

Development of questionnaire for metabolic disease with blood stasis: A Delphi survey

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Abstract

Objectives : The aim of this study was to investigate expert opinions on the questions contained in a questionnaire for diagnosing blood stasis accompanying metabolic disorders.

Methods : Two rounds of Delphi survey were conducted online targeting on one hundred Korean medicine doctors. Respondents rated the appropriateness of the 30 questions in diagnosing metabolic disorder on a five-point scale, anchored at '5 = very appropriate', '4 = appropriate', '3 = somewhat appropriate', '2 = inappropriate', and '1 = very inappropriate'.

Results : The mean score on 30 questions of first and second Delphi survey was 3.26 points and 3.31 points, respectively. The ranking of the top 10 questions that were rated as appropriate for diagnosing blood stasis accompanying metabolic disorder were 'sublingual varices', 'reddish black tongue', 'reddish black gum', 'reddish black lips', "dark purple palatal mucosa and venous edema", 'night pain', 'ecchymosis of the tongue', 'piercing pain', 'ecchymosis of the skin' and 'prolonged numbness'.

Conclusions : The experts agreed that three of the most typical symptoms of blood stasis and the conditions of capillary vessels in the tongue or the oral cavity were highly associated with metabolic disorder, whereas the questions related to abdominal pain lacked an association with metabolic disorders.

Key words : blood-stasis, metabolic disease, Delphi survey, questionnaire

I. Introduction

Blood stasis is a disease pattern characterized by blood circulation problems or pooling of blood in certain parts of the body. Manifestations of blood stasis vary depending on its cause and the location affected by it, but the disease commonly affects patients with diseases related to blood

circulation or with hemorrhagic disease¹⁾. Blood stasis treatments often effectively treat blood lipid abnormalities such as hyperlipidemia and atherosclerosis²⁾.

Korea Institute of Oriental Medicine (KIOM) integrated and summarized diagnostic questionnaires for blood stasis used in South Korea, China and Japan³⁻⁵⁾. The different traditional medical systems and similar yet different traditional

• 접수 : 2018년 11월 12일 • 수정접수 : 2018년 12월 7일 • 채택 : 2018년 12월 11일

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medical concepts in these countries has precluded the standardization of blood stasis diagnosis. A group of experts have previously combined or separated questions and excluded duplicate questions from questionnaires used in these countries, ultimately selecting 36 questions that diagnose blood stasis. Thirty-three of these questions (three questions on female-related markers excluded) were used to develop the Blood Stasis Questionnaire I (BSQ-I), and the validity and reliability of the questionnaire were verified among 1,214 patients in six Korean medicine clinics in 2013⁶⁾. Blood stasis research conducted among 942 patients in departments of gynecology, cardiovascular system, and musculoskeletal system in 2014 also verified the validity and reliability of the Blood Stasis Questionnaire II (BSQ-II), an expanded version of BSQ-I with additional questions⁷⁾.

The BSQ-II diagnoses blood stasis with no regard to accompanying diseases and may not be appropriate for diagnosing blood stasis in a disease-specific manner. China has a questionnaire that exclusively diagnoses blood stasis accompanying coronary heart disease⁸⁾ Although a questionnaire is available in Korea that gives an overall diagnosis of blood stasis, a questionnaire for disease-specific blood stasis is yet to be developed. However, since diagnoses are usually based on Korean Classification of Disease codes in clinical settings, it is necessary to develop a diagnostic tool for diseases that are commonly accompanied by blood stasis. Thus, a Delphi survey was conducted in this study to gain expert opinions on the questions contained in a questionnaire for diagnosing blood stasis accompanying metabolic disorders.

II. Methods

1. Study design

This study adopts a Delphi survey method to select appropriate questions for diagnosing blood stasis accompanying metabolic disorder from the total 30 question items in a diagnostic questionnaire for blood stasis developed by the KIOM. One hundred Korean medical doctors were recruited by KIOM research team via Mediresearch, the online research company (<https://www.mediresearch.co.kr>). They got online questionnaire and rated the appropriateness of the 30 questions in diagnosing metabolic disorder on a five-point scale, anchored at '5 = very appropriate', '4 = appropriate', '3 = somewhat appropriate', '2 = inappropriate', and '1 = very inappropriate'.

2. Respondents

One hundred selected Korean medical doctors completed the questionnaire. Experts in Internal Korean Medicine and Cardiology and professors in Pathology and Diagnostic Medicine, 15 in total, were included to increase the validity of the results.

3. Survey period

Two rounds of Delphi survey were conducted online between May 2018 and June 2018. To prevent the results of the first survey from affecting the second survey, the second survey was conducted 10 days after the first survey was completed.

4. Statistical analysis

The statistical analyses were conducted by using SPSS 18.0 software (Chicago, IL, USA).

III. Results

1. Basic characteristics

Of the 100 experts, 99 completed the first survey. Of these, 92 completed the second survey as well. Of the 99 experts, 72 (72.7%) were men, and 27 (27.3%) were women. Twenty-one respondents (21.2%) were in their 20s, 38 (38.4%) in their 30s, 23 (23.3%) in their 40s, 12 (12.2%) in their 50s, and 5 (5.1%) in their 60s or above. Twenty-four respondents (24.2%) had under 5 years of clinical experience, 30 (30.3%) over 5 and under 10 years, 13 (13.1%) over 10 and under

15 years, 18 (18.2) had over 15 and under 20 years, and 14 (14.2%) had over 20 years. Twelve experts in Internal Korean Medicine and Cardiology, 17 experts from other medical fields, and 70 general practitioners participated in the survey (Table 1).

2. Results of Delphi survey

The results of the Delphi survey are as follows.

In the first survey, the respondents gave the score of 3 (normal) or above to the following 22 questions of the total 30 questions diagnosing blood stasis accompanying metabolic disorder: 'sublingual varices' (4.01), 'reddish black tongue' (3.88), 'reddish black gum' (3.86), 'reddish black lips' (3.82), 'dark purple palatal mucosa and venous edema' (3.75), 'night pain' (3.69), 'ecchymosis of the tongue' (3.62), 'piercing pain' (3.58), 'ecchymosis of the skin' (3.52), 'prolonged numbness' (3.46), 'darkening of the face' (3.45), 'darkening around the eyes' (3.44), 'chest pain without angina' (3.41), 'choppy pulse (滯脈)' (3.38), 'getting bruised easily' (3.38), 'thickening and roughening of the skin' (3.36), 'symptoms (bruise, pain, etc.) due to a recent accident (fall, car accident, etc.)' (3.34), 'sprained pain of ankle, wrist, and back' (3.33), 'dark feces' (3.16), 'lower abdominal pain (少腹痛)' (3.05), 'capillary collateral (細絡)' (3.05), and 'palmar erythema' (3.03). The mean score on the 30 questions was 3.26 points in the first survey.

In the second survey, the respondents rated the following 20 questions at the score of 3 or above: 'sublingual varices' (4.20), 'dark purple palatal mucosa and venous edema' (4.10), 'reddish black gum' (4.08), 'reddish black lips' (4.07), 'reddish black tongue' (4.02), 'ecchymosis of the tongue' (3.97), 'piercing pain' (3.82), 'night pain' (3.77), 'ecchymosis of the skin' (3.74), 'prolonged numbness' (3.73), 'symptoms (bruise, pain, etc.) due to a recent accident (fall, car accident, etc.)'

Table 1. Demographic characteristics of respondents

Classification		N (%)
Sex	Men	72(72.7)
	Women	27(27.3)
Age	20-29	21(21.2)
	30-39	38(38.4)
	40-49	23(23.3)
	50-59	12(12.2)
	Over 60	5(5.1)
Duration of clinical experience	Under 5 years	24(24.2)
	Over 5 under 10 years	30(30.3)
	Over 10 under 15 years	13(13.1)
	Over 15 under 20 years	18(18.2)
	Over 20 years	14(14.2)
General/specialist	Specialist of Internal Korean Medicine and Cardiology	12(12.1)
	Other specialist except Internal Korean Medicine and Cardiology	17(17.1)
	General doctor of Korean medicine	70(70.7)
Total		99(100%)

(3.61), ‘darkening around the eyes’ (3.60), ‘darkening of the face’ (3.58), ‘choppy pulse (澀脈)’ (3.47), ‘getting bruised easily’ (3.46), ‘chest pain without angina’ (3.43), ‘thickening and roughening of the skin’ (3.41), ‘capillary collateral (細絡)’ (3.24), ‘lower abdominal pain (少腹痛)’ (3.12), and ‘sprained pain of ankle, wrist, and back’ (3.10). The mean score was 3.31 points in the second survey. The respondents gave an average of less

than three points to the items ‘dizziness’, ‘flank pain’, ‘hemorrhoids’, ‘hypochondrial tenderness and resistance’, ‘naval tenderness and resistance’, ‘twisted mouth and tongue’, ‘ileocecal tenderness and resistance’, and ‘sigmoid colon tenderness and resistance’ in both the first and second surveys. These items were the 7 lowest ranked questions (Table 2).

Table 2. Results of Delphi survey

Blood-stasis diagnosis question	First survey (N=99)			Second survey (N=92)		
	Mean	SD	Rank	Mean	SD	Rank
1. Sublingual Varicosities	4.01	0.92	1	4.20	0.73	1
2. Reddish black tongue	3.88	1.07	2	4.02	0.88	5
3. Reddish black gum	3.86	1.08	3	4.08	0.79	3
4. Blackish black lips	3.82	1.05	4	4.07	0.89	4
5. Dark purple palatal mucosa and venous edema	3.75	1.09	5	4.10	0.81	2
6. Night pain	3.69	1.13	6	3.77	0.84	8
7. Ecchymosis of the tongue	3.62	1.06	7	3.97	0.80	6
8. Piercing pain	3.58	1.08	8	3.82	0.95	7
9. Darkening around the eyes	3.52	1.28	9	3.74	1.05	9
10. Prolonged numbness	3.46	1.10	10	3.73	0.89	10
11. Darkening of the face	3.45	1.01	11	3.58	0.90	13
12. Darkening around the eyes	3.44	1.07	12	3.60	0.89	12
13. Chest pain without angina	3.41	1.18	13	3.43	0.91	16
14. choppy pulse (澀脈)	3.38	1.13	14	3.47	0.97	14
15. Getting bruised easily	3.38	1.23	15	3.46	1.01	15
16. Tickening and roughening of the skin	3.36	1.04	16	3.41	1.02	17
17. symptoms (bruise, pain, etc.) due to a recent accident (fall, car accident, etc.)	3.34	1.25	17	3.61	1.05	11
18. sprained pain of ankle, wrist, and back	3.33	1.27	18	3.10	1.06	20
19. dark feces	3.16	1.21	19	2.98	0.99	21
20. lower abdominal pain (少腹痛)	3.05	1.27	20	3.12	1.01	19
21. capillary collateral (細絡)	3.05	1.30	21	3.24	0.93	18
22. palmar erythema	3.03	1.19	22	2.96	0.98	22
23. Armpit pain	2.97	1.06	23	2.80	0.90	24
24. Hemorrhoids	2.78	1.13	24	2.67	1.01	25
25. Flank pain	2.75	1.18	25	2.57	0.88	26
26. Dizziness	2.72	1.01	26	2.83	0.85	23
27. naval tenderness and resistance	2.65	1.01	27	2.46	0.84	27
28. ileocecal tenderness and resistance	2.61	1.07	28	2.15	0.84	29
29. sigmoid colon tenderness and resistance	2.46	1.02	29	2.13	0.87	30
30. twisted mouth and tongue	2.42	1.29	30	2.24	0.99	28

IV. Discussion

This study used the Delphi method to develop a diagnostic questionnaire for blood stasis accompanied by metabolic disorder and assess the appropriateness of each question in diagnosing blood stasis. This is not the first study to use the Delphi method to develop a diagnostic questionnaire for blood stasis. Yang et al.'s study⁹⁾ also used the Delphi method to select questions that are deemed meaningful in diagnosing blood stasis in 2006. The Delphi method is a survey method used to collect expert opinions and to ultimately achieve convergence of opinions in a research or policy-making process¹⁰⁾. Opinions from many experts are congregated to derive a conclusion. The diagnostic criteria for blood stasis used in this study had sensitivity and specificity of over 80% based on the survey results of 887 respondents⁷⁾.

The mean scores and the ranking of the top 10 questions that were rated as appropriate for diagnosing blood stasis accompanying metabolic disorder were consistent between the first and second surveys despite small variations. In other words, the experts agreed that 'sublingual varices', 'reddish black tongue', 'reddish black gum', 'reddish black lips', "dark purple palatal mucosa and venous edema", 'night pain', 'ecchymosis of the tongue', 'piercing pain', 'ecchymosis of the skin' and 'prolonged numbness' are symptoms that manifest in patients with metabolic disorder accompanied by blood stasis. A similar tendency was also observed among the questions with low scores in the first and second surveys. Based on the results of the Delphi survey, 'night pain', 'piercing pain' and 'prolonged numbness', which are three of the most typical symptoms of blood stasis, and the conditions of capillary vessels in the tongue or the oral cavity were found to be highly associated with metabolic disorder, whereas

the questions related to abdominal pain lacked an association with metabolic disorders.

Consistent efforts have been made to develop a diagnostic tool for syndromes to standardize and establish a scientific rationale for diagnostic methods based on traditional Korean medicine. The *Han-Yol* (cold-heat) patternization questionnaire contains relatively simple and easy questions and has been commonly used¹¹⁾. The questionnaire distinguishes between cold and heat with no regard to the disease type and contains many questions that assess the overall systemic health.

However, the questionnaire merely assesses blood stasis in gynecologic, musculoskeletal and metabolic diseases and focuses on gynecologic symptoms, musculoskeletal pain and circulatory problems when assessing blood stasis (Questions on menstruation would not be necessary or meaningful when diagnosing pain caused by blood stasis following a car accident). Therefore, we tried to revise the existing diagnostic questionnaire for blood stasis and develop a questionnaire focusing on metabolic disorders. Our questionnaire may be used to diagnose blood stasis in patients with blood circulation problems such as hypertension, diabetes, hyperlipidemia, atherosclerosis, myocardial infarction, and angina.

This study has a few limitations. First, the diagnostic questionnaire for blood stasis had very few questions on circulatory or metabolic disorder. Therefore, this questionnaire cannot be used alone to diagnose metabolic disorders accompanied by blood stasis but must be used in conjunction with blood tests and evaluation of basic biological markers. Second, the surveys may be subject to recall bias. Although the first and second surveys were conducted 10 days apart and the questions were randomly organized to minimize recall bias, the possibility of recall bias cannot still be ruled out. Lastly, although online surveys are an efficient means to gain opinions from many experts, they cannot obtain

in-depth thoughts. Performing a focus group interview (FGI) additionally may have increased the reliability of the Delphi survey results.

We conclude this study with the following proposals. In order for disease patterns of Korean medicine to be used to medically diagnose and treat diseases, it is first necessary to standardize the method of diagnosing disease patterns and establish a scientific rationale behind it. In this light, we recommend endeavors to develop and distribute diagnostic questionnaires that are highly reliable and valid and, furthermore, to obtain a large amount of clinical data using diagnostic tools and revise the questionnaires accordingly over a long term. This study marks the beginning of these efforts, and the results of this study may be used to identify patients with metabolic disorders accompanied by blood stasis and measure the severity of blood stasis. Their use may also be expanded to treating blood stasis and predicting its prognosis.

V. Conclusion

This study conducted a Delphi survey to develop a questionnaire for blood stasis accompanied by metabolic disorders. The results are as follows.

1. Ninety-nine respondents completed the first survey. Ninety-two respondents completed the first and second surveys. Twelve experts in Korean Internal Medicine and Cardiology, 17 experts from other medical fields and 70 general practitioners participated.
2. The mean score on the 30 questions was 3.26 points in the first Delphi survey. The mean score was 3.31 points in the second survey.
3. The top 10 questions selected for diagnosing patients with blood stasis accompanying metabolic disorders were 'sublingual varices', 'reddish black tongue', 'reddish black lips',

'dark purple palatal mucosa and venous edema', 'ecchymosis of the tongue', 'ecchymosis of the skin', 'night pain', 'piercing pain' and 'prolonged numbness'.

Acknowledgement

This work was supported by a grant from the Korea Institute of Oriental Medicine (K18191 and K18192).

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