Roentgen stereophotogrammetric analysis to study dynamics and migration of stent grafts

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CHAPTER

7

Plain radiographic images have insufficient accuracy and precision to detect stent-graft migration

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ABSTRACT

Purpose: To determine the accuracy and precision of plain abdominal radiography (AXR) as a method to detect stent-graft migration and thereby define its clinical applicability.

Methods: Stent-graft migration was simulated in a static model of an aorta with stent-graft. Migration was measured by five different observers in AXR images with image acquisition and analysis according to a standardized protocol with correction for geometric distortion. The results were compared to Roentgen stereophotogrammetric analysis as the standard of reference. This way, accuracy and precision could be determined in-vitro. Next, the five observers determined stent-graft migration in two consecutive AXR images of four patients after endovascular aneurysm repair (EVAR). The results of the five observers were compared to determine the precision of the method in-vivo.

Results: In-vitro, migration as measured with RSA was 9.97 mm for the first and 27.75 mm for the second migration. The mean migration determined with AXR was 8.6 ± 2.5 mm (range 0.4 – 20.6 mm, n=57) and 23.7 ± 2.2 mm (range 14.7 – 27.4 mm, n=57), respectively. The mean pooled error of AXR as compared to RSA was 3.0 ± 2.4 mm (range 0.01-13.1 mm, n=114). Of all AXR measurements, 16% had an error larger than 5mm. In-vivo, the pooled mean variation was 3.0mm ± 4.5mm (n=76). The maximum difference between measurements in one patient was 33.0 mm. There was no significant inter-observer variability in the in-vitro and in-vivo groups.

Conclusion: The accuracy and precision of plain radiography for detection of stent-graft migration after EVAR is insufficient for clinical use, especially when early and accurate identification of minimal migration is required like in patients with short aneurysm necks. .

Introduction

Plain abdominal radiography (AXR) is widely used as a practical and reliable tool for routine surveillance after endovascular aneurysm repair (EVAR).[1-3] AXR is fast and requires only limited hospital resources in terms of personnel and equipment. Other advantages of AXR are that it does not require nephrotoxic contrast enhancement and has a low radiation dose per investigation. Therefore, it compares favorably to CT as a tool for surveillance after EVAR.

AXR reveals information about stent-graft position and integrity, enabling detection of stent-graft migration, kinking/deformity, limb dislocation, hook and stent fracture, anchor-stent separation, and progressive dilatation of the native vessels.[1] Hodgson et al. demonstrated that an accuracy of 2 mm could be achieved to detect stent-graft migration in a static model using standardized AXR and an algorithm to correct for geometrical distortion due to varying positioning of the Roentgen tube.[2] They did not describe the effect of inter-observer variation on the measurement, nor the precision of repeated measurements with AXR. These aspects of AXR remain unclear, even though AXR has found such widespread acceptance for an important aspect of surveillance after EVAR.

In AXR, the spine is used as the point of reference to detect stentgraft migration, by comparing the position of the stent-graft relative to the lumbar spine in sequential examinations.[2] However, the spine is not always a stable landmark over time. Moreover, cranio-caudal stent-graft motion during the cardiac cycle has been described up to 3 mm in a small number of patients, making a wider range of motion likely.[4-6] Because of this pulsatile motion of the graft, the use of bony points of reference seems to be hazardous in terms of measurement accuracy. Furthermore, the minimum acceptable aneurysm neck length continues to decrease with increased experience and new generation stent-grafts, approaching 5mm.[7] This requires increased accuracy of our tools for migration surveillance.

In this study, we determined the accuracy and precision of AXR as a method to detect in-vitro and in-vivo stent-graft migration to further define its clinical applicability.

METHODS

Plain Radiography (AXR) versus RSA in-vitro

For the in-vitro condition we used a static model to acquire AXR images according to a standard clinical protocol and compared the measurements to RSA, the standard of reference for this experiment. Roentgen stereophotogrammetric analysis (RSA) is a method that uses stereo roentgen images to determine the 3D position of markers relative to each other. RSA has been used for many years to detect micro-motion of orthopedic prosthesis with sub-millimeter accuracy.[8-10] In recent literature, it has also been proposed as a highly accurate tool for migration surveillance after EVAR.[11-12] An accuracy of 0.002 ± 0.044mm was demonstrated in a static model of stent-graft migration.[11] Because RSA acquires a calibrated stereo plain radiographic image, it has the same possibilities and advantages as AXR. RSA combines these advantages with a very high accuracy for micro-motion measurement.[11-12] RSA was regarded as the standard of reference in the static situation because of its proven high accuracy. This comparison of AXR to a highly accurate standard of reference is a measure for the accuracy of AXR, the measurement error.

A static model was developed to simulate stent-graft migration. The model consisted of a fresh thoracic pig aorta, fixed to a cadaver human spine complete with soft tissue. The spine was obtained from the anatomical department and used according to the standard consent procedures of our Institutional Review Board. It was conserved in a solution of formaldehyde, ethanol, glycerin, and phenol (Figure 1). The model was placed in an acrylic box, topped off with water to simulate soft tissue.

A Gianturco stent (Cook, Bjaeverskov, Denmark) was placed inside the aorta. A stent rather than a stent-graft was used to model migration since radiological imaging techniques use the stents of the stent-graft for analysis. Furthermore, deleting the fabric from the model facilitated the induction of migration. Three stent-graft positions were analyzed with RSA and AXR: the initial or reference position and 2 migrations, induced by pulling on a thin wire attached to the stent. For RSA analysis, markers were added at the cranial and caudal corners of the stent (i.e., *stent-graft markers*), and reference markers were attached to the aorta (i.e., *aortic markers*), as published previously.[12] RSA imaging and measurement was performed as published previously.[9,11-12]

For plain radiography, the same setup was used to determine migration as is current practice in our clinical setting for EVAR surveillance, as described by Murphy et al.[3] From every position one anterior- posterior and three left lateral radiographs were produced using a Bucky set-up by Oldelft (Triathlon DR, Oldelft Veenendaal, The Netherlands) with the tube positioned 1 meter above one 35 x 43 cm digital flat panel detector (CXDI-50G, Canon, Amstelveen, the Netherlands). As described by Hodgson et al.[2], the exact position of a stentgraft inside the body is impossible to determine from the outside of the patient in a clinical situation. Therefore, lateral photos cannot always be taken through the exact center of the top of the stentgraft. To

Figure 1. Model of an aorta with stent-graft. Fresh pig aorta fixed to a human spine complete with soft tissue. Spherical markers are attached to the adventitia as reference markers for RSA.

mimic a clinical setting, and reproducing the experiment performed by Hodgson et al [2], three different lateral radiographs were acquired, one with the center of the X-ray beam aimed at the center of the stent and one aimed 7.5 cm cranial and 7.5 cm caudal to this point.

The position of the stent was determined by measuring the distance between two reference points. We used the center of one end of the stent as the stent reference. Similarly, the vertebral reference was the center of the vertebral endplate closest to the stent reference point on the initial photo. It is preferable to choose the centers of the stent and vertebra as reference points instead of the edges, because the centers are less affected by variation in angulation, distortion or vertebral osteophytes at the border of the vertebra.[2]

The AXR images were randomly numbered and measured by 5 different observers. Two observers performed five measurements per image; three observers performed three measurements per image. All observers were blinded for the amount of migration. This way, a total of 19 measurements were performed on three images per position (cranial, center and caudal image). This lead to 57 measurements per migration, and therefore a total of 114 measurements of the two induced migrations. Geometric distortion was corrected according to the suggestions by Hodgson et al.[2] Migration was determined by calculating the difference in distance from the vertebral endplate to the stent, as measured in the reference radiographs and follow up images.[2]

Plain Radiography (AXR) in-vivo

Next, we measured the variability of AXR measurements of stent-graft migration in patients who had undergone EVAR. The standard deviation and the maximum variation between all observations per migration are a measure for the precision of the technique. To determine the precision of AXR in a clinical setting, migration was measured in four randomly chosen patients who underwent EVAR.

The AXR image pairs (AP and lateral) were acquired at two different points in time: one reference image directly post-operative and a randomly chosen follow-up image. The AXR image pairs were acquired according to the protocol as described by Murphy et al.[3], with a standard Bucky imaging set-up (Philips Medio 50 CP, Philips Medical Systems Europe, the Netherlands) positioned 1 meter above a 35 x 43 cm film (Kodak, Amsterdam, the Netherlands). The exposure was regulated automatically at approximately 75 kV. The AXR measurements of the stent-graft position were performed in the same way as described for the in-vitro experiment following the Hodgson protocol, determining the vertical distance between the vertebral endplate and the center of one end of the top stent of the stent-graft.[2] . As in the in-vitro experiments, two observers performed five measurements per image; three observers performed three measurements per image. This way, 19 measurements were performed in four patients, leading to a total of 76 measurements in-vivo. To determine the pooled mean deviation and standard deviation of AXR, we compared each AXR measurement to the mean of the AXR measurements of the same patient to determine the variation compared to the mean measurement. Subsequently, we pooled these data.

Statistics

Levene's test for variance was used to detect statistically significant interobserver variability between the measurement errors of the observers. $P<0.05$ represented a statistically significant difference. Standard deviation and maximum variation of the measurements were determined for each migration. The tests were performed in cooperation with the Medical Statistics department of the LUMC using SPSS for Windows (version 11.0; SPSS Inc., Chicago, IL, USA).

Results

Plain Radiography (AXR) versus RSA in-vitro

RSA analysis revealed a stent-graft migration of 9.97 mm for the first migration, and 27.75 mm for the second migration. The mean migration determined with AXR with correction for geometric distortion was 8.6 ± 2.5 mm (range 0.4 – 20.6 mm, n=57) and 23.7 ± 2.2 mm (range 14.7 – 27.4 mm, n=57), respectively. No significant difference was found between the observers using Levene's test for variance (P=0.466). The pooled mean error of AXR as compared to RSA in a static in-vitro condition was 3.0 ± 2.4 mm (range 0.01-13.1 mm, n=114). Of all 114 AXR measurements, 16% had an error larger than 5mm in this model without pulsatile stent-graft motion (Figure 2).

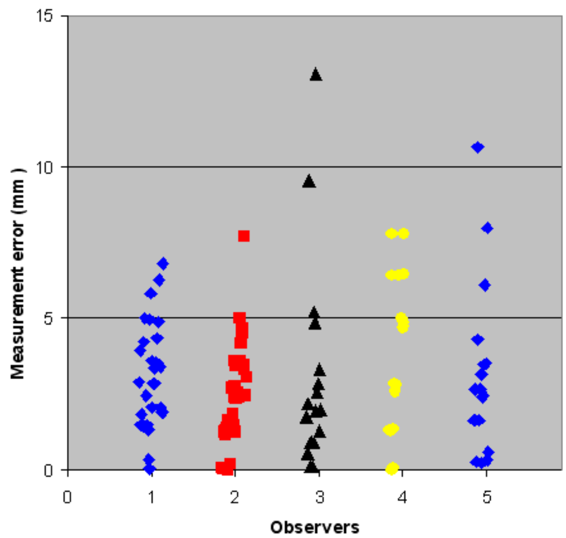

Figure 2. AXR measurement error of 5 different observers using a static model and RSA as standard of reference. In 16% the error was larger than 5mm. No significant difference was found between the observers.

Plain Radiography (AXR) in-vivo

Migration of the stent-graft as measured by AXR with correction for geometric distortion is shown in Figure 3. The pooled mean variation of AXR was 3.0mm ± 4.5mm (range 0.0 - 22.4 mm) (n=76). The maximum difference between measurements in one patient was 33.0 mm. No significant difference was found between the observers using Levene's test for variance (P=0.284).

Discussion

This study demonstrates that plain abdominal radiography has poor accuracy and precision to measure stent-graft migration despite adherence to a strict imaging and measurement protocol.

A mean error of 3.0 ± 2.4 mm was found in a model without pulsatile motion. This displays a low accuracy and precision. This is emphasized by the finding that 16% of the measurement errors were larger than 5mm. In the developments in design of stent-grafts and growing experience of endovascular specialists, the accepted neck length of aneurysms is constantly decreasing, approaching 5mm.[7] Stent-graft migration of only several millimeters could already be very significant in these cases. The cyclic cranio-caudal motion of the stentgraft relative to the spine, the point of reference for AXR, has been reported to be up to 5,8mm.[4-6,11,13] Combining the measurement error found in this study with the understanding of this cyclic motion, an aneurysm neck length of 5-10 mm seems to be too short for surveillance of stent-graft migration by AXR alone.

In the in-vivo measurements, the accuracy and precision could have been reduced due to the pulsatile motion of the graft relative to the spine. This could possibly explain the disappointing precision of AXR found in-vivo. The variation of 3.0mm was large, especially when considering the very high standard deviation of this result: 4.5mm. This standard deviation would yield a 95% confidence interval of stentgraft migration measurement with AXR of 9mm. When stent-graft migration of 5mm is considered significant, AXR is simply not precise enough to reliably determine presence or absence of this complication.

The current gold standard to detect stent-graft migration after EVAR is contrast enhanced multi-detector CT with sub-millimeter beam collimation and 3D image reconstruction.[14] This method has the advantage of enabling detection of possible endoleaks and aneurysm sac growth or shrinkage, apart from measuring stent-graft position. However, these advantages come at a price in terms of cost and logistical burden. The contrast requirement and, to a lesser

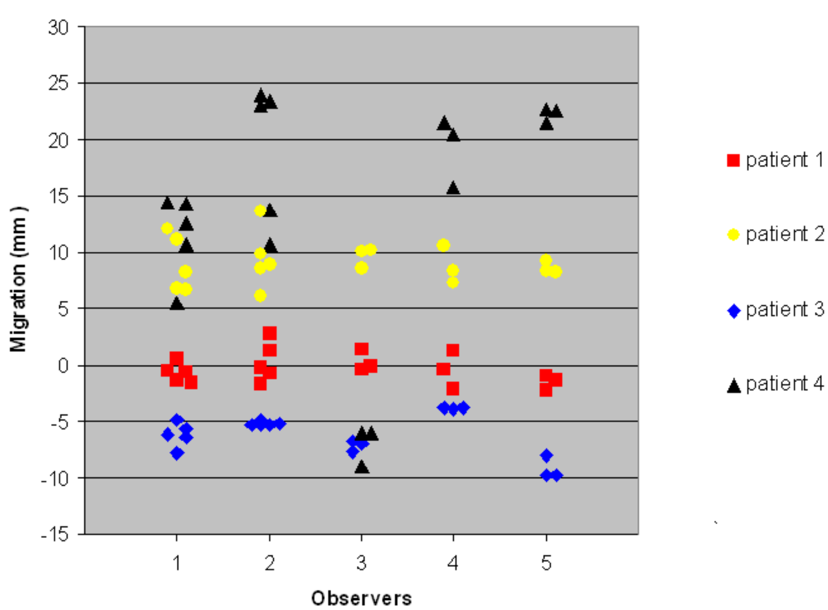

Figure 3. Results of migration measurements using AXR in patients after EVAR by 5 different observers, no significant difference was found between the observers.

extent, radiation dose can be a considerable disadvantage. Furthermore, 3D image reconstruction is not available in every hospital, nor is a multi-detector CT. CT without contrast enhancement, small acquisition slice thickness or 3D image reconstruction will undoubtedly produce less accurate results[14], however the accuracy of such measurements has not been quantified. Roentgen stereophotogrammetric analysis has been described as a possible tool to meet the requirements of high accuracy of stentgraft position measurement without the disadvantages of CT.[11,12] Unfortunately, RSA is still not suitable for widespread clinical introduction.

When considering the accuracy and precision of AXR, combined with a minimum length of the proximal neck zone to secure aneurysm exclusion, the results of our study imply that AXR is unreliable for surveillance of patients with an aneurysm neck of less than 15 – 20mm. For safety reasons, an aneurysm neck length of 30mm seems to be more appropriate when AXR is used for migration surveillance. In clinical practice, the vast majority of cases have an aneurysm neck length of less than 30mm, and the average length in reported series is deminishing.[15-17] Therefore, most of the patients after EVAR are unsuitable for this method of migration surveillance alone.

Limitations

This study is a combination of an in-vitro and an in-vivo study. The model is by nature of its design limited because of the absence of normal physiological behavior due to cardiac and respiratory motion. Furthermore, only a limited amount of soft tissue was simulated by means of water, an isodense substance. However, the accuracy and precision of AXR measurements will most likely further decrease if the above mentioned factors would have been present in the model.

We measured a limited number of four patients for the in-vivo part of the study. These results already show a considerable variation between measurements, without showing significant inter-observer variation. Considering the finding that the range of measurements as found in each patient was at least 5mm (Figure 2), a larger sample of patients and images will not contribute significantly to the data.

Conclusion

The accuracy and precision of plain radiography for detection of stent-graft migration after EVAR is insufficient for clinical use, especially when early and accurate identification of minimal migration is required like in patients with short aneurysm necks.

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