The study on the epidemiology of psychological, alimentary health and nutrition (SEPAHAN): Overview of methodology

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BACKGROUND: Functional gastrointestinal disorders (FGIDs) are common worldwide and cause considerable social and economic burden. The aims of SEPAHAN project were to 1) assess the prevalence of different FGIDs within an Iranian population, 2) investigate the relationship of FGIDs and their symptoms with lifestyle and nutritional factors, and 3) investigate the relationship of FGIDs and their symptoms with psychological factors. METHODS: It was a cross-sectional study among staff of Isfahan University of Medical Sciences and Health Sciences (Isfahan, Iran) and consisted of two main phases. In the first phase, a detailed dietary questionnaire was used to assess dietary habits and usual dietary intakes. Other lifestyle factors were investigated using appropriate questionnaires. In the second phase, the epidemiology of different FGIDs was determined using Rome III criteria. In addition, different psychological assessment tools were used to screen for anxiety, depression, psychological distress, coping styles, stressful life events, personality trait, and level of social support. Self-administered questionnaires were used in this study. RESULTS: In the first and second phases of the study, 8691 and 6239 adults were recruited, respectively. The complete information of 4763 subjects has been provided after linking the questionnaires from both phases. CONCLUSIONS: SEPAHAN project is a novel study that provides the opportunity of investigating epidemiological aspects of FGIDs and their relationship with different lifestyle and psychological factors.

KEYWORDS: Functional Gastrointestinal Disorders, Anxiety, Depression, Personality Trait, Nutrition, Iran

BACKGROUND

Functional gastrointestinal disorders (FGIDs) are defined as a variable combination of chronic or recurrent gastrointestinal symptoms not explained by structural or biochemical abnormalities.^[1] FGIDs are a typical example of how the digestive system plays a crucial role in the normal lives of humans regardless of where they live.^[2] Although FGIDs are not life-threatening conditions, they significantly impair quality of life.^[3] The impact of FGIDs on population health is large as they are remarkably common, can hinder daily activities and are associated with a major social and economic burden.^[3-5]

The pathophysiology of FGIDs is not completely understood. A biopsychosocial conceptualization of the pathogenesis of FGIDs demonstrates the putative relationships between psychosocial and physiological factors and how they contribute to gastroin-

testinal symptoms and clinical outcome. Genetic liability and early life experiences, such as family influences on illness expression, abuse, major losses, or exposure to infections, may affect psychosocial development in terms of vulnerability to life stress or psychological state and coping skills. These may also influence susceptibility to gut dysfunction/abnormal motility, altered mucosal immunity, or visceral hypersensitivity. Furthermore, these "brain-gut" variables reciprocally influence their expression. Therefore, an FGID may be the clinical product of an interaction of psychosocial factors and altered gut physiology via the brain-gut axis.^[6]

In the early 1990's the Rome criteria were introduced as a standard tool to diagnose and classify FGIDs. Along with many studies and publications on FGIDs, the criteria were then updated as Rome

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II in 2000 and Rome III in 2006.^[6,7] According to the Rome III committee, FGIDs are classified into six major domains for adults: esophageal (category A); gastro-duodenal (category B); bowel (category C); functional abdominal pain syndrome (FAPS) (category D); biliary (category E); and anorectal (category F). Each category site contains several disorders, each having relatively specific clinical features. For example, the functional bowel disorders (category C) include irritable bowel syndrome (IBS) (C1), functional bloating (C2), functional constipation (C3) and functional diarrhea (C4), which anatomically is attributed to the small bowel, colon, and rectum. Each condition also has different diagnostic and treatment approaches.^[6]

The relationship between lifestyle factors and FG-IDs has been investigated in different studies with controversial results. Among the lifestyle factors, the role of diet in symptoms of FGIDs has received increasing attention. It has been suggested that management of patients with functional dyspepsia might be improved by reduced fat content of the diet.[8,9] In one quarter of IBS patients, symptoms may be caused or exacerbated by one or more dietary components.[10] Despite a long history of enthusiastic use, fiber is marginally beneficial, and insoluble fiber may worsen symptoms in IBS.¹⁰ Prebiotic fibers have not been adequately tested, and the usefulness of probiotics in the form of foods such as live-culture yogurt and buttermilk for IBS symptoms is not established.[10] Obesity has also been related to some FGID symptoms, most notably diarrhea, not constipation.[11] Anecdotal evidence suggests that patterns of food ingestion of individuals with functional dyspepsia differ from healthy controls in which patients eat smaller, more frequent meals; but limited experimental evidence is available to support this supposition.[12]

Psychological and social influences can affect the perception of symptoms, health care-seeking behaviors, and outcomes in patients with FGIDs. These psychosocial influences affect gut function, the experience of pain, health-related quality of life, work absenteeism, health care use, and medical and societal costs.^[13] Considerable research has shown the interrelationships among biological, psychological, and social factors and the development and maintenance of the FGIDs.^[13] Concomitant psychological disorders, notably anxiety and depressive disorders are strongly associated with FGIDs, and these psychological co-morbidities correlate with severity of FGID symptoms. Early life adversity, such as sexual and physical abuse, is more commonly reported in patients with FGIDs. There is

mounting evidence showing that psychological disorders are commonly associated with abnormal central processing of visceral noxious stimuli.^[14] The possible causal link between psychological disorders and FGIDs involves functional abnormalities in various components of the brain-gut axis. Psychological distress may alter systemic and gut immunity, which is increasingly recognized as a pathophysiological feature of certain FGIDs.^[14]

Worldwide, there is an increasing interest in the epidemiology of FGIDs.[15] It has been estimated that more than one-third of the general population have one or more FGIDs.[16] FGIDs are common in Asia and healthcare utilization is very high.[3] IBS has been the focus of most epidemiological studies. IBS is a common condition, affecting approximately 3 to 15% of the general population based on various diagnostic criteria.[17] The reported prevalence of IBS in Asian countries varies from 5 to 10% depending on the study population and diagnostic criteria.[3] In recent years, several studies have been conducted in Iran in order to investigate the epidemiology of different FGIDs.[18-22] The epidemiological data of FGIDs in Iran are quite heterogenous.[23-26] For example, the prevalence of IBS in Iranian studies was reported to be in the wide range of 1.1-25%.[18,20] Such significant variation could be related to differences in characteristics of the studied populations, diagnostic criteria to define IBS and methodological aspects of each study.[23]

Functional dyspepsia is believed to be common in Asia as well as in Western countries.^[3] Functional dyspepsia affects up to 10-25% of individuals.^[27] The prevalence of functional dyspepsia in Asia was reported to be 8-23%.^[28] In a large population-based study in Tehran, 8.5% of subjects had dyspepsia.^[29] In another study in Shiraz, about 30% of subjects had dyspepsia.^[30] Similar to IBS and functional dyspepsia, the prevalence of functional constipation varies significantly among different Iranian populations and has been reported to be 2.4-32.9%.^[26] Few studies have investigated the epidemiology of functional bloating in Iran.^[24]

During Ramadan, which is the 9th month in the Islamic lunar calendar, all adult Muslims are obliged to fast; i.e., refraining from eating, drinking, smoking and engaging in sexual activities from sunrise to sunset. To date, no consensus exists regarding how gastrointestinal tract might be affected by the fast of Ramadan.^[31]

The epidemiology of FGIDs and their potential risk factors have not been investigated extensively in

developing countries such as Iran. The main problems with previous studies are recruitment of highly selective populations, patient-based studies from health institutions, small sample size, and a focus on only limited FGID conditions.

The Study on the Epidemiology of Psychiatric-Alimentary Health and Nutrition (SEPAHAN) mainly aimed to 1) assess the prevalence of different FGIDs, according to Rome III criteria, within an Iranian population, 2) investigate the relationship of FGIDs and their symptoms with lifestyle and nutritional factors, and 3) investigate the relationship of FGIDs and their symptoms with psychological factors.

METHODS

Preparation activities:

One year before the study was launched, the first session of experts from different Departments of Isfahan University of Medical Sciences and Health Services (IUMS) was held and the main aims of SEPAHAN were defined. We also invited a group of international experts in the field of FGIDs to cooperate with us as consultants. In bi-weekly sessions of experts, the scientific and methodological aspects of the project were reviewed. Ethical approval to conduct the study was provided by the Medical Research Ethics Committee of IUMS (#189069, #189082, and #189086).

The project was designed to be a cross-sectional study and we decided to gather all information through self-administered questionnaires. After 7 months, the final list of questionnaires was compiled. Most questionnaires were selected from standard questionnaires that were previously validated in Iranian settings. However, we had to design some new assessment tools or translate some questionnaires into Persian using the forward-backward translation procedure.[32] Two health professionals performed the forward translation independently. The backtranslation was done by a third person who was a professional English translator. The translators and principal investigator of the project (PA) held several sessions in order to evaluate and edit the translations. The translations were then sent to a group of faculties (one gastroenterologist, three psychiatrists and one nutritionist) for content validity and administered in 100 apparently healthy adults for face validity. Considering the feedback from the faculties and the participants who tested the translations, the final version of each questionnaire was developed. The list of questionnaires we used was as follows:

- 1. A questionnaire to gather complete demographic information and medical history
- 2. Self-reported anthropometric measurements
- 3. General Practice Physical Activity Questionnaire was used to assess an individual's current physical activity.^[33]
- 4. Questions to assess health seeking behavior, cost of care, and response to commonly prescribed medications for gastrointestinal conditions
- 5. A dietary questionnaire that consisted of two main questionnaires: 1) dietary habits related to gastrointestinal symptoms, and 2) a validated 106-item-semiquantitative food frequency questionnaire to assess usual dietary intakes in the previous one year.^[34] It is worthy to note that for each food item we asked about the self perceived gastrointestinal symptoms following taking that food item.
- 6. A questionnaire to evaluate masticatory function and tooth loss[35]
- 7. A questionnaire to investigate symptoms of FGIDs: Rome III questionnaire⁶ in its complete form and additional questions from Talley Bowel Disease Questionnaire.[36] During the face validation of this questionnaire, we found that most participants could not discriminate the difference between the rating scales used in Rome III. Therefore, we modified the rating scale to a 4-item-rating scale (never or rarely, sometimes, often, always) for each question. We also decided to ask about the presence of each symptom in the past three months. Consequently, the question on the beginning of each symptom in more than 6 months prior to the evaluation, which exists in Rome III questionnaire, was deleted (Table 1). In addition, we asked about the severity of each gastrointestinal complication using a 4-item-rating scale (mild, moderate, severe and very severe).
- 8. Somatic Symptom Checklist as a measure of somatization^[37]
- 9. The Iranian validated version of General Health Questionnaire-12 as a measure of current psychological distress^[38]
- 10. The Iranian validated version of Hospital Anxiety and Depression Scale to screen for anxiety and depression^[39]
- 11. The Persian version of Multidimensional Scale of Perceived Social Support to assess social support [40,41]
- 12. Stressful Life Event questionnaire for the stress

Table 1. An example of the differences in rating scale of symptoms presence between Rome III questionnaire and the SEPAHAN project		
Question	Rome III	SEPAHAN
In the last 3 months, how often did you have pain or burning in the middle of your abdomen, above your belly button but not in your chest?	 Never Less than one day a month One day a month Two to three days a month One day a week More than one day a week Every day 	 Never or rarely Sometimes Often Always
Have you had this pain or burning 6 months or longer?	No Yes	This question was deleted
Did this pain or burning occur and then completely disappear during the same day?	①Never or rarely① Sometimes② Often③ Most of the time④ Always	 Never or rarely Sometimes Often Always

measurement[42]

13. COPE scale was used to assess the coping strategies.[43]

14. NEO Five-Factor Inventory to measure personality traits^[44]

To increase the participation rate and the accuracy of collected data, we decided to distribute the questionnaires in two "waves" with a short period between them (3-4 weeks). Therefore, questionnaires 1-6 were included into the first wave and questionnaires 7-14 into the second.

To save time and decrease errors in the data extraction phase, we developed an optical mark recognition (OMR) system that could distinguish the selected answer for each question in the scanned pictures of questionnaires. All data management was performed according to the principles of confidentiality.

Sample size calculation:

We hypothesized the prevalence of FGIDs in Iran would be 15%. We further hypothesized that psychological distress or eating a diet low in fiber would double the risk of having any FGIDs. With an 80% power, a type I error of 0.05, and desired confidence interval of 0.03, the minimum required sample size was calculated to be 1387 subjects.

Study population:

As one of the oldest scientific institutions in Iran, Isfahan University of Medical Sciences and Health Services (IUMS) has been a pioneer in medical education and research, as well as delivery of health and treatment services in the country. IUMS covers a population of nearly 4 million in Isfahan Province. Health and treatment services are provided to this population through

rural and urban health centers run by IUMS. The University currently has 20,000 non-academic employees. After discussions with managers of IUMS, it was approved to perform the study on 10500 IUMS nonacademic staff working in 50 different centers across Isfahan province. These staffs were working in hospitals, university campus, and health centers. It is worthy to note that not all these staffs are involved in health services. For example, the majority of the 2000 staffs working in the university campus are not health providers and they are mainly involved in the administrative tasks of IUMS. With the above-mentioned items, we developed a census in all eligible IUMS staffs. To select 10500 subjects out of all IUMS staff, we excluded some university teaching hospitals and research centers. We assumed that staff in those units would be unlikely to participate in the study due to their very busy schedule.

Recruitment of subjects:

IUMS central office has direct contact with all staff in different cities and centers through 50 staffs working in Public Relation Unit (PRU). Monthly sessions with PRU staff started 4 months prior to the recruitment of subjects. In these sessions, the principal investigator of the project (PA) and its coordinator (AHK) described the rationale and methodological aspects of SEPAHAN completely and answered PRU staff questions. Two months prior to the initiation of SEPAHAN, the first official letter was sent to all managers of IUMS working in different cities and centers and the study was introduced to them briefly. Some of them later called the coordinator of the study and, if requested, more details were provided. The last letter was sent to the managers of IUMS units one week prior to the launch of the study. Forty-five days before distributing the first wave of questionnaires, staffs in the selected centers were informed about the study through brochures

and posters that were distributed among them by PRU staff. Such communications with IUMS staff was repeated 15 days and one week before the initiation of SEPAHAN.

In April 2010 the first wave of questionnaires was distributed among IUMS staff in different cities and centers. PRU staff informed participants about the contents of questionnaires and study aims, while they were handing out the questionnaires. Each subject was provided with an envelope in which to put the completed questionnaires and asked to return the completed questionnaires to PRU staff within 7 days. All questionnaires were distributed and collected within three weeks and sent to the main office of the project. In mid-May 2010, the second wave of questionnaires was distributed and similar to the first phase, this stage finished in two weeks. In September 2010 the data entry phase started using the computerized process described before. It took almost three months to build the merged file of data in phases 1 and 2. Data collection and data entry was monitored continuously by the principal investigator of the project (PA) and its coordinator (AHK). In July 2012, a health profile was created for each individual using the database made from the two phases. Such profile will be printed and distributed among participants of SEPAHAN. The health profile and different awards given to a group of randomly selected participants were used as incentives to increase the number of participants.

Analysis plan:

FGIDs will be defined according to the scoring algorithm of the ROME III questionnaire. Prevalence of FGIDs will be determined in the whole population as well as in different age categories and genders. The association between diet and FGIDs will be explored by considering diet as dietary patterns, diet quality measures, food groups, food and nutrient intakes. The association between FGIDs and psychological factors including anxiety, depression, stressors, coping strategies, and personality dimensions will be investigated too. The association of these exposures with different FGIDs will be assessed in the whole population as well as among different genders.

RESULTS

In the first and second phases of the project, 10087 and 9652 questionnaires were distributed, respectively. In the first phase of SEPAHAN, which included different questionnaires on demographic information, lifestyle and nutritional factors, 8691 subjects took part (response rate: 86.16%). After this phase, the second wave

of questionnaires which was designed to gather information on gastrointestinal and psychological profile of participants were distributed and 6239 completed questionnaires were returned to the main office of the project (response rate: 64.64%). There was no major problem during these phases. Sometimes we had to provide more information to a group of staff that previously did not receive the study's brochures. We used national identification numbers of subjects to link the questionnaires from both waves. In addition, after this step, a manual procedure was done to increase the number of matched questionnaires based on the name of each subject who took part in phase two. After a time-consuming process, we could match 4763 questionnaires in phase 2, with its equivalent questionnaire in phase 1. This means, we could get the complete demographic, lifestyle, nutritional, gastrointestinal, and psychological profile of 4763 participants at this stage. We were unable to match 1476 questionnaires in phase 2 with a questionnaire in phase 1. This occurred because 1) there were some subjects in phase two that did not participate in phase one, 2) there were many subjects that did not write down their national identification numbers and/or their name in phase 1 and/or 2. We will continue our manual process to get as more matched questionnaires as possible.

DISCUSSION

The response rate in SEPAHAN was satisfactory. Training PRU staff, providing enough information to subjects before and during the study, distribution of questionnaires by PRU staff which were experienced enough to motivate IUMS staff to take part in the study, and using reasonable incentives were the main reason for the acceptable rate of participation in our study.

The main advantage of a population-based epidemiological approach is the opportunity of studying the spectrum of symptoms in the whole population. Patient-based studies from health institutions are likely inherently biased by health care seeking because only a minority of subjects consults a health care provider regarding their symptoms.^[15]

The SEPAHAN project will provide a unique opportunity to study the epidemiology of FGIDs in Iran. Furthermore, it will give the opportunity to investigate the role of different lifestyle, nutritional, and psychological factors in FGIDs symptoms and their severity, all in one study. We hope such invaluable data that are provided through this study can help us in developing public health policies and re-

gional strategies in health promotion of patients and FGIDs prevention.

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