Intraoperative C-arm cone-beam computed tomography in fenestrated/branched aortic endografting

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Objectives: To evaluate the use of intraoperative guidance by means of C-arm cone-beam computed tomography (CT) (cone-beam computed tomography [CBCT]) and the use of postoperative CBCT to assess for successful aneurysm exclusion in fenestrated branched endovascular aneurysm repair (FEVAR).

Methods: Patients with FEVAR who underwent CBCT were retrospectively evaluated and categorized into one of two groups. The CBCT-fusion group was comprised of patients who underwent preprocedural CBCT to guide FEVAR using fusion imaging with multidetector computed tomography (MDCT). The postprocedure CBCT group consisted of patients undergoing CBCT following deployment of the endograft. Outcomes from the CBCT-fusion group were compared with historical controls. These controls were patients who underwent FEVAR for similar groups of abdominal and thoracoabdominal aortic aneurysms in the 12 months preceding the initiation of a CBCT program. The findings on postprocedural CBCT were compared with those on predischarge MDCT. Results are expressed as mean ± standard error of the mean, or as median and interquartile range.

Results: Forty patients were included in the “CBCT-fusion” group and compared with the historical cohort. The use of perioperative guidance of FEVAR by means of CBCT resulted in a significantly lower contrast dose (94 cc [72-131] vs 136 cc [96-199]; P = .001). While there was a trend toward lower operative (330 minutes [273-522] vs 387 minutes [290-477]; P = .651) and fluoroscopy times (81 min [54-118] vs 90 minutes [46-128], P = .932); this difference did not reach statistical significance. Nineteen patients were included in the “postprocedural CBCT” group and compared with predischarge MDCT. Postoperative CBCT identified eight endoleaks. Type I and III (n = 6) endoleaks were identified and treated during the primary procedure. When CBCT did not show an endoleak, this was confirmed by MDCT. The use of CBCT required significantly less contrast compared to MDCT (50 cc [set amount] vs 100 cc [80-125]; P < .0001). Mean skin dose was 0.27 (0.011) Gy for preoperative CBCT and 0.552 (0.036) Gy for postoperative CBCT.

Conclusions: CBCT is a valuable addition to complicated aortic interventions such as FEVAR. Intraoperative use utilizing fusion imaging limits contrast dosage and postdeployment CBCT is of sufficient quality to evaluate successful aneurysm exclusion and for detection of early complications after FEVAR. With the information we are able to obtain from the CBCT at the completion of the FEVAR, we can intervene on problems earlier and potentially decrease the subsequent need for reintervention. (J Vasc Surg 2011;53:583-90.)

Endovascular technology has evolved at a rapid rate, allowing for the treatment of more complex diseases. The endovascular treatment of complex aortic disease relies heavily on a combination of imaging modalities, but pre- and postoperative computed tomography (CT) and intraoperative fluoroscopy remain the two most widely used radiologic tools. CT provides detailed morphologic information about the aorta, which allows for accurate preoperative planning and postoperative surveillance. While the complexity of the procedures increases, such as with the development of fenestrated/branched endovascular aneurysm repair (FEVAR), the ability to more accurately evaluate the three-dimensional (3D) architecture of the aortic tree before, during, and after surgery becomes increasingly important. While the use of multidetector computed tomography (MDCT) has allowed for the 3D imaging of these arterial structures in the pre- and postoperative period, intraoperative arterial assessment has historically been limited to two-dimensional (2D) angiography and fluoroscopy. Flat panel detectors (FPD) have begun to replace the standard imager intensifiers used on conventional fluoroscopy units. The application of FPD has provided the ability to perform intraoperative 3D imaging using rotational angiography. C-arm cone-beam computed tomography (CBCT) is an advanced imaging capability that uses C-arm flat panel fluoroscopy systems to acquire and display 3D images. The FPD functions much like the multilane detectors used in MDCT and provides “CT-like” images in multiple viewing planes. CBCT systems are now commercially available and each manufacturer has its own imaging

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protocol that is tailored to each system’s different rotation time, number of projections acquired, image quality, and time required for reconstruction.

There are at least three potential applications of CBCT in aortic endografting including its use for preprocedure anatomic assessment and stent-graft sizing,1-3 fusion imaging to guide device implantation, and postprocedural assessment of successful aneurysm exclusion. Preliminary experience has demonstrated its potential utility in pre- and postdeployment scenarios.1-5 One of the most potentially useful applications of CBCT is intraoperatively to guide the performance of fluoroscopy-driven procedures using fusion of CT images and fluoroscopy, similar to traditional “road-mapping.” Intraoperative CBCT images can be registered, or fused, with preoperative MDCT allowing the MDCT image to be superimposed on the live fluoroscopic image. The superimposed image will then update in the correct projection depending on the arc angle of the C-arm. There is little information about the usefulness of this technology in the treatment of aortic aneurysms or complex aortic disease. It has been shown, however, to accurately outline the coronary sinus anatomy and assist in guiding cardiac resynchronization therapy placement, which relies heavily on understanding the 3D structure of the heart.6

The aim of this study is to evaluate our initial experience using CBCT during FEVAR. CBCT is currently not sophisticated enough to allow for preoperative planning and sizing for FEVAR. This study will assess our initial experience with two other applications of CBCT: (1) the intraoperative use of CBCT to direct placement of fenestrated/branched endografts; and (2) the postdeployment use of CBCT to assess for the adequacy of endograft exclusion of the aortic aneurysm.

METHODS

All patients who underwent FEVAR between August 2009 and March 2010 were retrospectively evaluated. FEVAR was performed as part of an investigational device exemption protocol. Written informed consent was obtained from all patients and the study was approved by the Institutional Review Board (IRB # 4281). Patients in whom CBCT was performed were reviewed and categorized into one of two groups. The “CBCT-fusion” group was comprised of patients who underwent predDeployment CBCT and fusion of this image with a preoperative MDCT to guide placement of the fenestrated graft. The “postprocedural CBCT” group contained patients in whom CBCT was performed postdeployment to assess the effectiveness of aneurysm exclusion and maintenance of branch patency.

CBCT was performed at the Cleveland Clinic since August 2009. Scans were performed on Artis zeego with syngo DynaCT (Siemens Healthcare, Forchheim, Germany) at the discretion of the operating surgeon using standardized protocols. The decision to perform CBCT was dependent on multiple factors including total radiation and contrast dose used during the primary procedure and baseline renal function. Excluded from both cohorts were patients who underwent FEVAR for type II thoracoabdominal aneurysms (TAAAs) and those patients undergoing staged endovascular procedures. Predischarge contrast-enhanced MDCT scanning was routinely performed for patients following FEVAR as part of the investigational device exemption study protocol. Patients who did not have a predischarge MDCT scan were excluded from the “postprocedural CBCT” group analysis. Patient demographics, operative data, and follow-up data were extracted from the medical records.

CBCT fusion. This cohort entailed patients who used preddeployment CBCT fusion with preoperatively performed MDCT to direct FEVAR placement. Predeployment CBCT was performed using a 5sDR or an 8sDR protocol. The 5sDR protocol has a 5-second acquisition time capturing 133 frames at 30 frames/second (fps) where the 8sDR takes 8 seconds with 397 frames at 60 fps. Typically, bony structures and areas of heavy calcification identified on the CBCT were used as landmarks to “fuse” the CBCT image with the MDCT (Fig 1). In case of a
heavily calcified aorta, or a stent graft in situ, the 5sDR protocol is sufficient for adequate registration to MDCT. In all other cases, the 8sDR allowed registration by means of soft tissue landmarks. The MDCT image can then be seen overlying the fluoroscopy image (Fig 2). Alternately, after adequate registration, the system automatically graphically outlines the aorta, and the ostia of the target vessels are identified and manually encircled in the MDCT dataset (Fig 3). These graphics are then overlaid and displayed live on the in-suite monitors (Fig 3). The system adjusts the overlay according to C-arm and table positions, making the location of the target vessel ostia and the outline of the aorta visible throughout the procedure. In this setting, predeployment aortography was not performed. FEVAR was performed based on the fusion imaging.

To assess whether the use of fusion technology altered early outcomes of FEVAR, results from this initial cohort were compared with outcomes from historical controls. The historical cohort was collected from patients undergoing FEVAR at the Cleveland Clinics in the 12 months prior to initiation of CBCT. These included all patients undergoing FEVAR with the exception of patients undergoing treatment for a type II TAAA. Demographics, operative details, and outcomes were compared between the two groups.

Postprocedural CBCT. The postprocedural CBCT group included patients in whom a completion CBCT was performed to assess the adequacy of repair. Postprocedural images were acquired using the 8sDSA protocol. Two complete runs are acquired including a native and a contrast run. The contrasted run required an injection rate of 10 cc per second for a total of 10 seconds. Fifty percent dilute contrast (Visipaque; GE Healthcare, Buckinghamshire, UK) was used routinely for a total of 50 cc of contrast per run.

After acquisition, the data were automatically sent to the Syngo X-Workplace (Siemens Healthcare) and reconstructed to 3D datasets. CBCT images were reviewed by the operator and the main investigator in 2D side-by-side viewing, native vs contrast-injected images, and dedicated 3D postprocessing reconstructions (Fig 4) were developed and reviewed to optimize sensitivity and specificity. Reviewing was done using the Aquarius Workstation (TeraRecon, San Mateo, Calif). CBCT and MDCT were evaluated for endoleaks, stent graft integrity, vessel patency, and aortic diameter measurements. Attenuation (Hounsfield unit [HU]) measurements of the stent graft lumen, aneurysm sac, and contrast extravasation (endoleak) if present were assessed. Results from postprocedural CBCT were compared with those on the predischarge MDCT.

Statistical analysis. Data analysis was performed using SPSS statistics 17.0 (SPSS Inc, Chicago, Ill). Continuous variables are described as mean and standard deviation.
or median and interquartile range (IQR) in case of skewed data. Differences between continuous variables were tested using independent t test for pre-CBCT vs historical cohort and paired t test or the Wilcoxon rank-sum test (if n < 30) for post-CBCT vs MDCT. Categorical variables were tested using Pearson $\chi^2$ test or the Fisher exact test (if n < 5). Two-sided P values <.05 were considered significant. Radiation dosage for CBCT is noted as skin-absorbed dose expressed in mGy. Radiation dosage for MDCT is noted as dose length product expressed in Gy·cm.

RESULTS

A total of 82 patients who underwent FEVAR were reviewed. In 40 patients, CBCT fusion was performed, 19 patients underwent a postprocedural CBCT, and eight patients underwent both. In the remaining 23 patients, no CBCT was performed, and they were excluded from further analysis.

CBCT fusion. Demographics and operations performed were similar between the CBCT fusion group (n = 40) and the historical controls (n = 49) (Table I). Median follow-up was 2 (1.3-4.0) months for the CBCT fusion group compared and 10 (8.0-14.5) months for the historical controls. All but one preoperative-acquired CBCT proved of sufficient quality for adequate image overlay (39/40 [98%]). The 5sDR protocol was used in eight (20%) cases, and the 8sDR protocol in 32 (80%) cases. Median radiation dose was 0.18 Gy (0.11-0.25) for the 5sDR protocol and 0.29 Gy (0.27-0.31) for the 8sDR protocol. Median contrast dose was 94 cc for the CBCT fusion group compared to 136 cc in the historical cohort ($P = .001$) (Table II). There was a trend toward lower operative times and fluoroscopy times in the CBCT fusion group, but this did not reach statistical significance (Table II).

Technical success was defined as successful deployment of the endograft with stenting of all the target vessels. The procedure was technically successful in 84.8% of the cases in the CBCT fusion group, compared with 89.8% in the historical cohort ($P = .98$). In the CBCT group, there were four (10%) cases in which one of the target vessels could not be cannulated (two renal arteries, one celiac artery, and one hypogastric artery) and thus were not stented. All visceral vessels were successfully stented at a follow-up procedure, and the hypogastric artery ultimately occluded and was left untreated. Early endoleak rates, detected on 1-month follow-up MDCT, did not differ in the CBCT fusion group (7 [17.5%] type II and 1 [2.5%] type III (endoleaks) compared to the historic control group (3 [6.1%] type I, 5 [6.1%] type II, and 4 [8.2%] type III endoleaks).

Postprocedural CBCT. A total of 19 patients underwent evaluation by postdeployment CBCT. In this series, two infrarenal, four juxtarenal, and eight thoracoabdominal aneurysms underwent primary endovascular repair. In the remaining five cases, diagnostic imaging by means of CBCT was performed prior to treatment for a known endoleak after FEVAR.
A total of 8 (36.8%) endoleaks were found on postprocedural CBCT. Endoleaks were easily discernable. The stent lumen was found to have a mean attenuation value of 583.4 ± 58.6 HU. Contrast extravasation in the aneurysm sac measured a mean attenuation 319 ± 20.8 HU compared with a mean attenuation 72.2 ± 44.5 HU for aneurysm sac without contrast extravasation, making endoleaks clearly visible (Fig 4). CBCT demonstrated two (10.5%) type I endoleaks. One originated from the right common iliac artery and the second case was a proximal type I endoleak. In both cases, the endoleaks were successfully treated with a limb extension and a proximal cuff, respectively. Four type III (21.1%) endoleaks were found (Fig 4). Three originated from a renal artery branch, and one originated from a superior mesenteric artery (SMA) branch. All cases were successfully treated with either reangioplasty (n = 3) or placement of another stent (n = 1). Two (10.5%) type II endoleaks from single lumbar arteries were diagnosed and left untreated. When there were no endoleaks visible on CBCT, this was confirmed by MDCT. There were no endoleaks found on MDCT that were not visible on CBCT. One type II endoleak found on CBCT was not visualized by the predischarge MDCT. No stent fractures were noted and all incorporated vessels were patent on CBCT, which correlated to MDCT findings. Diameter measurements obtained by CBCT were the same as those obtained on MDCT. All images had metal artifacts from the stent graft and guidewires in situ. These included two (10.5%) stripe artifacts and two (10.5%) calibration error artifacts. The latter arose from misalignment of the detector after it was accidentally dislodged. No movement artifacts were observed.

Median radiation dose for the whole procedure was 3.81 Gy (IQR 2.18-5.44). Postoperative CBCT contributed a median radiation dose of 0.55 ± 0.036 Gy. For MDCT, mean radiation dose was 2.56 ± 0.76 μGy/cm².
Contrast dose for CBCT was 50 cc (set amount) compared to median contrast dose of 100 cc (80-125) for MDCT ($P < .0001$).

**DISCUSSION**

Endovascular technology is rapidly advancing, allowing for the treatment of more complex disease processes such as complex aortic aneurysmal disease. Corresponding with these advancements is the need for improved intraoperative imaging capabilities that will allow the successful execution of these procedures. The advent of FPDs and development of CBCT is a significant step forward in this process. As imaging systems at many centers are updated, this technology will become increasingly available. Given this, it is imperative that practitioners become familiar with these technologies and their potential applications.

To date, little research has been presented regarding the application of CBCT during abdominal aortic interventions. This preliminary evaluation demonstrates that the use of intraoperative CBCT to guide deployment of fenestrated endografts results in significantly lower contrast dosage ($P = .001$), with a trend toward lower fluoroscopy and radiation exposure.
total operative times. Certainly, based on this data, one could call into question the significance of this technology, as the only significant difference was a 40-cc reduction in contrast use. In the authors’ opinion, however, the findings are extremely important. There is evidence to suggest that repeated doses of contrast agent may contribute to the development of lifelong nephrotoxicity.\(^8\) In addition, the application of this technology was limited to patients that did not have the need for more complicated fenestrated/branched endograft placement, and few of the patients had significant renal impairment. This was at the discretion of the operating surgeons and represents self-imposed limitations during the initial application of this technology. Patients requiring aortic interventions, however, are not without significant contrast-associated risks due to the presence of pre-existing renal insufficiency.\(^8\) All efforts to reduce the use of contrast agents to the lowest dose that will allow successful performance of the procedure should be employed. With growing experience with this technology, the authors have found the use of CBCT-guided deployment of fenestrated/branched endografts invaluable, particularly in very complex anatomy and in patients with renal insufficiency. In fact, since the analysis of the analysis of these initial outcomes, the use of CBCT in this manner has been liberalized and the deployment of fenestrated/branched endografts has been performed using as little as 10 cc of contrast in patients with significant renal impairment. We suspect that on later analysis, as the experience grows, we will see an additional reduction in fluoroscopy and operative times as well.

Postoperative CBCT provides an image quality sufficient for evaluating successful aneurysm exclusion and assessment of complications following endovascular aneurysm repair. One of the difficulties in assessing adequacy of treatment with FEVAR using completion angiography is determining the potential source of endoleaks. Typically, if the source of an endoleak is not discernible by conventional angiography, it can be identified on follow-up MDCT. This requires, however, return to the operating room for a secondary intervention in the postoperative period.\(^9\) As described above, and by others,\(^4,5\) postdeployment CBCT allows for the immediate recognition of the endoleak source, with greater detail than can be provided by angiography and subsequent treatment during the initial surgery. In fact, case reports have been published showing CBCT is able to detect an endoleak where angiography fails to do so.\(^4,5\) We did not perform completion angiography in conjunction with completion CBCT to avoid the additional radiation and contrast loads. As such, direct comparison of sensitivity and specificity of endoleak identification between angiography and CBCT is not possible. It was noted, however, that when no abnormality was identified on CBCT, none was visualized on MDCT. With increased application of this technology, however, we will be able to more effectively evaluate the rate of subsequent reinterventions to determine whether this is reduced by the use of CBCT. One limitation, however, may be in the identification of type II endoleaks. In one case, CBCT identified a type II endoleak, which was not visible on the predischarge MDCT. There are multiple explanations for this finding including resolution of the endoleak prior to follow-up MDCT. Alternatively, MDCT failed to show the endoleak due to the fact that these scans are made on fixed times. CBCT acquisition is done during continuous contrast injection, allowing for uninterrupted evaluation of early arterial to venous phase images, not only demonstrating where the endoleaks might originate, but also when they do.

In addition, postdeployment CBCT proved to be adequate for assessment of incorporated vessel patency and stent graft integrity. As has been previously demonstrated that diameter measurements on CBCT and MDCT showed comparable outcomes,\(^8,10\) results from this study support these findings. While not applicable to current fenestrated endografting, this technology may prove useful in the on-table planning and sizing of patients undergoing endovascular aneurysm repair (EVAR)\(^1,2\) particularly in the setting of ruptured abdominal aortic aneurysms. In addition, while this study was limited to the deployment of fenestrated endografts, the technology, both to guide deployment and to assess adequacy of aneurysm exclusion, can easily be applied successfully to the performance of elective EVAR and thoracic aortic endograft placement. In addition to using this imaging modality to plan and size for EVAR or thoracic endovascular aneurysm repair, the fusion technology can be used to more accurately deploy the graft near important branch vessels—without the use of contrast. In addition, it can be used to immediately assess the success of aneurysm exclusion. With increased experience and improvements with this imaging modality, it may be possible to ultimately supplant follow-up MDCT, at least in the short-term period. The use of CBCT, however, is not without its limitations. First, it is limited by the fixed area available for scanning. For instance, DynaCT (Siemens Healthcare) is limited by a maximum of 18-cm scanning distance in the z-axis, thus, in cases in which a long length of aorta is covered with a stent graft, the entire treatment area would not be imaged by CBCT. In addition, imaging artifacts were identified in 10% of the CBCT scans performed. Other problems include difficulty with contrast differentiations, particularly in areas of low radiographic contrast.\(^11\) Of some concern is the additional radiation dose provided by CBCT, particularly if two applications of this technology are performed during one operation. The radiation dose for a 14-second acquisition is similar to that of a biplane digital subtraction acquisition during a routine cerebral angiogram.\(^12\) Radiation dose, however, is higher in CBCT (236 mGy) compared to traditional 3D-DSA with a standard image intensifier (50 mGy).\(^11\) A comparison between the CBCT and MDCT in terms of radiation exposure is complicated by a lack of a universally accepted common dose metric. Previous experiments done using CBCT demonstrated a lower radiation dose compared to single helical CT, however in this experiment, contrast and spatial resolution were inferior to MDCT.\(^10\) Eide et al reported radiation doses to be comparable between these modalities, but effective dose was calculated using a con-
version factor to overcome some of the differences that cannot be directly measured. Estimates of radiation dosages in this article are derived from unpublished data supplied by Siemens Healthcare. These data suggest CBCT radiation dosage to be comparable or slightly higher compared with MDCT. Internal Alderson phantom measurements by Siemens report an estimated dose of 11 mSv for the 8sDR. The 5sDR protocol was not tested. An estimate derived from the values for the 8sDR would be roughly 11 mSv * (133/397) = 4 mSv. In comparison, literature reports an average estimated dose for completion aortography of 12 mSv (values reported 4.0-48.0) and 8 mSv (values reported 3.5-25) for abdominal MDCT. CBCT is a valuable addition to the endovascular suite and the treatment of complex and routine aortic diseases. In the preprocedural setting, it can be used to identify pathology and accurately plan treatment. Its use intraoperatively to guide the accurate placement of endovascular devices results in lower contrast doses and may ultimately reduce operative and fluoroscopy times. This will improve overall safety for both patients and surgeon. Lastly, CBCT appears to identify success of repair as readily as follow-up MDCT. Its use intraoperatively may reduce subsequent rates of reintervention following procedures such as FEVAR, but this has yet to be shown. Further studies evaluating a larger number of patients could potentially demonstrate the valuable nature of this technology in evolution.

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Analysis and interpretation: MD, ME, RG, TM, AH
Data collection: MD, ME
Writing the article: MD, ME, RG, TM, AH
Critical revision of the article: MD, ME, RG, TM
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