Improved Efficiency and Safety for EVAR with Utilization of a Hybrid Room ☆

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WHAT THIS PAPER ADDS
This study is novel in that it shows for the first time inherent differences in doing endovascular aneurysm repair with a standard fluoroscopy versus hybrid operating room setup. The implication is that ultimately a hybrid room may be safer and more efficient in the long run, and perhaps a valued investment by hospitals across the world.

Objective: Access to a hybrid endovascular suite is touted as a necessity for advanced endovascular aneurysm repair (EVAR) to improve imaging accuracy and safety. Yet there remain little data documenting this intuitive advantage of a hybrid setup versus a traditional operating room (OR) utilizing a portable fluoroscopic unit (C-arm) for imaging. We hypothesized that standard elective EVAR performed in a hybrid suite would improve procedural efficiency and accuracy, as well minimize patient exposure to both contrast and radiation.

Methods: We retrospectively reviewed a single attending surgeon's EVAR practice, which encompassed the transition to a hybrid endovascular suite (opened July 2010). Only consecutive abdominal aneurysms were included in the analysis to attempt to create a homogenous cohort. All emergent, aorto-uni-iliac (AUI), snorkel, fenestrated, or hybrid procedures were excluded. Standard variables evaluated and compared between the two study subgroups included fluoroscopy time, operative time, contrast use, stent-graft component utilization, complication rates, and short-term endoleaks.

Results: From January 2008 to August 2012, we performed 213 EVAR procedures for abdominal aortic aneurysms. After excluding emergent, AUI, snorkel, or hybrid procedures, we analyzed 109 routine EVARs. Fifty-eight consecutive cases were done in the OR with a C-arm until July 2010, and the last 51 cases were done in the hybrid room. Both groups were well matched in terms of demographics, aneurysm morphology, and procedural characteristics. No difference was found in terms of complication rates or operative mortality, although there was a trend towards decreased fluoroscopy time, type I/III endoleaks, and a number of additional endograft components utilized. Compared with patients repaired in the OR/C-arm, EVAR done in the hybrid room resulted in less total OR time and contrast usage ($p < .05$).

Conclusions: Routine EVAR performed in a hybrid fixed-imaging suite affords greater efficiency and less harmful exposure of contrast and possible radiation to the patient. Accurate imaging quality and deployment is associated with less need for additional endograft components, which should lead to improved cost efficiency. Confirmation of these findings might be necessary in a randomized control trial to fully justify the capital expenditure necessary for hybrid endovascular suites.

INTRODUCTION

Contemporary vascular surgery has seen dramatic changes in the last two decades owing to the advances in image-guided and catheter-based interventions. The field of endovascular surgery and its application towards aneurysm treatment changed when endovascular aneurysm repair (EVAR) was first reported.[1] Since then, the number of open

vascular cases reported by trainees has been declining, while endovascular cases have taken over as the majority of procedures done for patients with vascular disease with improvement in morbidity and mortality.[2–4] Historically, most vascular surgeons began their endovascular efforts using a portable fluoroscopic unit or C-arm in the operating suite. This occurred often owing to availability, comfort, sometimes turf battles, and ease of scheduling. Anecdotally, a C-arm imaging was often not precise enough to perform more complicated cases as the technology rapidly improved to include fenestrated grafts, small vessel catheterizations, and the need for intraoperative cross-sectional or rotational imaging. Further, C-arms have only a finite time of use before overheating, adding time for cool-down in what can already be a time-consuming procedure. Finally, potential

risk to the patient in terms of radiation scatter is still being accurately measured and studied, as studies have found radiation exposure to simply be a function of complexity of the EVAR cases, although often minimized when the operating surgeon has control of the table and controls.[5–7]

As the procedures became more complex and experience improved, it became clear that a dedicated interventional suite with fixed imaging was necessary to provide optimal care for patients. Having a dedicated operating room and interventional suite-trained staff also became vital to the success of programs given the differences in equipment needed, as well as the language of wires, catheters, and instruments. More often, vascular surgeons performed so-called "hybrid" procedures with partial open techniques and equipment, and concomitant endovascular portions. To combat these limitations, the "hybrid operating room (OR)" was developed, using state-of-the-art fixed-imaging fluoroscopy in rooms equipped to handle all aspects of an open and endovascular intervention.[8] While there seems to be an intuitive advantage to this setup, there remains a paucity of data documenting the value and efficacy of a hybrid room. Prior studies document that EVAR with a C-arm is acceptable, and may even be the primary mode in many centers, but the use of a hybrid suite is likely to improve upon its deficiencies. The purpose of this study was to determine whether utilizing a hybrid OR setup was warranted for EVAR, and hypothesized that standard elective EVAR performed in a hybrid suite is safe, would improve procedural efficiency and accuracy, and would minimize patient exposure to both contrast and radiation.

METHODS

Consecutive EVAR was retrospectively reviewed in our prospectively maintained aneurysm database from a single surgeon (JTL) from 2008 to 2012 at our tertiary care referral center. Only one surgeon's data were included to ensure a standardized approach to EVAR to account for any differences in the cohort. Only elective standard anatomy abdominal aortic aneurysms (AAA) repaired with an endograft were included in the study to minimize heterogeneity and complexity of the cases. Therefore, patients undergoing emergent, debranching, thoracic, snorkel, and fenestrated cases were all excluded. Additional patient and case information, including demographics, comorbidities, and outcome variables were obtained through review of inpatient and outpatient clinical records.

The hybrid endovascular suite at our institution went into use in mid-2010; thus, patients prior to this time were identified as undergoing EVAR using a C-arm in the OR (C-arm), and those after as undergoing EVAR using the hybrid suite (hybrid). The C-arm group had EVAR performed in a standard OR with imaging captured utilizing an OEC 9800 (General Electric, Fairfield, CT, USA). The hybrid group had EVAR performed in our hybrid OR with fixed imaging captured utilizing an Artis Zee biplane system (Siemens, Washington, DC, USA). Procedures were typically done under general anesthesia with standard OR and

Table 1. Device types.

	Operating room/C-arm (n = 58)	Hybrid (n = 51)
Endologix	1	0
Gore	15	20
Medtronic	5	14
Cook	37	17

interventional suite staff and equipment for both groups. Access approach (percutaneous or open) was dictated by the patient's anatomical factors.

Choice of endograft (Table 1) also was determined according to the patients' anatomy and included the Zenith Flex (Cook Medical, Bloomington, IN, USA), Endurant (Medtronic, Santa Rosa, CA, USA), Excluder/C3 (W.L. Gore, Flagstaff, AZ, USA), and AFX (Endologix, Irvine, CA, USA). All preoperative planning from 2008 to 2012 was done by an experienced attending surgeon (JTL) on a three-dimensional (3D) workstation (TeraRecon, Foster City, CA, USA) utilizing centerline measurements to accurately plan out procedures and components necessary to safely exclude the aneurysm in question. Intravascular ultrasound was used rarely in patients with renal insufficiency, but occurred in equal numbers in both cohorts (<2% of the time).

Variables evaluated in both study periods were mean fluoroscopy time, mean operative time, contrast usage, complication incidence, and endoleaks in patients having EVAR performed in the OR with C-arm versus in the hybrid suite. Additional components per patient was calculated depending on the theoretical "perfect" utilization of modular endografts with either one or two docking limbs. In an optimal configuration, utilization of single docking limbs (Gore; Medtronic) needs only two pieces total, while grafts with unibody (Endologix) or two docking limbs (Cook) require three pieces. In order to accurately account for differences in types of endografts used, we calculated excess pieces utilized compared to the optimal number of components.

Subset analysis was performed to identify any differences for learning curve, even though the senior author had experience of over 500 EVAR cases since the study began. Thus, each cohort was split into two groups, early (the first half for OR/C-arm and the first half for hybrid) and late (second half for OR/C-arm and second half for hybrid). The same variables were then further analyzed in each group. All data were collected and statistical analyses performed using Excel 2007 (Microsoft, Redmond, WA, USA). Paired t tests and Wilcoxon rank sum test or Fisher's exact test were used to test for statistical differences between groups, where appropriate, with values of $p < .05$ considered significant.

RESULTS

From January 2008 to August 2012, 260 endograft procedures were performed by a single surgeon, 82% of which were done for AAA. Of these 213 AAA patients, 109

Table 2. Baseline demographics.

	OR/C-arm (n = 58)	Hybrid (n = 51)	p
Patient age	75.3	75.9	NS
Female gender (%)	17.2	23.5	NS
Aneurysm size (mm)	60.4 (±14.6)	60.2 (±12.2)	NS
Proximal aortic neck (mm)	24.1 (±11.2)	23.4 (±10.9)	NS
Percutaneous (%)	67.2	66.6	NS
Total EVAR components	3.0	2.6	.003
Additional components/patient	0.38	0.31	NS
Femoral patch/bypass (%)	8.0	15.0	NS
Contrast dose (mL)	106.6 (±51.9)	76.3 (±26.2)	.0001
Fluoroscopy time (min)	27.7 (±18.4)	24.9 (±12.4)	NS
Total OR time (min)	145.6 (±65.8)	115.1 (±48.3)	.007
Type 1 or 3 endoleak at 30 days (%)	5 (13.7)	1 (1.9)	NS

Note. EVAR = endovascular aneurysm repair; OR = operating room; NS = not significant.

consecutive patients were identified as undergoing routine EVAR for infrarenal AAA after exclusion criteria were applied. This formed the study cohort, and was divided into the OR/C-arm group from 2008 to 2010 (n = 58) and the hybrid group from 2010 to 2012 (n = 51). Both groups were well-matched for demographics, aneurysm morphology, and procedural characteristics (Table 2). The mean age of the cohort was 75.9 years for the hybrid group and 75.3 years for the OR/C-arm group (p = not significant [NS]) and mean aneurysm size was 60.2 and 60.4 mm, respectively (p = NS). There was also no difference in the proportion of patients undergoing percutaneous or open exposure, as well as need for femoral reconstruction at the conclusion of EVAR. There was a significantly lower amount of contrast required (76.3 vs. 106.6 mL, p < .05; Table 1; Fig. 1) and less total OR time (115.1 vs. 145.6 minutes, p < .05; Table 1; Fig. 2) for hybrid versus OR/C-arm. There was no difference in mean additional EVAR components utilized between the hybrid and OR/C-arm cohorts (0.31 vs. 0.38; Table 1), nor large difference in fluoroscopy time measured in minutes (Fig. 3). However, there was a slight trend towards improvement in the hybrid group for these two variables. Subset analysis for early versus late EVAR in either OR/C-arm versus hybrid group showed no differences, indicating no learning curve issues in the new room (Table 3).

In terms of postoperative issues, there was no difference between the cohorts in endoleaks at 30-day follow up (Table 2). There was also no difference in the incidence of postoperative complications in each group, which included three patients in the OR/C-arm group (5.2%) and one in the hybrid group (2.0%) with renal insufficiency from proximal fabric issues of the stent-graft encroaching on the renal artery leading to unilateral renal ischemia, although no patients required postoperative or long-term hemodialysis. There were also two myocardial infractions (3.4%) in the OR/C-arm group and one stroke (2.0%) in the hybrid group. There was one iliac limb thrombosis requiring open thrombectomy in the OR/C-arm group and one iliac artery rupture upon placing the main body of a device in the hybrid group. Both these patients required revascularization but suffered no other long-term complications. Overall 30-day mortality was 0% for both groups (Table 4).

DISCUSSION

Our experience with EVAR performed in a hybrid endovascular suite has proven to be beneficial in multiple tangible ways, and we believe it should be the standard for modern vascular and endovascular surgical procedures and practices. The efficiency in performing these now-routine procedures, both in a temporal and economical sense, was enhanced when using a fixed-imaging suite. We were able to reduce our total operative time by more than 30 minutes per procedure. Although often difficult to quantify, the cost per OR minute may be up to $20 for a basic surgical procedure.[9] With increasing pressures currently to reduce the costs of healthcare delivery in the USA, as well as the rising number of EVARs performed over open surgery, the potential benefit of reducing total operative time should have economic benefits.

One of the main contributors to overall cost of EVAR is related to the number of endograft components utilized during a case.[10] While improved preoperative planning using 3D workstations contributes to minimal surprises during a case and having a solid preoperative plan, accurate intraoperative measurements and markings can contribute to minimizing errors in covering optimal landing zones. Even when we controlled for the "ideal" number of pieces based on manufacturer's configurations, the OR/C-arm group used more total components, and slightly more additional components than in the hybrid group (Table 2). Accurate first
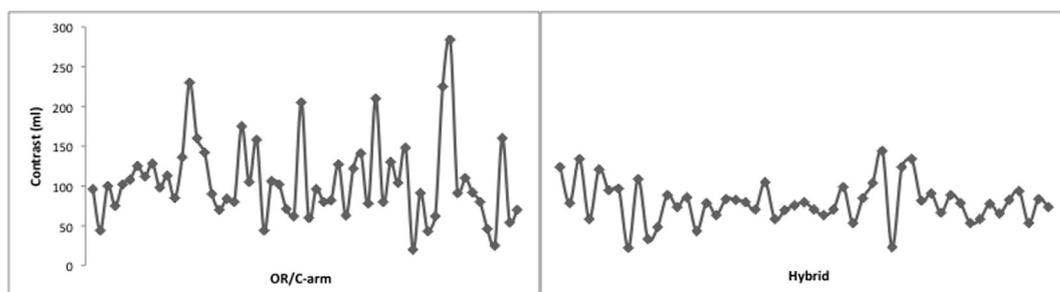

Figure 1. Temporal relationship of contrast utilized for consecutive patients in the operating room (OR)/C-arm group (left panel) and hybrid group (right panel).
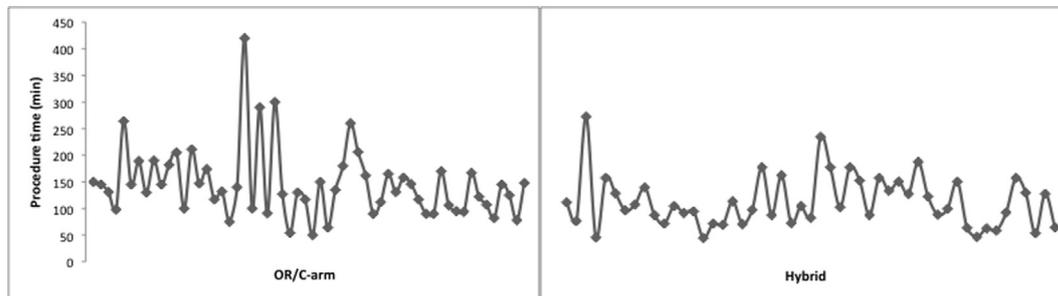
Figure 2. Temporal relationship of procedure time for consecutive patients in the operating room (OR)/C-arm group (left panel) and hybrid group (right panel).

time deployment of components leads to fewer adjunct cuffs and limbs during EVAR, and we believe the improved imaging in the hybrid room maximizes the accuracy.

Improved imaging and its effects on accurate deployment of devices also should, theoretically, affect postoperative EVAR complications, and we did note a trend towards lower number of type 1 and 3 endoleaks in the hybrid group. This finding, if corroborated in other future studies, would have important implications, as endoleaks can lead to costly future secondary interventions.

Besides reduced operative time, a slightly fewer number of components and possible cost savings,[11] we demonstrated in our transition to the hybrid room a reduction in the mean contrast usage. Many patients undergoing EVAR already have intrinsic kidney disease or even chronic kidney disease (CKD) and will have a higher mortality when undergoing AAA repair.[12] Contrast used for any endovascular procedures is known to exacerbate renal failure, and judicious use is prudent, specifically in this patient population. In the hybrid study period, nearly a third less contrast was used, on average, which we believe was a result of improved imaging quality and ability to save reference images to deploy components. There was also less variability in use of contrast in the hybrid group (Fig. 1), again likely secondary to enhanced imaging and more uniform imaging sequences. Further studies will be necessary to see if this contrast saving during the index procedure translates to improved protection from CKD in long-term follow up after EVAR.

Although we hypothesized that fluoroscopy time and therefore radiation would be less, we were not able to demonstrate a statistically significant difference during the hybrid study period. We acknowledge that minutes of fluoroscopy time is only a marker for radiation exposure, and

certainly more important is the milligray exposure,[13,14] which even newer hybrid OR rooms are now measuring. We postulate that the hybrid room will have better shielding, less scatter, and therefore improved safety provided to the surgeons, ancillary staff, and patients. We are currently measuring prospectively during all endovascular cases milligray of radiation exposure to document the inaccuracy of total number of minutes as a surrogate measure of radiation exposure.

Finally, the transition to the hybrid OR room did not lead to increase in wound or traditional operative complications. Approximately one third of cases in both groups required open femoral cutdown for delivery of the endoprosthesis and were equally feasible in both the OR setting and the endovascular suite without increases in postoperative wound infections or seromas. In fact, we performed more adjunctive procedures (iliac artery conduits and femoral patch angioplasty for iliofemoral occlusive disease) in the hybrid group and were able to do these without significant complication. Other morbidity (cardiac, limb complications) were on par with those reported in other large case studies and, to reiterate, the relative success of our routine EVAR program was shown by having no mortality in either cohort.[15]

There are obvious limitations to this retrospective study. This is a single center, single surgeon review, which has biases related to patient selection, applicability towards other practices, and that this constituted only 40% of this surgeon's endovascular aneurysm practice. Confirmation of these findings is likely necessary in other reports—perhaps a prospective, randomized trial to fully justify the expenditure needed to build a state of the art endovascular hybrid suite. Further, we compared consecutive routine cases, while also performing more complicated cases, and any historical control will always be subject to learning
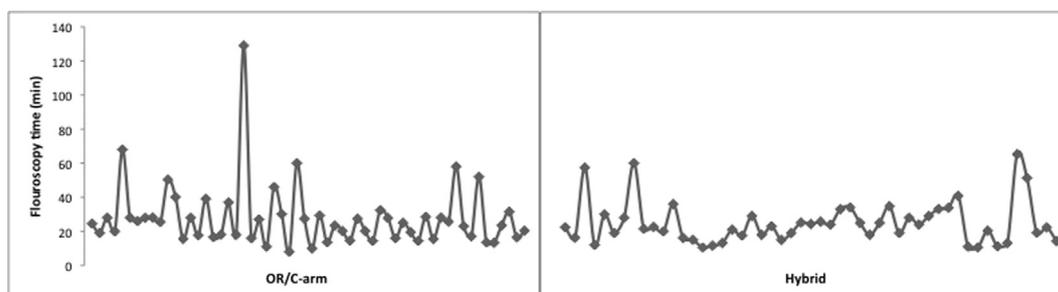

Figure 3. Temporal relationship of fluoroscopy time for consecutive patients in the operating room (OR)/C-arm group (left panel) and hybrid group (right panel).

Table 3. Baseline demographics showing results split into early (first half of cohort) and late (second half of cohort).

	OR/C-arm early (n = 29)	OR/C-arm late (n = 29)	p
Patient age	76	74.9	NS
Aneurysm size (mm)	58.0	63.5	NS
Proximal aortic neck (mm)	25.0	23.3	NS
Total EVAR components	3.0	3.3	NS
Contrast dose (mL)	111.0	102.6	NS
Fluoroscopy time (min)	32.0	23.3	NS
Total OR time (min)	163.0	128.6	NS
	Hybrid early (n = 26)	Hybrid late (n = 25)	p
Patient age	77.2	74.5	NS
Aneurysm size (mm)	59.3	61.1	NS
Proximal aortic neck (mm)	24.0	22.8	NS
Total EVAR components	2.5	2.8	NS
Contrast dose (mL)	75.5	77.1	NS
Fluoroscopy time (min)	23.2	26.6	NS
Total OR time (min)	107.8	122.7	NS

Note. EVAR = endovascular aneurysm repair; OR = operating room; NS = not significant.

curve biases. This was minimized in our analysis of each cohort in terms of the first and second half being equivalent, as well as the fact that this group performed nearly 500 EVAR cases from 2004—2007.

In summary, we report that using an endovascular hybrid room with fixed imaging is associated with significantly better intraoperative imaging and precision, improved patient safety, more efficient operating time, and improved outcomes. Since the preliminary results of this study, we have significantly broadened the case mix in the hybrid room with tremendous success, to even include median sternotomy with antegrade thoracic stent-graft placement for arch aneurysms. We have developed a regional aortic referral center to repair more complex aortic pathology in the hybrid room, nearly always requiring a mix of open and endovascular techniques. As more complicated procedures are undertaken by the vascular workforces,[16] we feel it would be a disadvantage and in many ways potentially dangerous to perform these without the optimal imaging and durability a hybrid room provides. With endovascular procedures, particularly for aneurysms, success is measured in millimeters, and a portable fluoroscopic unit is a far cry

Table 4. Postoperative complications.

	Operating room/C-arm (n = 58)	Hybrid (n = 51)
Morbidity		
Myocardial infarction	2 (3.4%)	0
Cerebrovascular accident	0	1 (2.0%)
Renal insufficiency	3 (5.2%)	1 (2.0%)
Renal failure	0	0
Limb thrombosis	1 (2.0%)	0
Arterial rupture	0	1 (2.0%)
Mortality	0	0

from the precision needed to ensure patient safety and technical perfection.

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