Costs of repair of abdominal aortic aneurysm with different devices in a multicenter randomized trial

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Objective: **Prior analysis in the Open vs Endovascular Repair Veterans Affairs (VA) Cooperative Study (CSP #498) demonstrated that survival, quality of life, and total health care costs are not significantly different between the open and endovascular methods of repair of abdominal aortic aneurysm. The device is a major cost of this method of repair, and the objective of this study was to evaluate the costs of the device, abdominal aortic aneurysm repair, and total health care costs when different endograft systems are selected for the endovascular repair (EVR). Within each selected system, EVR costs are compared with open repair costs.**

Methods: **The study randomized 881 patients to open (n = 437) or EVR (n = 444). Device selection was recorded before randomization; therefore, open repair controls were matched to each device cohort. Data were excluded for two low-volume devices, implanted in only 13 individuals, leaving 423 control and 431 endovascular patients: 166 Zenith (Cook Medical, Bloomington, Ind), 177 Excluder (W. L. Gore & Associates, Flagstaff, Ariz), and 88 AneuRx (Medtronic, Minneapolis, Minn). Mean device, hospitalization, and total health care costs from randomization to 2 years were compared. Health care utilization data were obtained from patients and national VA and Medicare data sources. VA costs were determined using methods previously developed by the VA Health Economics Resource Center. Non-VA costs were obtained from Medicare claims data and billing data from the patient's health care providers.**

Results: **Implant costs were 38% of initial hospitalization costs. Mean device (range, \$13,600-\$14,400), initial hospitalization (range, \$34,800-\$38,900), and total health care costs at 2 years in the endovascular (range, \$72,400-\$78,200) and open repair groups (range, \$75,600-\$82,100) were not significantly different among device systems. Differences between endovascular and corresponding open repair cohorts showed lower mean costs for EVR (range, \$3200-\$8300), but these were not statistically different.**

Conclusions: **The implant costs of endovascular aneurysm repair are substantial. When evaluating total health care system expenditures, there is large individual variability in costs, and there is no significant difference at 2 years among systems or when an individual system is compared with open repair. (J Vasc Surg 2015;61:59-65.)**

Efforts to contain health care costs have gained greater prominence, and physicians are in a pivotal role of determining which treatments their patients receive. Endovascular repair (EVR) of abdominal aortic aneurysms (AAAs) is particularly visible, with high volume and very high device cost. Victor Fuchs has stated,

> *The role of new medical technology deserves special attention in thinking about future health care spending because biomedical innovations as a whole have been the primary source of both improvements in health and increasing expenditures. On the one hand, it is fiscally irresponsible to continue to accept innovations regardless of cost, even if they pass tests of safety and efficacy—and it is particularly irresponsible when the interventions are provided at public expense. On the other hand, we must avoid an innovation policy that cuts off new interventions prematurely.*[1]

Several randomized trials have demonstrated similar long-term survival and quality of life when AAAs are electively repaired by EVR or open methods.[2-4] Comparisons of costs have been evaluated with contrasting results, with some studies showing cost-effectiveness of EVR, and others finding EVR was more costly.[2,5-7]

The Department of Veterans Affairs (VA) Open vs Endovascular Repair (OVER) trial (ClinicalTrials.gov number, NCT00094575) reported a comparison of costs at 2 years between EVR and open repair of AAA. Specifically, mean graft costs were higher with EVR (\$14,052 vs \$1363; $P<.001$), but length of stay was shorter (5.0 vs 10.5 days; $P<.001$), with the result that the mean AAA repair hospitalization cost is less with EVR (difference, \$5901; 95%

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*Participants in the study group are listed in the Appendix (online only).

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Table I. Mean and median costs of abdominal aortic aneurysm (AAA) repair by device selected and randomized assignment

Variable	*Zenith*[a]	*Excluder*[b]
EVR (n = 431), No.	166	177
Mortality rate, %	6	6
Implant, mean (SD), $	14,400 (2600)	13,600 (3800)
Initial hospital, mean (SD), $	38,100 (27,500)	34,800 (31,200)
Total cost at 2 years, $		
Mean (SD)	78,200 (60,200)	73,500 (65,100)
Median (IQR)	62,000 (48,000-85,400)	54,100 (39,400-76,300)
Open (n = 423), No.	175	150
Mortality rate, %	9	11
Total cost at 2 years, $		
Mean (SD)	82,100 (113,800)	81,800 (84,500)
Median (IQR)	57,000 (36,100-85,400)	56,800 (39,600-88,800)
Difference EVR − open, $ (95% CI)	−3900 (−27,800 to 11,400)	−8300 (−27,100 to 6000)

CI, Confidence interval; *EVR,* endovascular repair; *IQR,* interquartile range; *SD,* standard deviation.
[a]Cook Inc, Bloomington, Ind.
[b]W. L. Gore and Associates, Flagstaff, Ariz.
[c]Medtronic, Minneapolis, Minn.

confidence interval [CI], $821-$12,135). Further, total health care costs were not significantly lower with EVR (difference, $5019; 95% CI, −$4928 to $16,720).[5]

We studied device, hospitalization, and total health care costs when different devices are used for EVR to inform physicians on the cost implications of device selection.

METHODS

The general methods, clinical outcomes, and cost-effectiveness of the OVER trial have been reported previously in detail.[4,5] The study was approved by a central human rights committee and the Institutional Review Boards at each participating center. Informed consent was obtained from all participants. Between October 2002 and April 2008, 881 patients were randomized at 42 VA medical centers: 444 to EVR and 437 to open repair. There was no statistically significant difference between the groups in major morbidity, reintervention, aneurysm-related hospitalization, or health-related quality of life.

The device system was selected and documented by the local investigator before randomization, and so open control patients correspond with each device cohort. Data were excluded for two low-volume devices that were implanted in only 13 patients. The clinical trial database of OVER patients was linked to national VA and Medicare databases to obtain information on health care utilization and cost. The device components used for each patient were recorded in the OVER case report forms, and prices were obtained from the VA's National Patient Prosthetics Database. This did not include backup devices that were not implanted.

Hospitalization costs of AAA repair were obtained from the VA Decision Support System (DSS) National Data Extracts.[8] The DSS combines data from accounting, payroll, patient care, and administrative sources to calculate costs, which can be categorized in six mutually exclusive categories: surgery, nursing, laboratory, radiology, pharmacy, and others. Each of these includes fixed direct costs that are related to the direct provision of care and do not vary by volume, such as clerical personnel and nursing supervisor time, and fixed indirect costs that are indirectly related to care and do not vary by volume, such as building maintenance, housekeeping, engineering, and administration. These costs are assigned per diem according to individual length of stay.

Local VA electronic medical records were used to identify VA utilization data, including other hospital stays, outpatient visits, contract care, and outpatient medications acquired from VA. These data were obtained from the VA Medical SAS Inpatient and Outpatient Datasets extracted from the National Patient Care Database, which captures information from local electronic medical records.[9,10] Fee basis files captured care provided to VA patients by contract providers outside of VA facilities.[11]

Nonrepair hospitalization costs were obtained from the VA Health Economics Resource Center (HERC) average cost data sets,[12-14] which are modeled from Medicare claims data and adjusted to costs using cost-to-charge ratios from reports to the Center for Medicare and Medicaid Services.[12] Costs for nonacute hospital stays (eg, rehabilitation, mental health, and long-term care) were calculated from length of stay and average daily cost from the DSS National Data Extracts. Costs for VA outpatient visits were based on reimbursement rates of Medicare and other payers. Prescriptions costs were based on the VA's acquisition and dispensing costs from the VA DSS National Data Extracts Pharmacy Datasets.[15]

Non-VA health care utilization was obtained from Medicare claims data and from patient reports verified with billing data from the facilities where care was received. Costs were estimated by multiplying the Medicare charges by the hospital-specific cost-to-charge ratios.[16] Total health care costs were summed from all of the above; that is, the VA and private-sector providers. Costs were adjusted to 2008 United States dollars with the Consumer Price Index.

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