Office-based endovascular suite is safe for most procedures

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Objective: **This study was conducted to identify the safety of endovascular procedures in the office endovascular suite and to assess patient satisfaction in this setting.**
Methods: **Between May 22, 2007, and December 31, 2012, 2822 patients underwent 6458 percutaneous procedures in an office-based endovascular suite. Demographics of the patients, complications, hospital transfers, and 30-day mortality were documented in a prospective manner. Follow-up calls were made, and a satisfaction survey was conducted. Almost all dialysis procedures were done under local anesthesia and peripheral arterial procedures under conscious sedation. All patients, except those undergoing catheter removals, received hydrocodone and acetaminophen (5/325 mg), diazepam (5-10 mg), and one dose of an oral antibiotic preprocedure and three doses postprocedure. Patients who required conscious sedation received fentanyl and midazolam. Conscious sedation was used almost exclusively in patients having an arterial procedure. Measurements of blood urea nitrogen, creatinine, international normalized ratio, and partial thromboplastin time were performed before peripheral arteriograms. All other patients had no preoperative laboratory tests. Patients considered high risk (American Society of Anesthesiologists Physical Status Classification 4), those who could not tolerate the procedure with mild to moderate conscious sedation, patients with a previous bad experience, or patients who weighed >400 pounds were not candidates for office based procedures.**
Results: **There were 54 total complications (0.8%): venous, 2.2%; aortogram without interventions, 1%; aortogram with interventions, 2.7%; fistulogram, 0.5%; catheters, 0.3%; and venous filter-related, 2%. Twenty-six patients required hospital transfer from the office. Ten patients needed an operative intervention because of a complication. No procedure-related deaths occurred. There were 18 deaths in a 30-day period. Of patients surveyed, 99% indicated that they would come back to the office for needed procedures.**
Conclusions: **When appropriately screened, almost all peripheral interventions can be performed in the office with minimal complications. For dialysis patients, outpatient intervention has a very low complication rate and is the mainstay of treatment to keep the dialysis access patent. Venous insufficiency, when managed in the office setting, also has a low complication rate. Office-based procedural settings should be seriously considered for percutaneous interventions for arterial, venous, and dialysis-related procedures. (J Vasc Surg 2014;59:186-91.)**

Office-based endovascular centers are being opened throughout the country, partly due to the Deficit Reduction Act of 2005 and the development of endovascular techniques. These centers have opened because of multiple reasons, the first being convenience for the patient, along with ease of scheduling cases for the doctor and better reimbursement for physicians because technical components can be billed in addition to the professional component. Despite more than 100 centers currently operating in United States, there is dearth of data about the use of these centers and the safety of procedures. Most units were opened to provide outpatient management of dialysis access and that is why many facilities are called "access centers." Predating these were office-based venous centers that treated patients with venous insufficiency.

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As the confidence in providing intervention has increased in the office setting, an increasing number of arterial and other procedures are being carried out in this setting. In 2008, Samson[1] recommended adding an angiography suite to the vascular laboratory. It has been shown that there are savings in overall health expenditures when the procedure is done in the office setting compared with the hospital.[2] The savings to Medicare in 1 year was >$800,000.00 when the cases were performed in the office.

Multiple questions that remain unanswered include:

1. Is it safe to provide this service in the office?
2. Are the patients satisfied?
3. What is the short-term, medium-term, and long-term efficacy when procedures are done in the office compared with the hospital?

In this report we look at the safety of the procedures done in the office along with patient satisfaction.

METHODS

After 1 year of planning, our center opened on May 22, 2007, as described in a previous article.[2] One of the surgeons is a designated medical director. Data were prospectively entered in Access software (Microsoft Corp,

Redmond, Wash). We are reporting the results of procedures performed until December 31, 2012. Demographic data and risk factors (diabetes, hypertension, smoking, and hyperlipidemia) were collected. Procedure-related complications, transfer to the hospital, and subsequent outcomes were documented. Mortality data at 30 days were collected retrospectively.

All registered nurses and physicians are certified in Advance Cardiac Life Support. For conscious sedation, hospital guidelines adapted for the office are followed. Triage criteria have evolved to identify patients not suitable for an office procedure: weight >400 pounds, American Society of Anesthesiologists Physical Status Classification 4, those with a history of contrast anaphylaxis, those who require general anesthesia, and those with a previous bad experience. Patients who are already admitted to the hospital undergo the procedure in the hospital.

Thirty minutes before the procedure, all patients, except those undergoing catheter removal, received hydrocodone and acetaminophen (5/325 mg), diazepam (5-10 mg), and cephalexin (500 mg; one dose preprocedure and three doses postprocedure). In patients with penicillin or cephalexin allergy, clindamycin (300 mg) was substituted. Fasting is only required for conscious sedation. Conscious sedation patients were given an antibiotic preprocedure and midazolam and fentanyl during the procedure. Conscious sedation was almost exclusively used for arterial procedures. Occasionally during dialysis or a venous procedure, fentanyl was given through the catheter already in the vessel if patient was having severe discomfort.

Preprocedure assays for blood urea nitrogen, creatinine, prothrombin time, and partial thromboplastin time were obtained for patients undergoing arterial procedures. No laboratory studies were done in any other category of patients. No postoperative laboratory studies were performed. Patients with a glomerular filtration rate of <60 mL/min/1.73 m^2 were hydrated before an arteriogram.

Diagnostic arterial procedures were performed using 4F catheters, almost always through a femoral approach, although we occasionally used brachial or radial approaches. When intervention was required, appropriately sized catheters were used, 6F being the commonest. Closure devices were used by operator preference. Access to the artery was always obtained using ultrasound guidance. Rotation atherectomy was done using a Stealth 360° catheter (Cardiovascular Systems Inc, St. Paul, Minn).

Clopidogrel was started after the intervention according to operator preference. Most patients received 30 days of antiplatelet treatment with clopidogrel and indefinite treatment with aspirin, if tolerated. Clopidogrel was not given before the procedure to decrease the incidence of bleeding and not knowing if intervention would be completed.

A fistulogram was carried out if one of the following criteria were met: (1) rising venous pressure as identified by the dialysis unit, (2) 15% increase in recirculation, (3) graft blood flow of <600 mL/min, (4) Doppler ultrasound imaging showing >70% stenosis, (5) increased bleeding from the needle site, or (6) fistula not maturing. Routine fistulograms at fixed intervals and balloon-assisted maturation[3] of the fistula were not carried out.

The fistulogram was generally performed through 4F sheaths that were upsized to 5F or 6F for balloon interventions. Covered stents, when used, were placed "bare back" to avoid a large sheath size. Thrombectomy procedures were done with two sheaths with intra-access tissue plasminogen activator and balloon-assisted clot maceration/retrieval.[4] Hemostasis was achieved with manual pressure or nylon suture.

For patients receiving dialysis, data were collected from the hospital and office to calculate procedures performed per patient per year. These included all procedures performed to maintain a functional dialysis fistula or graft or temporary catheter access for each patient.

For venous insufficiency, endovenous laser therapy (EVLT) using a Dornier (Dornier, Wessling, Germany) 940-diode laser wavelength was done under tumescent anesthesia. Radiofrequency ablation was used in seven cases while evaluating the machine. Microphlebectomy was carried out in a standard manner under local anesthesia. Within 7 to 10 days, venous ultrasound scanning was done to assess the success of the procedure and identify possible deep vein thrombosis (DVT). Sclerotherapy, which was done by a registered certified nurse under physician supervision, is not included in this report because most of these procedures were carried out for cosmetic reasons.

Venograms were performed for dialysis patients or for chronic venous insufficiency of the legs. PowerPorts (Bard Access Systems Inc, Salt Lake City, Utah) were placed in cancer patients and removed when no longer needed. Inferior cava filters were placed for elective indications. Retrievable filters were removed in the office after patient was discharged from the hospital and the risk of DVT or pulmonary embolism was minimal.

In the first 2 years of opening the center, an attempt was made to call every patient the next day after the procedure. Now, 10% of the patients are called at random by office staff, which is done to avoid bias and is representative of the procedures done in the office (ie, patients undergoing different types of procedures are called). Patients are asked if the experience was satisfactory and if they would come back to the center if a procedure were needed in the future. Every patient is followed up in the office in the postprocedural period. Any complication is documented.

RESULTS

During the study period, 2822 patients, 1474 females (52%) and 1348 males (48%), underwent 6458 procedures. There were 2398 Caucasians (85%), 357 African Americans (13%), 56 Hispanics (2%), and 11 others (<1%). Patients were an average age of 61 years (range, 15-94 years). Comorbidities included hypertension in 1750 (62%), hyperlipidemia in 1492 (53%), diabetes in 950 (34%), and nicotine addiction in 448 (16%). More than two comorbidities were present in 1600 patients (57%).