Opinions on chelation therapy in patients undergoing coronary angiography: Cross-sectional survey

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H Quan, PD Galbraith, CM Norris, et al. Opinions on chelation therapy in patients undergoing coronary angiography: Cross-sectional survey. Can J Cardiol 2007;23(8):635-640.

BACKGROUND: Chelation therapy is frequently used by patients for the treatment of coronary artery disease. However, relatively little is known about patient attitudes and beliefs that underlie the use of this treatment. The aim of the present study was to document patients' opinions and beliefs about health care decision making, physician and patient communication and relationships, and reasons for using or not using chelation therapy as treatment for coronary artery disease.

METHODS: A mail survey was sent to patients who underwent coronary angiography between 1998 and 2000 in Alberta. Information was collected on self-reported reasons for chelation therapy use, sociodemographic characteristics, communication and relationships between patients and physicians, as well as beliefs regarding surgery, medications and chelation therapy.

RESULTS: Of the 780 patients who received surveys, 96 users and 264 nonusers of chelation therapy completed questionnaires. Among the users, 20.8% believed that chelation therapy could cure heart disease, 44.2% believed that it could relieve symptoms, 16.7% believed that it could have side effects and 58.4% believed that it could increase quality of life. Users and nonusers were similar in their beliefs about safety and benefits of heart surgery, but users of chelation therapy were less likely than nonusers to believe that using conventional medications could prevent worsening of heart disease (53.1% versus 67.4%), increase quality of life (74.0% versus 85.2%) and give a feeling of control over heart disease (61.5% versus 77.7%).

CONCLUSIONS: Many chelation therapy users appeared to have negative views toward the benefits of conventional medications and positive views toward the safety of chelation therapy. Users and nonusers of chelation therapy had the same views toward the benefits and safety of heart surgery.

Key Words: *Cardiac disease; Chelation therapy; Complementary and alternative therapy; Survey*

Chelation therapy involves the intravenous administration of the chelator EDTA in combination with vitamins and minerals. The mechanism of action of EDTA is unknown, but it is speculated that EDTA alters plaque morphology and volume, and improves function of vessel cell membranes (1). Since chelation therapy was first used in the treatment of vascular disease in 1955, the effectiveness of the therapy for vascular disease has been studied and greatly debated (2-6).

Des avis sur le traitement par chélation chez les patients qui subissent une coronarographie : Une enquête transversale

HISTORIQUE : Les patients font souvent appel au traitement par chélation pour soigner une coronaropathie. Cependant, on ne sait pas grand-chose sur les attitudes et les croyances des patients qui sous-tendent l'utilisation de ce traitement. La présente étude visait à documenter les avis et les croyances des patients au sujet de la prise de décision des soins, des communications et des relations entre les médecins et les patients, ainsi que des raisons d'utiliser ou de ne pas utiliser le traitement par chélation pour soigner la coronaropathie.

MÉTHODOLOGIE : On a posté un questionnaire aux patients qui avaient subi une coronarographie en Alberta entre 1998 et 2000. On a recueilli de l'information sur les raisons autodéclarées de recourir à l'utilisation du traitement par chélation, les caractéristiques sociodémographiques, les communications et les relations entre patients et médecins, ainsi que les croyances au sujet des opérations, des médicaments et du traitement par chélation.

RÉSULTATS : Sur les 780 patients qui ont reçu le questionnaire, 96 utilisateurs et 264 non-utilisateurs du traitement par chélation y ont répondu. Chez les utilisateurs, 20,8 % pensaient que le traitement par chélation pouvait guérir les maladies cardiaques, 44,2 % qu'il pouvait soulager les symptômes, 16,7 % qu'il pouvait s'accompagner d'effets secondaires et 58,4 % qu'il pouvait améliorer la qualité de vie. Les utilisateurs et les non-utilisateurs avaient des croyances similaires au sujet de l'innocuité et des bienfaits de la chirurgie cardiaque, mais les utilisateurs du traitement par chélation étaient moins susceptibles que les non-utilisateurs de croire que les médicaments classiques pouvaient prévenir l'aggravation de la maladie cardiaque (53,1 % par rapport à 67,4 %), accroître la qualité de vie (74,0 % par rapport à 85,2 %) et apporter un sentiment de contrôle de la maladie cardiaque (61,5 % par rapport à 77,7 %).

CONCLUSIONS : De nombreux utilisateurs du traitement par chélation semblent avoir un point de vue négatif sur les bienfaits des médicaments classiques et un point de vue positif sur l'innocuité du traitement par chélation. Les utilisateurs et les non-utilisateurs du traitement par chélation ont les mêmes points de vue quant aux bienfaits et à l'innocuité de la chirurgie cardiaque.

Four systematic reviews of chelation therapy have been published (7-11). In 1997, Ernst (7) reviewed four clinical trials of chelation therapy use for peripheral arterial occlusive disease (PAOD) and concluded that "chelation therapy for PAOD is not superior to placebo. It is associated with considerable risks and costs. It should now be considered obsolete". In 2000, Ernst (8) located two controlled trials and 22 investigations without control groups of chelation therapy use for cardiovascular disease. Ernst again concluded that chelation

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Received for publication March 20, 2006. Accepted January 4, 2006

therapy use should be considered obsolete, given its potential for severe adverse effects. In 2003, Villarruz et al (9) systematically reviewed seven randomized controlled trials of chelation therapy use and concluded that there was insufficient evidence to determine the effectiveness or ineffectiveness of its use in improving the clinical outcomes of cardiovascular disease patients. Finally, in 2005, Seely et al (10) reviewed seven studies and concluded that there was no evidence to support the use of chelation therapy for the treatment of cardiovascular disease. Most recently, because of methodological limitations in previous trials, the National Institutes of Health has funded a large, randomized clinical trial (11) to test the efficacy of chelation therapy for the treatment of cardiovascular disease and expects that the multicentre study will produce conclusive findings.

Patients currently use chelation therapy for the treatment of atherosclerosis at their own expense. In Canada, approximately 8% of adults who are undergoing coronary angiography have used or are using chelation therapy, and in doing so, they have spent approximately \$17 million out-of-pocket for the therapy (12). In the United States, some 800,000 patients receive EDTA treatment each year, which is approximately the same number of patients treated with coronary artery bypass surgery (13).

We previously reported (12) on the sociodemographic and clinical characteristics of chelation therapy users, and demonstrated that users were more likely to have more severe coronary artery disease than nonusers. Users were less likely than nonusers to undergo coronary revascularization in the first year after coronary angiography but were subsequently more likely to undergo revascularization in the succeeding five years. These findings raise questions as to what motivates patients with heart disease to use chelation therapy.

To shed light on the issue of chelation therapy use, we conducted a cross-sectional mail survey of patients who had undergone cardiac catheterization. Our specific objectives were to compare chelation therapy users' and nonusers' views about decision making in health care, physician-patient communication and relationships, and beliefs regarding heart surgery and conventional medications; to describe users' and nonusers' beliefs regarding conventional revascularization and medication therapy; to describe what users explicitly reported to be their reasons for the use of chelation therapy and their specific beliefs regarding chelation therapy itself; and to determine whether nonusers had any knowledge or specific opinions regarding chelation therapy.

METHODS

Study population

The present study was a cross-sectional survey that used a self-administered mail questionnaire. Three steps were taken to establish the study population. The first step was to identify patients undergoing coronary angiography in Alberta. Patients from the Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease (APPROACH) initiative database (14) were included. The initiative captures all patients undergoing coronary angiography in Alberta. The second step was to determine chelation therapy use status among APPROACH participants. The APPROACH database captures chelation therapy use status in the subset of APPROACH patients who have had at least some degree of coronary artery disease (ie, more than 50% stenosis in at least one coronary vessel) and who have agreed to participate in a follow-up survey (see reference 12 for details). The third step

was to determine the survey sample. All patients who defined themselves as chelation therapy users ($n=280$) were selected, as were the 600 randomly selected patients from the 5320 patients who defined themselves as nonusers between 1999 and 2001.

Data collection

Data were collected through a postal mail survey. Before conducting the survey, three focus groups were convened to assist with development of the survey questionnaire. Two groups were composed of five patients who used chelation before 1999 and one group had two patients who had never used the therapy. The users and nonusers were asked to state all possible reasons for using or not using chelation therapy. By the end of the meetings, all participants were invited to complete the preliminary versions of our study questionnaire and were asked to make comments on the questionnaire itself. Based on the information obtained from the focus groups and the literature (15-17), the questionnaire was revised for use in the study. The instrument included items in the following domains of inquiry: sociodemographic information; history of chelation therapy use; reasons associated with use or nonuse; opinions about health care decision making; opinions about physician-patient communication and relationships; and beliefs about revascularization and medications. Additional information was collected from chelation therapy users, including beliefs about chelation therapy and whether consultation with physicians about chelation therapy had occurred before use. Opinions and beliefs were measured using a Likert five-point scale response set (strongly agree, agree, unsure, disagree or strongly disagree).

The questionnaire was mailed to potential respondents with a self-addressed, stamped envelope and a covering letter. Up to three reminders were sent to patients who did not return the questionnaire.

Data analysis

Data were analyzed using descriptive statistics for reporting proportions and χ^2 tests for between-group comparisons of proportions. The Likert five-point scale responses were grouped into two categories (strongly agree or agree versus unsure, strongly disagree or disagree). Discriminant function analysis was used to identify significant variables for allocating respondents to user or nonuser groups among variations related to physician-patient communication, surgery beliefs and medication beliefs. In this analysis, the Likert scale data were treated as numerical variables. The discriminant analysis supported the conclusion made based on descriptive analysis.

RESULTS

Of 880 mailed surveys (280 sent to chelation users and 600 sent to nonusers), 437 responses were received. One hundred surveys were returned due to incorrect mailing addresses, with patients having moved or died before receipt of the survey. Among the 437 responses, 77 had missing data for key study variables, leaving 360 patients (96 users and 264 nonusers) for which data were suitable for analysis (46% of 780 who received surveys).

Table 1 presents patient sociodemographic and clinical characteristics. Compared with nonusers, chelation therapy users were more likely to be older (65 years of age or older) and male. The proportion of patients who had received a physician's recommendation to undergo angioplasty or bypass surgery was significantly higher among users than nonusers (86.5% versus 71.6%, $P=0.004$).

Table 2 shows patient opinions regarding health care decision making. More than 50% of users and nonusers would like physicians to determine the causes of symptoms, identify available treatment options and judge the benefits or risks of each treatment option. A similar proportion of users (46.9%) and nonusers (51.1%) identified that they would like to select treatment options together with their physicians.

Table 3 presents opinions about physician-patient communication and relationships. The proportion of patients who perceived communication difficulties with their physicians (ie, their cardiologists or surgeons) was significantly higher among chelation therapy users than nonusers (21.9% versus 10.2%, $P=0.004$). Before using chelation therapy, 35% of users did not ask their physicians to endorse their decision to use chelation; 64% of users asked their family physician and only 30% asked their cardiologist or surgeon.

Table 4 presents comparisons of users and nonusers on their beliefs about the benefits of heart surgery and conventional medication use. There were no statistically significant differences between users and nonusers of chelation therapy in their beliefs about heart surgery. Regarding beliefs about conventional medications, fewer users than nonusers of chelation therapy believed that medications would prevent the worsening of their heart disease (53.1% for users and 67.4% for nonusers, $P<0.001$), increase their quality of life (74.0% versus 85.2%, $P=0.006$) or give a feeling of control over the disease (61.5% versus 77.7%, $P<0.001$).

Regarding beliefs about the benefits of chelation therapy, varying proportions of chelation therapy users reported that they believe that therapy would cure heart disease (20.8%), prevent worsening of heart disease (49.0%), relieve symptoms (81.3%), have the potential for side effects (63.5%), be safe (31.3%) and give a feeling of control over the heart disease (58.3%). The primary self-reported reasons for chelation use were to promote health to the highest possible level (60.7%), experience every possible option for treatment (58.1%), maintain health (58.1%) and avoid heart surgery (55.6%). The four major reasons for not using chelation therapy (among nonusers) were lack of information (52.1%), confusing information (35.4%), cost (35.1%) and never having heard of chelation therapy (34.8%).

Table 5 presents data concerning beliefs about heart surgery, medication and chelation treatment benefit in patients who used chelation to avoid heart surgery and those who used the therapy for other reasons. Patients who used chelation to avoid heart surgery were less likely than those using it for other reasons to believe that heart surgery would prevent the worsening of heart disease (37.0% versus 64.3%, $P=0.01$), be safe (22.2% versus 42.9%, $P=0.035$) or give a feeling of control over the heart disease (50.0% versus 69.1%, $P=0.05$). There were no significant differences between the two groups of patients in their beliefs about the benefits of chelation therapy.

DISCUSSION

Our study provides some insight into chelation therapy users' and nonusers' opinions about factors associated with chelation therapy use. We found the following: the majority of patients relied on their physicians to determine the benefits and risks for treatment; patients appear to have reliable and trusting relationships with their physicians, but some users appeared to have communication difficulties with their physicians; many users believed that chelation is safe, but that it does not relieve

TABLE 1
Sociodemographic characteristics and status of needing revascularization among chelation users and nonusers

Characteristics	Users, n (%) (n=96)	Nonusers, n (%) (n=264)	P
Age of 65 years or older	58 (60.4)	92 (34.9)	0.001
Sex			0.005
Female	7 (7.3)	52 (19.7)	
Male	89 (92.7)	212 (80.3)	
Marital status			0.289
Never married	2 (2.1)	17 (6.4)	
Married or common-law	81 (84.4)	218 (82.6)	
Divorced or separated	4 (4.2)	13 (4.9)	
Widowed	9 (9.4)	16 (6.1)	
Income			0.558
Less than \$30,000	20 (20.8)	50 (18.9)	
\$30,000–\$49,999	33 (34.4)	94 (35.6)	
\$50,000–\$69,999	25 (26.0)	55 (20.8)	
\$70,000 or more	18 (18.8)	65 (24.6)	
Education			0.703
High school or less	48 (50.0)	126 (47.7)	
Some college or university	25 (26.0)	59 (22.4)	
College diploma or undergraduate university degree	14 (14.6)	50 (18.9)	
Masters or PhD degree	9 (9.4)	29 (11.0)	
Physician suggested heart surgery or angioplasty*	83 (86.5)	189 (71.6)	0.004
Heart condition was not amenable to heart surgery or angioplasty†	1 (1.4)	17 (6.4)	0.116

*Question asked was, "Did your cardiologist or surgeon tell you that you need heart surgery or angioplasty?"; †Question asked was, "Did your cardiologist or surgeon ever tell you that your heart condition was so bad that you could not have heart surgery or angioplasty?"

coronary artery disease symptoms or improve quality of life (although some users believed that chelation cures heart disease); many users did not believe that conventional medications help; both users and nonusers believed that heart surgery helps; many patients who used chelation to avoid surgery were more likely to believe that heart surgery is unsafe and would not prevent the worsening of the heart disease than patients who used the therapy for other reasons.

While each individual is unique in his or her own personal reasons for using this controversial treatment, our study findings suggest that the majority of patients use chelation therapy as complementary therapy to promote their health or enhance benefits of conventional medications. We found that more nonusers than users believed that medications could prevent the worsening of the heart disease, improve quality of life and give a feeling of control over the disease. Therefore, dissatisfaction with medical therapy appears to motivate some patients to turn to chelation therapy. Nevertheless, approximately one-half of patients used chelation therapy to avoid heart surgery. Although physicians recommend heart surgery to patients, those patients may not accept this as their first choice because they may consider heart surgery unsafe, or they may believe that it will not prevent the worsening of disease and give them a feeling of control over their disease. These individuals would rather seek other noninvasive alternatives to improve their heart condition after having used (or in addition to using) conventional medications. Chelation therapy, as a noninvasive option, is frequently chosen because it is considered to be safe and have few side effects.

TABLE 2
Participant opinions about health care decision making

Question		Users, n (%) (n=96)	Nonusers, n (%) (n=264)	P
Who should determine the likely causes of the patient's symptoms?	Physician	71 (74.0)	198 (75.0)	0.024
	Patient	4 (4.2)	1 (0.4)	
	Physician and patient	21 (21.9)	65 (24.6)	
Who should determine what the treatment options are?	Physician	49 (51.0)	152 (57.6)	0.54
	Patient	4 (4.2)	10 (3.8)	
	Physician and patient	43 (44.8)	102 (38.6)	
Who should determine what the risks and benefits for each treatment options are?	Physician	60 (62.5)	146 (55.3)	0.397
	Patient	5 (5.2)	12 (4.6)	
	Physician and patient	32 (33.3)	106 (40.2)	
Who should determine how likely each of these risks and benefits is to happen?	Physician	66 (68.7)	157 (59.5)	0.121
	Patient	7 (7.3)	14 (5.3)	
	Physician and patient	23 (24.0)	93 (35.2)	
Given the risks and benefits of these possible treatments, who should decide how acceptable those risks and benefits are for you?	Physician	18 (18.8)	47 (17.8)	0.479
	Patient	37 (38.5)	86 (32.6)	
	Physician and patient	41 (42.7)	131 (49.6)	
Given all the information about risks and benefits of the possible treatments, who should decide which treatment option should be selected?	Physician	16 (16.7)	63 (23.9)	0.074
	Patient	35 (36.4)	66 (25.0)	
	Physician and patient	45 (46.9)	135 (51.1)	

TABLE 3
Opinions about physician-patient communication and relationships (ie, cardiologist and surgeon)

Statement	Users, n (%) (n=96)	Nonusers, n (%) (n=264)	Adjusted P*
My physician is hard to talk to	21 (21.9)	27 (10.2)	0.004
My physician provides emotional support	54 (56.3)	143 (54.2)	0.765
My physician spends enough time with patients	64 (66.7)	160 (60.6)	0.508
My physician cares more about the disease than the person	12 (12.5)	30 (11.4)	0.506
My physician gives me hope	70 (72.9)	205 (77.7)	0.146
I can trust my physician to tell me the truth	80 (83.3)	227 (86.0)	0.360
My physician is up-to-date in his or her knowledge	72 (75.0)	201 (76.1)	0.864
My physician encourages patients to ask questions	66 (68.8)	184 (69.7)	0.926
I can understand what my physician tells me	84 (87.5)	223 (84.5)	0.554
My physician listens carefully to what I say	66 (68.8)	198 (75.0)	0.186
My physician is open-minded about treatment options	42 (43.7)	129 (48.9)	0.286

*Age and sex are adjusted

Dissatisfaction with the relationships between patients and physicians plays a role in the use of chelation therapy in at least some cases. However, the majority of users and nonusers in the present study wanted physicians to determine the causes of the disease and the benefits and risks of treatment. When selecting a specific treatment, more patients wanted to make the decision together with their physicians. Many chelation therapy users and nonusers trusted their physicians, and obtained emotional support from them. They believed that their physicians give them sufficient time to ask questions, listen to them carefully and give them hope.

TABLE 4
Beliefs regarding heart surgery and medication treatment use

Statement	Users (n=96)	Nonusers, n (%) (n=264)	Adjusted P*
Heart surgery			
Cures heart disease	20 (20.8)	66 (25.0)	0.289
Prevents the worsening of heart disease	47 (49.0)	138 (52.3)	0.274
Relieves symptoms	78 (81.3)	227 (86.0)	0.426
Has side effects	61 (63.5)	168 (63.6)	0.525
Is perfectly safe	30 (31.3)	82 (31.1)	0.610
Increases the quality of life	80 (83.3)	230 (87.1)	0.232
Gives a feeling of control over the heart disease	56 (58.3)	170 (64.4)	0.190
Medication			
Cures heart disease	6 (6.3)	33 (12.5)	0.119
Prevents the worsening of heart disease	51 (53.1)	178 (67.4)	<0.001
Relieves symptoms	79 (82.3)	225 (85.2)	0.263
Has side effects	82 (85.4)	225 (85.2)	0.862
Is perfectly safe	19 (19.8)	79 (29.9)	0.060
Increases quality of life	71 (74.0)	225 (85.2)	0.006
Gives a feeling of control over the heart disease	59 (61.5)	205 (77.7)	<0.001

*Age and sex are adjusted

Communication about chelation therapy challenges not only physicians, but also patients. Our study demonstrated that users of chelation therapy tended to identify more communication problems with their physicians than nonusers. Among users, 35% of patients did not ask their physicians questions about chelation therapy before using it. Although many nonusers considered that benefits of chelation therapy are controversial, 35% of nonusers had never heard of the therapy. These findings suggest that information exchange between patients and their physicians, specifically about chelation therapy, often does not occur. Some patients do not ask questions

TABLE 5

Beliefs about heart surgery, medication and chelation therapy use among patients who used chelation to avoid heart surgery and those who used the therapy for other reasons

Statement	Patients who used chelation to avoid surgery, n (%) (n=54)	Patients who used chelation for other reasons, n (%) (n=42)	Adjusted P*
Heart surgery			
Cures heart disease	11 (20.4)	9 (21.4)	0.946
Prevents the worsening of heart disease	20 (37.0)	27 (64.3)	0.01
Relieves symptoms	47 (87.0)	31 (73.8)	0.085
Has side effects	35 (64.8)	26 (61.9)	0.831
Is perfectly safe	12 (22.2)	18 (42.9)	0.035
Increases quality of life	43 (79.6)	37 (88.1)	0.207
Gives a feeling of control over the heart disease	27 (50.0)	29 (69.1)	0.05
Medication			
Cures heart disease	1 (1.9)	5 (11.9)	0.978
Prevents the worsening of heart disease	28 (51.9)	23 (54.8)	0.939
Relieves symptoms	45 (83.3)	34 (81.0)	0.643
Has side effects	48 (88.9)	34 (81.0)	0.288
Is perfectly safe	12 (22.2)	7 (16.7)	0.465
Increases quality of life	37 (68.5)	34 (81.0)	0.162
Gives a feeling of control over the heart disease	27 (50.0)	32 (76.2)	0.015
Chelation			
Cures heart disease	11 (20.4)	9 (21.4)	0.882
Prevents the worsening of heart disease	26 (48.2)	16 (38.1)	0.427
Relieves symptoms	32 (59.3)	20 (47.6)	0.333
Has side effects	9 (16.7)	7 (16.7)	0.884
Is perfectly safe	35 (64.8)	28 (66.7)	0.849
Increases quality of life	33 (61.1)	25 (59.5)	0.929
Gives a feeling of control over the heart disease	32 (59.3)	24 (57.1)	0.944

*Age and sex are adjusted

about chelation therapy or do not reveal their interest in trying chelation therapy because they are afraid of eliciting a negative response from their physicians. Physicians should develop a habit of routinely probing their patients' expectations and preferences regarding alternative therapy, with explicit discussion of whether they are contemplating using chelation therapy. In instances in which a patient is considering the use of chelation therapy instead of appropriately indicated coronary artery bypass surgery (eg, cases in which a patient has left main coronary artery disease or severe three-vessel disease amenable to bypass), the treating physician should take care to fully inform the patient of the demonstrated benefits of surgery while pointing out the relative lack of data suggesting any benefits of chelation therapy. If a patient nonetheless chooses to use chelation therapy after such communication, the patient's decision should be respected, and both parties can rest assured that the patient's decision has been made after an appropriate exchange of information (18,19).

Our study has limitations. First, 54% of the study population did not complete the survey. It is somewhat reassuring, however, that there were no significant differences between respondents and nonrespondents among the sociodemographic or clinical variables, aside from a larger proportion of men among the nonrespondents. Second, the sample size was relatively small. Therefore, some differences between users and nonusers may not have been detected. Third, this cross-sectional study gained some insights on the potential reasons for chelation therapy use; insights on 'decision mechanisms' need to be gained from the application of qualitative research methods (eg, ethnographic decision modelling) to this clinical issue.

Despite these limitations, our study supports the idea that many patients use chelation therapy due to disappointment with conventional medications. Users and nonusers of chelation therapy seem to have positive views toward the benefits of heart surgery. After using chelation therapy, patients appear to have negative views toward the benefits of chelation therapy and positive views toward the safety of chelation therapy. However, many patients are still unaware that evidence is lacking on the efficacy of chelation therapy.

ACKNOWLEDGEMENTS: This study was funded by the Calgary Health Region, Calgary, Alberta. The authors thank Fatima Chatur for assistance with data collection, Andrew Fong for statistical support and Dr Heather Boon for her advice regarding our survey questionnaire. Drs Quan, Norris and King are supported by Population Health Investigator Awards from the Alberta Heritage Foundation for Medical Research, Edmonton, Alberta. Drs Quan and Norris are also supported by New Investigator Awards from the Canadian Institutes of Health Research. Dr Ghali is supported by a Senior Health Scholar Award from the Alberta Heritage Foundation for Medical Research, and by a Government of Canada Chair in Health Services Research.

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