48.5 (10.8)	47.3 (11.1)	48.6 (10.8)	47.8 (11.0)	48.2 (10.8)	47.0 (11.0)	48.5 (10.8)	44.6 (11.3)**	50.6 (9.8)**
BMI, kg/m²	30.2 (4.1)*	29.1 (4.7)*	30.3 (5.0)*	29.0 (4.1)*	30.1 (4.5)*	28.8 (4.5)*	29.9 (4.6)	29.1 (4.5)	30.0 (4.1)	29.2 (4.8)	31.2 (4.5)**	28.1 (4.1)**
Waist, cm	95.9 (10.5)*	92.9 (9.8)*	95.3 (11.8)	93.1 (8.8)	95.1 (10.9)*	92.7 (9.2)*	95.0 (10.0)	92.9 (10.2)	95.0 (9.4)	93.3 (10.5)	96.8 (11.1)**	91.7 (8.8)**
Hip, cm	107.7 (9.4)*	104.2 (10.4)*	107.6 (10.5)*	104.2 (9.8)*	106.7 (10.3)*	104.2 (9.9)*	106.3 (10.4)	104.7 (10.4)	107.0 (9.4)*	104.6 (10.5)*	109.1 (10.2)**	102.7 (9.2)**
SBP, mmHg	137.9 (16.7)	138.8 (18.2)	140.7 (18.5)	137.0 (17.1)	138.4 (16.4)	137.0 (17.9)	140.3 (17.9)	136.7 (17.4)	139.7 (17.2)	137.8 (18.0)	138.7 (16.5)	138.4 (18.6)
DBP, mmHg	82.0 (10.8)	83.2 (11.2)	83.6 (11.5)	82.2 (10.7)	82.6 (11.6)	83.1 (10.5)	82.6 (11.3)	83.0 (10.8)	83.2 (11.8)	82.6 (10.6)	83.0 (11.7)	82.7 (10.6)
Biochemical data												
Glucose, mg/dl	119.1 (45.7)	123.2 (35.4)	123.3 (46.9)	120.7 (34.0)	124.7 (45.2)	118.6 (32.1)	120.9 (38.9)	122.6 (40.1)	122.5 (47.2)	121.2 (34.2)	117.9 (42.6)	124.8 (36.6)
Triglyceride, mg/dL	181.0 (70.8)	186.9 (74.6)	185.8 (74.7)	184.1 (72.4)	191.7 (77.0)	177.4 (68.4)	185.7 (76.6)	183.8 (69.8)	187.3 (70.0)	183.2 (75.1)	182.5 (84.1)	186.5 (63.3)
T.chol., mg/dL	208.7 (28.8)	214.0 (40.7)	213.7 (36.0)	210.2 (36.3)	209.3 (29.9)	214.1 (41.4)	207.6 (34.0)	216.1 (38.0)	211.0 (32.6)	212.2 (38.3)	208.7 (34.6)	215.1 (37.7)
HDL-C, mg/dL	43.8 (8.4)	44.2 (8.9)	44.4 (9.5)	43.8 (8.2)	44.5 (9.4)	43.6 (9.1)	44.8 (7.9)	43.3 (9.4)	44.9 (7.8)	43.5 (9.2)	43.0 (8.3)	44.9 (8.9)
LDL-C, mg/dL	133.8 (28.9)	131.4 (39.1)	134.5 (34.1)	130.9 (36.7)	130.5 (31.1)	134.2 (40.0)	130.9 (35.3)	134.7 (35.4)	128.7 (33.5)	134.4 (36.8)	135.0 (34.8)	130.1 (36.3)
GPT, IU/L	41.7 (35.1)	34.2 (19.4)	38.7 (31.2)	35.2 (21.4)	40.2 (30.8)*	33.0 (18.7)*	38.2 (30.5)	35.1 (20.2)	38.1 (32.1)	35.7 (21.3)	39.4 (31.4)	34.5 (20.4)
Creatinine, mg/dL	0.7 (0.1)	0.7 (0.2)	0.7 (0.2)	0.7 (0.1)	0.7 (0.1)	0.7 (0.2)	0.7 (0.1)	0.7 (0.1)	0.7 (0.1)	0.7 (0.2)	0.7 (0.1)	0.7 (0.2)
Insulin, μIU/ml	18.6 (13.1)	16.7 (9.9)	17.6 (10.5)	17.3 (11.6)	18.3 (12.5)	16.4 (9.5)	18.7 (13.2)*	16.1 (8.5)*	18.4 (12.5)	16.9 (10.3)	17.9 (12.1)	17.1 (10.4)
HOMA-IR index	5.2 (3.5)	5.0 (3.2)	5.2 (3.2)	5.1 (3.4)	5.4 (3.6)	4.8 (3.0)	5.4 (3.8)	4.8 (2.8)	5.3 (3.5)	5.0 (3.2)	5.0 (3.3)	5.2 (3.4)
SF-12												
PCS-12	45.2 (8.2)	44.8 (7.5)	43.6 (8.2)*	45.9 (7.3)*	43.5 (8.0)**	46.6 (7.2)**	43.9 (8.4)*	46.1 (6.8)*	43.9 (8.5)*	45.7 (7.2)*	44.2 (7.9)	45.6 (7.6)
MCS-12	44.7 (9.4)**	49.5 (9.5)**	44.6 (9.4)**	49.8 (9.4)**	46.4 (9.0)*	49.1 (10.2)*	47.0 (10.0)	48.5 (9.5)	44.4 (8.9)**	49.7 (9.7)**	45.0 (8.8)**	49.9 (9.9)**

The data are presented with mean (standard deviation).
*p < 0.05, **p < 0.001.
SHS, Stomach Heat syndrome; YDS, Yin Deficiency syndrome; QDS, Qi Deficiency syndrome; KDS, Kidney Deficiency syndrome; SDS, Spleen Deficiency syndrome; BMI, Body Mass Index; SBP, systolic blood pressure; DBP, diastolic blood pressure; T.chol., Total Cholesterol; HDL-C, High Density Lipoprotein; LDL-C, low Density Lipoprotein; GPT, Glutamate Pyruvate Transaminase; HOMA-IR, Homeostasis model assessment for insulin resistance; SF, Short form; PCS, Physical condition score; MCS, Mental condition score.

4. Discussion

Correct classification of TCM (中醫 zhōng yī) syndrome groups is very important because all diagnostic and therapeutic methods in TCM are based on the differentiation of TCM syndrome groups. In recent decades, basic and clinical studies related to TCM syndrome classification have been increasing and growing.[22] However, there has been little discussion of TCM syndrome groups among MS patients. In our study, groups with QDS and KDS accounted for 51% and 50% of the women with MS, respectively.

In terms of basic data, TCM syndrome groups had influences on BMI, waist circumference, and hip circumference. We found that the MS patients in TCM syndrome groups, except KDS, seemed fatter than those not in TCM syndrome groups. As for biochemical data, there was almost no significant difference between women with MS in and not in TCM syndrome groups. However, findings in a previous study revealed that the prevalence rates of central obesity, high blood pressure, high fasting glucose, and high triglyceride all significantly increase with age in females.[23] Evaluation of the effects of TCM syndrome groups on MS component factors, such as waist circumference, blood pressure, fasting glucose, and triglyceride might be confounded by participants' age. In our study, there were significant differences in age between the women with MS with and without SHS and SDS. More detailed analyses of the cross-reaction of age and TCM syndrome groups are required.

The results of our study show that the women with MS in TCM syndrome groups had poor QOL than those not in TCM syndrome groups. We found that there were significantly lower scores in PCS-12 among the patients with YDS, QDS, QSS, and KDS. No significant difference in physical domain was noted between the patients with/without SHS and SDS. This is possibly because the patients with SHS and SDS were younger. Recent studies have reported a negative relationship between age and physical health of QOL.[24,25] Difference in age may mask the negative impacts of SHS and SDS on PCS values of SF-12. On the other hand, the findings related to the relationship between age and mental health of QOL were inconsistent in previous research. MCS was found to be significantly lower among elderly in a Southern Italy survey,[24] but another observational study found that MCS is not associated with age.[25] This may be attributable to the different definitions and methods used in the assessment of QOL. Our study revealed TCM syndrome groups, except KDS, were also associated with lower mental domain in SF-12. According to TCM concepts, each TCM syndrome group is a reflection of all the pathological presentations of a patient at a certain stage in the development of the disease, including physical and psychological characteristics. It might account for the poor physical and mental domain in QOL in the patients in TCM syndrome groups.

A limitation of this study is that only three questions were designed for diagnosing each TCM syndrome group, which may result in a false positive or overestimation. Whether more questions should be added to the TCM syndrome groups questionnaire remains inconclusive. Nevertheless, the three questions designed can make differentiation of TCM syndrome groups easy and quick and provide good reliability. In addition, age difference of distribution between the women with MS with and without SHS and SDS was noted and the effects of age might confound the results in this study. A larger sample of MS syndrome would be helpful to further analyze the interactive effects of age and TCM syndrome groups on women with MS. Besides, men with MS might also be enrolled in the future. The distribution of different TCM syndrome groups might differ between men and women with MS. Due to the complexity of TCM concept, mutual existence of the different syndrome groups could be found in the same subject. Analysis of co-existing TCM syndrome groups is necessary for the further

research about influence of TCM syndrome groups on quality of life in metabolic syndrome.

In summary, TCM syndrome groups were associated with worse physical and mental domains in QOL. It seems that the MS diagnosed females in TCM syndrome groups had poorer QOL than those not classified as belonging to these groups. However, there was no difference in most biochemical characteristics between TCM syndrome groups. More analysis of TCM syndrome groups among MS patients is necessary in the future.

Conflicts of interest

None declared.

Acknowledgments

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