

# Informed consent for abdominal aortic aneurysm repair: Assessing variations in surgeon opinion through a national survey

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**Objective:** Informed consent discussions for elective abdominal aortic aneurysm (AAA) repair should reflect appropriate risks of the open or endovascular repair (EVAR), but few guidelines exist describing what surgeons should discuss. This study examines expert opinion regarding what constitutes informed consent.

**Methods:** Design. We conducted an anonymous, web-based, national survey of vascular surgeons. Associations between surgeon characteristics and opinions regarding informed consent were measured using bivariate statistics; multivariable logistic regression was performed to estimate effects adjusted for covariates. Setting. Academic and private practice surgeons were surveyed. Subjects. United States members of the International Society for Vascular Surgery membership. Main Outcome Measure. Surgeons' self-reported opinions regarding the content of informed consent for AAA repair.

**Results:** A total of 199 surgeons completed the survey (response rate 51%). More than 90% of respondents reported that it was essential to discuss mortality risk for both procedures. However, only 60% and 30% of respondents reported that it was essential to discuss the risk of myocardial infarction and stroke, respectively. Opinions varied by procedure regarding the risks of impotence (32% vs 62%; EVAR vs open repair), reintervention (78% vs 17%), and rupture during long-term follow-up (57% vs 17%). Younger and private practice surgeons were more likely to discuss complications compared with older surgeons and those in academic practice. Surgeons who perform predominantly EVAR were more likely to quote higher mortality rates for open repair (odds ratio [OR] = 3.1, 95% confidence interval [CI] = 1.4-6.4) and lower reintervention rates for EVAR (OR = 0.3, 95% CI = 0.1-0.7) compared with other surgeons.

**Conclusions:** This is the first study of the practice of informed consent for AAA repair. The only risk that the vast majority of surgeons agreed should be included in informed consent for AAA repair was mortality. Significant variation exists regarding whether other complications should be discussed and what complication rates should be quoted. Surgeon characteristics may influence how risks are presented to patients. Further efforts are needed to develop guidelines to ensure consistent communication of appropriate risk during informed consent for AAA repair. (*J Vasc Surg* 2008; 47:287-95.)

Abdominal aortic aneurysm (AAA) is common, affecting 1% of individuals over the age of 55<sup>1-4</sup> and increasing in incidence by 2% to 4% per decade thereafter.<sup>5,6</sup> Although in early stages it is usually asymptomatic, the simple presence of an AAA still poses a significant mortality risk. Indications for surgical repair vary depending on the individual patient's preferences, both in terms of the decision to repair

the aneurysm at all and whether to use an open or endovascular technique. In general, AAA repair is indicated for aneurysms of at least 5.5 cm.<sup>7,8</sup>

Few studies have directly compared the long-term outcomes of open and endovascular repair. Open repair is remarkably successful for most patients, with perioperative mortality ranging from 1% to 5% at centers of excellence<sup>9</sup> and quality of life measures returning to baseline by 6 months after the operation for most patients.<sup>10</sup> However, up to 28% of patients may experience complications related to the invasiveness of the operation.<sup>11</sup> Endovascular repair (EVAR) has recently emerged as an alternative to open repair. Evidence demonstrates decreased short-term morbidity and mortality with this procedure compared with open repair.<sup>12-14</sup> Long-term outcomes associated with this newer technique are uncertain, however, and annual reintervention rates as high as 10% have been reported.<sup>15</sup> Reintervention can often be managed with endovascular techniques, but open revision may be required in up to 1% to 2% of patients per year.<sup>16</sup> Observational studies evaluating quality of life and quality-adjusted life expectancy have revealed no significant differences between EVAR and open repair.<sup>10,17,18</sup>

The decision to undergo elective AAA repair, a prophylactic intervention in generally elderly and asymptomatic

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patients, and whether to proceed with an open repair or EVAR, is an extremely complex one that should rely on clear, consistent communication of the risks and benefits that are associated with each option. Therefore, the objective of this study was to define national surgeon opinion regarding the content of informed consent discussions for both EVAR and open AAA repair.

## METHODS

### Study design and sample

We conducted a cross-sectional survey of the US members of the International Society for Vascular Surgery (ISVS) in 2007. This society was formed in 2003 in order to promote vascular surgery as a distinct medical specialty worldwide. The membership of the society (approximately 400 US members) includes vascular surgeons from academic and private practice settings. We developed a web-based survey (see Appendix, online only) in a collaborative effort between several vascular surgeons and an expert in survey design (EHB). The survey was pilot-tested on five vascular surgeons, revised, and then distributed by e-mail to all US members. All research procedures were approved by the Yale University School of Medicine Human Investigation Committee.

### Survey measures

The primary outcomes of interest were surgeons' perspectives on: (1) the importance of discussing various complications, and (2) the rates that should be quoted for each complication. We asked respondents to rate the importance of discussing each complication described in the survey using a 1-5 scale where 1 indicated "essential" and 5 indicated "not needed." This task was repeated for patients with varying hypothetical comorbidity profiles, and surgeons were given the opportunity to list additional complications at the end of the survey. We also asked respondents which complication rates should be quoted to patients with and without comorbidities, using a scale of <1%, 1%, 2%-3%, 4%-5%, or other (open-ended).

We collected data regarding practice setting, gender, age group, number of years in practice, and number of EVAR and open repairs performed per year. We also asked respondents to describe their current practice with regard to obtaining informed consent from patients who are candidates for both EVAR and open surgery. For the purpose of the analysis, the following surgeon characteristics were included: surgeon age ( $\leq 50$  vs  $> 50$ ), practice setting (academic vs private practice), and reported case majority ( $> 50\%$  EVAR vs  $\leq 50\%$  EVAR). To examine whether attitudes toward the legal consequences of informed consent may be shaping surgeons' opinions, we compared the responses of surgeons practicing in states that are currently experiencing a malpractice crisis as determined by the AMA<sup>19</sup> (Wash, Ore, Nev, Wyo, Mo, Ill, Ky, Tenn, NC, Ohio, Fla, Pa, NY, NJ, Conn, RI, Mass) to those practicing in non-crisis states.

### Data analysis

We performed standard frequency analyses to describe the study sample and responses to survey questions. We classified surgeons' opinions related to the necessity of including specific complications as part of the informed consent process into one of three categories: "Should be included," "Not necessary to include," and "Uncertain." This classification was based on the most frequently reported response for each complication. If "essential" was the most frequently reported response, then that complication was classified as "should be included," and if "not needed" was most frequently reported, then that complication was classified as "not necessary to include." All other complications were categorized as "uncertain," as there was lack of agreement among surgeons as to whether or not they should be discussed during informed consent.

In order to examine associations between surgeon characteristics and survey responses, we performed bivariate analyses, using  $\chi^2$  and Fisher's exact test as appropriate. For the analyses of survey responses related to the importance of discussing specific complications, responses were dichotomized as "essential" vs "non-essential," with 1 labeled "essential" and 2 through 5 labeled "non-essential." Survey responses regarding complication rates to be quoted were analyzed as a four-level outcome variable (<1%, 1%, 2%-3%, 4%-5%). To adjust for covariates, we performed multivariable logistic regression on outcome variables for which a significant association ( $P < .05$ ) had been identified during bivariate analysis. All statistical analyses were performed using SAS, 9.1 (SAS Institute Inc., Cary, NC).

## RESULTS

We received responses from 199 of the 388 surgeons who were contacted (response rate 51%).

### Description of sample (Table I)

The majority of respondents were male (83%), which is reflective of a strong male majority in the population that was surveyed (97%). Most surgeons were between the ages of 40 and 60 (58%) and had been in practice for at least 11 years (66%). With regard to practice setting, 48% reported that they were in private practice, and 37% were academic surgeons. A total of 32% of surgeons reported that they perform mostly open repairs (median 15 open and 10 EVAR per year), 47% reported that they perform mostly EVAR (median 25 EVAR and 10 open per year), and 11% stated that they perform both procedures with equal frequency. Close to half of the sample (47%) lives in malpractice crisis states, and 38% live in non-crisis states. Approaches to the preoperative discussion of intervention options with a patient who is a candidate for both open repair and EVAR can be summarized as follows: 56% would discuss both options and recommend one or the other, 31% would discuss both and ask which one the patient would prefer, and less than 1% would recommend one or the other without discussing both.

**Table I.** Surgeon characteristics

<i>Characteristic</i>	<i>Number (%)</i>
Gender	
Male	165 (83%)
Female	7 (4%)
Missing	27 (13%)
Practice setting	
Academic	73 (37%)
Private	95 (48%)
Missing	31 (15%)
Age group	
<40 y	22 (11%)
40-50 y	52 (26%)
51-60 y	63 (32%)
61-70 y	27 (14%)
>70 y	10 (5%)
Missing	25 (12%)
Years in practice	
1-5	27 (13%)
6-10	17 (9%)
11-20	49 (25%)
21-30	48 (24%)
>30	33 (17%)
Missing	25 (12%)
Majority surgery performed	
Open	63 (32%)
EVAR	93 (47%)
Equal open and EVAR	22 (11%)
Missing	21 (10%)
Malpractice climate	
Crisis state	94 (47%)
Non-crisis state	75 (38%)
Missing	30 (15%)
Approach when patients are candidates for both procedures	
Discuss both, ask which patient prefers	62 (31%)
Discuss both, recommend one	111 (56%)
Recommend one without discussing both	1 (1%)
Missing	25 (12%)

EVAR, Endovascular repair.

### Surgeons' opinions related to the necessity of including specific complications (Table II)

The percent of surgeons responding in each category (from 1 = essential to 5 = not needed) for each of the complications included in the survey are listed in Table II. Additional risks to be included during the informed consent process suggested by respondents are listed in Table III.

**Complications related to open repair.** For open repair, respondents felt that mortality, myocardial infarction, renal failure, impotence, and prolonged mechanical ventilation should be discussed during informed consent, and radiation, contrast exposure, and postoperative rupture were not necessary to include. There was no agreement among respondents as to whether to discuss stroke, permanent disability, or reintervention.

As expected, a history of specific risk factors increased surgeons' perceived importance of disclosing the related complication. For example, a history of previous stroke increased the percent of surgeons classifying stroke as an essential complication to discuss during informed consent from 26% to 43%.

**Complications related to EVAR.** As with open repair, surgeons reported that mortality, myocardial infarction, renal failure, and impotence should be discussed; permanent disability was not necessary to discuss, and whether to discuss stroke was uncertain.

In contrast to open repair, however, surgeons reported that risks related to postoperative surveillance (radiation and contrast exposure), postoperative rupture, and reintervention should be included when informing patients about EVAR. In addition, although surgeons reported that the risk of prolonged mechanical ventilation should be included in the informed consent process for open repair, there was no agreement regarding disclosure of this risk for EVAR.

As with open repair, a history of specific risk factors increased surgeons' perceived importance of disclosing the related complication. For example, for patients with chronic obstructive pulmonary disease, 43% of surgeons felt that prolonged mechanical ventilation should be included, compared with only 17% for the average patient.

### Surgeons' opinions on complication rates

Surgeons' opinions regarding complication rates varied, however, most responses were within the range of those reported in the literature (see Table IV). As noted in Table IV, there are few published reports on how complication rates vary according to patient comorbidity status. In general, survey respondents quoted higher rates of mortality, myocardial infarction, and impotence, similar rates of renal failure, and lower rates of reintervention and postoperative rupture after open repair compared with EVAR.

### Associations between surgeon characteristics and opinions (Tables V, VI, and VII)

Surgeon experience, age, and practice setting were each related to differences in opinions regarding the necessity of including specific complications in the informed consent process. Those who perform primarily EVAR were less likely to state that renal failure and mechanical ventilation should be discussed during informed consent for open repair or EVAR compared with those who perform primarily open or equal numbers of EVAR and open repairs. Younger surgeons were more likely to state that the risk of myocardial infarction for both EVAR and open repair, and disability for open repair, be discussed. Surgeons in private practice reported that a greater number of complications should be discussed (renal failure for open and EVAR, and myocardial infarction and prolonged mechanical ventilation for open) compared with academic surgeons (Table V).

There were also a number of significant associations between surgeon characteristics and survey responses regarding which complication rates to quote. Surgeons who perform mostly EVAR were more likely to quote higher mortality rates after open repair and lower reintervention rates after EVAR compared with surgeons who perform equal numbers of both procedures, or more open repairs. Younger surgeons were more likely to quote higher mortality rates after open repair and higher myocardial infarction

**Table II.** Percentage of surgeons responding in each category for importance of discussing risks during informed consent

Risk	Open					EVAR				
	1 Essential	2	3	4	5 Not needed	1 Essential	2	3	4	5 Not needed
Mortality	97%	2%	1%	0%	0%	94%	4%	2%	0%	0%
Myocardial infarction	67%	21%	6%	3%	2%	58%	21%	11%	5%	3%
Stroke	26%	14%	27%	12%	13%	28%	14%	23%	13%	15%
Renal failure	48%	22%	12%	7%	2%	53%	18%	12%	6%	3%
Impotence	62%	17%	6%	3%	2%	32%	14%	10%	13%	19%
Mechanical ventilation*	34%	25%	15%	9%	5%	17%	12%	21%	20%	17%
Permanent disability	19%	20%	20%	13%	13%	12%	12%	20%	18%	23%
Contrast exposure	12%	4%	16%	16%	39%	69%	9%	7%	2%	0%
Radiation exposure	4%	6%	12%	13%	51%	38%	19%	13%	9%	8%
Reintervention	17%	19%	22%	23%	6%	78%	5%	2%	0%	0%
Postoperative rupture	17%	5%	11%	23%	28%	57%	11%	9%	6%	1%

EVAR, Endovascular repair.

\*Refers to prolonged mechanical ventilation for >24 hours after surgery.

**Table III.** Open-ended survey responses

Complication	Number of respondents listing complication
Infection (graft/wound)	19
Paralysis/paraplegia	15
Limb loss/ischemia/ Claudication	15
Bowel ischemia/possible ostomy	12
Hernia	7
Embolization	7
Ileus/obstruction	6
DVT/PE	6
EVAR conversion to open	6
Need for transfusion	5
Retrograde ejaculation	4
Bleeding	4
Graft thrombosis	4
Lymph leak	3
Pneumonia	2
Ureteral injury	2
Aorto-enteric fistula	2

EVAR, Endovascular repair; DVT/PE, deep vein thrombosis; PE, pulmonary embolism.

tion rates after open repair and EVAR compared with older surgeons. Compared with private practice surgeons, academic surgeons were more likely to quote higher myocardial infarction rates after open repair and lower rupture rates after EVAR (Table VI).

There were no significant differences in opinions regarding what should be discussed between surgeons in malpractice crisis states and those in non-crisis states. For example, 53% of crisis state surgeons considered renal failure essential to discuss for open repair informed consent, compared with 54% of non-crisis state surgeons ( $P = .92$ ).

Many associations between surgeon characteristics and opinions regarding informed consent persisted in multivariable analysis after controlling for practice setting, most frequently performed surgery, and surgeon age (Table VII).

**DISCUSSION**

This is the first study describing surgeon opinion regarding the content of what should be included during

the process of informed consent for AAA repair. The survey responses are a valuable representation of collective surgeon opinion, as we were able to achieve a high response rate. The results of this survey improve our understanding of surgeon opinion related to the informed consent process for AAA repair. Although open AAA repair has been performed safely for over 50 years, and endovascular methods have been maturing for over 10 years, most reports regarding repair of aneurysms focus on a limited number of short-term outcome measures such as mortality and major morbidity. Other outcomes, including those which may be particularly important to patients such as stroke and long-term disability, have not been well studied.

Consequently, it is not surprising that there are no established guidelines to advise physicians on how to discuss informed consent for AAA repair. Our results indicate that the risks of mortality, myocardial infarction, renal failure, and impotence should be discussed during informed consent for both EVAR and open repair. For open repair, the risk of prolonged mechanical ventilation should also be included, whereas risks related to long-term endograft surveillance (contrast and radiation exposure) and risks of reintervention and postoperative rupture should be included for EVAR only.

Although we have summarized survey responses in order to create a framework for the informed consent discussion, it is important to recognize that our results reflect substantial variability in opinion. For example, 48% of surgeons answered that it was “essential” to discuss risk of renal failure after open repair, and because this was the most frequent response, we classified this risk as one that should be included in the informed consent process even though 52% of the respondents had a different opinion. In other cases, the variability was even more striking. For example, 19% of surgeons reported that it was essential to discuss risk of permanent disability after open repair, 13% reported that it was not needed, and 43% were less certain. Similar variability was seen in responses regarding the importance of discussing reintervention after open repair,

**Table IV.** Complication rates most frequently quoted in survey compared with literature-based values

Complication	Open repair rates		EVAR rates	
	Survey	Literature	Survey	Literature
Mortality	2 to 3	0 to 16	1	0.6 to 6
Myocardial infarction	2 to 3	5 to 21 <sup>a</sup>	1	1 to 5 <sup>a</sup>
Myocardial infarction for patient with coronary artery disease	≥5	NA	2 to 3	NA
Myocardial infarction for patient with risk factors for coronary artery disease	2 to 3	NA	1 to 3	NA
Stroke	<1	0 to 3	<1	0.4 to 2
Stroke for patient with stroke history	1	NA	1	NA
Renal failure	1	0.6 to 2.2 <sup>b</sup>	<1	0 to 1.2 <sup>b</sup>
Renal failure for patient with renal insufficiency	≥4 to 5	NA	≥4 to 5	NA
Renal failure for patient with diabetes	2 to 3	NA	2 to 3	NA
Impotence	≥4 to 5	NA	<1	NA
Reintervention rate (percent per year)	<1	0.3 to 4.6	≥4 to 5	2 to 15
Rupture rate (percent per year)	<1	NA	<1	1

NA, Not available.

<sup>a</sup>Literature refers to “cardiac complications” including myocardial infarction.

<sup>b</sup>Literature refers to any postop hemodialysis (not necessarily permanent).

prolonged mechanical ventilation after EVAR, and stroke after either procedure. With regard to which complication rates should be quoted, the survey results again demonstrated variability, but most responses were in the range of literature-based values.

The variability seen in survey responses is in part explained by surgeon characteristics. For example, surgeons whose caseload is greater than 50% EVAR were significantly more likely to quote higher mortality rates with open surgery, and lower reintervention rates with EVAR, compared with surgeons whose caseload is at least 50% open. This suggests that surgeons who primarily perform EVAR would be more likely to present patients with a risk profile which favors the endovascular option.

We also found that younger surgeons and surgeons in private practice believe that a greater number of risks are essential to discuss compared with their older and academic counterparts. For example, younger surgeons were more than three times as likely to rate discussion of myocardial infarction as essential for EVAR and open informed consent compared with older surgeons, and private practice surgeons were more than three times as likely to rate myocardial infarction or renal failure as essential for open informed consent compared with academic surgeons. It is possible that younger, less experienced surgeons would be more conservative about risk estimates, and more inclusive of various risks when discussing informed consent, compared with older surgeons. As for the differences between private and academic surgeons, there could be variation between these groups with regard to concerns about liability, perhaps related to whether or not a practice is self-insured. It is also likely that there are differences in case mix between groups; that is, if a group of surgeons has a practice comprised of high-comorbidity patients, they may be less likely to consider certain risks essential to discuss during informed consent for an “average” patient. We did not find any significant differences in the opinions of surgeons prac-

ticing in malpractice crisis states versus non-crisis states. However, it is possible that our measure was not sensitive enough to capture the effect of attitudes towards legal consequences of inadequate informed consent on surgeons’ opinions.

Another important potential factor influencing surgeon opinion is surgeon experience. Surgeons are likely to adapt the content of the informed consent process to include outcomes relevant to their own practice and quote complication rates that are reflective of their own experience or the experience of the center in which they practice. Therefore, we would expect to see some variability in opinions related to complication rates due to the range of surgeon experience and/or expertise.

The variability noted in this study is consistent with other reports that have examined the process of informed consent for other procedures.<sup>20-24</sup> It is well-documented in the cardiac surgery literature that there is a great deal of variation in what surgeons tell patients about a particular operation during the informed consent encounter, and perhaps even more so in what patients take away from this encounter. For example, Vohra et al administered a questionnaire to patients after they underwent informed consent for cardiac surgery and found that although patients were well-informed about the type of operation they were having and the reason for surgery, there was inconsistent communication of information about risks of and alternatives to the intervention.<sup>24</sup>

Inconsistent communication and comprehension during informed consent can have legal consequences. Although only about 2% of paid malpractice claims are known to be attributable to informed consent grounds, informed consent features prominently in malpractice litigation as a component of other claims that involve medical negligence or breach of contract.<sup>25</sup> The legal definition of informed consent includes discussion of the risks, benefits, and alternatives to an intervention. This is a broad definition, and

**Table V.** Association of surgeon characteristics with opinions on what is essential to discuss

<i>Surgeons who perform &gt;50% EVAR vs ≤50% EVAR</i>			
<i>Complication</i>	<i>% rating complication as "essential"</i>		<i>P value</i>
	<i>&gt;50% EVAR</i>	<i>≤50% EVAR</i>	
Renal failure			
Open	46%	70%	.007
EVAR	50%	69%	.03
Mechanical ventilation			
Open	33%	50%	.04
EVAR	14%	26%	.09
<i>Surgeons ≤50 years old vs surgeons &gt;50 years old</i>			
<i>Complication</i>	<i>% rating complication as "essential"</i>		<i>P value</i>
	<i>Age ≤50</i>	<i>Age &gt;50</i>	
Myocardial infarction			
Open	81%	58%	.001
EVAR	72%	50%	.003
Impotence			
Open	63%	76%	.07
EVAR	30%	42%	.1
Disability			
Open	32%	15%	.009
EVAR	18%	12%	.2
<i>Surgeons in academic vs private practice</i>			
<i>Complication</i>	<i>% rating complication as "essential"</i>		<i>P value</i>
	<i>Academic</i>	<i>Private</i>	
Myocardial infarction			
Open	59%	74%	.04
EVAR	56%	60%	.7
Renal failure			
Open	40%	62%	.005
EVAR	43%	66%	.003
Mechanical ventilation			
Open	28%	49%	.006
EVAR	17%	22%	.4

EVAR, Endovascular repair.

there is variation among states with regards to further explanation of full disclosure. The majority of states follow a physician-based disclosure rule, that is, what is considered essential to disclose is a matter of medical professional judgment that should be resolved by reference to what other practitioners would commonly disclose in a similar situation. There are a significant number of states, however, that follow a patient-based, or "materiality," standard, where the scope of the physician's communication is determined by what the patient would consider material to the decision.<sup>26</sup>

This legal context suggests that in determining what content should be included in the informed consent process, the patient's perspective must be considered. This is especially important because, as suggested by other studies,<sup>27-29</sup> there may be differences between patient and surgeon values. Surgeons may be more likely to discuss complications which are easier to study (usually 30-day

outcomes), simply because the data are more readily available. This phenomenon could explain some of the most frequently reported open-ended responses (for example, wound infection), as these outcomes are often reported in the literature but are not necessarily likely to factor into preoperative decision-making from the patient perspective. In contrast, outcomes such as permanent disability, which are clearly important to patients, are more difficult to quantify and track prospectively and, therefore, may be less likely to be discussed.

Analysis of the complication rate responses revealed that, in general, surgeons quote rates that are consistent with those reported in the literature. However, published data related to complication rates are limited (Table IV). There are no standard definitions for many important post-operative outcomes, and few studies stratify outcomes by patient risk factor profiles or provide data on long-term functional status and quality of life outcomes.

**Table VI.** Association of surgeon characteristics with reported complication rates

<i>Surgeons who perform &gt;50% EVAR vs ≤50% EVAR</i>			
<i>Rates to quote</i>	<i>&gt;50% EVAR</i>	<i>≤50% EVAR</i>	<i>P value (trend)</i>
Mortality after open			.003
<1%	2%	0%	
1%	1%	12%	
2%-3%	47%	59%	
4%-5%	49%	29%	
Reintervention after EVAR			.02
<1%	3%	0%	
1%	13%	10%	
2%-3%	30%	12%	
4%-5%	54%	78%	
<i>Surgeons ≤50 years old vs surgeons &gt;50 years old</i>			
<i>Rates to quote</i>	<i>Age ≤50</i>	<i>Age &gt;50</i>	<i>P value (trend)</i>
Mortality after EVAR			.02
<1%	26%	14%	
1%	33%	49%	
2%-3%	41%	32%	
4%-5%	0%	5%	
Myocardial infarction after open repair			.05
<1%	13%	21%	
1%	23%	28%	
2%-3%	44%	44%	
4%-5%	21%	7%	
Myocardial infarction after EVAR			.04
<1%	34%	55%	
1%	39%	26%	
2%-3%	25%	19%	
4%-5%	1%	1%	
<i>Surgeons in academic vs private practice</i>			
<i>Rates to quote</i>	<i>Academic</i>	<i>Private</i>	<i>P value (trend)</i>
Myocardial infarction after open repair			.05
<1%	14%	19%	
1%	20%	32%	
2%-3%	56%	34%	
4%-5%	10%	16%	
Rupture after EVAR			.003
<1%	45%	40%	
1%	45%	33%	
2%-3%	7%	28%	
4%-5%	3%	0%	

EVAR, Endovascular repair.

This study has several limitations. First, there is an inherent bias that survey respondents are likely to have a particular interest in the informed consent process compared with non-responders, so their opinions may not be generalizable to the larger population of surgeons. Second, the degree of variability in responses makes it difficult to draw conclusions as to whether a given complication should or shouldn't be discussed during informed consent. Third, in this survey, we did not assess the patient perspective on what should be discussed during informed consent. Finally, it is not agreed upon as to whether surgeons should use their own or generalized data when obtaining informed consent.<sup>30</sup> Conveying surgeon-specific information is not

always possible, which is why it is necessary to establish guidelines that would be tailored to individual patients based on their own risk factors as opposed to individual surgeon biases.

## CONCLUSION

Ensuring that patients are informed of the risks and benefits associated with EVAR and/or open repair is an important responsibility of the treating surgeon.<sup>9</sup> This is a particularly difficult task when considering AAA repair because of the uncertainty related to outcomes and the complexity of having to choose between two procedures with distinct risk profiles. Whether or not to undertake a pro-

**Table VII.** Associations of surgeon characteristics and informed consent opinions<sup>a</sup>

	<i>Private vs academic practice<sup>b</sup></i> <i>Odds ratio (95% CI)</i>	<i>Caseload &gt; 50% vs ≤ 50% EVAR<sup>c</sup></i> <i>Odds ratio (95% CI)</i>	<i>Age ≤ 50 vs &gt; 50<sup>d</sup></i> <i>Odds ratio (95% CI)</i>
<i>Odds of including complication</i>			
Myocardial infarction after EVAR	1.7 (0.7-3.7)	0.6 (0.3-1.3)	3.7 (1.8-7.7) <sup>e</sup>
Myocardial infarction after open repair	3.5 (1.5-8.1) <sup>e</sup>	1.0 (0.4-2.1)	3.7 (1.7-8.3) <sup>e</sup>
Renal failure after EVAR	3.6 (1.6-7.9) <sup>e</sup>	0.4 (0.2-0.9) <sup>e</sup>	1.0 (0.5-2.0)
Renal failure after open repair	3.3 (1.5-7.5) <sup>e</sup>	0.3 (0.2-0.7) <sup>e</sup>	1.1 (0.5-2.3)
Prolonged ventilation after open repair	5.5 (2.1-14.3) <sup>e</sup>	0.4 (0.2-0.9) <sup>e</sup>	2.0 (0.9-4.2)
Permanent disability after open repair	2.2 (0.8-6.0)	1.5 (0.6-3.7)	2.6 (1.1-6.3) <sup>e</sup>
<i>Odds of quoting higher complication rates</i>			
Mortality after open repair	1.8 (0.8-3.9)	3.1 (1.4-6.4) <sup>e</sup>	0.8 (0.4-1.5)
Reintervention rates after EVAR	1.4 (0.6-3.0)	0.3 (0.1-0.7) <sup>e</sup>	1.8 (0.9-3.6)

EVAR, Endovascular repair.

<sup>a</sup>This table includes outcome variables with at least one significant association. Odds ratios are adjusted for practice setting, age, and most frequently performed surgery.

<sup>b</sup>Odds ratio > 1 indicates greater tendency for private practice surgeons to discuss or quote a higher rate for given complication compared with academic surgeons.

<sup>c</sup>Odds ratio > 1 indicates greater tendency for surgeons who perform majority EVAR to discuss or quote a higher rate for given complication compared with surgeons who perform majority open AAA repair.

<sup>d</sup>Odds ratio > 1 indicates greater tendency for younger surgeons to discuss a given complication compared with older surgeons.

<sup>e</sup>Statistically significant at  $P < .05$ .

phylactic intervention for an asymptomatic condition is a particularly difficult decision for the elderly, who are at the highest risk for postoperative morbidity and yet have the least potential to experience long-term survival benefits.

The variability in surgeons' opinions demonstrates the need for further studies to ascertain reliable data on outcomes that may be difficult to measure, but are particularly relevant to patients. Standardized definitions of complications and measurement of complication rates in subgroups stratified by risk factors are essential in order to facilitate communication of tailored information. Informed consent, as currently practiced, appears to be a flawed process. Further efforts are needed to establish informed consent guidelines, which could be accomplished by formation of a panel comprised not only of vascular surgeons but also patients and legal experts. Dissemination of such guidelines would facilitate consistent communication of risk to patients in an unbiased manner, and improve the quality of informed consent.

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#### AUTHOR CONTRIBUTIONS

Conception and design: LB, AD, EB, RG, LF

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Statistical analysis: LB, AD, EB, RG, LF

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#### REFERENCES

1. Scott RA, Ashton HA, Kay DN. Abdominal aortic aneurysm in 4237 screened patients: prevalence, development and management over 6 years. *Br J Surg* 1991;78:1122-5.
2. Newman AB, Arnold AM, Burke GL, O'Leary DH, Manolio TA. Cardiovascular disease and mortality in older adults with small abdominal aortic aneurysms detected by ultrasonography: the cardiovascular health study. *Ann Intern Med* 2001;134:182-90.
3. Lederle FA, Johnson GR, Wilson SE, Chute EP, Littooy FN, Bandyk D, et al. Prevalence and associations of abdominal aortic aneurysm detected through screening. Aneurysm Detection and Management (ADAM) Veterans Affairs Cooperative Study Group. *Ann Intern Med* 1997;126:441-9.
4. Collin J, Araujo L, Walton J, Lindsell D. Oxford screening program for abdominal aortic aneurysm in men aged 65 to 74 years. *Lancet* 1988;2:613-5.
5. Singh K, Bona KH, Jacobsen BK, Bjork L, Solberg S. Prevalence of and risk factors for abdominal aortic aneurysms in a population-based study: The Tromso Study. *Am J Epidemiol* 2001;154:236-44.
6. Powell JT, Greenhalgh RM. Clinical practice. Small abdominal aortic aneurysms. *N Engl J Med* 2003;348:1895-901.
7. Mortality results for randomized controlled trial of early elective surgery or ultrasonographic surveillance for small abdominal aortic aneurysms. The UK Small Aneurysm Trial Participants. *Lancet* 1998;352:1649-55.
8. Lederle FA, Wilson SE, Johnson GR, Reinke DB, Littooy FN, Acher CW, et al. Immediate repair compared with surveillance of small abdominal aortic aneurysms. *N Engl J Med* 2002;346:1437-44.
9. Brewster DC, Cronenwett JL, Hallett JW, Jr, Johnston KW, Krupski WC, Matsumura JS. Guidelines for the treatment of abdominal aortic aneurysms. Report of a subcommittee of the Joint Council of the American Association for Vascular Surgery and Society for Vascular Surgery. *J Vasc Surg* 2003;37:1106-17.
10. Prinssen M, Buskens E, Blankensteijn JD. Quality of life endovascular and open AAA repair. Results of a randomized trial. *Eur J Vasc Endovasc Surg* 2004;27:121-7.
11. Prinssen M, Verhoeven EL, Buth J, Cuypers PW, van Sambeek MR, Balm R, et al. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. *N Engl J Med* 2004;351:1607-18.

12. Blum U, Voshage G, Lammer J, Beyersdorf F, Tollner D, Kretschmer G, et al. Endoluminal stent-grafts for infrarenal abdominal aortic aneurysms. *N Engl J Med* 1997;336:13-20.
13. Aarts F, van Sterkenburg S, Blankensteijn JD. Endovascular aneurysm repair versus open aneurysm repair: comparison of treatment outcome and procedure-related reintervention rate. *Ann Vasc Surg* 2005;19:699-704.
14. Du Toit DF, Saaiman JA, Carpenter JP, Geldenhuys KM. Endovascular aortic aneurysm repair by a multidisciplinary team: lessons learned and 6-year clinical update. *Cardiovasc J S Afr* 2005;16:36-47.
15. Laheij RJ, Buth J, Harris PL, Moll FL, Stelter WJ, Verhoeven EL. Need for secondary interventions after endovascular repair of abdominal aortic aneurysms. Intermediate-term follow-up results of a European collaborative registry (EUROSTAR). *Br J Surg* 2000;87:1666-73.
16. Harris PL, Vallabhaneni SR, Desgranges P, Becquemin JP, van Marrewijk C, Laheij RJ. Incidence and risk factors of late rupture, conversion, and death after endovascular repair of infrarenal aortic aneurysms: the EUROSTAR experience. European Collaborators on Stent/graft techniques for aortic aneurysm repair. *J Vasc Surg* 2000;32:739-49.
17. Schermerhorn ML, Finlayson SR, Fillinger MF, Buth J, van Marrewijk C, Cronenwett JL. Life expectancy after endovascular versus open abdominal aortic aneurysm repair: results of a decision analysis model on the basis of data from EUROSTAR. *J Vasc Surg* 2002;36:1112-20.
18. Finlayson SR, Birkmeyer JD, Fillinger MF, Cronenwett JL. Should endovascular surgery lower the threshold for repair of abdominal aortic aneurysms? *J Vasc Surg* 1999;29:973-85.
19. AMA. America's medical liability crisis: A national view. [http://www.ama-assn.org/ama/pub/upload/mm/450/med\\_liab\\_jan07.pdf](http://www.ama-assn.org/ama/pub/upload/mm/450/med_liab_jan07.pdf).
20. Kriwanek S, Armbruster C, Beckerhinn P, Blauensteier W, Gschwantler M. Patients' assessment and recall of surgical information after laparoscopic cholecystectomy. *Dig Surg* 1998;15:669-73.
21. Mishra PK, Ozalp F, Gardner RS, Arangannal A, Murday A. Informed consent in cardiac surgery: is it truly informed? *J Cardiovasc Med (Hagerstown)* 2006;7:675-81.
22. Stanley BM, Walters DJ, Maddern GJ. Informed consent: how much information is enough? *Aust N Z J Surg* 1998;68:788-91.
23. Turner P, Williams C. Informed consent: patients listen and read, but what information do they retain? *N Z Med J* 2002;115:U218.
24. Vohra HA, Ledsham J, Vohra H, Patel RL. Issues concerning consent in patients undergoing cardiac surgery-the need for patient-directed improvements: a UK perspective. *Cardiovasc Surg* 2003;11:64-9.
25. Birnbaum IM, Capron AM. Consent to medical treatment. Treatise on health care law. San Francisco, CA: Matthew Bender; 2007.
26. Birnbaum IM, Capron AM. Appendix 17A. Treatise on health care law. San Francisco, CA: Matthew Bender; 2007.
27. Devereaux PJ, Anderson DR, Gardner MJ, Putnam W, Flowerdew GJ, Brownell BF, et al. Differences between perspectives of physicians and patients on anticoagulation in patients with atrial fibrillation: observational study. *BMJ* 2001;323:1218-22.
28. Elstein AS, Chapman GB, Knight SJ. Patients' values and clinical substituted judgments: the case of localized prostate cancer. *Health Psychol* 2005;24(4 Suppl):S85-92.
29. Montgomery AA, Fahey T. How do patients' treatment preferences compare with those of clinicians? *Qual Health Care* 2001;10 (Suppl 1):i39-43.
30. Burger I, Schill K, Goodman S. Disclosure of individual surgeon's performance rates during informed consent: ethical and epistemological considerations. *Ann Surg* 2007;245:507-13.

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## APPENDIX (online only)

### Surgeon Survey

In order to improve patients' understanding of infrarenal AAA and how it is treated, we are designing an interactive educational tool for patients who are candidates for open or endovascular AAA repair.

This tool will explain the diagnosis as well as discuss the risks and benefits associated with intervention.

In determining which information to include, we would like to consider input from experts in the field; thus, we are seeking your opinion. Filling out the questionnaire should take approximately 5–10 minutes. There are 20 questions.

Please assume for each question regarding open AAA repair that you have chosen the approach (i.e. retro-peritoneal vs. trans-peritoneal) which would be the least risky for a given patient. Responses to this survey will be kept confidential.

1. How important is it to include discussion of mortality risk?

For EVAR:

1  2  3  4  5

essential not needed

What mortality rate should be quoted?

For EVAR:

<1%  1%  2-3%  4-5%  Other:

For open AAA repair:

1  2  3  4  5

essential not needed

For open AAA repair:

<1%  1%  2-3%  4-5%  Other:

*All of the following questions use the same response scales as described above and are not relisted.*

2. How important is it to include discussion of myocardial infarction (MI) risk?

For the average patient:

For patient with known history of coronary artery disease (CAD):

For patient without CAD but with known risk factors (i.e. smoking, diabetes, hypertension, hyperlipidemia):

What MI rate should be quoted for the average patient?

What MI rate should be quoted for a patient with known history of CAD?

What MI rate should be quoted for patient without CAD but with known risk factors?

3. How important is it to include discussion of stroke risk?

For the average patient:

For a patient with known history of stroke:

What stroke rate should be quoted for the average patient?

What stroke rate should be quoted for a patient with history of previous stroke?

4. How important is it to include discussion of risk of renal failure? This question refers to permanent, dialysis-requiring renal failure.

For the average patient:

For a patient with pre-operatively compromised renal function:

For a patient with diabetes:

What renal failure rate should be quoted for the average patient?

What renal failure rate should be quoted for a patient with pre-operatively compromised renal function?

What renal failure rate should be quoted for a patient with diabetes?

5. How important is it to include discussion of risk of impotence?

What impotence rate should be quoted?

6. How important is it to include discussion of risk of need for prolonged mechanical ventilation (beyond the first 24 hours after surgery)?

For average patient:

For patient with COPD:

7. How important is it to include discussion of risk of long-term disability (e.g., disposition to permanent extended care facility where the patient was living at home pre-op)?

For the average patient:

For someone whose functional status is mildly compromised preoperatively (e.g., lives at home but is somewhat dependent on spouse for help with activities of daily living):

8. How important is it to include discussion of post-operative surveillance practice? In discussing post-operative surveillance for EVAR, how important is it to include the following?

Risk of contrast exposure:

Risk of radiation exposure:

9. How important is it to include discussion of the likelihood of need for re-intervention after the operation?

Which rate should be quoted?

10. How important is it to include discussion of risk of rupture after repair?

Which rate should be quoted?

11. How important is it to include discussion of outcomes if no surgery is performed?  
Which of the following possible outcomes should be discussed? Please rate all three.  
Risk of rupture if no surgery is performed?  
Likelihood of death from rupture if no surgery is performed?  
Nature of death from a ruptured aneurysm?  
Other:
12. Are there any other issues that should be addressed in an educational tool that we have not asked about in this questionnaire? If so, please list.
13. If a patient is a candidate for both EVAR and open AAA repair, I generally:  
 Discuss both options and ask which one the patient would prefer.  
 Discuss both options and recommend one or the other.  
 Recommend one or the other without discussing both options.  
 Other:
14. Which of the following best describes your primary practice setting?  
 Academic     Private practice     Other:
15. Do you practice in a VA hospital?  
 Yes     No
16. What is your gender?  
 Female     Male
17. What is your age group?  
 <40  
 40-50  
 51-60  
 61-70  
 >70
18. For how many years have you been practicing vascular surgery?  
 1-5  
 6-10  
 11-20  
 21-30  
 >30
19. In which state is your practice located? (States to be listed on drop down menu)
20. Please estimate the number of AAA repairs you do per year:  
EVAR: \_\_\_\_\_  
Open: \_\_\_\_\_