Watchful waiting in cases of small abdominal aortic aneurysms—appropriate for all patients?

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Objective: The purpose of this study was to determine the effect of patient compliance on a program of watchful waiting in cases of small abdominal aortic aneurysms and to document the proportion of patients who become prohibitive operative risks during follow-up.

Study Design: A retrospective review was conducted at a regional military veterans medical center. The subjects were 101 male military veterans with abdominal aortic aneurysms measuring less than 5 cm who did not have medical contraindications to operative repair. The main outcome measures were (1) the proportion of patients who missed three scheduled radiologic tests in a row despite written notifications mailed to their homes and (2) the proportion of compliant patients who had medical illnesses and became prohibitive operative risks during follow-up.

Results: During a follow-up (mean ± SEM) of 34 ± 2 months, 69 patients (69%) were fully compliant with the watchful waiting program and underwent a mean of 4.5 ± 0.3 radiologic tests. There were no abdominal aortic aneurysm ruptures in this subgroup. Twenty-five patients (36%) had indications for abdominal aortic aneurysm repair, and 28 (41%) have not met the criteria for repair. Sixteen (23%) of the 69 compliant patients developed prohibitive medical risks during follow-up; eight (50%) of these 16 patients died, all of the causes unrelated to their abdominal aortic aneurysms. Thirty-two (32%) of the 101 study subjects were noncompliant with the watchful waiting program. Twenty-seven (84%) of the noncompliant patients did not keep any scheduled appointments, and five (16%) were lost after one or two examinations. Three of the noncompliant patients experienced documented abdominal aortic aneurysm rupture, and it is suspected in a fourth. Direct contact was made with 28 (88%) of these patients or their families; all acknowledged having received written notifications regarding their watchful waiting program tests and had decided not to continue with surveillance for a variety of socioeconomic reasons. Between the 69 compliant patients and the 32 noncompliant patients, there were no differences with respect to mean age (70 ± 1 years vs 73 ± 2 years), distance from home of record to the hospital (62 ± 14 miles vs 73 ± 23 miles), or abdominal aortic aneurysm size at initial detection (3.75 ± 0.5 cm vs 3.8 ± 0.5 cm).

Conclusions: Watchful waiting programs are imperfect and highly reliant on the motivation levels and means of the individual patients. Watchful waiting is reasonable among compliant patients with abdominal aortic aneurysms, inasmuch as fewer than half will meet the criteria for intervention within a mean of 3 years. Approximately one fourth of these patients will have medical contraindications to abdominal aortic aneurysm repair during follow-up, and many of these will die of causes other than abdominal aortic aneurysm rupture. In our experience, one third of candidates for watchful waiting programs are unable to participate and are at risk of rupture. These patients need special attention so that the reasons for their noncompliance can be determined, and they may be candidates for earlier intervention. (J Vasc Surg 2000;32:441-50.)
The risk of rupture of an abdominal aortic aneurysm (AAA) is predicated mainly on the basis of its greatest diameter.\(^1\) The risk is substantially higher in AAAs larger than 5 cm than in aneurysms that are smaller.\(^2,3\) Although most surgeons recommend elective repair of an AAA with a diameter of 5 cm or greater, the need for repair of AAAs smaller than 5 cm remains controversial. The UK Small Aneurysm Trial failed to show a survival advantage for early repair of AAAs less than 5.5 cm in diameter in comparison with selective repair based on ultrasonographic surveillance.\(^4\) However, the operative mortality rate of 5.8% for patients randomized to early repair in the United Kingdom study may have negated any benefit of early repair that would have been found with better results.\(^5\) Regardless of the risk, currently available data suggest that the benefit of prophylactic repair of AAAs less than 5 cm in diameter is small because the risk of rupture is minor.\(^2,3,6\) However, it is not zero. In the UK Small Aneurysm Trial, 17 (3%) of 563 patients randomized to AAA surveillance died of ruptured AAAs.\(^4\) The mean risk of rupture was 1% per year for AAAs measuring 4.0 to 5.5 cm.\(^4\) The rupture rate was higher in the subgroup of patients who experienced AAA growth to greater than 5.5 cm but became medically unfit for surgery during surveillance.

The low risk of rupture for AAAs smaller than 5 cm has prompted many surgeons to recommend a selective management policy whereby serial radiologic measurements are used until the AAA meets size or growth criteria for repair. Published results have demonstrated that these so-called watchful waiting programs (WWPs) are safe\(^3,6-8\) and capable of selecting patients whose AAAs are at highest risk of rupture.\(^3,9,10\) However, these prospective studies were carried out in selected patients with complete follow-up. The impact of incomplete follow-up has not been evaluated in WWPs. We hypothesized that for patients with small AAAs who do not follow strict surveillance protocols, WWPs are not suitable because of the risk of undetected AAA growth and missed opportunities for timely intervention. The primary purpose of this study was to determine outcomes in patients who were not compliant with a WWP. We also wished to determine the proportion of compliant patients who developed prohibitive operative risk during follow-up.

## METHODS

In accord with the suggested standards of the International Society for Cardiovascular Surgery/Society for Vascular Surgery,\(^11\) we defined an AAA as a focal dilatation of the infrarenal abdominal aorta resulting in a diameter at least 50% larger than the expected normal diameter. The diameter of the normal infrarenal aortic “neck” proximal to the AAA was used as the reference measurement. In all cases, this meant that the AAA was larger than 3 cm. For purposes of this study, small AAAs were defined as those that did not meet the threshold criteria for repair. Our criteria for AAA repair were similar to those of others: (1) any AAA larger than 5 cm and (2) any AAA with a diameter of 4 cm or more that became tender or increased in size by more than 0.5 cm in 6 months.\(^3,12\)

Patients with small AAAs were entered into a WWP, which involved serial radiologic examinations every 6 months until the AAA met size or growth criteria for repair. Routine follow-up examinations were performed with ultrasound scanning because its cost is lower than that of computed tomography (CT). Patients in whom small AAAs were detected were automatically scheduled for follow-up ultrasound scanning examinations every 6 months and given appointments to the Vascular Surgery Clinic. Patients were seen in the Vascular Clinic by residents and attending vascular surgeons. Those who missed appointments or radiologic examinations were iden-
tified in a hospital computer-based program and automatically rescheduled, and written notifications were mailed to their homes. Any patient who missed three scheduled radiologic examinations in a row was dropped from further notification efforts. We therefore designated any patient who failed to keep three appointments in a row as noncompliant.

All patients with small AAAs that were evaluated by means of CT (CTI, General Electric Company, Milwaukee, Wis) at the Department of Veterans Affairs North Texas Health System between 1994 and 1997 were studied. Patients with AAAs that were initially measured only by means of other modalities, such as ultrasound scanning or abdominal roentgenography, were excluded because of the potential for size measurements that were inaccurate (in comparison with CT measurements).13 We estimate that 70% of new AAAs were diagnosed by means of CT scanning during the study period.

Measurements were determined through use of calipers and magnification. AAA size was determined as the largest transverse dimension in any axial plane. Sixty-one patients who were not appropriate for a WWP because of metastatic disease or other terminal illness were excluded from the study. Medical records of the remaining study subjects were scrutinized to determine demographics, indications for the initial radiologic examination, and clinical outcomes. AAA measurements derived from subsequent ultrasound scanning examinations (ATL HDI 3000, Advanced Technology Laboratories, Bothell, Wash) were documented, and indications for repair were noted. We also determined the proportion of subjects entered into WWPs without severe illness who became prohibitive operative risks because of the development of chronic illness during follow-up. All living patients were contacted by telephone, and attempts were made to contact the families of patients who had died during the study period.

From these interviews, we determined the reasons why patients who were noncompliant with the WWP did not keep their scheduled appointments. The distance from each patient's home of record to the medical center was measured to the nearest mile through use of a state map (Texas State Map, Rand McNally, Skokie, Ill) to determine the effect of location on compliance. Admissions to other medical centers for AAA repair were verified, and the status of the AAA (ruptured, symptomatic/intact, or asymptomatic) was documented. Causes of death were determined from autopsy reports, inpatient records, and records from other medical centers.

Continuous data are expressed as means ± SEMs. Total AAA growth was calculated as the change in largest diameter between the initial ultrasound-derived measurement and the latest ultrasound-derived measurement. The annual AAA growth rate for each subject was determined by dividing the total AAA growth rate by the number of years between these two examinations. Statistical comparisons between categoric parameters were performed with \( \chi^2 \) analysis, and comparisons between large groups of unpaired data were made with the unpaired Student \( t \) test. The Mann-Whitney \( U \) test was used to compare AAA growth rates between subgroups. Differences were considered significant at a level of \( P \) less than .05.

**RESULTS**

In all, 101 patients met the inclusion criteria. The mean age of these patients was 71 ± 1 years, and the mean AAA size at initial detection was 3.8 ± 0.1 cm. Outcomes for the 101 study subjects are presented in Fig 1.

**Compliant patients.** During a mean follow-up of 34 ± 2 months, 69 patients (69%) were fully compliant with the WWP and underwent a mean of 4.5 ± 0.3 ultrasound scanning examinations (Table).
There were no AAA ruptures in this group. The mean change in AAA size during the follow-up among the 69 compliant patients was 0.8 ± 0.1 cm, and the mean growth rate was 0.43 ± 0.06 cm/y. The proportion of compliant patients who remained on the WWP during the study period is shown graphically in Fig 2.

Indications for AAA repair developed in 25 (36%) of the compliant patients: 16 patients had increase in AAA size to 5 cm or more, 5 patients had rapid growth (≥ 0.5 cm) between examinations, and 4 patients had symptoms (2 embolic complications and 2 intact AAAs with tenderness). The mean AAA size at initial detection was 3.9 ± 0.1 cm among these 25 patients. The initial AAA size was 3 to 3.9 cm in 8 patients (32%) and 4 to 4.9 cm in 17 patients (68%). During follow-up, the average AAA growth rate for the 25 patients was 0.64 ± 0.14 cm/y. The mean time between AAA diagnosis and repair in the 25 patients was 36 ± 4 months. None of these patients came to AAA repair within 12 months of diagnosis. Twenty-four patients underwent AAA repair at our institution; one patient with AAA tenderness underwent repair of an intact aneurysm at an outside hospital. Of the 24 patients who came to elective repair at our institution died in the perioperative period of multisystem organ failure, as did the patient who underwent repair at an outside hospital. Two other patients died of myocardial infarction within 1 year of AAA repair. The remaining 21 patients were still alive at the end of the study period.

Twenty-eight (41%) of the 69 compliant patients did not meet criteria for repair and did not have prohibitive operative risks. The mean AAA size at initial detection was 3.7 ± 0.09 cm, which was not significantly different from that for the 25 patients who came to repair. The initial AAA size was 3 to 3.9 cm in 17 patients (61%) and 4 to 4.9 cm in 11 patients (39%). Twice as many patients in this group had initial AAA measurements less than 4 cm than in the group of 25 patients who came to AAA repair, but the difference in these proportions did not achieve statistical significance (P = .07). The average AAA growth rate among the 28 patients who did not come to AAA repair was 0.33 ± 0.06 cm/y during follow-up, which was significantly less than the growth rate among the patients who came to AAA repair (P = .03). Ten of the 28 patients who did not come to repair died of causes unrelated to the AAA within 6 months of their last examination (4 of cancer, 3 of chronic pulmonary disease, 2 of gastrointestinal bleeding, and 1 of myocardial infarction); the other 18 are presently being followed up. The 10 patients who died were being actively followed up at the time of death, and none had been dropped from the WWP because of advanced illness.
Sixteen (23%) of the 69 compliant patients were dropped from the WWP because of advanced illness. These patients became prohibitive medical risks during a mean of 29 ± 4 months as a result of illnesses: 6 had metastatic disease, 6 had refractory ischemic heart disease, 2 had end-stage chronic obstructive pulmonary disease requiring home O₂ administration, and 2 had intra-abdominal abscesses and chronic intestinal fistulas. Eight of the 16 patients have died (including the two with chronic fistulas), all of causes unrelated to their AAAs. There have been no AAA ruptures in this group.

Noncompliant patients. Thirty-two (32%) of the 101 study subjects were noncompliant with the WWP (Table). Twenty-seven (84%) of the noncompliant patients did not keep any scheduled appointments, and five (16%) were lost to follow-up after one or two radiologic examinations. It should be emphasized that at least three rescheduled appointments in a row were missed in each case, despite the fact that written notifications were sent directly to these patients’ homes. Three of the 32 noncompliant patients had documented AAA ruptures and presented at other hospitals; of these, one survived repair. These diagnoses were made on the basis of operative reports from the respective hospitals. A fourth patient is suspected of having had a ruptured AAA on the basis of abdominal pain, distention, and falling hematocrit, but he died at an outside institution before he could be transported to the operating room.

Direct contact was made with 28 (88%) of the noncompliant patients or their families (Fig 1). Of the 4 patients who could not be contacted, 2 moved to other states without providing forwarding addresses, and 2 have become homeless. Ten of the 28 noncompliant patients have died; of these, 4 died of sepsis, 2 of metastatic disease, 1 of subarachnoid hemorrhage, 2 of AAA rupture, and 1 of shock from unknown causes (AAA rupture is suspected). All 28 patients (or members of their families) acknowledged having received written notifications regarding follow-up appointments. None of the 18 living patients has prohibitive medical risks.

The primary reasons determined for noncompliance were as follows: 14 of the patients were unaware that they had an AAA despite written documentation of counseling by primary care physicians or physician assistants in the medical records; 7 simply ignored their appointments; and 7 others refused to be followed up for any reason. In addition, 12 of the 28 patients stated that they could not come to the hospital because of transportation problems. After telephone interviews, all 18 living patients have been rescheduled for follow-up examinations and are expected to resume the WWP.

The 69 patients who kept their scheduled appointments were compared with the 32 who did not to determine possible risk factors for noncompliance with the WWP (Table). The mean age of the compliant patients was 70 ± 1 years, which was not significantly different from the mean age of the noncompliant patients (73 ± 2 years). The mean distance from home of record to our hospital was 62 ± 14 miles for compliant patients and 73 ± 23 miles for noncompliant patients (P = .09).

DISCUSSION

Surgeons favoring early repair of small AAAs base their argument on the probability of aneurysm growth and the risk that patients will become higher operative risks as they age and chronic illnesses develop. The current data indicate that surveillance programs have the potential to identify small AAAs with rapid growth and thereby to select patients presumed to be at higher risk of rupture. WWP’s appear to be safe: although two patients in the compliant group had AAA tenderness, there were no cases of AAA rupture among the 69 compliant patients. Although the risk of developing medical contraindications to AAA repair was substantial (23% within a mean of 2 years), half of these ill patients died of causes unrelated to their AAAs. In principle, then, surveillance programs appear to be reasonable alternatives for managing patients with small AAAs. Our data are in keeping with those of others, demonstrating that WWP’s are reasonable for use with compliant patients, inasmuch as the rupture risk is negligible and fewer than half of these patients will meet criteria for repair within a mean of 3 years. When all candidates are considered, however, our study demonstrates that WWP’s are imperfect, relying on the motivation levels of individual patients. In contrast with previous reported experience with WWP’s, one third of the subjects in this study were noncompliant with follow-up despite our aggressive attempts to reschedule missed appointments. The 3-year rupture rate of 13% in this group is sobering evidence that WWP’s are unsafe for patients with small AAAs who are unable to participate.

A number of possible risk factors for noncompliance were not evaluated in this study, including socioeconomic status, education level, associated medical conditions, and type of health care provider who provided the AAA follow-up. Financial status
has been identified in previous epidemiologic studies as having a strong influence on whether a patient will accept health care. The retrospective nature of this study precludes a determination of whether financial status and education had an impact on compliance with the WWP. However, the direct costs associated with AAA follow-up are not likely to have been a factor, because surveillance tests are available to eligible military veterans at no cost and travel expenses are reimbursable. Similarly, incomplete medical records precluded a complete analysis of the impact of associated medical conditions. However, poor medical health was never given as a reason for missing appointments by any of the noncompliant patients.

The type of health care provider may have had a profound influence on the compliance rate in this study. Whereas compliant patients were seen by surgery residents or attending surgeons at least twice each year, the noncompliant patients may never have seen a vascular surgeon at any time. Because medical records of all visits at the military veterans medical center were not available for all study subjects, it is not possible to determine the exact numbers and types of practitioners seen. We suspect that the need for complete follow-up was not stressed by some practitioners, and we are working to improve the education of providers at our hospital about the natural history of small AAAs.

The reasons for noncompliance were highly variable among the study subjects. Although transportation problems were mentioned by a substantial proportion of the noncompliant patients, compliance was not determined by traveling distance between home and hospital. Half of the patients in this study lived more than 30 miles away from the hospital, and these patients were just as likely to keep their appointments as patients who lived closer. On the basis of the present data, we submit that compliance with a WWP is related most directly to patient understanding. Preliminary analysis suggests that most of the noncompliant patients in this study were unaware that they had an AAA despite evidence that they had been counseled by a physician and despite their acknowledgment of receipt of written notifications regarding rescheduled follow-up appointments. It should be stressed that most of these patients were not followed up longitudinally by the same physicians, and this may have affected the degree of patient awareness.

The issue of whether the caregivers themselves were informed about the natural history of AAA simply compounds the problem. Half of these patients had AAAs smaller than 4 cm, and it is possible that the need for follow-up studies was not properly emphasized, inasmuch as AAAs less than 4 cm in diameter do not rupture. However, one third of the patients who came to AAA repair in the present study had initial measurements of more than 4 cm, emphasizing that surveillance is necessary once the diagnosis of small AAA is made. This suggests that more effort is required to educate patients about the presence and natural history of their AAAs.

We submit that the main risk factor for noncompliance in this population is failure to keep appointments for AAA measurement. It is not possible to determine how many patients missed appointments in the compliant group. However, the available data suggest that this was rare, because measurement findings from serial ultrasound examinations performed every 6 months were available for every compliant patient. This suggests that a single missed appointment may be construed as indicating a high risk for future noncompliance. Accordingly, we suggest that all patients with small AAAs who fail to keep their appointments be contacted directly by their physicians to ensure that proper counseling has been offered. We have been able to persuade all of the remaining patients in the noncompliant group to make follow-up appointments, but it remains to be seen how many patients actually return for follow-up tests.

The elective mortality rate of 8% in the current series is troubling, being more than twice the 3.3% mortality rate for elective aortic revascularization previously reported from our institution. We are unable to account for this difference, other than to note that one of the two deaths in this series occurred at an outside institution. Our adjusted institutional death rate was 4.2% (1/24), which is more in keeping with our reported experience. It is worth noting that the adjusted 30-day operative mortality rate for the surgical group in the UK Small Aneurysm Trial was 7.1%4 This rate was not significantly different from the 5.8% mortality rate for patients undergoing elective surgery.

We cannot evaluate the long-term survival effects of WWPs versus early repair because our study was not prospective and there was no comparison group of patients who underwent early repair. In addition to having a comparison group, a larger sample with longer follow-up would be necessary to evaluate the utility and safety of WWPs. The Aneurysm Detection and Management Study trial should help to settle this issue in the future.16
Despite the fact that ours was a relatively large series of consecutive patients with small AAAs who had long-term follow-up, study limitations did exist. The first potential limitation is that the study was retrospective in nature; a number of AAA ruptures may thus have been missed. We are reasonably certain, on the basis of telephone interviews and medical record data, that there were no AAA ruptures among the 69 patients who were compliant with the WWP. All four deaths in the compliant group were verified by medical records as due to causes other than AAA rupture. We cannot be completely certain that other AAA ruptures did not occur among the noncompliant patients, especially the four subjects who were lost to follow-up. However, additional AAA ruptures would not have altered the findings in this study, considering that the current data show WWPs to be unsafe for noncompliant patients.

A second limitation relates to the nature of our referral population. The subjects were consecutive patients from a large military veterans medical system; therefore, the present conclusions cannot be generalized to all populations of patients with small AAAs. Compliance rates may be expected to vary according to specific variables, such as the socioeconomic status of the population being studied. Therefore, the problem of noncompliance may not be universal. Because nearly half of the noncompliant patients admitted to difficulties in obtaining transportation to the medical center, the study population may also be viewed as representing indigent patients. However, medical care is available at no cost to our patients, and transportation expenses are fully reimbursable. The compliance rate might have been much worse without these advantages. City-county hospital populations with high proportions of transient or indigent patients may be expected to have an even higher noncompliance rate. On the other hand, compliance may be much better in subgroups of patients who have medical insurance and live closer to medical centers. Because the subjects in the current study were not selected for the WWP on the basis of experimental protocol or individual motivation, we submit that regardless of socioeconomic status, they represent a realistic sample of the total population of patients with small AAAs. By extrapolation, the current study may represent a more realistic analysis of WWPs in the general population than any previously reported. However, because the nature of our referral population resulted in an all-male study group, we concede that the findings in the current study do not apply to women.

A third possible limitation relates to the type of radiologic tests chosen for the WWP. We specifically included only those patients who had AAA measurements determined by means of CT scanning because we wished to have a standardized AAA measurement at study inception. Therefore, a number of patients with small AAAs detected by means of other radiologic tests were not included in the current analysis. Each CT scan was performed on one of two identical machines at our institution, and reported measurements were verified on hard copies under magnification through use of calipers. Our decision to use follow-up measurements from ultrasound scanning examinations was based on our routine WWP protocol. All ultrasound scanning measurements were obtained from the same machine at our institution, and the same three technologists were used throughout the study period. Although there might have been some variation between CT scan and ultrasound scanning measurements, the initial AAA measurements were all standardized from CT. It was not possible to evaluate the correlation between CT and ultrasound scanning measurements in this study, because many of the AAAs grew between examinations. However, it is noteworthy that none of the ultrasound scanning measurements were smaller than the CT measurements. None of the patients who became candidates for early repair on the basis of AAA size did so within the first 6 months of follow-up, after which measurement data changed from CT to ultrasound scanning. Although the natural history and AAA growth data in this study may be limited by less accurate measurements determined from ultrasound scanning, they are still in keeping with data reported by others.

In summary, WWPs appear to be imperfect and highly reliant on the means and motivation levels of individual patients. For compliant patients, WWPs appear to be safe and to have the potential of selecting patients at highest risk of AAA rupture. However, up to one third of candidates for WWPs are unable to participate and are at risk of rupture. These patients require special attention so that the reasons for their noncompliance can be determined. In our experience, noncompliance is usually related to inadequate patient education. It remains to be seen whether more aggressive efforts at explanation will affect compliance among these patients. The increased risk of AAA rupture in noncompliant patients suggests that they represent a subgroup that should be considered for early repair.

REFERENCES
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DISCUSSION

Dr. Spence M. Taylor (Greenville, SC). I appreciate the opportunity to discuss this interesting presentation by Dr. Valentine and associates from the University of Texas Southwestern and have had the privilege to review the manuscript prior to this meeting.

In this paper, the authors have challenged what has become a cornerstone of most vascular surgical practices, namely, the selective management of small aortic aneurysms utilizing a protocol that employs every 6-month ultrasound surveillance and watchful waiting. In this retrospective analysis performed over a 3-year period on a military veteran population, Dr. Valentine’s group found that an alarming 32% of patients with small aneurysms enrolled in the watchful waiting program failed to keep consistent follow-up, missing at least three consecutive appointments despite written reminders and confirmations. For the purpose of the study, the authors were subsequently able to contact 88% of noncompliant patients or their families and documented an abdominal aortic aneurysm rupture rate of 13% over a 34-month period. This contrasts with the compliant patient group who did well. No aneurysms ruptured, and 25 elective repairs were performed. The authors conclude that a watchful waiting program is effective in compliant patients, but the watchful waiting program for small aortic aneurysm surveillance appears to be imperfect and highly reliant on individual patient motivation. While the authors advocate more aggressive efforts to educate patients of the importance of follow-up, they suggest in the last sentence of their manuscript that this noncompliant patient group may be a candidate for early aneurysm repair.

I congratulate the authors on an extremely well-written manuscript. The hypothesis and purpose are stated well in the presentation and the manuscript. The results were clear, and their conclusions were reasonably substantiated by the results. I find this paper to be timely as it academically tackles a rather blue-collar problem of patient noncompliance and its effect on treatment outcome. The study graphically illustrates what we as physicians have always known and what politicians are discovering: access to patient care does not automatically result in patient care. I have an observation and several questions for the authors. A noncompliant follow-up rate of 32% for outpatient aortic aneurysm surveillance seems extremely high to me. After reviewing the manuscript, I roughly analyzed our outpatient experience in Greenville. Our vascular surgery service has approximately 10,500 outpatient visits a year in our private office and about 1000 visits a year in the resident vascular surgery clinic. Patients who cancel appointments and are lost to follow-up regardless of illness represent less than 2% of cases in the private offices and probably 5% of cases in the clinic. Therefore, the phenomenon described in your study, in our experience, is rel-


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most of the noncompliant patients never came back to the clinic. It was also interested that the majority of noncompliant patients, when asked why they had not returned for follow-up, stated that they were unaware that they had an aneurysm despite documentation in the chart by a physician to the contrary. My second question is, who sees these patients? Are they surgery residents? Fellows? Often residents in our service, while meticulous in matters of patient care, sometimes lack the communication skills with patients and their families. Is this the case, or do attending physicians see the patients initially and discuss in detail the treatment plans?

Finally, the authors suggest that perhaps the subgroup of noncompliant patients with small aneurysms should be considered for early repair. How do you in your practice identify a patient up front whom you believe will be noncompliant so that this recommendation can be made?

Again, I congratulate the authors on a very well done study that looks to evaluate a real clinical problem, and I appreciate the privilege of discussing this paper. Thank you very much.

Dr R. James Valentine. Thank you, Dr Taylor, for your excellent comments and questions. I certainly agree that a noncompliance rate of 32% is unacceptable for a watchful waiting program, and frankly, we were surprised to learn that such a high proportion of our patients did not return for follow-up in a system that we thought was virtually fail-safe. The vast majority of our patients receive all of their medical care in the VA system, and as I indicated, there were a number of different reasons given for noncompliance. We are mostly concerned about the inadequate communication with these patients, as half did not realize that they had an aneurysm by report. Although these patients are seen by surgical residents, they are checked out by attending faculty who cover the clinics on a full-time basis. It is important to note, however, that most of the noncompliant patients never came back to the vascular clinic. Most of the medical chart notes were written by primary care physicians or physicians' assistants. You are exactly right that a watchful waiting program should not be impugned, and we have taken steps at our institution to ensure significant improvement in this area. However, we took this opportunity to evaluate the impact of noncompliance on a watchful waiting program, and that is really the message of our study. Our data suggest that the individuals who do not follow up on the watchful waiting program, whatever their proportion, are at risk for aneurysm rupture.

I also agree with you that compliance rates can be expected to vary with institutional patient populations. Although our compliance results are certainly not applicable to all patient populations, I submit that the effect of noncompliance is universal. I am not surprised at your estimate of 2% noncompliance in your private hospital and 5% in your clinic population. It is likely that your patients are more highly motivated and probably live closer to the medical center. Transportation was a real problem with our patients who lived an average of more than 1½ hours' driving time from the medical center. On the other hand, medical care is available at no cost to our eligible veterans, and transportation expenses are fully reimbursable. Our compliance rate might have been much worse without these advantages, and I suspect that city/county hospitals with a high proportion of transient or indigent patients would have an even worse compliance problem with their watchful waiting programs.

Your last question was, how do we identify a patient up front whom we believe will be noncompliant? This is obviously not simple, especially since most of the noncompliant patients never came to the vascular clinic. In general, we were able to identify patients with aneurysms who did not keep follow-up appointments through the computerized patient database at our institution. After these patients were contacted, most agreed to begin taking part on a watchful waiting program although it remains to be seen whether they will actually return for follow-up. The secondary compliance rate is currently being monitored. Until these data are known, I would recommend repair for larger aneurysms, 4.5 cm or larger, in patients who still have problems with compliance. Of course, patients who refuse follow-up outright are also likely to refuse aneurysm repair. It is also reasonable to consider patients with transportation problems for early repair, especially those whose aneurysms are approaching the 5-cm threshold.

Dr P. Kevin Zirkle (Knoxville, Tenn). It looked like in the compliant group your overall mortality was about 4% if I read that figure right. You operated on about half, and you had an 8% mortality, operative mortality?

Dr Valentine. Operative mortality was 8% including one patient who died after elective aneurysm repair at an outside institution.

Dr Zirkle. Then in the noncompliant group you had a 13% rupture rate. One of them was repaired successfully, it sounds like, so you had about an 8% or 9% mortality in that group. I was just wondering if there was any statistically significant difference in those two groups.

Dr Valentine. There was actually a 30% mortality in the noncompliant group of the patients whom we could find, and we documented four patients with aneurysm ruptures, three of whom died. The other deaths were due to myocardial infarctions, upper gastrointestinal bleeds, and the like. It is difficult to compare the two groups in order to determine whether you can reduce mortality by operating versus watchful waiting. The numbers are too small, and the study is retrospective in nature. I think the important take-home message is that these patients do rupture their aneurysms if they are lost to follow-up.

Dr Larry Hollier (New York, NY). Jim, I think it is a
very valuable paper for vascular surgeons. In general, I agree with your conclusions and findings on that. There is one area I have some disagreement. I agree with you that patients do not get healthier as they get older, but in the average 3-year follow-up that you had, I understood you to say that 25% developed prohibitive operative risk. I think that is the question—what do you mean by that? In a previous study that I had done at the Mayo Clinic on 106 patients with exceptionally high operative risk, including nonreconstructible coronary disease, recent recurrent congestive heart failure, and oxygen at home, we operated on 106 of these patients, and the mortality rate was 5.7%. I did not think that was prohibitive, and I cannot imagine a population where I would not operate on 25% of the aneurysms. My question is, when you say prohibitive risk, do you mean that they would be inoperable? That is very similar to the number that Vaughn Ruckley came up with in the Scottish trial where they turned down 24% of their patients that walked in the door as being too high a risk. Endovascular grafts may make this a moot point, but I would like for you to clarify that a bit.

Dr Valentine. Sure. As you mentioned, a large percentage of patients in the UK Small Aneurysm Trial were turned down for surgery, and their aneurysms grew to larger than 5.5 cm in about half the cases. A significant number of these patients had aneurysm ruptures, so we were somewhat nervous about turning down these patients with advanced illness for operation. In our patients with advanced medical illness, four had refractory coronary ischemia; that is, unstable angina, congestive heart failure, and ejection fractions less than 20%. Our cardiologists felt that these patients had a mortality rate from general anesthesia of around 50%. There were also some people with severe COPD who were on home oxygen with PO2 averaging in the 40s to 50s, and with pCO2 in the 60s. Although some of those patients might have been able to get through an operation, they would have required long-term ventilation and hospitalization. We had two other patients who developed intra-abdominal abscesses unrelated to their aneurysms who were felt to be prohibitive risks for any kind of graft placement, and they ultimately died from long-term abscess complications. Overall, all of us in this room would have regarded these patients as too ill for operation.