Informed decision-making in elective major vascular surgery: analysis of 145 surgeon–patient consultations

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Background: Prior studies show significant gaps in the informed decision-making process, a central goal of surgical care. These studies have been limited by their focus on low-risk decisions, single visits rather than entire consultations, or both. Our objectives were, first, to rate informed decision-making for major elective vascular surgery based on audiotapes of actual physician–patient conversations and, second, to compare ratings of informed decision-making for first visits to ratings for multiple visits by the same patient over time.

Methods: We prospectively enrolled patients for whom vascular surgical treatment was a potential option at a tertiary care outpatient vascular surgery clinic. We audiotaped all surgeon–patient conversations, including multiple visits when necessary, until a decision was made. Using an existing method, we evaluated the transcripts for elements of decision-making, including basic elements (e.g., an explanation of the clinical condition), intermediate elements (e.g., risks and benefits) and complex elements (e.g., uncertainty around the decision).

Results: We analyzed 145 surgeon–patient consultations. Overall, 45% of consultations contained complex elements, whereas 23% did not contain the basic elements of decision-making. For the 67 consultations that involved multiple visits, ratings were significantly higher when evaluating all visits (50% complex elements) compared with evaluating only the first visit (33% complex elements, $p < 0.001$.)

Conclusion: We found that 45% of consultations contained complex elements, which is higher than prior studies with similar methods. Analyzing decision-making over multiple visits yielded different results than analyzing decision-making for single visits.

Contexte : Des études antérieures révèlent des lacunes importantes dans le processus de prise de décisions éclairées, objectif central des soins chirurgicaux. Ces études ont été limitées par leur convergence sur les décisions à faible risque, les consultations ponctuelles plutôt que les consultations complètes, ou les deux. Nous voulions d'abord évaluer la prise de décisions éclairées portant sur des interventions en chirurgie vasculaire électives importantes en nous fondant sur des enregistrements de conversations réelles entre médecin et patient. Nous voulions ensuite comparer des évaluations de la prise de décisions éclairées portant sur les premières consultations à celles de décisions reliées à de multiples visites effectuées par le même patient au fil du temps.

Méthodes : Nous avons inscrit de façon prospective des patients pour lesquels la chirurgie vasculaire constituait une option possible à une clinique de chirurgie vasculaire en soins tertiaires fournis en service externe. Nous avons enregistré toutes les conversations entre chirurgien et patient, y compris celles qui ont eu lieu au cours de multiples consultations au besoin, jusqu'à ce qu'une décision soit prise. Nous avons utilisé une méthode existante pour évaluer les comptes rendus afin de déterminer les éléments de la prise de décisions, y compris les éléments de base (par exemple, une explication de l'état clinique), les éléments intermédiaires (par exemple, risques et avantages) et les éléments complexes (par exemple, incertitude entourant la décision).

Résultats : Nous avons analysé 145 consultations chirurgien–patient. Dans l'ensemble, 45 % des consultations comportaient des éléments complexes, tandis que 23 % ne contenaient pas les éléments fondamentaux de la prise de décisions. Dans le cas des 67 consultations comportant de multiples visites, les cotes ont été beaucoup plus élevées lorsqu'on a évalué toutes les visites (50 % d'éléments complexes) comparativement à celles qu'a produites l'évaluation de la première visite seulement (33 % d'éléments complexes, $p < 0{,}001$.)

Conclusion : Nous avons constaté que 45 % des consultations comportaient des éléments complexes, proportion plus élevée que celle qu'ont révélée des études antérieures réalisées au moyen de méthodes semblables. L'analyse de la prise de décisions étalées sur de multiples visites a produit des résultats différents de celle de la prise de décisions reliées aux visites ponctuelles.

Informed decision-making is based on the legal concept of informed consent but applies more broadly to all decisions, including consent to major procedures, recommendations for conservative or nonsurgical therapy and patient refusal of recommended treatment. Informed decision-making is a central ethical component of the doctor–patient relationship, yet there remain significant gaps in informed decision-making. Patients are not offered complete information[1] and may not recall information that has been discussed.[2] Consent forms are difficult to read[3] and are often not read.[4]

Prior informed decision-making studies have some important limitations. First, many studies focus on patient recall rather than actual physician–patient conversations. Second, the few studies of actual physician–patient conversations do not examine the entire decision-making process across multiple visits when necessary.[1,2,5] Third, many of the clinical decisions in prior studies were low-risk decisions, such as consent for blood-taking or electrocardiograms. In this study, we sought to address the limitations of prior studies by audiotaping actual physician–patient conversations. When necessary, we audiotaped multiple visits over time to capture the entire set of surgeon–patient conversations. We focused on complex decisions where major vascular surgery was a potential option.

Our objectives were, first, to rate informed decision-making for major elective vascular surgery based on audiotapes of actual physician–patient conversations and, second, to compare ratings of informed decision-making for single visits to ratings for multiple visits by the same patient over time.

Methods

We conducted this prospective study at the outpatient vascular surgery clinic at the Toronto General Hospital, University Health Network, a large, academic, hospital affiliated with the University of Toronto. The research program was focused on developing methods to improve informed decision-making.

Each physician and patient provided written signed consent. The Committee for Research on Human Subjects reviewed and approved the study protocol.

Participants

We sought newly referred patients for whom a surgical decision would likely be necessary. The research coordinator screened patients for the following criteria: abdominal aortic aneurysm at least 5 cm in diameter, carotid stenosis of at least 70% based on Doppler ultrasound or angiogram, peripheral arterial insufficiency with severe symptoms (night pain, rest pain or ulceration) or varicose veins with symptoms. We excluded patients who had nonsurgical conditions, who had conditions too mild to consider surgery, who spoke no English or who were judged unable to consent to the study.

The coordinator approached potentially eligible patients in the waiting room before the surgical consultation. Only 1 patient could be taped at any time. If more than 1 potentially eligible patient was present at the clinic, the coordinator would choose the patient who arrived first.

The coordinator audiotaped the initial visits and all subsequent visits with the surgeon until a decision was made. The coordinator was physically present but silent during the visits. A medical transcriptionist prepared a transcript of each visit. The written transcripts were validated against the original tape by the research coordinator.

Main measure

Our primary outcome was the level of informed decision-making, based on a previously developed framework.[1,5] A basic level of decision-making includes the following elements: a description of the patient's role in the decision-making process, an explanation of the clinical condition and an elicitation of the patient's preferences regarding treatment. An intermediate level of decision-making includes the basic level, plus the following elements: a discussion of risks and benefits, a discussion of alternatives to surgery and an assessment of patient understanding. A complex level of decision-making includes the intermediate level, plus a discussion of uncertainty around the decision (see Table 1 for examples).

Each transcript was reviewed by a trained coder using NVIVO 2.0 software. This software facilitates categorization and analysis of elements of the conversation. We instructed coders to give credit for any element if they were uncertain. If any aspect of an element was present, then we gave credit. For example, discussion of any benefit or any risk would give the surgeon credit for a discussion of risks and benefits. A subset of charts was reviewed by 2 coders, with 67%–83% simple agreement (κ 0.25–0.59), indicating fair to moderate agreement for each element of decision-making.

We aggregated all coding elements for all visits to obtain the decision-making level (less than basic, basic, intermediate or complex) for each consultation. The principal

investigator reviewed all cases where the decision-making level hinged on the presence of a single coding element. For example, if the initial rating was basic, but the only intermediate element missing was a discussion of benefit or risk, then the entire transcript was reviewed to ensure that a discussion of benefit or risk was truly absent. The principal investigator also rereviewed all transcripts if the level was less than basic.

Sample size

We sought a sample size of 150, which would yield a confidence interval (CI) of plus or minus 8% for the proportion of consultations at each decision-making level.[6]

Statistical analysis

We used the sign test to compare decision-making ratings for first visits with those for the entire consultations. We used a polytomous logistic regression to explore relations between baseline variables and the decision-making level. We did not find any difference between physicians, so physician was not included as a variable in the model. The outcome was an ordered categorical variable of decision-making level (less than basic, basic, intermediate, complex).

RESULTS

We enrolled 203 patients. Fifty-eight (58) patients did not complete the study for the following reasons: the surgeon felt that the patient's condition had no surgical options ($n = 14$), the patient did not return for the follow-up visit ($n = 13$), the patient returned when the research coordinator was unavailable ($n = 7$), the patient withdrew consent ($n = 6$), tape failure ($n = 4$), the patient had been previously seen by the surgeon for a similar condition ($n = 4$), the patient was transferred to another surgeon ($n = 3$), the patient required emergency admission ($n = 2$) and the patient died of an unrelated condition ($n = 1$). Another 4 patients were excluded after receiving a diagnosis of symptomatic subclavian steal syndrome rather than carotid stenosis. This left 145 patients for analysis.

Participants

The typical patient participant was a 63-year-old retired, married, English-speaking man who had completed high school or college. Similar proportions of patients had aneurysms, carotid disease, peripheral arterial disease and varicose veins. Surgery was recommended for 46% of the patients, whereas nonsurgical treatment was recommended for the remaining 54%. The demographic and clinical characteristics of study participants are reported in Table 2.

Level of informed decision-making

Overall, 45% (95% CI 37%–53%) of consultations were rated as a complex level of informed decision-making, whereas 8% (95% CI 4%–12%) were rated as intermediate. There were 23% (95% CI 16%–30%) of consultations rated as basic and 23% (95% CI 16%–30%) as less than basic (Table 3).

There were 67 consultations that included more than 1 visit. Patients with more than 1 visit were older (mean age 67 v. 59 yr) and were more likely to have carotid or aortic aneurysm disease (54% v. 35%) than patients who had only 1 visit. We compared an analysis of first visits only with an analysis of the entire consultation over multiple visits. For these 67 consultations, there was a significant difference in the decision-making rating based on analysis of the first visit alone compared with analysis of all visits ($p < 0.001$, sign test). There were fewer ratings of less than basic (16% v. 33%) and more ratings of complex (50% v. 33%) when all visits of the consultation were analyzed (Table 4). Overall, there were 15 consultations where the ratings improved. The changes were: less than basic to complex (8 consultations), less than basic to basic (2 consultations), less than basic to intermediate (1 consultation),

Table 1. Decision-making levels

Level	Description	Examples from study transcripts
Basic	Discussion of patient's role in decision-making	Surgeon: "Let me just be really clear. The decision to operate is your father's … and it's my responsibility to give you what I think is my best advice."
	Explanation of clinical condition	Surgeon: "Now, an aneurysm is your major blood vessel's supposed to be this big. When it gets in — like an aneurysm, it gets bigger. It gets big enough it'll burst."
	Assessment of patient preference	Patient: "So that should be — with those kind of odds it sounds that I should have one"
Intermediate	Discussion of risks and benefits	Surgeon: "… my real reason for doing it would be to prevent you from having a stroke."
	Discussion of alternatives	Surgeon: "So that's number one. Um, you know, if — a — and — and this sort of comes down now, more to the lifestyle issue as opposed to anything else, because in terms of operating for this, if we did nothing — ok, if we didn't operate and you quit smoking, then the risk of losing a leg or something here, is relatively low. It's only about 1%–2% per year."
	Assessment of patient understanding	Surgeon: "What do you think the risks are of the surgery that I've described to you?"
		Surgeon: "Do — do you understand what I'm saying?"
Complex	Discussion of uncertainty about decision	Surgeon: "Now, we have to — you know, we're looking at balancing here the risks of doing something and the risks of doing nothing. And this is what we had talked about — uh, when you were in my office before."

basic to complex (2 consultations) and intermediate to complex (1 consultation).

In the multivariate analysis, the surgical recommendation was significantly associated with the decision-making level (odds ratio 3.8, 95% CI 2.0–7.4, $p < 0.001$). When surgery was recommended, 58% of consultations had a complex rating, whereas only 35% of consultations had a complex rating when surgery was not recommended.

Discussion

We found that 45% of consultations regarding major elective vascular surgery were rated at a complex level of decision-making. We also found that all visits related to a surgical consultation must be considered to obtain an accurate picture of the informed decision-making process. In an exploratory analysis, consultations where surgery was recommended were rated at higher decision-making levels than those where surgery was not recommended.

Prior studies that showed gaps in informed decision-making focused on single visits and could not exclude the possibility that information was shared at subsequent visits with the surgeon. In one such study, only 1 (0.5%) of 217 major decisions, including about 120 surgical decisions, achieved a complex rating.[1] Another study of orthopedic visits found that only 57% of visits had at least a basic level of informed decision-making,[5] By contrast, we found that 77% of consultations had at least a basic level of decision-making.

Our study used a clinical ethical framework to evaluate decision-making. This framework has similar elements to current Canadian legal standards for informed consent, such as the nature of the clinical condition, the proposed treatment, alternatives, benefits and risks.[7] The Canadian legal standards for informed consent also include the concept of scope of disclosure. Scope of disclosure refers to the amount of information that a reasonable person in the same circumstances would need to make an informed decision.[8] The scope of disclosure may need to take into account the patient's occupation, financial and personal concerns. Consider, for example, a patient with asymptomatic severe carotid stenosis who is within 6 months of full pension benefits at work. A reasonable person in this circumstance would want to minimize the risk of stroke over the next 6 months so that a full pension could be obtained. Such a patient would need to know that the risk of stroke over the next 6 months may be higher with surgery than with medical management.[9] We did not explore scope of disclosure in this study, nor did we apply a legal standard to our evaluations, so the relation between our findings and legal standards is unclear. We speculate that a legal analysis would give lower ratings of the informed decision-making process.

Limitations

Our conclusions have some important limitations. Our results, which differ from those of prior studies with similar methods, could be explained by our analysis of multiple

Table 2. Demographic and clinical characteristics of the study population

Characteristic*	No. %†
Age, mean (SD) yr	63 (14)
Male sex	86 (59)
Retired	71 (49)
Language	
English	111 (77)
English and other	20 (14)
Other only	13 (9)
Married	94 (65)
Condition	
Aortic aneurysm	20 (14)
Peripheral arterial disease	42 (29)
Carotid asymptomatic	23 (16)
Carotid symptomatic	20 (14)
Varicose vein	40 (28)
Prior vascular surgery	30 (21)
Number of visits	
1	78 (54)
2	58 (40)
> 2	9 (6)
Previous myocardial infarction	33 (23)
Current smoker	43 (30)
Level of education	
Above high school	55 (38)
High school	52 (36)
Below high school	38 (26)

SD = standard deviation.
*Missing data: language ($n = 1$), retired ($n = 1$), smoking ($n = 2$), diabetes ($n = 1$), myocardial infarction ($n = 1$).
†Unless otherwise indicated.

Table 3. Levels of informed decision-making for 145 surgeon–patient consultations

Decision-making level	No. (%)
Less than basic	34 (23)
Basic	33 (23)
Intermediate	12 (8)
Complex	66 (45)
Total	145 (100)

Table 4. Comparison of decision-making level when analyzing the first visit only compared with analyzing all visits in a surgeon–patient consultation*

	Visit; no. (%)	
Decision-making level	First visit only	All visits combined
Less than basic	22 (33)	11 (16)
Basic	20 (30)	20 (30)
Intermediate	3 (4)	3 (4)
Complex	22 (33)	33 (50)
Total	67 (100)	67 (100)

*Analysis restricted to the 67 consultations involving more than 1 visit. Difference in ratings $p < 0.001$, sign test.

visits, variation in coding methods between studies or the individual practices of our small sample of study physicians. There could have been a change in surgeon behaviour (Hawthorne effect) caused by our study coordinator being present during consultations. We chose to have our study coordinator present because in our pilot testing there were relevant discussions in other areas of the clinic that we would have missed. A less intrusive but more complex approach could be to attach a small recording device to the patient that is returned to the study team when the consultation is complete. Our research team was interested in methods to improve informed decision-making. Our interest and our discussions with the study surgeons may have influenced the surgeons' practices. We may have missed some relevant decision-making discussions with other physicians or information provided in the form of printed material. However, we reviewed all printed material provided to patients and no material discussed risks, benefits or uncertainties regarding decision-making. Finally, our study was focused on vascular surgery, where risks of treatment are related to the nature of the procedures and patient comorbidities. These clinical factors may lead to a greater discussion of risks and benefits and a greater number of visits during consultation. Our results may not apply to other surgical settings with lower risks and fewer patient comorbidities.

Our findings have clinical and educational implications. First, our findings support the importance of seeing patients several times before making a complex decision. However, our data do not address the ideal number of visits. Second, although our sample showed higher ratings of informed decision-making than those of prior studies, we still found that 23% of consultations were rated as "less than basic." This clinical performance gap needs to be closed. One recommended method to improve performance is to elicit and address patient concerns.[10] Asking patients to specifically recall what they have been told during the interview, was ranked as one of the top 11 patient safety practices by the Agency for Healthcare Research and Quality.[11–13] Eliciting patient understanding was endorsed as safety best practice by the National Quality Forum in 2006.[14] One simple method to invite such dialogue is to say, "I think we are moving toward a plan for surgery/no surgery. I just want to make sure everything is clear. Can you tell me why you think surgery/no surgery is best for you? Is there anything you are worried about?" Methods to train surgeons in these communication techniques need to be developed and evaluated. Standardized (simulated) patient actors portraying informed decision-making scenarios have been developed to train surgeons,[15] but such training may be no more effective than traditional lectures.[16] Other methods targeted at patients, such as decision aids,[17] counselling,[18] interactive videodiscs[19] or audiotapes of visits,[20] may improve the decision-making process.

Conclusion

Future studies of surgical informed decision-making should ensure all visits in a consultation, rather than single visits, are evaluated, so that the entire decision-making process can be analyzed. Important areas for future study include comparison between legal analyses and informed decision-making ratings, and evaluation of interventions that focus on eliciting patient concerns and patient understanding during the surgical consultation.

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