Expert Exchange

Breakfast Debate: Management of Small Abdominal Aortic Aneurysms

MODERATOR: Peter Gloviczki, M.D.[1]
PANELISTS: Peter G. Kalman, M.D.[2]
Samuel E. Wilson, M.D.[3]
Wesley S. Moore, M.D.[4]

ABSTRACT **Controversy over optimal management of small abdominal aortic aneurysms (AAAs) continues, and in this debate three expert panelists present convincing data to support different management strategies: observation, open surgical repair, and endovascular treatment. Recently published data of a multicenter study from the United Kingdom and preliminary information available on the ADAM (Aneurysm Detection And Management) study suggest that close observation and regular follow-up with ultrasound is safe. Rupture rate of small aneurysms (< 5.5 cm) in these studies did not exceed 1% per year. Proponents of surgical treatment argue that small aneurysms increase in size in half of the patients within 3 years and then older patients with higher risk will undergo surgical treatment, leading to elevated morbidity and mortality. If the surgeon has documented low mortality rate, the patient is low risk, and has a long life expectancy, then repair of small aneurysms appears to be justified. Patient preference, however, is becoming increasingly important, and even younger, good-risk patients may decide on endovascular treatment, in spite of the need for regular surveillance and the lack of data on long-term complications following aortic stent-graft placement. There is no consensus on optimal management of small AAAs, although the correct question may not be if patients with small AAAs should undergo repair but when should they undergo repair using either open or endovascular techniques.**

Perspectives in Vascular Surgery and Endovascular Therapy, Volume 14, Number 1, 2001. Address for correspondence and reprint requests: Peter Gloviczki, M.D., Division of Vascular Surgery, Mayo Clinic, 200 First Street SW, Rochester, MN 55905. [1]Division of Vascular Surgery, Mayo Clinic, Rochester, MN; [2]Vascular Surgery, University of Toronto, Toronto, Ontario, Canada; [3]Dept. of Surgery, University of California, Irvine, Orange, CA; [4]Dept. of Surgery, Div. of Vascular Surgery, UCLA Medical Center, Los Angeles, CA. Tel: +1(212) 584-4662. 1531-0035,p;2001,14, 01,115,128,ftx,en;00111x.

Keywords **Abdominal aortic aneurysm, observation, surgery, endovascular treatment**

Moderator: Thank you for getting up so early today. We are looking forward to a stimulating discussion on a topic that is very close to our hearts. As you know, in the United States about 50,000 aortic aneurysms are repaired annually using either conventional techniques or endovascular techniques. There is more and more a voice in the literature that observation of small aneurysms may not be a bad idea. The discussion this morning is going to start by making a point: why should we observe small abdominal aortic aneurysms? The format of the debate will be that each participant, Peter Kalman, Samuel Wilson, and Wesley Moore, will have 10 minutes to make a statement of why we should observe small aortic aneurysms, why we should repair them using the conventional technique, and perhaps the reasons that we should repair them using endovascular techniques, and then we will have 3 to 4 minutes of rebuttal from each of them commenting on the previous presentations. We then will open the floor for discussion. I would like Dr. Wilson to tell us why should we observe small AAAs.

Dr. Wilson: Let it be resolved that this house does not support early operation on small aneurysms. Consider one surgical group's experience reported just 2 years ago, showing that 59% of patients are over 70 years. The size of the aneurysm is decreasing steadily by decade, and the operative mortality, perhaps because of the older age in the patient group, remains fairly fixed. Operation would only be appropriate for small aneurysms if all mortality is decreased; that is, if the patients who had early operation for small aneurysms and the patients who had selected or delayed operation had the same survival at the end of 5 years from all causes. The benefits of early operation would be prevention of rupture. A secondary benefit of earlier operation may involve less risk because the patients are a little younger and the smaller aneurysm may be technically easier. The benefits of surveillance may be that you would avoid an unnecessary operation. In one sense, the best outcome of an aneurysm is for the patient to die with an intact aneurysm of some other cause, thus avoiding the high morbidity of open operation, and it might be that we would avoid the expense of an operation at all. The time is pressing on us to make this decision. *Southwest Airlines Magazine* has a double-page ad describing endovascular repair, which is currently more applicable to the smaller-sized aneurysm.

Fortunately, we have a good set of information to apply to this problem. There have been two randomized trials in the United States: the Department of Veterans Affairs, Aneurysm Detection and Management Program and the other, now-published U.K. study. Immediate surgery, with a window of 30 days to weeks to accomplish operation, was compared with selective surgery, meaning that the patients would be observed until the aneurysm ruptured, became symptomatic, or enlarged to 5.5 cm, the expected outcome. The ADAM study had an age limit of 80 years because mortality increases in aneurysm repair. Four to 5.5 cm was the agreed-upon definition of small aneurysm. High-risk patients excluded were particularly those with severe pulmonary diseases, renal failure, and heart disease, but extensive cardiac workups were not required. We did not want our study to becomes a study of the outcome of treatment of silent coronary artery disease. An ultrasound of computed tomography (CT) was done every 6 months to follow the patients in the selective group and operation undertaken when the size criteria were met.

Here are the assumptions that were made in planning the ADAM study. We assumed an operative mortality of 5%, but that was high. Operative mortality in the VA system is lower and was lower in the study. We assumed a 5-year late operative-related mortality of 2% from such complications as graft infection or aortoenteric fistula. We designed the study to have the power to detect a 5% absolute reduction or a 50% relative reduction in aneurysm-related mortality by immediate surgery compared with selective surgery. We calculated 1000 patients in 3 to 4 years at 15 large VA hospitals. In fact, it turned out that we entered almost 1200 patients in 4 years at 16 hospitals.

The U.S. and U.K. studies were both quite similar in design. The aneurysm diameter selected for study was 4 to 5.5 in both the ADAM study and the U.K. study. The period of study overlapped. Duration of follow-up was 5 and 4.6 years. The number of patients in the ADAM study was 1136; the number in the U.K. study was 1090.

The risk of rupture in selected patients in the U.K. study was less than 1% per year in their total group of patients. It is our expectation that the rupture rate will be the same for ADAM.

Another major outcome factor is remarkably similar between the two trials, and that is that the rate of required operation in selectively managed patients. About 12% of patients per year in ADAM reached the threshold for operation, that is, 5.5 cm, or developed symptoms. In the U.K. study it was 17% per year. About 8% of selectively managed patients will die of lung cancer; more than will die of aneurysmal disease. The U.K. data show that there is a straight-line progression toward operation so that, at 5 years, approximately 70% of patients will eventually need operation.

Mortality is different between the two studies. It was 5.8% overall in the U.K. study, and in the ADAM study we project 3 to 4%. How can we explain this difference? In the United Kingdom there were 93 institutions, and each hospital randomized about two patients per year, thus operating on about one patient per year, whereas the average number of patients per institution randomized each year in the ADAM study was higher. For example, my hospital randomized over 100 patients during the study. Also, the U.S. study was tightly controlled, with hospitals and surgeons vetted for experience, whereas with 93 hospitals this degree of control is less likely.

The survival data from the U.K. study shows there is no difference at the end of 5 years between early surgery and surveillance.

In one waits to repair the aneurysm until it reaches 5.5 cm, the patient is a little older, and the aneurysm is a little larger. Does the mortality go up? There is some suggestion that that is the case in the U.K. study where elective mortality was 5.8% in the early surgical group but rose to 7.1% in patients who were in the selective group. There was no difference in the length of stay between the two groups. These will bear further examination using the U.S. data. Survival advantage is only 6 weeks on the average if you have early surgery done in the U.K. The cost per person would be about $1500 for that 6 weeks' advantage or about $10,000 prorated for a quality-adjusted life year. If you consider patients who have a lower operative mortality, the subgroup who are younger and have a larger aortic diameter, then early operation may be more favorable. Drop the mortality down to 2% as it will be in the U.S. study and project a 6-year average survival and you can see that the cost for the early surgery is really not going to be that much, especially if you consider that the cost for a patient on hemodialysis is about $60,000 for quality-adjusted year.

So, let me conclude by saying that overall survival is projected to be the same in both groups at 6 years, at 64%. There is no long-term survival advantage to have open aneurysm repair done early. The rupture rate for 4 to 5.5 cm appears to be about 1% per year in the United Kingdom in carefully followed patients. Enlargement is predictable, greater than 5.5 cm in almost half of the patients by 3 years. One side benefit of a screening program is that it does reduce incidence of rupture. In the United kingdom, rupture rate was reduced by 50% in the screened population.

So, ladies and gentleman, my position is that, first, as a guideline only, we should not routinely operate on aneurysms smaller than 5.5 cm but that we should follow them until they reach certain defined guidelines. Second, we should have a screening program in place for high-risk patients. Third, results of cooperative trials cannot dictate treatment for an individual patient but provide data to assist the vascular surgeon in a unique, personal, and professional recommendation.

Thank you very much. I greatly appreciated being on the panel. (applause)

Moderator: Thank you very much, Eric (Dr. Wilson); that was masterful. We know now the definitive opinion why we should not operate aneurysms smaller than 5.5 cm, and we are almost convinced. Still, we are going to ask Peter Kalman now why should we operate on aneurysms 5.5 cm in size or smaller.

Dr. Kalman: Thank you, Peter, for including me on this distinguished panel this morning, and that's probably the last nice thing I'll say about them today. I disagree with both of the other panelists, and you will see how we will use identical data and come to totally different conclusions.

I'm going to argue to support early surgery for small aneurysms, and we just heard that ultrasound surveillance is safe unless a larger threshold is reached, rapid expansion occurs, or if the patient becomes symptomatic. You are all familiar with most of the natural history data from the last 10 to 15 years, and I think we would all agree that the 5-year risk of rupture of an aneurysm smaller than 5 cm is low. Most notably, the two series, one from Kingston, Ontario, and the second from the Mayo Clinic, demonstrated a 0% risk of rupture for aneurysms less than 5 cm in diameter. So from the start we have to define what we are calling a small aneurysm, and, for the purpose of this discussion, I am defining a small aneurysm as one that measures 5 to 5.5 cm in greatest diameter.

We have already heard a review of the recently published U.K. aneurysm study, and now I will present my interpretation of those results. Briefly, 93 hospitals participated, where aneurysms between 4 and 5.5 cm were randomized. More than 1000 patients were randomized, with an age range of 60 to 76 years and a mean follow-up of 4.6 years. As was indicated, there was no survival advantage at the end of 6 years. So then how should these results influence our management? Do we agree with Dr. Wilson and say don't bother operating? Well, rather than reach this global conclusion, I am proposing that an appropriate approach is to consider multiple selection factors for each individual patient rather than having one number to hang your hat on. So, I'd like to review the following five factors before reaching a conclusion.

First, risk of rupture. We all find it comforting to have a critical size for an aneurysm, above which we are absolutely sure that operation is indicated and below which it's safe to follow nonoperatively. The natural history study from Kingston, Ontario, nicely demonstrated that aneurysms greater than 5 cm on CT scan had an increased risk of rupture. From the U.K. study, although not statistically significant, there was a suggestion that the mortality increased for aneurysms between 4.9 and 5.4 cm in diameter. But you have to remember that, in both studies, aneurysm rupture was avoided because about half of the patients had surgery within 3 years.

Now I think most would agree on a definition of a low-risk aneurysm, and we would probably agree that 6 cm represents a high-risk aneurysm. Other predictors of risk that are generally accepted are documented expansion and symptoms such as tenderness. We also know from multiple clinical studies that other factors such as hypertension, chronic lung disease, smoking, family history, and saccular configuration of the aneurysm all increase the rupture risk, but we still can't define the magnitude of increased risk for the individual patient. Therefore, searching for one critical size to make your decision is a bit too simplistic.

What about consideration of the elective operative risk? There are multiple factors that determine an individual patient's operative mortality. First, surgeon factors should be considered in addition to patient factors. The surgeon's experience, the volume of surgery performed, and specialty training all affect the mortality rate, not to mention the patient's presentation, symptomatic versus asymptomatic status, as well as associated comorbidity. In the U.K. trial, the elective operative mortality was 5.7%, which is virtually identical to these other well-noted clinical trials. We know from the New York State study that, in high-volume hospitals, defined as those performing greater than 26 cases per year, the mortality is significantly less. This data from the Province of Ontario summarize mortality results from 69 hospitals within the province with a definite relationship between case volume and operative mortality. Carrying this further, the 11 highest-volume hospitals in the province continue to demonstrate a trend toward increasing mortality as the volume decreases. Specialty training also has an impact, and we now know that, if aneurysm repair is performed by a cardiac or vascular trained surgeon, the mortality is significantly less.

These data from the Canadian aneurysm study demonstrated that patient factors can predict a higher operative mortality rate. A multivariate model was developed, where the presence of chronic obstructive lung disease, EKG evidence of myocardial ischemia, and a creatinine greater than 1.5 could predict operative mortality. The presence of none to three of these variables is summarized on this graph. With all variables absent, the expected mortality is quite low, and, if all variables are present, the mortality is quite significant. All of the remaining combinations of presence of one or two variables fall somewhere in between. Therefore, it is not such a simple answer to the question of which factors determine operative rate, and one must consider all of the factors together. Therefore, when faced with a small aneurysm (5–5.5 cm) and an individual surgeon with a low documented mortality rate and a good-risk patient, especially when some of those other risk factors for rupture that I mentioned are present, repair is certainly justified.

What about consideration of the patient's life expectancy? After all, we are performing a prophylactic procedure in patients that essentially feel well, and we are expected to prolong life. We already discussed that there was no survival advantage in the U.K. study for early surgery. This is particularly important to consider in the light that aneurysm patients, in general, are made up of a population with significant comorbidity and, therefore, significantly reduced 5-year survival compared with an age- and gender-matched population.

From the Canadian aneurysm study, we know that there are patient factors that predict a lower long-term survival, and the three variables that were important independent predictors were EKG evidence of an old infarct, an elevated creatinine, and age. For example, in those patients where EKG changes were absent, the 5-year expected survival was 72% compared with 54% when there was evidence of a previous infarct. When the creatinine was less than 1.5, the 5-year survival was 72% compared with 40% if it was greater than 1.5. There is no magic about the 1.5 cutpoint; this simply is a measure of systemic atherosclerosis. For patients younger than 65 years of age the 5-year survival was 82% compared with a 55% 5-year survival when age was greater than 75. With knowledge of these three variables in isolation or in combination, 5-year survival can be predicted. If all three variables are absent, or let's say favorable, the 5-year survival is 86% compared with a 5-year survival of 11% when all three variables are present.

What about patient follow-up? We know from the U.K. study that about 40% of aneurysms expanded to greater than 5.5 cm, thus becoming candidates for surgery within a 3-year period. If nonoperative management is the choice, then follow-up must be as meticulous as was performed in the U.K. study, that is, at 3-month intervals for an aneurysm 5 to 5.5 cm; if it was smaller, at 6-month intervals, with essentially 100% compliance. If follow-up cannot be this meticulous, then surgical repair is preferable. The U.K. study conclusion was that surveillance with timely OR is safe, but keep in mind that 40% will require elective repair within 3 years.

What about patient preference? We know from the U.K. study that the average expansion rate was 3.3 mm per year and in the Kingston, Ontario, study it was 7 mm per year. So, as Dr. Wilson already alluded, in some patients the question is not *if* but *when*. Patient preferences probably should be a guiding factor because quality of life may favor a surgical approach. In the U.K. study, quality of life was compared in the follow-up group and the early surgery group 12 months after randomization using the MOS SF 36 quality-of-life questionnaire. There was essentially no difference in physical functioning, role functioning, social functioning, and mental health between the two groups. However, there was a significant increase in health perception in the surgical group at 12 months compared with the ultrasound group and a slight increase in bodily pain, which is not surprising, in the surgical group compared with the ultrasound follow-up group. Therefore, this is arguably support and is debatable for a more aggressive approach in selected patients.

In summary, I feel surgery for an aneurysm smaller than 5.5 cm is justified, if the patient is a good operative risk, has a good long-term survival, has some of the risk factors known to increase the risk of rupture, and if the surgeon has a documented low mortality rate. Finally, patient preferences must not be ignored.

Thank you very much. (applause)

Moderator: Thank you very much, Peter. You provided convincing data and certainly a fantastic electronic presentation. I think all of us are going to go out and buy a new notebook after this.

You heard from Dr. Wilson that mortality is important, and we have a procedure that has a very low mortality. We could not have selected a better expert than Dr. Wesley Moore to tell us about endovascular treatment of small AAA. Dr. Moore, we are very honored to have you here to participate in this meeting and tell us why endovascular technique is the way to go with these patients.

Dr. Moore: Dr. Gloviczki, thank you very much for the invitation, and it is a pleasure to participate in this excellent breakfast symposium. May I have the first slide, please. When Dr. Gloviczki asked me to address the issue of small aneurysm within the context of endovascular repair, I thought about this for awhile and decided to come up with a title for this presentation, which is, "Does the Availability of an Aortic Stent Graft Change the Indication for Repair of AAA?" During the course of this presentation, I will attempt to answer this question, and I believe that I will convince you that the answer to the question is no. You have already heard two excellent presentations this morning. They have given you the essential database that will be required to answer the question that I have posed. I do not intend to repeat what has already been presented but rather to give you a perspective based upon the data that you have heard and put it into the context of the option of endovascular repair.

Let me begin by stating some fairly obvious observations, but ones that I believe are worth repeating. First, the indication for repairing an AAA is to prevent a fatal rupture that may occur sometime during the patient's remaining lifetime. This is done with the expectation that the duration of the patient's lifetime is sufficiently long as to expose the individual to a reasonable risk of rupture during that interval. We know that elective repair of AAA carries a very much lower morbidity and mortality in contrast to emergency operation for a ruptured aneurysm. When you review the literature concerning the lethality of aortic aneurysm rupture, what is most commonly cited are publications concerning patients treated emergently for aneurysm rupture after admission to the hospital. Those centers that have a good track record are the ones that will publish their results, and they usually suggest that the mortality rate for operation on acute aneurysm rupture is approximately 50%. What you are not told is that the majority of patients who rupture an AAA never reach a hospital alive. If you examine the mortality rate of outpatients who rupture an AAA, either at home or en route to a hospital, and to this add the in-hospital mortality rate, the total mortality rate for aneurysm rupture turns out to be in excess of 90%. It is important to keep that particular figure in mind and compare it with the predictability, or perhaps the lack of predictability, of when an aneurysm rupture is likely to occur.

The other item that needs to be kept in mind is the fact that there is a relationship between the size or diameter of AAA and the risk of rupture. With increasing diameter, there is actually an exponential relationship with respect to an increasing risk of rupture. This is well demonstrated in this slide. You can see that very small increments in aortic aneurysm diameter, beginning at 4.0 cm, are associated with a rapid, increased risk of aneurysm rupture.

The decision to operate on an individual patient with an AAA is based upon surgical judgment. What we have heard this morning is that this judgment represents a balance between the imminent risk of rupture and the likelihood that the patient will live long enough for rupture to occur. Dr. Kalman has emphasized the importance of trying to make a decision as to whether or not a patient will live long enough for an aneurysm to rupture. If the patient's life expectancy significantly exceeds the interval of expected rupture, then there is a clear indication to proceed with operation. Other factors that enter into the judgment of recommending operation for an individual patient is the assessment of morbidity and mortality associated with the operation itself. On balance, the younger and the healthier an individual patient, the smaller the size of an aneurysm can be that one would be willing to operate upon with clear justification. As we evaluate older patients with multiple risk factors, recommendation for operation would be based upon larger aneurysms that carry a higher risk of rupture within a relatively short period of observation. Clearly, at some point when patients reach the end of their life expectancy and have significant comorbid conditions, the justification for operation irrespective of aneurysm size disappears.

The next issue has to do with the definition of what is a "small" aneurysm? Dr. Kalman defined a small aneurysm as one in the range of 5.0 to 5.5 cm. Yet we have heard that, in both the ADAM trial as well as in the U.K. trial, small aneurysm definition ranged from 4.0 to 5.5 cm. From my personal perspective, I would define a small aneurysm as one being 4.0 cm or smaller. I believe that a healthy, good-risk patient with an aneurysm 5.0 cm or greater clearly has an indication for an operation. What is the risk of rupture in a small aneurysm? Dr. Wilson indicated that, during the course of follow-up in the U.K. trial, the risk of rupture was 1.0% per year. But that occurred in spite of the fact that these patients were kept under very careful surveillance with examination and measurement every 3 months for those with aneurysms at the larger end of the spectrum and every 6 months for those with aneurysms at the smaller end of the spectrum. In spite of this very intensive surveillance, there was a 1.0% per year risk of rupture, and, in spite of the surveillance, while the physicians were waiting for the aneurysm to reach an appropriate size, a rupture risk occurred in spite of careful follow-up. I do not have a personal experience in following patients with smaller aneurysms with the exception of an interval during our endovascular investigational experience when the implant program was temporarily shut down for graft redesign. During that interval, we accumulated a waiting list of patients. A number of those patients had aneurysms that were in the 5.0-cm diameter range, and I would confidently tell them that there was no problem waiting while the device was reengineered. Unfortunately, two patients with 5.0-cm aneurysms went on to rupture while on the waiting list. Fortunately, both were living close to medical centers and were able to under emergent repair with a successful outcome. This serves to emphasize that small aneurysms do indeed rupture. This reminds me of a conference that I attended a number of years ago, during which time Dr. George Morris of the Baylor Medical Center in Houston was sitting on a panel such as this. He was asked about the risk of a 4.0-cm aneurysm, and his response was that, "They are the most dangerous kind." The moderator was a bit confused and asked Dr. Morris to explain himself. Dr. Morris replied that, if you don't operate on that patient, somebody else will. (laughter)

With these comments, let me proceed to the meat of what I'm supposed to be talking about, which is does the availability of a stent graft change the size indication for repair? In my opinion, it should not. I believe that the indication for operation should be the same irrespective of what particular technique for repair is being utilized. The reason that I have taken this position is based upon the fact that the so-called less-invasive procedures may well carry the same mortality rate as a standard open repair. In both endovascular trials that have gone on to completion with FDA approval, there was in fact no difference in mortality rate between endovascular repair and the control of patients who underwent open repair. Although this may seem surprising, there are actually several reasons for this. First, centers were carefully selected to participate in these trials based upon the expertise of the surgeons doing the operation. Therefore, the quality of the surgeons participating in both the endovascular as well as the open repair was excellent. As a result of this, the mortality rate of both endovascular and open repair fell under 3.0%. It is very difficult to improve on a mortality rate of less than 3.0% in the open control group. If you then examined the morbidity in the experimental and control groups, there did appear to be a benefit in favor of the less-invasive approach if you looked at morbidity collectively rather than individually. It would appear that the real reason for doing an endovascular repair is not so much the reduction of mortality because that clearly does not occur. You may be able to offer the patient some reduction in morbidity. However, the real reason for performing endovascular repair is patient preference. An endovascular repair is what the patient wants in contrast to an open repair. A patient will come to the hospital the morning of endovascular repair. Following successful repair, the patient may very well have a regular meal that evening and go home the next day. How can you beat that? The alternative is a longer hospital stay with a postoperative ileus, a nasogastric tube, and the discomfort associated with a big incision. Therefore, from a patient standpoint, endovascular repair is clearly desirable even though there may not be a defined reduction in morbidity and mortality.

Having presented data suggesting that aneurysm size selection should be no different in endovascular repair, I'm quite confident that the availability of endovascular devices will, in fact, push the aneurysm size down in many centers. What is the justification for operating on smaller aneurysms in those centers? The argument has been offered that the small aneurysm is more likely to meet endograft inclusion criteria. In other words, as aneurysms are allowed to enlarge, the enlargement may efface the length of the proximal neck and therefore make a patient less likely to be a candidate for endovascular repair. By performing endovascular repair while the aneurysm is still relatively small, you may be arresting the development of the aneurysm in the area of the aneurysm neck and therefore be able to offer endovascular repair to a larger percentage of the patients. As aneurysms get larger, their necks certainly do shorten and widen. Hopefully, with a stent graft in place, this enlargement will be stopped. However, this has yet to be proven.

In conclusion, Mr. Chairman and fellow colleagues, I would say that endograft availability should not change the size indication for aneurysm repair. Will it? It probably will. The size threshold for aneurysm repair should be liberalized in younger and healthier patients. From my perspective, there is no magic size that can be applied uniformly to all patients. If I am managing a young patient with an aneurysm that is approaching to 5.0 cm, and that patient is healthy and with minimal risk factors, I would expect that patient to live for a long time. Therefore, why play Russian roulette by waiting and watching when I can repair it now and get it out of harm's way?

Thank you very much for your attention.

Moderator: Very good. Thank you very much. Eric, we are going to change the format a little bit. Why don't you sit down first because, in the interest of time, I would love to open up the floor for discussion, and I ask anybody who would have a question to the panelists to generate a little bit more discussion. Dr. Ricotta has a burning question.

Dr. Ricotta (From the audience): I don't know whether it's burning but I'd be interested to know if during follow-up of patients in your study, Eric, the necks of the aneurysms have enlarged or not.

Dr. Wilson: That's really an excellent question because, just yesterday, we were able to get approved an addition to the study of CT scan done at the end of the study, to evaluate recurrence of aneurysm, and also to evaluate dilatation and change in the aortic neck.

Moderator: Wes, could you address the question of aneurysm neck dilatation after endografting?

Dr. Moore (Responding to Dr. Ricotta): John, I think that is an excellent question. I will address the issue of neck dilatation, but I would also like to address the problem of aneurysm recurrence, particularly when one operates on a relatively small aneurysm that has a long neck. Using conventional open repair, there is a temptation to make the operation easier by mobilizing the distal portion of the proximal neck rather than by carrying out a resection up to the level immediately below the renal arteries. I believe that that is a mistake. The instances of aneurysm recurrence that I've seen usually occur when there is a significant amount of neck left between the renal arteries and the proximal anastomosis. This is not really a recurrent aneurysm, but it is an occurrent aneurysm in a segment of aorta that could have been but was not resected. In the case of endovascular repair, the neck of the aneurysm is a very precious commodity, and the length of the neck is crucial to determining whether or not a patient is a candidate for endovascular repair. In the devices that are currently approved, it is important to place the proximal attachment system as close to the renal arteries as possible to maximize neck length and to achieve appropriate seal to avoid endoleak. There are other endovascular devices that are currently in phases of investigation that place the stent portion of the attachment system above or across the renal arteries. I believe that the likelihood of recurrence due to continued dilatation of aortic neck diameter is low, based upon observations to date. In the case of the Guidant system, we are currently 7 years out from our initial experience, and we have not yet seen that happen.

Dr. Kalman: John, I could answer your question regarding the anticipated other late aortic complications. We looked at the surviving patients in the Canadian aneurysm study 8 to 9 years after surgery, and 94 patients agreed to a follow-up CT scan. Approximately 14% had a potential indication for surgical intervention, with a thoracic, visceral aortic or "cuff" aneurysm and asymptomatic proximal anastomotic aneurysms. These findings led us to advocate routine CT scan follow-up 5 years in anticipation of other problems.

Moderator: Jeb Hallett reported the Olmsted County experience, and Jae-Sung Cho, our fellow, looked up the late follow-up after ruptured aortic aneurysm repairs in our institution. We found that the overall late complication rate was very low, about 7% and pseudoaneurysm or a proximal aneurysm required repair that was even less. After ruptured aneurysm that number was about twice as high, so patients after repair of ruptured AAA get CT scans about 1 year after the repair first, but it looks like after elective repair it's about 3 to 5 years. Any other questions that you may have from the panel? Yes, go ahead, Fred.

Dr. Weaver (From the audience): Should we recommend endografts to patients?

Dr. Moore: It's an excellent question, and oftentimes I'm not given the opportunity to make that decision because the patient ends up in my office primarily because he wants an endograft; we don't see that many young healthy patients, but for the few that we do see, somebody in their mid- to late 50s, for example, the obvious thing to do is say, "Look, we've got a very good open repair with a 40-plus year history. You're going to be around for a long period of time. You ought to go with the tried and true rather than going with the new and somewhat experimental." But the answer that I usually get is, "Doc, if it doesn't work I can always have the other operation, right?" And I say, "Yeah that's true." He says, "I want the endograft." That's what happens.

Moderator: I think we also see that with more and more frequency. Eric, if I could ask you to comment on Wesley's question about the range of the complications between 4 and 5.5 because that obviously is an important question. None of us really is eager to repair any more aneurysm between 4 and 4.5, but we are much more eager to do selectively between 4.5 and

5, and just as in Los Angeles we would operate on aneurysms 5 cm or larger.

Dr. Wilson: We arrived at the definition of 4 to 5.5 cm by sending questionnaires to the members of the vascular groups and to the surgeons that we thought we'd be likely to be working with and asked them, "What is the smallest aneurysm that you would operate on and the largest size you would observe?" The consensus was 4 to 5.5 cm. Remember, if size is measured by ultrasound, the CT is going to read it another 2 to 3 mm larger in diameter. This doesn't negate consideration of other factors such as the hereditary aneurysm, the athletic patient, distance from a qualified surgeon, and so on, any of which may be important in decision making.

Moderator: You have a relatively nervous patient in the office with a 4.5-cm aneurysm whose brother just died of a ruptured aneurysm. What would you recommend, Dr. Kalman?

Dr. Kalman: I did mention that that is a risk factor for consideration, that is, family history, but how much weight do we put on it? It doesn't fit into an algorithm that completely, but it fits into the whole picture. I just wanted to bring up one point about the decision to operate on a 4-cm aneurysm, where that data come from, and why there are individuals who would suggest to operate on aneurysms that small. You remember that came from an autopsy study from the Massachusetts General Hospital by Darling, so it was obviously a very select group of patients that had already ended up in an autopsy suite and were measured by rulers or whatever postmortem, so I don't think we have good data that those aneurysms are at all dangerous.

Moderator: Wes, is that important? How big the aorta is proximal to the renal arteries?

Dr. Moore: I believe that it is important to look at the size of the aneurysm in relation to some marker and to express it as a ratio. The marker may be the suprarenal aorta, the L3 vertebra, or the body mass of the patient. At this point, I am not sure which is best. Obviously, a 5.0-cm aneurysm in a small woman who is 4′ feet tall should not be compared with a 5.0-cm aneurysm in a man who is 6′ feet tall. Therefore, it may well be more appropriate to look at size ratios as something like a bony landmark rather than speak about aneurysm diameters.

Moderator: Wes, how many patients meet the criteria for endograft in your experience?

Dr. Moore: At the present time, approximately one third of the patients that are referred to me meet the inclusion criteria for endovascular repair. I have a tendency to be somewhat restrictive in identifying patients as candidates for endovascular repair. I do not like to offer endovascular repair to patients with neck lengths much smaller than 15 mm, and certainly the size of recipient iliac arteries will restrict the ability of endovascular repair in some patients. It is important to keep in mind that conventional repair of AAA is an excellent operation, which has stood the test of time. If I see a patient who

I consider to be a good candidate for endovascular repair and it is the patient's desire to have this approach, then I believe it is reasonable to offer endovascular repair as an option. I believe it is a big mistake to try to perform endovascular repair in patients who are poor anatomic candidates.

Moderator: Any other comments? I don't think we should leave without really finding out how much you are convinced of which way to go to treat aneurysms. I would need a show of hands of those who would observe an aneurysm 5.3 cm in size and just obtain 6-month ultrasound studies in a good-risk, 65-year-old patient. Seeing how many hands are up it looks like most of us would do it. Who would just observe the patient and not intervene? This looks to be the minority. All right. Who is going to suggest that this good-risk, 65-year-old patient with a 5.3-cm aneurysm have conventional surgical repair? Most of you. Who is going to suggest endografting for this patient? Very few hands are up.

Dr. Moore: If anatomically suitable.

Moderator: If anatomically suitable. If this patient were 85 years old and has a valve, they wouldn't operate. Would we operate?

Dr. Moore: I just operated on somebody 99, celebrating his 100th birthday next week.

Moderator: Well, I think you would operate; the question is would you operate on that patient with a small aneurysm? Probably not. Well, who in this group, just put your hands up, has been doing endograft repair in the last 6 months since the FDA approval. So, that is about 20. That is excellent. I think it's going to be more and more. Well, I would like to thank, first, Impra for putting this breakfast meeting on. We appreciate very much your support of this meeting. (applause) I appreciate very much our distinguished faculty getting up so early and sharing their experience with us. The meeting is adjourned.

Note

The "Breakfast Debate: Management of Small Abdominal Aortic Aneurysms" was presented at the 28th Annual Meeting of the Society for Clinical Vascular Surgery, March 16–19, 2000, Rancho Mirage, California.