Eur J Vasc Endovasc Surg **35**, 198–204 (2008)
doi:10.1016/j.ejvs.2007.08.009, available online at http://www.sciencedirect.com on ScienceDirect

REVIEW

The Creation of the Optimal Dedicated Endovascular Suite

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Background. *During the last decade endovascular therapy has been established as an alternative treatment for a variety of vascular diseases. Neither the classic operating room (OR), nor the conventional angiography suite is optimal for both open surgery and endovascular procedures. Important issues include: quality of the imaging equipment, radiation burden, ease of use of the equipment, need for specially trained personnel, ergonomics, ability to perform both open and percutaneous procedures, sterile environments, as well as quality and efficiency of patient care.*
Methods. *A literature search identified articles pertinent to the key issues during the decision-making process of creating the optimal endovascular suite. Manual cross-referencing also was performed.*
Results and conclusion. *The most important feature of working in a dedicated endovascular suite should be the ability to attain best treatment of vascular patients. Whether the interventional radiologist or the vascular surgeon uses the facilities is of less importance. A fixed fluoroscopy unit is preferred, above a portable C-arm. Establishment of an endovascular operating room suite has the benefit of a sterile environment, the possibility of performing hybrid procedures and conversions when necessary. Moreover, angiography immediately before treatment gives contemporary anatomical information, and after treatment provides quality control. As a consequence, better quality and service can be provided to the individual patient.*

Keywords: Endovascular suite; Angiosuite; Fluoroscopy; Minimally invasive; Vascular surgery.

Introduction

The ongoing development in endovascular procedures has changed vascular practice dramatically. This has led to the need of a new type of vascular specialist, who can handle both endovascular, as well as open surgical procedures.[1] It is not surprising that this leads to new demands on the working environment. Neither the classic operating room (OR), nor the conventional angiography suite is optimally suited for both open surgery and endovascular procedures. Several scenarios may be considered in order to find a balance between the sometimes conflicting needs of endovascular procedures and open vascular surgery: modification of an angiography suite to meet OR standards, adaptation of the OR by use of a portable C-arm and a carbon fiber table, or more rigorous refurbishment of the OR by adding fixed imaging equipment (Fig. 1). In decision making on this topic, several matters are of importance: quality of the imaging equipment, radiation burden, ease of use of the equipment, necessity for specially trained personnel, ergonomics, ability to perform both open and percutaneous procedures, sterility issues, as well as quality and efficiency of patient care.

During the decision-making process of creating the optimal endovascular suite, it is helpful to keep the following questions in mind, as stated earlier by Fillinger *et al.*:[2] what procedures are to be performed, how often and by whom? This implies that different hospitals might come to different definitions of their own optimal endovascular suite. In this manuscript the key issues in this decision process are discussed.

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1078–5884/000198 + 07 $34.00/0

Fig. 1. Endovascular suite integrated in the operating room comprising a biplane digital substraction angiography unit with multipurpose surgical capabilities.

Limitations of the Conventional Angiography Suite

Sterility issues

It is obvious that sterility in an OR is superior to that in an angiography suite.[3,4] Several prerequisites have been identified to reduce the risk of infection: a sufficient number of air exchanges per hour, positive air pressure, optimal temperature and humidity, easily washable ceilings, walls and (seamless) floors.[5,6] In standard operating rooms, these conditions are met. However, it is questionable whether such sterile environments are required for every vascular intervention, particularly when considering endovascular stent-grafts.

Little is known about the incidence of infection of endovascular stent-grafts, although it is obvious that this is a rare complication. From the few studies reporting this end-point, an incidence of about 0.5% can be deduced.[4,7,8] In most hospitals endovascular stent-graft placement is performed in the sterile conditions of the operating room. It is unclear whether the incidence of graft infection would be higher if procedures were performed in angiography suites. Katzen *et al.*,[9] describing the results after conversion of an angiography suite to an endovascular suite, mention a major infection rate of 2.5% and a minor infection rate of 5%. Since the consequences of graft infection can be dramatic, sterility may be an important issue.

Another point of consideration is the impact of the choice of a portable or fixed fluoroscopy unit on sterility. When choosing a floor mounted fluoroscopy unit and/ or table, sterility problems might arise after blood spillage, due to cleaning problems of the floor connection points. Any blood-trapping ridge can act as a refuge for bacteria. Optimal covering of equipment and cleaning therefore is essential. Ceiling-mounted equipment is less prone to these problems. However, it is thought that large ceiling-mounted image intensifiers influence air-flow in operating rooms with a negative impact on sterility.[10]

Ability to convert

The majority of endovascular procedures are performed without major intra-operative complications. However, an increasing number of challenging cases are scheduled for endovascular treatment. This implies that the total number of conversions may rise, due to the technical impossibility of performing a ''closed'' procedure, or due to complications during the procedure. A recent review showed a pooled estimate for primary conversion to open repair of 3.8%.[11] Acute open surgery in an angiography suite is far from ideal; lack of adequate lightning, suction, surgical and anaesthetic equipment and room for surgical instruments, and the extra personnel can make even small procedures challenging. It is clear that it would be preferable to convert *in situ* without moving the patient.

Anaesthesia

Although endovascular procedures are minimally invasive, adequate monitoring of the cardiopulmonary system is essential in certain procedures. For example during carotid artery stenting, severe blood pressure problems might occur, which in turn are directly related to an increased number of cerebral complications.[12] Therefore, the presence of an anaesthesiologist, a specialized nurse and all anaesthetic equipment seem to be of major importance. Conventional angio-suites may be too small to introduce anaesthetic equipment without increasing the risk of problems concerning sterility.

Ergonomics

The introduction of endovascular procedures in the OR has changed the way vascular surgeons perform their procedures. They no longer are looking at the patient's anatomy directly, but at images on a video screen. Poor ergonomics is one of the major drawbacks of mobile systems.[13] Usually, only two screens are available on a single cart. Using carts, the screens always are located outside the operating field, leading

to inferior ergonomic conditions. Ideally, a monitor should be placed just below eye level, because the angle of view is 10° downwards, when looking with relaxed neck muscles. The screens should be placed in a straight line with the operator's position, but the assisting personnel also should be able to view the screens without taking an uncomfortable position. This implies that there should be monitors on both sides of the table. Ceiling-fixed monitors have the advantage that they can be placed in a great range of positions, without claiming space on the floor of the operating room. Adjustment of the position of these monitors is easier too.[14]

Another drawback of mobile systems is that they have to be moved into the OR before the procedure. Video cables and electrics have to be positioned and connected. They usually lie on the floor of the OR which may hinder smooth adjustments of positioning of the C-arm or cart-based monitors. This is time consuming and potentially harmful for both patient and personnel.

A carbon fibre table is preferred and should be considered essential when working with a portable C-arm.[2] Advantages of a carbon fibre table include reduction of radiation, improvement of the imaging quality and reduction of the radiation burden to personnel. When choosing for fixed carbon fibre table that can be controlled by a table-side console, one should realize that these tables are broad and therefore working in the groin area and at the lower extremities may be awkward. Patient transfers are less convenient using these broad tables. Modern tables, however, have a table top that can be moved longitudinally, away from the broad part, over such a distance that the patient easily is accessible. This requires sufficient space in the operation room, and anticipation when placing anesthetic equipment. Furthermore, one should realize that these ''radiologic'' tables are not supplied with side bars on the narrow part; these are useful for connection of retractor systems or armrests. Finally, although an operation table that could bend in the middle would be useful, especially for hybrid procedures, such constructions can only be built by using metal non-radio-opaque articulations, which to our knowledge are not available commercially. As a result, until now only two planes of tilt, craniocaudal and lateral, have been possible.

Imaging Equipment

The increasing number of patients with challenging anatomy, who have endovascular treatment necessitates very accurate images. When deploying grafts near aortic side branches, placement of fenestrated grafts or grafts with side branches, imaging quality can make the difference between success and disaster.[15] After surgery, completion studies are increasingly appreciated, in order to assess the result of the procedure and allow immediate adjustments in cases of suboptimal outcome.[16,17]

It is obvious that imaging quality is dominated by the quality of the fluoroscopy unit. Available systems can be divided roughly into two categories: portable or fixed C-arm units. Both systems have advantages and disadvantages, discussed below.

Image quality

For the quality of angiography units, one should compare the imaging quality of the entire systems. The whole process of image acquisition, data processing and final display determines unit quality. This implies that the quality of the unit is defined by the weakest link in the system. Usually the monitor resolution of a unit is very high, and therefore the quality is defined by the image intensifier and the processing system. Manufacturers of angiography units usually express the resolution of the system in line pairs per mm. However, this is usually the best resolution, in the centre of the image intensifier using the highest magnification.

The image quality of fixed systems is usually superior to portable systems. This is explained mainly by the focal spot size of the X-ray tube; the focal spot sizes of fixed systems are significantly smaller than those of portable units.[18,19] A smaller focal spot size means higher resolution through more line pairs per millimeter. Nevertheless, the latest portable C-arm systems are able to reach resolutions up to 2.5–3 line pairs per mm, values which only could be attained by fixed systems until recently. Furthermore, monitor resolution of fixed systems differs from portable systems, with the monitors of fixed systems usually having twice the lines of resolution as the monitors of portable systems.[2]

Fixed and portable systems generators are another issue. Portable systems have a smaller generator in order to keep the system ''practical''. In fixed systems, a large remote generator provides more power, with better tissue penetration and improved imaging quality.[18] Despite these differences, the newest, state-of-the-art portable C-arm units have been improved enormously, in many ways. Currently, portable C-arm systems are able to provide sufficient quality for the majority of the standard procedures in vascular surgery. However, the more complex procedures

seem to benefit from the superior quality of fixed systems.

Field of view

The size of the image intensifier determines the field of view: the larger the size, the larger the field. Standard portable C-arms used to be equipped with 6 inch image intensifiers. However, today portable systems with image intensifiers of up to 12 inch are available. In fixed systems, much larger intensifiers can be used. This has obvious advantages; within a single shot there is a general view of a large area, obviating repeated repositioning of the C-arm. This leads to a calmer procedure, less radiation and less physical effort in the case of portable systems. Furthermore, a large field of view is essential when performing endovascular aneurysm repair. During the deployment of the endovascular graft it is desirable to be able to see the whole graft in a single view. Especially when using devices that are not fixed proximally immediately (due to a top cap), one needs to monitor the proximal position, while deploying the endovascular stent-graft until the contra-lateral limb has been opened. When bifurcated endografts are being positioned, an intensifier of at least 12 inch is desirable.

Image acquisition and display

For radiographic imaging of the arterial system, digital subtraction angiography (DSA) is the gold standard. All modern imaging units are equipped with this feature, which eliminates static elements, resulting in imaging of contrast-filled vessels only. Due to this post-processing, less contrast is necessary. Other features simplifying endovascular procedures are road-mapping and the opportunity to perform measurements. With road-mapping it is possible to superimpose live fluoroscopy on a radiographic image. This is especially helpful during percutaneous transluminal angioplasty, with or without stent placement, and during passage of guidewires through tortuous vessels. Measurement of vessel diameter can be useful during angioplasty and/or stent placement. Furthermore, recording and storage of images and angiographic runs are obligatory. It is important to realize that due to the size of the current high resolution images and films, the size of the hard disk must be large enough to be able to store data from several patients. Although these features were formerly only available on fixed systems, the current state-of-the-art portable systems are equipped with these options as standard. Nevertheless, it is often difficult to quickly archive DICOM images to and retrieve studies from PACS using mobile intensifiers.

Radiation exposure

Radiation exposure during fluoroscopy can be divided into exposure of the patient and exposure of personnel. It varies greatly between different procedures and is dependent on multiple factors. One factor is the fluoroscopy unit itself. In general, radiation exposure is higher using portable C-arms than fixed systems. This is explained partially by the fact that in mobile C-arms the image intensifier distance to focus is fixed, whereas this distance can be adjusted in fixed systems. Positioning closer to the patient will lead to less scatter and radiation exposure for operating room personnel, while improving image quality.[18,19] In addition, ceiling-mounted transparent shields are available for optimal scatter protection of the operator's upper body and face. Moreover, the newer portable C-arm units are less restricted as to the energy they can deliver, compared to fixed systems. This implies an increasing imaging quality, but the boost setting on these units delivers radiation doses with intense scattered radiation.[20]

Heat capacity

Overheating the system can be an obstruction in complex endovascular procedures, although this does not happen easily. The system shuts down for a period of cooling. This can take up to 20 minutes, during which it is not possible to perform any imaging. Due to excellent cooling systems (water or oil recirculating systems), overheating of fixed systems is rare. Portable C-arms, especially the older types, are prone to overheating. In some low power X-ray tubes, the only means of cooling was by thermally conductive materials and heat radiating fins. Oil is used in portable systems for cooling, and in the newer types, the oil recirculates, resulting in smaller risk of overheating. Furthermore, newer portable systems are available using tubes with rotating anodes, with subsequent higher heat capacity.

Costs

The quality of the fluoroscopy unit controls both the quality of the image and the costs of the endovascular suite. The difference in price between fixed and mobile equipment is enormous, with fixed systems usually being much more expensive. These costs can be distributed over several medical specialties, if a mobile

system is chosen. Choosing fixed, expensive systems is cost-effective when large numbers of endovascular procedures are performed. Again, the optimal choice is dictated by the type and the number of these procedures.

If use of a fixed system is desired, despite a limited amount of procedures, the solution might be efficient use of the angio-suite; sharing the suite with more specialties, can be cost-effective even when relatively few procedures are performed by the vascular interventionalist This, requires careful and creative planning. Potential ''partners'' for the use of the suite are cardiologists (placement of pacemakers under sterile conditions), urologists (intravenous pyelograms), gastro-enterologists (endoscopic retrograde cholangio-pancreaticographies) and radiologists (acute, non-scheduled procedures).

Additional equipment

It is obvious that in the optimal vascular working environment ultrasound is required as well. Ultrasound can be helpful in guiding vascular access for percutaneous procedures. Furthermore, more and more angioplasties are guided entirely by ultrasound, and it also can assess of the adequacy of procedures in certain cases. Apart from conventional ultrasound, intravascular ultrasound also could be included in an optimal environment, with a specific role for evaluation of vessels before stent placement and evaluation of the procedure afterwards.

Quality of Care and Efficiency

Collaboration or territorial demarcation

The most important feature of working in a dedicated angio-suite should be the ability to provide best treatment for vascular patients. It is of utmost importance to realize that only an optimal collaboration of vascular surgeons and radiologists will lead to progress in the field. The type of treatment and personal skills should dictate by whom a procedure is performed. Combined sessions of a vascular surgeon and a radiologist together, will prove beneficial, each profiting from the others knowledge and specific skills, lifting vascular care to a higher level. This exchange of knowledge and skills also is interesting for radiology personnel and operation room personnel, with potential benefits for both departments.[21,22]

Quality and efficiency

With an increasing amount of endovascular options, more procedures, formerly performed in angiography suites, are now performed in operating rooms for several reasons: the need for vascular cut-down, possibility of immediate conversion, hybrid procedures and the sterility issues discussed above. The hybrid procedures, combining open and endovascular treatment, are an example of how modern vascular surgery is developing. Instead of a treatment consisting of angiography with percutaneous endovascular treatment followed by open surgery in another session, these procedures are combined, offering patients a ''one-stop-shop treatment''.[22–24] From the patients' point of view this hybrid treatment is superior.

Access

The availability of the suite and equipment for endovascular treatment is essential for routine practice and elective scheduling of procedures. In a recent study by Sternbergh *et al.*[25] a dramatic increase in percutaneous endovascular case volume and complexity was observed after routine access to fixed-imaging equipment was implemented. The endovascular code usage increased 174%. Open surgical therapy decreased overall by 11.4%. Unlimited access to mobile C-arms could offer the same freedom of choice on whether to perform endovascular or open procedures. Furthermore, ideally an inventory of disposables such as sheaths, catheters, wires, balloons, and stents is available in the operating room. This equipment can be provided in mobile or fixed cabinets in the same way as the imaging equipment. Clinical decision making should not be hindered by practical and logistic problems.

Ease of use and the necessity of specially trained personnel

The issue of ''ease of use'' is not to be underestimated. Use of ''difficult to operate'' equipment requires the availability of highly trained radiology personnel. This again has an impact on scheduling: procedures have to be carefully planned, and the skilled radiology personnel has to be on ''stand-by'' for a much longer time than actually needed. Furthermore, this group has to be large enough to offer a ''24/7'' coverage of interventional activities. Using ''user-friendly'' equipment enables regular operating room personnel to operate these devices as well, after training. This

will simplify the creation of a pool of personnel large enough to cover the different shifts working around the clock. It is evident that this will have advantages regarding planning and personnel use. Furthermore ongoing endovascular developments require operating room personnel to have more knowledge about catheter techniques and the various materials that are used such as sheaths, guide wires, catheters and stent-grafts. This training of personnel is essential in order to build a team, that knows what to do, and deliver optimal workflow.

Future Considerations

The field of imaging develops continuously, with improvement of the image quality through technical progress. Voice control is a new option on angiography units. Using a headset, one is able to operate frequently used imaging functions, such as change of the magnification, road-mapping and review of images, which enables performance of procedures with minimal assistance, resulting in increased workflow.

Modern fluoroscopy units are equipped with flat panel detector technology. This have several advantages compared with the standard image intensifier. First, their size ensures a less obstructed view area and they provide better patient coverage, due to their large, flat format. Images are more homogeneous, and image quality-diminishing factors such as optical couplings and magnetic fields are ruled out, resulting in superior image quality.[26] Progress is also recorded in the ''software part''. Applications for workstations are available in order to create 3-dimensional images reconstructed from 2-dimensional images. This enables provision of information, which in some cases could not be derived, due to the limitations in positioning of the patient and/or image intensifier. Even cross-sectional imaging is possible using modern fluoroscopy units. The images from a rotational angiography run are used to create an angiographic computed tomography dataset. This provides soft tissue information, reducing or even obviating the need for additional CT imaging.

The opportunities that will arise from the possible integration of techniques also are interesting. Use of 3-D reconstructions from preoperative MR or CTA scans for superimposing these images on a real intra-operative view (''augmented reality'') or even integration of the reconstructed images and images derived during X-ray and/ or fluoroscopy guided interventions seem challenging and potentially useful extensions of the vascular imaging modalities.[27]

Conclusions

Developments in the treatment of vascular pathology have led to a new less invasive approach to patients. Both occlusive and aneurysmal vascular disease increasingly are being treated endovascularly. This demands a new type of vascular specialist and leads inevitably to other demands on the working environment in which these patients are treated. In order to offer optimal care this environment has to meet certain standards. These standards are summarized and one can deduce that by simply using a modern portable C-arm unit in the operating room, one is able to perform the most complicated endovascular procedures. However, when going beyond essentials and trying to create an optimal working environment, the picture is different. A refurbished operating room with a fixed fluoroscopy unit for endovascular procedures will be of benefit for both patients and the operating team. The extra costs for superior imaging, decreasing radiation and optimal ergonomics, will be a barrier for some institutions. Nevertheless, these optimal circumstances should result in improved workflow. The realization of an endovascular suite is essential for large vascular centres.

Acknowledgements

We wish to thank Professor Yuichi Murayama, Jikei University School of Medicine, Tokyo, Japan, for providing the figure.

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Accepted 8 August 2007
Available online 25 October 2007