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Perspective: RIFAT LATIFI: Transformation of the Healthcare System in Kosovo and Medical Diplomacy

SELMAN URANEUS: Damage Control Surgery in Severe Trauma

JORG TEBAREK: Aortoiliac treatment with IVUS guidance as a standalone imaging solution: is it feasible and where are the benefits?

JAMES HU: Familial Adenomatous Polyposis: Review of Current Diagnosis, Screening and Management

Aortoiliac Treatment with IVUS Guidance as Standalone Imaging Solution: Is it feasible and where are the benefits?



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Abstract

Introduction: Endovascular aortoiliac procedures are most often performed using angiographic guidance with iodinated contrast media. This generates high radiation doses for patient and staff members and bears the risk of acute kidney injury or allergic reactions. IVUS for guidance can reduce the radiation dose and the risk of adverse kidney events but additional equipment in such settings might become a surcharge and deteriorate the workflow quality and the staff members' contentment.

Method: To compare the workflow and procedural quality and outcome of angiographic versus IVUS guidance for aortoiliac severe stenosis the BMI adjusted skin entrance dose (dose area product), the procedure time and the amount of contrast applied for these procedures were compared (24 cases with angiographic and 28 with IVUS guidance). The need for c-arm repositioning by staff members was also documented.

Results: IVUS guidance for aortoiliac stenosis with steady c-arm position instead of angiographic guidance with needed c-arm motion reduced the procedure time, the physical stress for staff members, and the radiation dose ($p < 0.001$) and amount of applied contrast media ($p < 0.001$).

Discussion: IVUS guidance for aortoiliac intervention is beneficial in terms of radiation dose, radiation and kidney function safety. The procedural quality increases with shorter procedure time and less physical stress for staff members. The immediate and long-term outcome is superior to angiographic imaging. Based on a self-contained workflow the implementation of IVUS into the setting of an operating theatre is unproblematic and represents an enhancement for the operative environment.

Keywords: IVUS guidance, mobile c-arm, radiation reduction, radiation safety, workflow improvement

Introduction:

Treatment of complex aortoiliac stenotic disease requires advanced imaging technique for guidance. But, angiography means high energy radiation and especially at the level of the aortoiliac segment the different projections necessary for target vessel mapping result in high amounts of scattered radiation conditional on the biologic tissue in the central ray. Radiation safety for patients and even more for staff members is a must but table mounted protection tools sometimes disturb the workflow and

operators remain working in the close vicinity of the radiation source and the center of the scattered radiation area. Therefore, it is crucial to reduce radiation dose by minimizing angiographic imaging. IVUS represents an alternative imaging technique that has shown to be feasible for treating lesions at various vessel segments (1, 2, 3). But the technique and the equipment have to be implemented into the operative environment, which might also require changes of the standardized workflow (4).

Methods:

To evaluate the workflow and procedural quality of percutaneous treatment for PAD with different imaging modalities we searched the patient files for the name of the operator and the terms “IVUS”, “aortoiliac stenosis”, “POBA” and “stenting”. Severe aortoiliac stenosis was chosen, because this represents a completely standardized procedure in the local setting, independent from the used imaging tools (table 1). Standardization applies for patient

preparation, the procedural steps and the materials used for vessel access and lesion treatment. The skin entrance dose (DAP in mGycm²) as documented in the radiation protocol was compared for both groups adjusted to the patient’s BMI. The DAP of the two methodologies and contrast amounts were compared using the Mann Whitney U Test calculator (one-tailed; 2021, December 1; retrieved from <https://www.socscistatistics.com/tests/mannwhitney/default3.aspx>).

Both modalities were performed under the same conditions using a mobile Pulsera™ or a Zenition 70™ c-arm (both Philips b.v., The Netherlands). The operating table has a carbon plate offering 60 cm longitudinal mobility with remote control allowing imaging of the thoracoabdominal aorta down to the popliteal artery without moving the c-arm. The IVUS system used here was the second-generation CORE TM mobile™ with the recent generation of the 8.2F PV 35 IVUS catheter (Philips b.v., The Netherlands) (Figure 1).

Table. 1: Procedural steps and workflow in aortoiliac PAD treatment. For IVUS guidance fluoroscopy only without oblique projections can be used (items in grey highlight workflow differences)

	Angiographic guidance	IVUS guidance
Patient preparation outside the OR	Venous access, ECG and blood pressure monitoring preparation, preop antibiotics	Venous access, ECG and blood pressure monitoring preparation, preop antibiotics
Patient transfer	Transfer to table via side door	Transfer to table via side door
On table preparation	Sterile draping	Sterile draping
	Positioning of radiation protection tools	Positioning of radiation protection tools
	Team time out	Team time out
Vessel access	DUS guided LA and puncture	DUS guided LA and puncture
	5F sheath, starter wire and guidewire under fluoroscopy	5F sheath, starter wire and guidewire under fluoroscopy
Heparin	70IE/ Kg bodyweight	70IE/ Kg bodyweight
Imaging technique	5F Pigtail and angiography ap, 1-2 oblique projections, resp.	9F sheath, IVUS catheter 8.2F and pull back maneuver in ap C-arm position without fluoroscopy
Treatment	Ballooning/ stenting	Ballooning / stenting
Completion control	Angiography in ap and oblique projection	Pullback of IVUS catheter without fluoroscopy
	Further projections if required, further treatment if required Further completion angiography if required	Further treatment if required, additional, pull back without fluoroscopy No oblique projections
C-arm/ table motion	Oblique projections, repositioning to ap projections prior and after implant deployment Rotation of table over longitudinal axis for CO2 angio	none
	Closure device, 6F	Closure device 8F



Fig. 1: The left image shows the operators side in the given technical setting. The right image shows the opposite side with the additional sterile draping of the wall. Under table radiation protection for the anesthesia team at the patients' head is provided by the pedestal. The black arrow indicates the sterile draping of the wall to prevent contamination when using long devices.

1: Zenition 70, 2: IVUS 3: Zenition workstation 4: lead glass
5: carbon plate table with under table and above table radiation protection

Twenty-eight aortoiliac procedures were performed with fluoroscopy and IVUS for guidance and compared to 24 procedures with fluoroscopy and angiographic guidance. The treated lesions showed equivalent morphology, position and stenosis severity. All procedures were performed by a single operator, thus excluding operator related individual differences. IVUS imaging using the 8.2F PV35 IVUS catheter demands a 9F sheath, while angiographic imaging requires a 6F sheath as minimum for aortoiliac stent-placement. 6F or 8F Angioseal™ closure devices were used (Terumo Global Inc., Japan) for puncture site sealing.

Radiation dose was measured as dose area product in mGy/ cm² and adjusted to the patients BMI. Procedure time was documented as well as contrast media amounts and the need for c-arm repositioning done by staff members to achieve optimal lesion mapping and control.

Results:

Containing the search terms, 52 procedures from a single operator were found. 28 lesions had been treated with IVUS guidance only and 24 with angiographic guidance under the above mentioned conditions. The radiation dose protocol, which is automatically copied to the patients' image files allowed to sum up the

different projections during the procedures indicating the physical stress for non-sterile staff members rotating the c-arm or moving it longitudinally. It also lists up the fluoroscopic and angiographic sequences. The operation protocol does also include a list of material, operating time, amounts of contrast applied and the BMI adjusted radiation dose represented by the dose area product (DAP). DAP is measured in mGy/cm² and represents the most important parameter for the periodical external quality surveillance, which is performed by the local authorities of the medical association.

All procedures were completed successfully starting with Duplex ultrasound guided vessel puncture under local anesthesia. Bilateral femoral access was necessary in six aortoiliac lesions (3 for IVUS, 3 for angiography). Fourteen patients with bilateral iliac stenosis could be treated using a single access site (8 with angiography, 6 with IVUS). In solitaire iliac lesions a PV 14 catheter (Philipsb.v., The Netherlands) was used for ipsilateral and crossover imaging via a 6F sheath. Access complications did not occur in either group.

Lesions were consistent concerning the degree of stenosis and lesion extent in both groups. Average lesions length was 6.2cm (range 2.1-8.1cm) for angiographic guidance and 6.6cm (range 3.1-11.4cm) for IVUS

guidance. The preprocedural average degree of stenosis was 70-90% estimated based on CTA and MRA. In the IVUS group, the degree of stenosis was intraoperatively measured before and after treatment and used for determining the implant sizes.

The procedure time was longer for angiographic guidance (41.8min \pm 17.5min vs 33.1 min. \pm 11.4min), but this was influenced by technical problems in two cases for the angiographic group.

While angiographic guidance required oblique projections and C-arm rotation for displaying the hypogastric orifice and for completion angiography in at least two different projections, this was not necessary for IVUS guidance. With IVUS the c-arm remained in a steady position while the table was moved

longitudinally via remote control, thereby avoiding physical stress for staff members.

With a comparable BMI in the two groups (30,4 vs. 32,9) the radiation dose with IVUS guidance showed a significant reduction of 81.2% ($p=0.001$) compared to angiographic imaging. Oblique projections for hypogastric orifice mapping were required in a single case with misleading MR angiography pretending a severe stenosis at the orifice. The average amount of iodinated contrast applied was 28 ± 14 cc in a saline dilution ratio of 1:2. For the IVUS group there was no need for additional angiography and zero contrast was applied. Table 2 shows the results from the key indicators and fig. 2 shows the DAP measurements of the different procedures as documented in the protocol.

Table 2: comparison of groups and results for the chosen key performance indicator

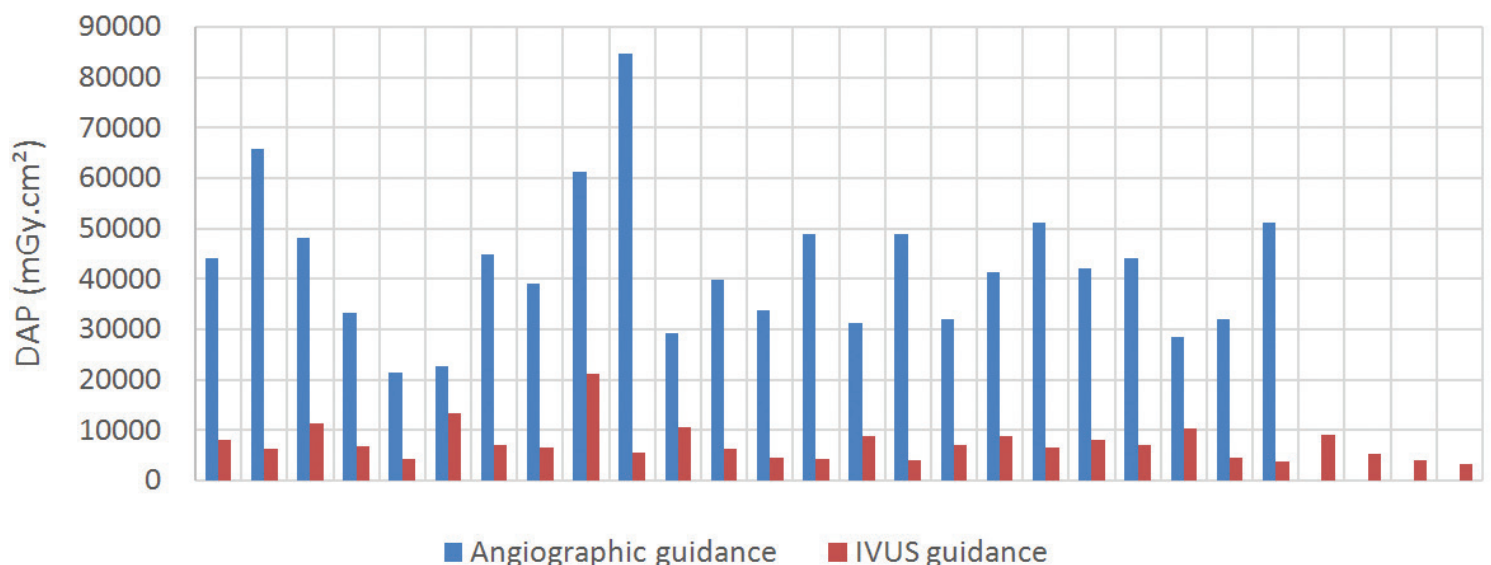
* Contrast was diluted with saline 1:2; ** One ap projection was used in both groups.

The c-arm is not motor driven, each rotation means physical stress for staff members

	Angiographic guidance	IVUS guidance	P value
BMI	30.4	32.9	
Contrast media in cc*	28 \pm 14	0	0.001
Procedure time	41.8min \pm 17.5min	33.1 min. \pm 11.4min	
Oblique projections**	1-5	0	
DAP	44178,88 (21478-84773)	8344,33(3191-21149)	0.001

Fig.2: The fig. shows the dose area product (DAP in mGy/cm²) for aortoiliac reconstruction with IVUS guidance and angiographic guidance for severe stenosis in 28 IVUS cases (orange) and 24 angiographic cases (blue).

Dose comparison



is long since known from literature (12,13,14,15), while angiography remains mandatory for run off vessel imaging only.

The radiation dose reduction for 82% in our small series might be biased by the team experience and the intention to avoid angiography and thereby the radiation associated risks for patient and staff members (16,17).

Although contrast media application has decreased over time and is relatively low in this analysis, the complete avoidance of iodinated contrast media might further help to protect kidney function by preventing contrast induced nephropathy or acute kidney injury (18). Costs remain probably one of the major issues, but a single patient with acute kidney injury after iodinated contrast application generates the same direct costs as 75 IVUS catheters in his first hemodialysis year.

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