

THE LIFESTYLE AND CLINICAL SURVEY: A MEDICAL HISTORY QUESTIONNAIRE

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Recognizing the limitations of the medical chart review as a data collection tool, these authors designed and tested an 88-item survey that captures information essential to research in patients with peripheral arterial disease.

The medical chart review is a method that's used commonly to gather baseline data and track outcomes in large cohort studies of patients with chronic disease. Unfortunately, its usefulness as a research tool is limited by the time it

takes to perform and the unreliability or unavailability of certain types of data. Information about some lifestyle behaviors, for instance, may not be included in medical records and may be obtained most accurately from patients themselves—through the use of either self- or clinician-administered questionnaires.

Previous surveys developed for patients with peripheral arterial disease (PAD) have focused on ascertaining symptoms of intermittent claudication and walking impairment.¹⁻³ When, in 2000, we at the Houston Center for Quality of Care and Utilization Studies, Michael E. DeBakey VA Medical Center (MEDVAMC), Houston, TX and the health services research section of Baylor College of Medicine, also in Houston, decided to undertake an epidemiologic study of patients at risk for PAD, we rec-

ognized the need for an additional questionnaire that would collect information on sociodemographics, medical history, medication use, and lifestyle behaviors relevant to this disease with more accuracy and thoroughness than a medical chart review. In response to this need, we developed the Lifestyle and Clinical Survey (LCS).

Here, we present a pilot study of the LCS that we conducted in a subset of veterans who were enrolled in our larger cohort study of patients screened for PAD. By assessing the reliability and validity of the LCS in this sample of patients, our aim was to establish preliminary data on the usefulness of the survey in research studies involving similar cohorts.

DEVELOPING THE LCS

Before constructing the survey, we developed a conceptual model to

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outline the types of information relevant to the process of care and the outcomes of patients with PAD. Using a review of medical literature and our own clinical experience, we identified four major domains of information—biological, psychosocial, health care system use, and limb outcomes—as well as subcategories of information for each domain (Figure 1).

We then constructed a survey that covered these domains and subcategories, using language that could be read easily by the interviewer and paraphrased as needed. Some questions (such as those concerning smoking, exercise, and the use of hormone replacement medications) were based on language that had been used previously in a

larger trial, the Women's Health Initiative (J. Hays, oral communication, July 2001).

The final survey contained 88 items: 30 in the biological domain, 27 in the psychosocial domain, 28 in the health care system use domain, and three in the limb outcomes domain (Figure 2). Across the domains, 11 items pertained to sociodemographics and 31 related to the patient's medical history (prior diagnoses and procedures). To ascertain information on symptoms of pulmonary or cardiovascular disease, we included five questions on blood clots, breathing difficulty, and swelling of the feet or ankles. Nine questions inquired about menopause history and the use of hormonal agents, and 18

questions addressed other medication use. The remaining 14 items inquired about lifestyle behaviors. Since the LCS was intended to be used in conjunction with other questionnaires designed to ascertain leg symptoms (the San Diego Claudication Questionnaire¹) and lower extremity function (the Walking Impairment Questionnaire^{2,3}), we did not include specific questions about functional impairment—a feature that could potentially increase the generalizability of the LCS for non-PAD cohort studies.

Sociodemographic items covered such topics as age, race and ethnicity (in accordance with definitions used by the U.S. Census Bureau), gender, marital status,

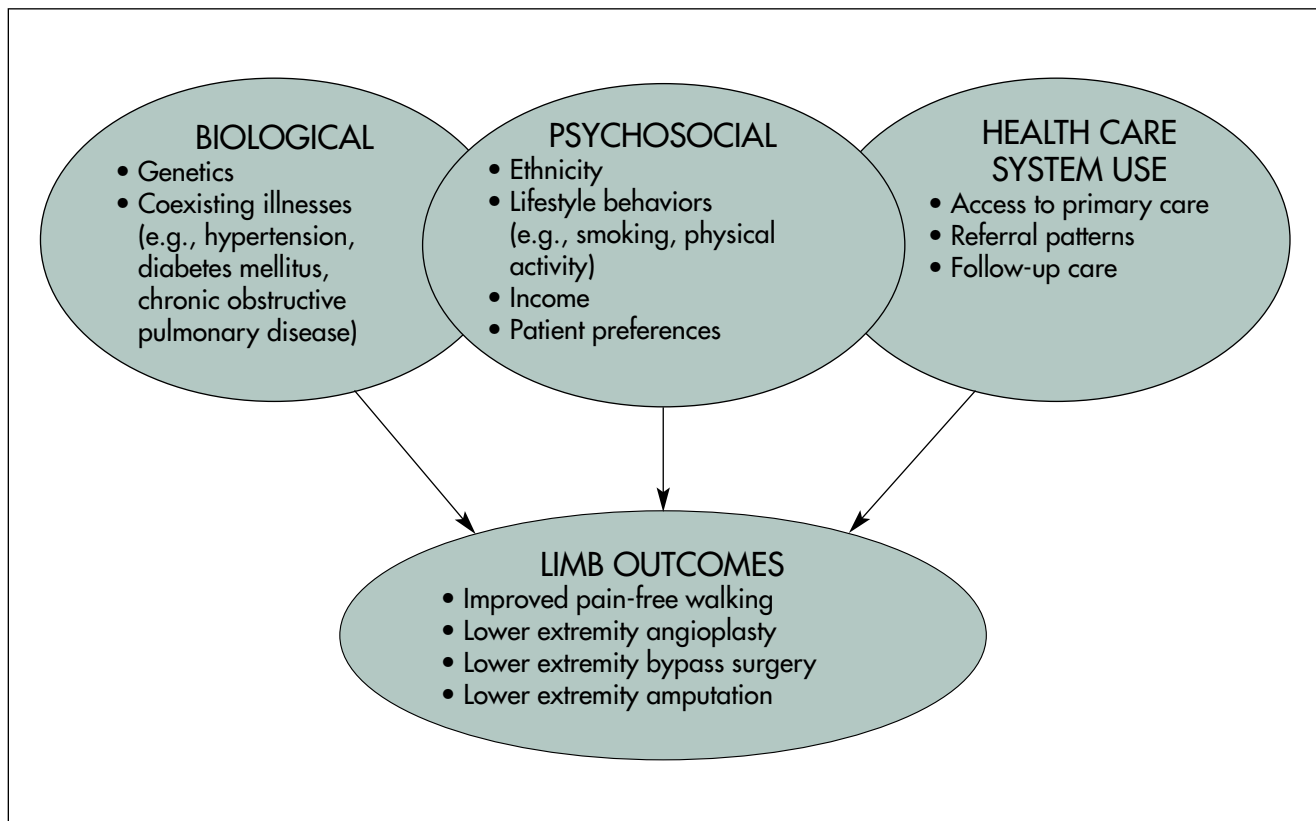


Figure 1. Conceptual model of the major categories and subcategories to consider for research in peripheral arterial disease.

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<p>16. Have you ever had angiography (dye in the arteries of the legs) for claudication or peripheral arterial disease? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>17. Have you ever had angioplasty (balloon catheter to open blockage) in the legs? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>18. Have you ever had surgery to improve blood flow in your legs (do not include surgery for varicose veins)? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Has a doctor ever said that you have any of the following:</p> <table border="0"> <thead> <tr> <th></th> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr><td>19. Abdominal aortic aneurysm</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>20. Atrial fibrillation (a type of irregular heart beat)</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>21. 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Have you ever been awakened at night by trouble breathing? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>43. Have you ever had swelling of your feet or ankles (excluding during pregnancy)? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>44. If you answered yes to the above question, did the swelling tend to come on during the day and go down overnight? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>The next several questions are about your menstrual history. If you are <u>male</u>, please skip to question #54.</p> </div> <p>45. Have you reached menopause? (no longer having a routine menstrual flow or period) Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/></p> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>If the answer to the above question is <u>no</u> or <u>unknown</u>, please skip the next question.</p> </div> <p>46. If yes to question #45, please check the type of menopause you experienced (otherwise, skip this question): <input type="checkbox"/> Natural <input type="checkbox"/> Radiation or chemotherapy <input type="checkbox"/> Surgery <input type="checkbox"/> Unknown</p> <p>47. Have you ever taken any kind of female hormone medication prescribed by a doctor, such as estrogen or progesterone, for menopause? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>If you answered no to the question above, please skip to question #54.</p> </div> <p>48. <u>Within the past 2 years</u>, have you used female hormone PILLS prescribed by a doctor which contained <u>only</u> ESTROGEN (for example, Premarin)? (Do not include the use of ESTROGEN taken along with a PROGESTERONE pill even if only for a few days of the month.) Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/></p> <p>49. If you answered yes to the question #48 above, for how long did you take female hormone pills containing <u>only</u> ESTROGEN? <input type="checkbox"/> < 1 month <input type="checkbox"/> 11–12 months <input type="checkbox"/> 1–6 months <input type="checkbox"/> 13–18 months <input type="checkbox"/> 7–10 months <input type="checkbox"/> 19–24 months</p>
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Figure 2. (continued) The Lifestyle and Clinical Survey.

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50. Within the past 2 years, have you used female hormone PILLS prescribed by a doctor which contained both ESTROGEN AND progesterin (PROGESTERONE) COMBINED in the same pill or package (for example, Prempro, Premphase)?
 Yes No Don't know

If you answered no to question #50 above, please skip the next question.

51. In the past 2 years, how many months did you use the COMBINED female hormone PILLS that contained both ESTROGEN AND PROGESTERONE in the same pill or package?
 < 1 month 11-12 months
 1-6 months 13-18 months
 7-10 months 19-24 months

52. In the past 2 years, did you use female hormone PILLS prescribed by a doctor which contained both ESTROGEN and TESTOSTERONE COMBINED in the same pill (for example, Estratest)? Yes No Don't know

53. If you answered yes to the above question #52, how many months did you use the COMBINED female hormone PILLS that contained both ESTROGEN AND TESTOSTERONE in the same pill?
 < 1 month 11-12 months
 1-6 months 13-18 months
 7-10 months 19-24 months

Do you currently take prescribed medication for any of the following medical problems?

	Yes	No
54. Poor blood supply to the legs	<input type="checkbox"/>	<input type="checkbox"/>
55. High blood pressure	<input type="checkbox"/>	<input type="checkbox"/>
56. Chronic or congestive heart failure	<input type="checkbox"/>	<input type="checkbox"/>
57. Diabetes mellitus (high blood sugar)	<input type="checkbox"/>	<input type="checkbox"/>
58. Chronic bronchitis or emphysema	<input type="checkbox"/>	<input type="checkbox"/>
59. Asthma	<input type="checkbox"/>	<input type="checkbox"/>
60. Arthritis	<input type="checkbox"/>	<input type="checkbox"/>

61. Do you take any of the following medications on a regular basis? (D = daily; W = weekly; O = occasionally; N = never)

Ecotrin	D <input type="checkbox"/>	W <input type="checkbox"/>	O <input type="checkbox"/>	N <input type="checkbox"/>
Bayer	D <input type="checkbox"/>	W <input type="checkbox"/>	O <input type="checkbox"/>	N <input type="checkbox"/>
Ibuprofen	D <input type="checkbox"/>	W <input type="checkbox"/>	O <input type="checkbox"/>	N <input type="checkbox"/>
Motrin	D <input type="checkbox"/>	W <input type="checkbox"/>	O <input type="checkbox"/>	N <input type="checkbox"/>
Aleve	D <input type="checkbox"/>	W <input type="checkbox"/>	O <input type="checkbox"/>	N <input type="checkbox"/>
Advil	D <input type="checkbox"/>	W <input type="checkbox"/>	O <input type="checkbox"/>	N <input type="checkbox"/>
BC	D <input type="checkbox"/>	W <input type="checkbox"/>	O <input type="checkbox"/>	N <input type="checkbox"/>
Celebrex (celecoxib)	D <input type="checkbox"/>	W <input type="checkbox"/>	O <input type="checkbox"/>	N <input type="checkbox"/>
Vioxx (rofecoxib)	D <input type="checkbox"/>	W <input type="checkbox"/>	O <input type="checkbox"/>	N <input type="checkbox"/>

Naproxen D W O N
 Alka Seltzer D W O N

62. Do you take aspirin (any dose)?
 D W O N

63. Do you now use insulin?
 Yes No

64. Do you now take Coumadin or warfarin?
 Yes No

65. Do you currently take ticlopidine (Ticlid)?
 Yes No

66. Do you currently take clopidogrel (Plavix)?
 Yes No

67. Do you currently take cilostazol (Pletal) daily to improve your walking ability? Yes No

68. Do you currently take Trental or pentoxifylline daily to improve your walking ability? Yes No

69. Do you currently take any medication on a schedule other than that prescribed by your doctor? (e.g., every other day vs. daily)
 Yes No

70. Are you currently taking any medications (other than the above medications) to help improve your walking ability?
 Yes No
 (If yes, please specify) _____

71. Do you currently use herbal therapy or alternative medicine (e.g., acupuncture) in place of or in addition to medication prescribed by your doctor? Yes No
 (If yes, please specify) _____

72. During your entire life, have you smoked at least 100 cigarettes? Yes No

73. How old were you when you first started smoking cigarettes regularly? (years old)

If no, please skip to #78

74. Do you now smoke cigarettes?
 No (please go to the next question)
 Yes (please skip to question #77)

75. How old were you when you quit smoking regularly?
 (years old)

76. On average, how many cigarettes do you usually smoke each day? (If you have stopped smoking how many cigarettes did you smoke each day?)
 < 1 1 pack per day
 1-4 > 1 pack per day
 5-15

Continued on next page

Figure 2. (continued) The Lifestyle and Clinical Survey.

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77. For how many years have you been (including your past history) a regular smoker? (Do not count the times you stayed off cigarettes.)
- < 5 years 20–30 years
 5–9 years 31–40 years
 10–20 years > 40 years

78. Do you smoke any other form of tobacco (e.g., cigars, pipes, cigarillos)? Yes No

79. Do you drink alcoholic beverages?
 Yes No

If yes to the above question, please check how often you drink alcohol:

- Daily Occasionally
 Weekly Rarely

80. Think about the walking you do outside the home. How often do you walk outside the home for more than 10 minutes without stopping? (please mark only one)
- Rarely or never (please skip to question #83)
 1 time each week
 2–3 times each week
 4–6 times each week
 7 or more times each week

81. When you walk outside the home for more than 10 minutes without stopping, for how many minutes do you usually walk?
- < 20 minutes 40–59 minutes
 20–39 minutes 1 hour or more

82. How would you describe your activity level while working (including housework)?
- Light (sitting at a desk for more than half of the day)
 Moderate (frequent walking including stairs)
 Strenuous (heavy lifting or moving of objects for at least half of the day)

Not including walking outside the home or work, how often each week (7 days) do you usually do the exercises below?

- 83a. STRENUOUS OR VERY HARD EXERCISE (such as aerobic dancing, jogging, tennis, swimming laps)
- None 3 days per week
 1 day per week 4 days per week
 2 days per week 5 or more days per week

- 83b. How long do you usually exercise like this at one time?
- < 20 min.
 20–39 min.
 40–59 min.
 1 hour or more

- 84a. MODERATE EXERCISE (biking outdoors, use of an exercise machine, easy swimming, folk dancing)
- None 3 days per week
 1 day per week 4 days per week
 2 days per week 5 or more days per week

- 84b. How long do you usually exercise like this at one time?
- < 20 min.
 20–39 min.
 40–59 min.
 1 hour or more

- 85a. MILD EXERCISE (slow dancing, bowling, or golf)
- None 3 days per week
 1 day per week 4 days per week
 2 days per week 5 or more days per week

- 85b. How long do you usually exercise like this at one time?
- < 20 min.
 20–39 min.
 40–59 min.
 1 hour or more

86. How would you describe your current work or retirement situation? (check one)
- Working at a paying job full-time
 Working at a paying job part-time
 Retired, not working at all
 Retired, but working part- or full-time
 Laid off or unemployed, but looking for work
 Laid off or unemployed, but not looking for work
 Not working because of disability
 Other, please specify: _____

87. Please specify your yearly household income by checking one of the following:
- < \$5,000 \$50,000–\$100,000
 \$5,000–\$30,000 > \$100,000
 \$30,000–\$50,000

88. What language do you more commonly speak at home?
- English Spanish
 Other, please specify: _____

Figure 2. (continued) The Lifestyle and Clinical Survey.

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educational level, work status, household income, and primary language spoken. Medical history items included questions about prior ischemic events; prior invasive diagnostic studies for vascular disease; and such previous diagnoses as diabetes mellitus, hypertension, arthritis, and gastrointestinal illnesses. Medication use items asked about disease-specific medications (such as antihypertensives and hypoglycemics), several commonly used over-the-counter and prescription drugs (including various preparations of aspirin, ibuprofen, and naproxen), antiplatelet agents, and herbal or alternative medicines. In order to increase patients' recognition of drug names, we included some common trade names in addition to generic names. The lifestyle behavior items pertained to smoking history, alcohol intake, and routine exercise patterns.

STUDY DESIGN

For our pilot study of the reliability and validity of the LCS, we enrolled patients from the cross-sectional cohort of patients who had been screened for PAD at four primary care sites within Houston, one of which was the MEDVAMC.⁴ Because the MEDVAMC site (which included both the primary care and the women's health clinics) had the advantage of computerized patient records that were readily accessible and easy to use, we recruited our subset of patients consecutively from this site. Although the full cohort included both English and Spanish speaking patients, our sample was exclusively English speaking. The study protocol was approved by Baylor College of Medicine's Institutional Review Board.

We assessed test-retest reliability by administering the LCS to participants twice within a two-week period and comparing agreement using Cohen's kappa statistic. To evaluate validity, we used Cohen's kappa statistic to compare agreement between survey results and information in patients' medical charts.⁵

Whereas the proportion agreement is the ratio of the number of positive and negative responses that agree between two response variables divided by the total number of responses, Cohen's kappa statistic is the observed proportion agreement corrected for agreement by chance alone.⁶ The strength of this agreement was determined according to the guidelines of Landis and Koch (Table 1).⁷ Because the kappa value, paradoxically, may be highly skewed if the prevalence of a response is extremely low or high, we also reported the sensitivity and specificity as recommended by Feinstein and Cicchetti.⁸ Furthermore, since the significance of test-retest agreement is diminished when the parameter being tested is uncommon in a given population, we excluded from our analysis certain LCS items for which many of our patients answered "No."

For the chart review used to assess validity, we constructed a data abstraction form containing 42 items. Due to the aforementioned limitations on chart reviews, not all of the questions developed for the LCS could be compared reliably to the chart review. Validation, therefore, was limited to those questions relevant to medical history, medication use, smoking history, and alcohol intake. The chart reviewer, who was blinded to the survey responses, reviewed

Table 1. Interpretation of kappa statistics⁷

Kappa statistic	Strength of agreement
< 0.00	Poor
0.00–0.20	Slight
0.21–0.40	Fair
0.41–0.60	Moderate
0.61–0.80	Substantial
0.81–1.00	Almost perfect

clinic notes starting at the date of study enrollment and going back one year. Information on medication use was obtained from the pharmacy records section of the electronic medical chart.

In some cases, items on the data abstraction form were more specific than those on the LCS, and comparisons to LCS items were not always made on a one-to-one basis. For example, the use of antihypertensives in general and of angiotensin converting enzyme inhibitors specifically, as documented in patients' charts, were each compared with patients' responses to LCS item 55, which asked patients whether they took any medication for high blood pressure. Similarly, chart documentation on the use of bronchodilators and inhaled steroids was compared with patients' responses to the two LCS items concerning medications for chronic bronchitis or emphysema (item 58) and for asthma (item 59).

STRONG AGREEMENT ON MANY KEY ITEMS

Of the total cohort of 403 patients, who had a mean age of 63.8 ± 7.3 (SD), 151 were enrolled from the

MEDVAMC. The first 30 of these were included in the LCS reliability and validation study. In this sample, the mean age was 67.2 ± 7.4 , 83.3% of the patients were white, and 86.7% of them had at least a high school education (Table 2). Although the VA population is predominantly male, just over half of our patients (53.3%) were female. This was because the cohort study recruited patients from the women's health clinic as well as the primary care clinic. The LCS was administered to each patient by an interviewer, and none of these interviews took more than 10 minutes.

On the reliability analysis, the kappa statistics for test-retest agreement were at least moderate for many of the LCS items—including several from the medical history, symptomology, and medication use categories (Table 3). For these items, specificity ranged from 50% to 100% and sensitivity ranged from 33% to 100%.

A total of 20 items (or subitems) generated test-retest kappa statistics in the substantial to almost perfect range. These included white or black race; history of cardiac catheterization, hypercholesterolemia, diabetes mellitus, rheumatoid arthritis, and osteoporosis; the need to sleep on two or more pillows to breathe; use of such medications as female hormones, asthma medications, celecoxib, and insulin; and lifestyle behavior items about lifetime cigarette use and alcohol use. Items that asked about the use of herbal medications or alternative therapies, use of Alka Seltzer (Bayer Consumer Care, Morristown, NJ), use of medication for arthritis, history of claudication or PAD, and foot or ankle swelling generated moderate kappa statistics. The kappa statistic was

Table 2. Patient characteristics for the participants in the reliability and validation study of the LCS* and for the total cohort		
Characteristic	LCS patients	Total cohort
No. of patients	30	403
Mean age (SD)	67.2 (7.4)	63.8 (7.3)
Mean ABI† (SD)	1.05 (0.13)	1.06 (0.25)
Race/ethnicity, no. (%)		
Black	3 (10.0)	136 (33.8)
White	25 (83.3)	136 (33.8)
Spanish/Hispanic/Latino	2 (6.7)	131 (32.5)
Risk factors, no. (%)		
Diabetes	9 (30.0)	153 (38.0)
Hypertension	16 (53.3)	278 (69.0)
Current smoking	4 (13.3)	76 (18.9)

*LCS = Lifestyle and Clinical Survey. †ABI = ankle brachial index.

fair for one item pertaining to walking outside the home for less than 20 minutes and slight for one item that inquired about mild exercise one or more days per week.

Although kappa statistics for the 42 items included in the validity analysis varied widely, from -0.06 to 0.87 , many dichotomous medical history questions performed moderately or better (Table 4). In all, 18 items attained kappa statistics that were at least moderate; among these, the sensitivity ranged from 33% to 100% and the specificity ranged from 75% to 100%.

There were 10 data abstraction items with substantial or almost perfect kappa validity statistics (five about medical history and five about medication use), and eight with moderate values (three pertaining to chronic medical illnesses, three about medication use, and two concerning lifestyle behaviors). Seven items achieved only fair kappa statistics (three about ill-

nesses, three about medication use, and one about lifestyle behaviors), and three had slight agreement (history of asthma, history of arthritis other than rheumatoid, and use of estrogen alone). Finally, two of the items—the presence of kidney disease other than an infection or stone and the use of Bayer aspirin (Bayer Consumer Care, Morristown, NJ)—had negative (poor) kappa statistics.

A PROMISING RESEARCH TOOL

The results of our pilot study suggest the LCS is a practical instrument for obtaining information on sociodemographics, medical history, medication use, and lifestyle behaviors from a population of patients being screened for PAD.

For test-retest reliability, questions about ethnicity, medical history, and symptomology related to cardiac or pulmonary disease all performed satisfactorily. Questions regarding use of specific medica-

Table 3. Test-retest reliability results for the LCS*

Item (LCS item no.)	Proportion agreement	Kappa statistic	Kappa 95% CI†	Sensitivity	Specificity
Sociodemographics					
Race (5)					
White	0.97	0.84	0.53–1.00	0.96	1.00
Black	1.00	1.00	1.00–1.00	1.00	1.00
Medical history					
Cardiac catheterization (11)	0.96	0.89	0.67–1.00	1.00	0.96
Claudication or PAD‡ (15)	0.93	0.47	–0.13–1.00	1.00	0.93
Atrial fibrillation (20)	0.96	0.84	0.53–1.00	0.75	1.00
Hypercholesterolemia (22)	0.97	0.93	0.79–1.00	1.00	0.95
Diabetes mellitus (26)	0.96	0.92	0.77–1.00	0.90	1.00
Kidney, eye, or circulation problems related to diabetes (27)	0.96	0.65	0.02–1.00	1.00	0.96
Chronic bronchitis or emphysema (28)	0.97	0.87	0.62–1.00	1.00	0.96
RA§ (34)	0.93	0.76	0.45–1.00	0.67	1.00
Arthritis other than RA (35)	0.86	0.72	0.48–0.97	0.92	0.81
Osteoporosis (37)	0.97	0.84	0.53–1.00	0.75	1.00
Symptomology					
Sleeps on two or more pillows (41)	0.93	0.81	0.57–1.00	0.75	1.00
Swelling of feet or ankles (43)	0.77	0.49	0.17–0.81	0.89	0.58
Menopause history and hormone use					
Surgical or natural menopause (46)	1.00	0.87	0.64–1.00	0.87	1.00
Hormone medication (47)	0.94	0.76	0.33–1.00	1.00	0.67
Other medication use					
Condition-specific medications:					
Asthma (59)	0.87	0.71	0.46–0.97	0.75	0.94
Arthritis (60)	0.93	0.46	–0.16–1.00	0.50	0.96
Advil¶ (61)	0.93	0.63	0.16–1.00	0.67	0.96
Alka Selzer¶ (61)	0.93	0.47	–0.12–1.00	0.33	1.00
Celebrex (celecoxib)# (61)	0.97	0.65	0.02–1.00	1.00	0.50
Insulin (63)	0.93	0.71	0.35–1.00	1.00	0.93
Herbal or alternative medicine (71)	0.87	0.42	–0.04–0.89	0.50	0.92
Lifestyle behaviors					
Lifetime cigarette use of ≥ 100 cigarettes (72)	0.97	0.93	0.80–1.00	1.00	0.92
Alcohol use (79)	0.87	0.61	0.31–0.92	0.70	0.90
Walking outside the home for < 20 minutes (81)	1.00	0.38	–0.02–0.78	1.00	1.00
Mild exercise at least one day a week (85a)	0.90	0.05	–0.11–0.02	1.00	1.00
*LCS = Lifestyle and Clinical Survey. Because the significance of test-retest agreement is diminished when the parameter being tested (such as a disease or the use of a particular medication) is uncommon in a given population, we excluded from our analysis certain LCS items for which many of our patients answered “No.” †CI = confidence interval. ‡PAD = peripheral arterial disease. §RA = rheumatoid arthritis. ¶Wyeth Consumer Healthcare Inc., Madison, NJ. ¶Bayer Consumer Care, Morristown, NJ. #Pfizer, New York, NY.					

Table 4. Validity results for the LCS* item responses compared to chart abstraction

Item (LCS item no.)	Proportion agreement	Kappa value	Kappa 95% CI†	Sensitivity	Specificity
Medical history					
Atrial fibrillation (20)	0.93	0.71	0.35–1.00	1.00	0.93
Hypertension (21)	0.83	0.66	0.39–0.93	0.82	0.85
Hypercholesterolemia (22)	0.83	0.63	0.34–0.92	0.73	0.89
Congestive heart failure (23)	0.90	0.36	–0.16–0.89	0.25	1.00
Stroke with continued weakness (24)	0.97	0.78	0.37–1.00	1.00	0.96
Diabetes mellitus (26)	0.93	0.85	0.64–1.00	0.90	0.95
Chronic bronchitis or emphysema (28)	0.87	0.42	–0.04–0.89	0.50	0.92
Asthma (29)	0.80	0.20	–0.14–0.55	1.00	0.79
Cancer other than squamous or basal cell skin cancer (30)	0.83	0.52	0.16–0.87	0.80	0.84
Kidney disease other than infection or stone (31)	0.73	–0.06	–0.17–0.04	0.00	0.96
Stomach or duodenal ulcer (32)	0.73	0.29	–0.04–0.63	0.75	0.73
RA‡ (34)	0.83	0.38	–0.01–0.77	1.00	0.82
Arthritis other than RA (35)	0.55	0.11	–0.24–0.47	0.50	0.61
Osteoporosis (37)	0.87	0.42	–0.04–0.89	0.50	0.92
Menopause history and hormone use					
Use of estrogen alone (48)	0.62	0.19	–0.23–0.60	0.89	0.29
Other medication use					
Any antihypertensive medication (55)	0.93	0.87	0.69–1.00	0.88	1.00
ACE§ inhibitors (55)	0.93	0.87	0.69–1.00	0.88	1.00
Oral hypoglycemic agents (57)	0.93	0.83	0.60–1.00	0.87	0.95
Bronchodilators or inhaled steroids (58, 59)	0.77	0.22	–0.19–0.64	0.17	0.92
Bayer (aspirin) (61)	0.87	–0.05	–0.13–0.03	0.00	0.90
Ibuprofen (61)	0.77	0.32	–0.06–0.70	0.60	0.80
Advil¶ (61)	0.93	0.47	–0.12–1.00	1.00	0.93
Celebrex (celecoxib)# (61)	0.93	0.63	0.18–1.00	0.50	1.00
Vioxx (rofecoxib)** (61)	0.93	0.47	–0.12–1.00	0.33	1.00
Naproxen (61)	0.83	0.35	–0.10–0.80	0.40	0.92
Insulin (63)	0.93	0.71	0.35–1.00	0.60	1.00
Coumadin†† or warfarin (64)	0.93	0.46	–0.16–1.00	0.50	0.96
Lifestyle behaviors					
Current smoking (74)	0.87	0.59	0.26–0.93	0.50	1.00
Past smoking (74)	0.60	0.23	–0.08–0.55	0.50	0.75
Alcohol use (79)	0.77	0.46	0.12–0.80	0.67	0.81
<p>*LCS = Lifestyle and Clinical Survey. †CI = confidence interval. ‡RA = rheumatoid arthritis. §ACE = angiotensin converting enzyme. Bayer Consumer Care, Morristown, NJ. ¶Wyeth Consumer Healthcare Inc., Madison, NJ. #Pfizer, New York, NY. **Merck & Company, Whitehouse Station, NJ. Vioxx was voluntarily withdrawn from the worldwide market in September 2004. ††Bristol-Myers Squibb Company, New York, NY.</p>					

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THE LIFESTYLE AND CLINICAL SURVEY

Continued from previous page

tions, over-the-counter medications, and alternative medicines; smoking history; and several other lifestyle behaviors (including alcohol use) also performed well, with high agreement between two sets of survey responses delivered within a two-week period. The low kappa statistic found for the item regarding mild exercise may reflect the low prevalence of exercise among the patients queried or poor wording of the question.

For the validation analysis, the item responses that agreed satisfactorily with the medical chart information included those about such common illnesses as hypertension, hypercholesterolemia, and diabetes mellitus. A question that performed less well was that regarding "kidney disease other than an infection or stone." This was a nonspecific question that likely lends itself to misinterpretation by the patient. Furthermore, many patients with renal insufficiency who do not require dialysis may be unaware of their diagnosis.

There were wide confidence intervals for the validation kappa statistics of items that inquired about the use of certain medications, including ibuprofen (generic), Advil (Wyeth Consumer Healthcare Inc., Madison, NJ), and naproxen (generic). As these are nonprescription medications, their use is not always recorded in a patient's chart. Similarly, a previous history of smoking may not be documented consistently for patients who have since quit, since such history may not be detected by primary care screening, which tends to be geared toward identifying candidates for smoking cessation programs.

Aside from issues with chart documentation, another factor that

might have contributed to the less than ideal performance of some survey items is poor patient recall of medication names. Although we made an effort in designing the LCS to cover all bases by including both generic and trade names of specific medications, patients may not always remember these names off-hand. A patient who is prescribed warfarin or rofecoxib, for example, may simply refer to the medication as a blood thinner or a painkiller.

STUDY LIMITATIONS

There are some limitations of this survey validation and reliability study. That fact that our patient sample was taken from a single VA medical center, for example, could limit the generalizability of the survey's performance to the non-VA setting. The LCS, however, was developed specifically for use in patients with PAD, many of whom are over the age of 60 and have multiple coexisting illnesses (such as diabetes mellitus and hypertension). Since these characteristics are common in the general VA population, studying the survey in such a setting would seem appropriate.

Another limitation was the similar prevalence of certain illnesses among the 30 patients who participated in our validation study, which may bias our results to a higher proportion of agreement than would exist among a more diversely ill population. Of the 42 items that could be validated by chart review, items 10 through 18 related specifically to severe atherosclerotic disease, inquiring about such procedures as cardiac catheterization and limb angioplasty. While these questions are very relevant to patients with PAD (particularly those who are referred to a vascular laboratory for

additional testing), the use of these procedures is far less common in a general primary care setting. For this survey to be useful in such broad settings, therefore, additional testing is needed to determine the value of including or excluding some or all of the LCS questions that focus on severe atherosclerotic illness.

Finally, there is a possibility that the patients who agreed to participate in this study (and, specifically, to take the survey twice) might not have been as sick as those who chose not to participate and, therefore, might have been less likely to have variation in their responses at two separate time points. If so, this type of bias would diminish the generalizability of our reliability findings to a more severely ill population. Nevertheless, we would expect a primary care population being screened for PAD to contain a significant number of patients who have relatively mild disease.

THE NEXT STEPS

As an instrument for ascertaining relevant data on sociodemographics, medical history, medication use, and lifestyle behaviors in patients with PAD, the LCS adds to the existing body of assessments developed for this population. Preliminary data indicate satisfactory reliability and validity, suggesting the practicality of the LCS as a research tool. Following additional reliability and validity testing in a larger number of patients, researchers might consider using this survey in place of more labor intensive chart reviews in studies of patients with PAD and other chronic diseases. Our future plans for the LCS include comparing self- and interviewer-administered versions of the survey in a large trial and

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gathering feedback on the instrument through patient and clinician interviews. After these steps, we should be able to report, more definitively, the validity and reliability of each version and the most efficient method for data collection.

We designed the LCS for use as a baseline screening questionnaire; at this time we cannot generalize its usefulness in tracking outcomes in a prospective cohort study. Prior work by Bergmann and colleagues, involving validation of the National Health and Nutrition Examination Survey, highlighted the risk of misclassification bias that exists when researchers collect self-reported outcome data.⁹ This work did demonstrate, however, that self-reports of outcomes for several chronic diseases (including ischemic heart disease and cataracts) were accurate 80% of the time.

Because PAD is common in geriatric populations, patients with this disease often have other chronic medical illnesses (such as hypertension, dyslipidemia, diabetes mellitus, or osteoarthritis). Obtaining information on patient demographics, medical history, and lifestyle behaviors can be useful for subsequent risk adjustment in studies of various chronic diseases. While the LCS was developed for use in studies of patients at risk for PAD, there is potential for it to be used in populations of elderly patients with other chronic illnesses. Perhaps future research will explore these other avenues of utility. ●

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