



University of Groningen

Endovascular aneurysm repair: prevention and treatment of complications

Goudeketting, Seline

DOI: 10.33612/diss.98524202

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version Publisher's PDF, also known as Version of record

Publication date: 2019

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA): Goudeketting, S. (2019). Endovascular aneurysm repair: prevention and treatment of complications. Rijksuniversiteit Groningen. https://doi.org/10.33612/diss.98524202

Copyright

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: https://www.rug.nl/library/open-access/self-archiving-pure/taverneamendment.

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): http://www.rug.nl/research/portal. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

3

Pros and Cons of 3D Image Fusion in Endosvascular Aortic Repair: A Systematic Review and Meta-Analysis

J Endovasc Ther. 2017 aug;24(4):595-603

Seline R. Goudeketting Stefan G. H. Heinen Çağdaş Ünlü Daniel A. F. van den Heuvel Jean-Paul P. M. de Vries Marco J. van Strijen Anna M. Sailer

ABSTRACT

Purpose: To systematically review and meta-analyze the added value of 3-dimensional (3D) image fusion technology in endovascular aortic repair for its potential to reduce contrast media volume, radiation dose, procedure time, and fluoroscopy time.

Methods: Electronic databases were systematically searched for studies published between January 2010 and March 2016 that included a control group describing 3D fusion imaging in endovascular aortic procedures. Two independent reviewers assessed the methodological quality of the included studies and extracted data on iodinated contrast volume, radiation dose, procedure time, and fluoroscopy time. The contrast use for standard and complex endovascular aortic repairs (fenestrated, branched, and chimney) were pooled using a random-effects model; outcomes are reported as the mean difference with 95% confidence intervals (CIs).

Results: Seven studies, 5 retrospective and 2 prospective, involving 921 patients were selected for analysis. The methodological quality of the studies was moderate (median 17, range 15–18). The use of fusion imaging led to an estimated mean reduction in iodinated contrast of 40.1 mL (95% Cl 16.4 to 63.7, P = .002) for standard procedures and a mean 70.7 mL (95% Cl 44.8 to 96.6, P < .001) for complex repairs. Secondary outcome measures were not pooled because of potential bias in nonrandomized data, but radiation doses, procedure times, and fluoroscopy times were lower, although not always significantly, in the fusion group in 6 of the 7 studies.

Conclusion: Compared with the control group, 3D fusion imaging is associated with a significant reduction in the volume of contrast employed for standard and complex endovascular aortic procedures, which can be particularly important in patients with renal failure. Radiation doses, procedure times, and fluoroscopy times were reduced when 3D fusion was used.

INTRODUCTION

Endovascular aortic procedures are performed using fluoroscopy and digital subtraction angiography (DSA), which rely on the administration of iodinated contrast media and the use of ionizing radiation.¹ With increased complexity of the vascular anatomy and the procedures, the volume of iodinated contrast employed may increase substantially. Reducing the amount of contrast during endovascular aortic procedures is relevant because of its potentially nephrotoxic effects in patients with renal failure.^{2–6} Furthermore, procedure complexity may increase the number of imaging series, increasing the radiation dose and procedure time.

Since its first report in 2011,⁷ fusion imaging guidance during endovascular aortic interventions has become more widespread. Three-dimensional (3D) image fusion involves the registration of a preoperative computed tomography angiography (CTA) or magnetic resonance angiography (MRA) image to a cone-beam computed tomography (CBCT) image (3D-3D registration) or 2 fluoroscopic orthogonal images (2D-3D image registration) for guidance during aortic procedures. The CTA or MRA image is manually registered to the CBCT based on landmarks, such as bone structures, clips, and, in case of a preoperative CTA, aortic wall calcifications. When an accurate alignment is achieved, the segmented vascular roadmap can be visualized on the 2D fluoroscopy screen, where the preoperative data set will follow the movements of the table and the C-arm.^{8,9} The acquisition and registration. Depending on the experience of the operator with the image fusion technique, the number of DSA runs can be decreased. In this manner, image fusion can potentially reduce the amount of iodinated contrast, radiation dose, procedure time, and fluoroscopy time.^{2,8}

The technique of 3D image fusion has been reported in a variety of endovascular procedures. Dijkstra et al.⁷ were the first to perform fenestrated endovascular aneurysm repair (FEVAR) using CBCT image fusion. Kobeiter et al.¹⁰ reported the first case of thoracic endovascular aortic repair (TEVAR) without contrast by using only 3D overlay techniques. More recent studies show a reduction in the amount of administered iodinated contrast for EVAR and TEVAR [(T)EVAR] procedures of varying complexity.^{11,12} Although several studies have reviewed the registration technique for CBCT image fusion and its different applications,^{1,2,8,9,13-15} a systematic review of the impact of 3D image fusion on (T)EVAR procedures is lacking. This study sought to systematically review available reports describing the use of preoperative CTA or MRA for 3D image fusion in (T)EVAR procedures and to pool the outcomes regarding the amount of iodinated contrast administered. Secondary goals were to collect data on radiation dose, procedure times, and fluoroscopy times.

METHODS

Literature Search

A literature search was performed using PubMed/MEDLINE, Embase, and the Cochrane Database of Controlled Trials databases to identify English-language clinical studies published between January 2010 and March 2016 on 3D image fusion during (T)EVAR procedures. A broad search was created with the following MeSH terms: "software" OR "computer-assisted surgery" OR "multimodal imaging" OR "cone-beam computed tomography" OR "interventional radiology" OR "fluoroscopy" OR "three-dimensional imaging" OR "angiography" in combination with (AND) "overlay" OR "fusion" OR "roadmap." To avoid missing recent publications without MeSH terms, the same keywords, including all combinations of these keywords, were added as free-text terms to the search. The search terms were limited to the title and abstract; only citations with full text articles available were retrieved.

Inclusion/Exclusion Criteria and Data Collection

Two reviewers (SRG and SGHH) independently reviewed the title and abstract of identified articles to select those that indicated the use of CTA or MRA images overlaid on live 2D fluoroscopy for guidance during (T)EVAR. Case reports (n < 5), letters to the editor, technical descriptions of image fusion, and articles without a 3D image control group were excluded.

The selected articles were compared between the reviewers and if one or both considered an article eligible, both reviewers evaluated the full text version. The reference lists of the eligible articles were crosschecked to identify additional relevant studies that might have been missed during the individual search. If necessary, authors were contacted for clarification of the data.

The reviewers extracted from the selected studies data on the year of publication, study design, number of patients in each study group, type and location of the procedure, preoperative imaging technique, image fusion method (i.e., 3D-3D or 2D-3D registration), registration time for 3D image fusion, contrast volume, radiation dose, fluoroscopy time, and procedure time.

Quality Assessment

The 12-item Methodological Index for Non-Randomized Studies (MINORS)¹⁶ scoring system was used to assess the methodological quality of the studies (0 = not reported, 1 = reported but inadequate, or 2 = reported and adequate). The scoring was independently performed by 2 reviewers (SRG and SGHH); in case of any discrepancies, the opinion of a third reviewer (AMS) was sought until consensus was reached. Of

the maximum score of 24, \leq 14 is considered poor quality; scores between 15 and 22 indicate moderate quality, and \geq 23 is good quality.

Outcome Measures and Data Analysis

The primary outcome measure was the amount of administered iodinated contrast used. Secondary outcome measures were radiation dose [dose area product (DAP, Gy·cm²), cumulative air kerma (AK, mGy), or skin dose (SD, mGy)], overall procedure time, and fluoroscopy time. Pooled data analysis was performed using a random-effects model for the primary outcome measure (volume of iodinated contrast) only. Because of the potential bias in nonrandomized data, differences in outcome measure units for radiation dose, and missing definitions of procedure times and fluoroscopy times in some of the included studies, the secondary outcome measures were not pooled.

The presence of heterogeneity was examined using forest plots, chi-square heterogeneity tests, and the *I*² indexes. To minimize heterogeneity, procedure type was dichotomized into standard infrarenal procedures [(T)EVAR] and complex procedures [FEVAR, branched EVAR (BEVAR), and chimney EVAR (chEVAR)].¹⁷ Outcome measures described as medians were recalculated to means to perform the meta-analysis, which was conducted using Meta-Analyst software (version 3.1; Tufts University, Medford, MA, USA).

RESULTS

Included Studies

The queries in the databases yielded 6049 articles, of which 5968 were excluded after the initial screening (Figure 3.1). Of 81 articles identified from the initial title and abstract search, the reviewers selected 26 articles using 3D image fusion for the full-text evaluation. No additional articles were identified after a crosscheck of references. Of the 26 articles,^{7,10-12,18-40} 19 were excluded because of (1) a small sample size (<5)^{10,27,28,33,36,40} or lack of a control group,^{24–26,34,37} or (2) an intervention other than (T) EVAR.^{23,29–32,35,38,39} Seven articles^{7,11,12,18–21} fulfilled the inclusion criteria. Characteristics and outcomes of the included studies are summarized in Table 3.1.

Of the 921 patients in the study articles, 337 were treated under fusion guidance and 584 without the 3D image fusion technique. None of the studies was a randomized controlled trial; 5 articles were retrospective studies^{7,11,18-20} and 2 had a prospective design.^{12,21} All studies used preoperative CTA for fusion; Stangenberg et al.¹⁹ employed preoperative MRA in 1 of 32 patients. Registration time was approximately 2 to 5 minutes.^{12,19-21} Three studies used Siemens Syngo fusion software (Siemens, Erlangen,



Figure 3.1. Flowchart of the search results. EVAR, endovascular aneurysm repair.

The median MINORS score for the selected articles was 17 (range 15–18; Figure 3.2). All studies were of moderate quality; none of the studies utilized a power calculation. The control groups were adequate for all 7 studies; however, only in the study by Stangenberg et al.¹⁹ were the intervention and control groups treated in the same time period.

Germany), 2 used Philips' XtraVision (Philips Healthcare, Andover, MA, USA), and the remaining articles used Philips' VesselNavigator or Innova Vision (General Electric Medical Systems, Milwaukee, WI, USA).

ומחוב סידי	SIUUIES	ונוכוחמבת ונו ה	le didiya.						
Study	z	Study type	Pre-	Fusion		Study	/ vs Cont	rol group.	MINORS
			operative imaging technique	with	Intervention	lodinated contrast media (mL) ^a		Secondary Endpoints ^a	
Dias	226	۲	CTA	CBCT	TEVAR	53 (40-175) vs 178	DAP:	90.4 (61.95-158.49) vs 172.98 (143.76-	15
2015 ¹¹					n=10 vs n=15	(128-282), P = .400		386.32), P = .041	
							PT:	83 (56-183) vs 144 (95-144), P = .459	
							Ë	14 (9-31) vs 28 (19-39), P = .688	
					TAAA BEVAR/	143 (196-197) vs 298	DAP:	262.87 (202.98-367.69) vs 638.91 (439.69-	
					FEVAR	(234-363), <i>P</i> < .001		1002.66), <i>P</i> < .001	
					n=33 vs n=23		PT:	349 (261-438) vs 459 (391-607), P = .007	
							Ë	103 (84-139) vs 127 (104-157), P = .103	
					FEVAR	96 (69-144) vs 208	DAP:	241.72 (140.44-432.04) vs 283.24 (192.08-	
					n=21 vs n=36	(162-238), <i>P</i> < .001		499.57), P = .581	
							PT:	231 (163-332) vs 277 (193-374), P = .319	
							Ë	72 (48-131) vs 87 (58-99), P = .581	
					Infrarenal EVAR	84 (49-136) vs 160	DAP:	98.85 (83.63-164.70) vs 213.83 (123.99-	
					n=22 vs n=25	(146-204), <i>P</i> < .001		290.14), P = .013	
							PT:	128 (102-151) vs 149 (119-193), <i>P</i> = .459	
							Ë	25 (18-40) vs 38 (30-45.3), P = .185	
					EVAR + IBD	132 (85-185) vs 255	DAP:	188.76 (121.94-234.93) vs 468.67 (328.87-	
					n=17 vs n=24)	(224-312), P < .001		617.08), <i>P</i> < .001	
							PT:	191 (130-258) vs 249 (191-281), P = .131	
							Ë	57 (35-76) vs 80 (60-101), P = .077	
					Combined	103 (63-145) vs 215	DAP:	199.34 (113.40-306.15) vs 328.56 (195.62-	
					n=103 vs	(166-280), <i>P</i> < .001		556.78), P < .001	
					n=123		PT:	230 (134 – 331) vs 235 (158 – 364),	
								P = .942	
							Ë	66 (33-102) vs 72 (42-102), P = .837	
Dijkstra	89	Ľ	CT	CBCT	FEVAR	94 (72-131) vs 136	SD:	7 (4-12) vs 7 (5-10), P = .782	16
2011^{7}					n=40 vs n=49	(96-199), P = 0.001	PT:	330 (273-522) vs 387 (290-477), P = .651	
	•				·		Ë	81 (54-118) vs 90 (46-128), <i>P</i> = .932	

Table 7.1 Studies included in the analysis

3

| 57

Table 3.1 c	ontinu	ed.							
Study	z	Study type	Pre- operative	Fusion with		Study	r vs Con	itrol group	MINORS
			imaging		Intervention	lodinated contrast		Secondary Endpoints ^a	
			technique			media (mL) ^a			
Hertault	403	P + P	CTA	2FP	Bifurcated	59 (50-75) vs 80 (65-	DAP:	12.2 (8.7-19.9) vs 30.0 (20.0-43.5),	18
201412		literature			EVAR	106),	PT:	<i>P</i> < .01	
		cohort			n=44 vs n=199	P = .34	ET:	92.5 (75-120) vs 93 (75-120), P = .97	
								10.6 (9.1-14.7) ^b	
					BEVAR	120 (100-170) vs 138	DAP:	47.4 (37.2-108.2) vs 159.0 (101.8-222.4),	
					n=20 vs n=20	(100-160), P < .01		<i>P</i> < .01	
							РТ	205 (169-240) vs 210 (150-260), P = .87	
								39.5 (34.8-51.6)	
							FT:		
					FEVAR	105 (70-136) vs	DAP:	43.7 (24.7-57.5) vs 72.9 (52-109.2), P < .01	
					n=18 vs n=54	226(150-278), P = .03		150 (150-160) vs 150 (105-180), P = .39	
							PT:	30.7 (20.2-40.5)	
							FT:		
					TEVAR	80 (50-100) vs	DAP:	26.0 (11.9-34.9) vs 20.0 (11.4-30.0),	
					n=14 vs n=28	100(78-140),		P =0.63	
						P = .07	PT:	80 (60-105) vs 117 (60-138), P = .22	
							Ξ.	8.9 (6.0-10.5)	
					EVAR + IBD	85 (60-120)	DAP:	41.2 (38.2-51.3)	
					n=6		PT:	140 (120-180)	
							ET:	27.3(22.4-30.1)	
					Combined		PT:	120 (85-180)	
					n=102		RT:	±2	
McNally	72	Ч	CTA	CBCT	2 vessels FEVAR	26±8 vs 69±16,	AK:	1380±520 vs 3400±1900, <i>P</i> = .001	15
2015 ¹⁸					n=12 vs n=8	P < .001	FT:	$41\pm11 \text{ vs } 63\pm29, P = .023$	
					3/4 vessels	39±17 vs 90±25,	AK:	2700±1400 vs 5400±2225, <i>P</i> < .001	
					FEVAR	P < .001	PT:	230±50 vs 330±100, <i>P</i> = .002	
					n=19 vs n=33		FT:	$64\pm 21 \text{ vs } 89\pm 36, P = .018$	
					Combined	34±15 vs 86±25,	AK:	2200 <u>+</u> 1300 vs 5000 <u>+</u> 280, <i>P</i> < .001	
					n=31 vs n=41	<i>P</i> < .001	FT:	55 ± 21 vs 84 ± 36 , $P < .001$	

σ
ā
Ē
5
.=
÷
Ē
ō
~~
•
-
М
d)
<u> </u>
9
a
E

Study	z	Study type	Pre-	Fusion		Study	vs Con	trol group	MINORS
			operative imaging technique	with	Intervention	lodinated contrast media (mL) ^a		Secondary Endpoints ^a	
Sailer	62	P + R case-	Dual energy	CBCT	FEVAR/BEVAR	159 (95% CI 132-186) 22 100 (05% CI 170-	ЪЩ.	312 (95% Cl 270-354) vs 378 (95% Cl 324- 423) b = 033	18
+102		cohort				VS 133 (33% CI 170- 229), P = 037	FT:	43.cl, r = .ucc 50.43 (95% Cl 30.55 -70.3) vs 59.48 (95% Cl 40.67-78 32) P = 38	
Stangen-	32	Retrospective	, CTA,	CBCT /	EVAR	37.4±21.3 vs	AK:	1067 <u>+</u> 470.4 vs 1768 <u>+</u> 696.2, <i>P</i> = .004	17
berg 2015 ¹⁹			MRA (n=1)	2442	n=16 vs n=16	//.5±25.0, P < .001	н. Н	80.4±21.2 vs 110.0±29.1, <i>P</i> = .005 18.4±6.8 vs 26.8±10.0, <i>P</i> = .01	
							RT:	3-5	
Tacher	37	Я	CTA	CBCT	FEVAR/BEVAR/	IF vs 2DA vs 3DA:	DAP:	IF vs 2DA: 656±457 vs 1188±1067, <i>P</i> = .35	17
201320					CHEVAR	65±28 vs 235±145 vs		IF vs 3DA: 656 <u>+</u> 457 vs 984 <u>+</u> 581, <i>P</i> = .06	
						225±119,	PT:	IF vs 2DA vs 3DA:	
					Groups:	P < .001		189±60 vs 223±123 vs 181±53, <i>P</i> = .59	
					IF: n=14		Ë	IF vs 2DA vs 3DA:	
					2DA: n=9	IF vs 2DA:		80±36 vs 82±46 vs 42±22, <i>P</i> = .04	
					3DA: n= 13	65±28 vs 235±145,	RT:	<5	
						<i>P</i> < .001			
						IF vs 3DA:			
						65±28 vs 225±119, P < 001			
Abbreviation.	s: 2DA/5	3DA, 2-/3-dime	nsional angiogr	aphy; 2FP,	2 fluoroscopic pr	ojections; AK, air kerma	(mGy);	BEVAR, branched endovascular aneurysm rep	air (EVAR);
CBCT, cone-	beam c	omputed tomog	graphy; DAP, do	se area pro	duct (Gy·cm2); SE), skin dose (mGy); FEVA	R, fenes	trated EVAR; FT, fluoroscopy time (min); IBD, il.	iac branch
device; IF, in	nage fus	ion; MINORS, N	Aethodological	Index for N	lon-Randomized	Studies; MRA, magnetic	resona	nce angiography; NR, not reported; PT, proce	edure time

| 59

made for this variable.

"The control group was a previously published prospective cohort in which the fluoroscopy time was recorded differently from the study group, so no comparison was

(min); R, retrospective; RT, registration time (min); SG, stent-graft; TAAA, thoracoabdominal aortic aneurysm; TEVAR, thoracic endovascular aortic repair.

 $^{\circ}$ Values given as median (interquartile range) or means \pm standard deviation or 95% confidence interval (CI).

Items MINORS score	Dias 2015	Dijkstra 2011	Hertault 2014	McNally 2015	Sailer 2014	Stangenberg 2015	Tacher 2013
1. A clearly stated aim	1	2	2	2	2	2	2
2. Inclusion of consecutive patients	1	0	2	1	0	0	2
3. Prospective collection of data	0	0	2	0	2	0	0
4. Endpoints appropriate to the aim of the study	1	2	2	2	2	2	2
5. Unbiased assessment of the study endpoint	1	1	1	1	1	1	1
6. Follow-up period appropriate to the aim of the study	2	2	2	2	2	2	2
7. Loss to follow-up less than 5%	2	2	2	2	2	2	2
8. Prospective calculation of the study size	0	0	0	0	0	0	0
Item 9-12 only for comparative studies							
9. An adequate control group	2	2	2	2	2	2	2
10. Contemporary groups	1	1	1	1	1	1	1
11. Baseline equivalence of groups	2	2	0	0	2	2	1
12. Adequate statistical analysis	2	2	2	2	2	2	2
Total MINORS score	15	16	18	15	18	17	17
Maximum possible score	24	24	24	24	24	24	24

Figure 3.2. Quality assessment of included endovascular aneurysm repair studies. Items were scored 0 (not reported), 1 (reported but inadequate), or 2 (reported and adequate). MINORS, Methodological Index for Non-Randomized Studies.

Description of Studies

Two articles described prospective data. In Hertault et al.¹², 102 patients were prospectively enrolled from December 2012 to July 2013 in a study comparing a hybrid room group and a previously published prospective C-arm cohort (EVAR, 44 vs 199; BEVAR, 20 vs 20; FEVAR, 18 vs 54; and TEVAR, 14 vs 28). The median (interquartile range, IQR) contrast volume was significantly lower in the BEVAR [120 (100–170) vs 138 (100–160) mL, P < .01] and FEVAR [105 (70–136) vs 226 (150–278) mL, P = .03] subgroups. The calculated means for contrast use in the intervention vs control groups were, respectively, 105 ± 48.9 vs 226 ± 94.8 mL for FEVAR (P = .03) and 59 ± 18.5 vs 80 ± 30.7 mL for EVAR (P = .34). The median DAP was significantly reduced in the bifurcated EVAR, BEVAR, and FEVAR groups (P < .01).

Patients undergoing FEVAR/BEVAR in the study by Sailer et al.²¹ were prospectively included in the fusion guidance group (n = 31). Retrospective case controls treated between 2010 and 2013 were matched with the fusion patients according to procedure

complexity. The mean volume of contrast in the fusion group was 159 ± 40 mL (95% CI 132 to 186) vs 199 ± 43.7 mL (95% CI 170 to 229) in the control group (P = .037). Mean procedure time was significantly shorter in the fusion group [312 minutes (95% CI 270 to 354) vs 378 minutes (95% CI 324 to 432), P = .022].

In the retrospective study from Stangenberg et al.¹⁹, 32 patients undergoing EVAR between January 2011 and April 2014 were matched according to body mass index in the fusion group (n = 16) and the control group (n = 16). The amount of contrast was significantly lower in the study group (37.4 ± 21.3 vs 77.3 ± 23.0 mL, P < .001). Radiation exposure (P = .004), procedure time (P = .005), and fluoroscopy time (P = .01) were also significantly lower in the study group.

Tacher et al.²⁰ retrospectively reviewed 37 consecutive patients with complex aortic aneurysms treated using FEVAR, BEVAR, or chEVAR between March 2009 and January 2011. Patients were grouped according to imaging type: 9 had 2D angiography (2DA), 14 had 3D angiography (3DA), and 14 had image fusion (IF). The amount of contrast used in the IF group was significantly reduced compared with the combined 2DA and 3DA groups [65 ± 28 vs 235 ±145 mL (P < .001) and 65 ± 28 vs 225 ±119 mL (P < .001) .001), respectively]. Fluoroscopy time was significantly reduced among the 3 groups; however, the fluoroscopy time of the IF group was longer than that of the 3DA group. Dijkstra et al.⁷ retrospectively evaluated 40 patients undergoing FEVAR (CBCT fusion group) between August 2009 and March 2010 and compared them with a historical cohort of 49 patients undergoing FEVAR in the 12 months before the initiation of CBCT. The median (IQR) contrast volume in the CBCT fusion group [94 mL (72–131)] was significantly lower than in the historical control group [136 mL (96-199), P = .001]. Dias et al.¹¹ retrospectively analyzed 226 patients (103 fusion imaging patients and a 123 historical controls) subdivided according to procedure type [TEVAR, BEVAR/FEVAR for thoracoabdominal aortic aneurysm (TAAA), FEVAR, infrarenal EVAR, and EVAR with iliac branch devices (IBDs)]. The median volume of contrast was significantly reduced (P < .001) in favor of the fusion technique in all but the TEVAR group. Calculated means for contrast use in the study vs control groups were 96+55.5 vs 208+56.3 mL (P < .001) for FEVAR and 84 ± 64.4 vs 160 ± 43.0 mL (P < .001) for EVAR. The radiation dose was significantly lower in the TEVAR (P = .041), TAAA BEVAR/FEVAR (P < .001), infrarenal EVAR (P = .013), and EVAR with IBD (P < .001) subgroups in which 3D image fusion was used. Furthermore, overall median contrast and radiation dose were significantly reduced (P < .001). Procedure time was reduced, but this was significant only in the TAAA BEVAR/FEVAR group (P = .007).

McNally et al.¹⁸ retrospectively reviewed data from 31 patients (3D-CT fusion group) undergoing FEVAR with image fusion and compared this with a 41-patient control group treated in the 12 months before the availability of the new hybrid

room. Intravascular ultrasound was used to determine branch vessel locations before device deployment. Contrast use was significantly lower in the 3D-CT group than in the control group (34 ± 15 vs 86 ± 25 mL, P < .001), which remained significant even when the groups were divided into 2-vessel and 3/4-vessel FEVAR. Furthermore, AK radiation exposure (2200 ± 1300 vs 5000 ± 280 mGy, P < .001) was significantly reduced. Procedure times were shorter in the study group but were significant only in the 3/4-vessel FEVAR subgroup. In addition, fluoroscopy time (55 ± 21 vs 84 ± 36 minutes, P = .004) was significantly shorter in the 3D-CT group.

Pooled Data

For standard (T)EVAR procedures, the estimated pooled mean difference revealed a significant reduction of 40.1 mL (95% CI 16.4 to 63.7, P = .002) in contrast use in favor of the 3D image fusion technique. The level of heterogeneity was high (l^2 =85%; Figure 3.3A). For complex EVAR procedures, the estimated pooled mean difference showed a significant reduction of 70.7 mL (95% CI 44.8 to 96.6, P < .001) in contrast administration, with a high heterogeneity among the studies (l^2 =87%; Figure 3.3B).



Figure 3.3. Forest plots of the pooled mean difference in the volume of contrast used for **(A)** endovascular aortic repairs and **(B)** complex endovascular aneurysm repair (EVAR) procedures [fenestrated EVAR (FEVAR), branched EVAR (BEVAR), and chimney EVAR]. Hertault refers to their FEVAR subanalysis and Hertault1 to their BEVAR subgroup. CI, confidence interval.

DISCUSSION

This systematic review of guidance techniques in standard and complex (T)EVAR procedures showed a significant decrease in contrast use between the 3D image fusion and control groups. Six of the 7 studies reported lower radiation doses for the procedures employing 3D fusion; 4 were significant reductions in the DAP or AK. Radiation dose may be further reduced by fusing 2 fluoroscopic orthogonal shots instead of a CBCT image during registration. A simulation by van den Berg¹⁵ estimated that CBCT results in an effective dose of 1.53 to 1.66 mSv, whereas 2 fluoroscopic orthogonal shots can be acquired with a considerably lower effective dose of 0.14 to 0.20 mSv. Of note, these values may be lower or higher depending on the patient's body mass index and exposure conditions (e.g., voltage, field size, and position). Hertault et al.¹² and Stangenberg et al.¹⁹ both used this 2D-3D registration technique, which may explain their reported significant reduction in radiation dose. Furthermore, the 2D-3D registration method is described as fast and easy.^{12,15} However, Stangenberg et al.¹⁹ preferred 3D-3D registration, which they believed was more accurate even though it required more radiation.

None of the included studies measured registration accuracy, although inaccuracies in overlays were observed.²¹ Accuracy measurements were, however, performed in some of the excluded studies.^{23–26} Nonetheless, registration accuracy needs further investigation. Furthermore, the effects of registration inaccuracies on study outcomes remain unclear. In addition, all studies postulated that fewer angiographies will be required with growing experience and confidence in the 3D image fusion technique, which in return may result in an even greater reduction in contrast use and possibly radiation dose. Because of the differences in reported radiation dose units (i.e., DAP, AK, or SD), the radiation doses were not pooled.

Fluoroscopy times were decreased in 6 of the 7 studies, but only 3 studies reported a significant difference. Notably, the significance in the study of Stangenberg et al.¹⁹ may be based on the large reduction in fluoroscopy time in the 3DA group, not necessarily because of fusion imaging. Because fluoroscopy time can refer to the "on-pedal" time or the summation of X-ray pulse lengths and the definition was not always provided, data on fluoroscopy time were not pooled.

Seven articles reported procedure times, most of which were reduced; only 4 showed a significant difference though. McNally et al.¹⁸ was the only study to define procedure time (from skin incision/puncture to bandage application). Thus, procedure time can depend on many factors, such as the operators' experience or perioperative complications. Most of the studies^{11,18–21} mentioned that the same surgeons performed the procedures to minimize the influence of operator experience. However,

perioperative complications (e.g., blood loss, renal dysfunction, arterial thrombosis, or dissection) were reported only by McNally et al.¹⁸ They discussed that blood loss was favorably affected by the 3D image fusion. However, one could argue that the significantly higher amount of blood loss in the no-fusion group might have resulted in longer procedure times, hence the significant difference in overall procedure time. To be able to give a correct representation of the possible reduction in procedure time when 3D fusion imaging is used, external factors (e.g., perioperative complications) that could influence the total procedure time should be minimized. Because of the aforementioned external factors that affect procedure duration and the lack of definitions for procedure time, this outcome measure was not pooled.

The difference in the results of the secondary outcome parameters among the studies might also be a consequence of the quality of image fusion, which can be influenced by the CTA/MRA image quality, type of registration, and the procedure setup. Further studies need to evaluate optimal conditions for fusion guidance with respect to effects on secondary outcome measures.

One disadvantage of the fusion imaging technique is the initial cost to buy a new software package if needed. Moreover, it takes around 10 minutes to perform the CBCT scan and to register the images, which requires trained personnel.¹⁴ In the absence of trained personnel, operators will likely avoid using this technique because it demands additional actions that may require extra time, especially when not used regularly. In addition, a learning curve may exist for the fusion imaging technique, but any influence of the learning curve on the outcome measures was not investigated. The contribution of multimodality image guidance to interventional procedures, notably vascular, is at present dependent on operators who were previously accustomed to C-arm use, particularly in operating theaters. Any relationship between the sample size of the included studies and the outcome measures could not be determined.

Another limitation to the technique is fusion inaccuracy caused by (1) differences in acquisition between the preoperative CTA/MRA and intraoperative CBCT, (2) patient movement, or (3) rigid registration (i.e., the insertion of stiff guidewires can lead to vessel deformation). Unfortunately, the included studies did not measure fusion inaccuracies or their effect on the intervention and outcome measures. Despite possible inaccuracies, the overlay can still serve as a rough guide to the physician. It is expected that registration time and fusion inaccuracies may be reduced with growing experience, which may be beneficial for the fusion imaging technique. However, future studies should be conducted to report any influence of a learning curve on the 3D image fusion technology.

Limitations

A limitation in the current analysis was the relatively small patient numbers and high heterogeneity among the study groups. None of the included studies was a randomized controlled trial. The 2 prospective studies^{12,21} implied risk of bias caused by selection of the controls and/or differences in operator experience; the remainder of the studies had a retrospective design. Furthermore, the included studies were of moderate methodological quality. Finally, pooling of the data was possible only for the primary outcome measure because of the potential for bias of nonrandomized data, difference in radiation dose units, and missing definitions for procedure time and fluoroscopy time in some of the included studies.

CONCLUSION

Compared with standard roadmapping, 3D fusion imaging is associated with a significant reduction in the amount of contrast used for standard or complex (T)EVAR procedures. The latter seems to have a larger potential for reduction. Radiation doses, procedure times, and fluoroscopy times were reduced in most studies, although not always significantly, when 3D fusion imaging was used. Broad application of this technique seems to be useful in daily clinical practice.

REFERENCES

- Törnqvist P, Dias NV, Resch T. Optimizing imaging for aortic repair. J Cardiovasc Surg (Torino). 2015;56:189–195.
- van den Berg JC. Update on new tools for three-dimensional navigation in endovascular procedures. Aorta. 2014;2:279–285.
- 3. Kawatani Y, Nakamura Y, Mochida Y, et al. Contrast medium induced nephropathy after endovascular stent graft placement: an examination of its prevalence and risk factors. Radiol Res Pract. 2016;2016:1–5.
- Brooks CE, Middleton A, Dhillon R, et al. Predictors of creatinine rise post-endovascular abdominal aortic aneurysm repair. ANZ J Surg. 2011;81:827–830.
- Gleeson TG, Bulugahapitiya S. Contrast-induced nephropathy. AJR Am J Roentgenol. 2004;183:1673– 1689.
- Solomon R, Dumouchel W. Contrast media and nephropathy: findings from systematic analysis and Food and Drug Administration reports of adverse effects. Invest Radiol. 2006;41:651–660.
- Dijkstra ML, Eagleton MJ, Greenberg RK, et al. Intraoperative C-arm cone-beam computed tomography in fenestrated/branched aortic endografting. J Vasc Surg. 2011;53:583–590.
- Kaladji A, Daoudal A, Clochard E, et al. Interest of fusion imaging and modern navigation tools with hybrid rooms in endovascular aortic procedures. J Cardiovasc Surg (Torino). 2017;58:458–466.
- Abi-Jaoudeh N, Kruecker J, Kadoury S, et al. Multimodality image fusion-guided procedures: technique, accuracy, and applications. Cardiovasc Intervent Radiol. 2012;35:986–998.
- Kobeiter H, Nahum J, Becquemin JP. Zero-contrast thoracic endovascular aortic repair using image fusion. Circulation. 2011;124:e280-e282.
- Dias NV, Billberg H, Sonesson B, et al. The effects of combining fusion imaging, low-frequency pulsed fluoroscopy, and low-concentration contrast agent during endovascular aneurysm repair. J Vasc Surg. 2015;63:1147–1155.
- Hertault A, Maurel B, Sobocinski J, et al. Impact of hybrid rooms with image fusion on radiation exposure during endovascular aortic repair. Eur J Vasc Endovasc Surg. 2014;48:382–390.
- 13. Angle JF. Cone-beam CT: vascular applications. Tech Vasc Interv Radiol. 2013;16:144–149.
- Abi-Jaoudeh N, Kobeiter H, Xu S, et al. Image fusion during vascular and nonvascular image-guided procedures. Tech Vasc Interv Radiol. 2013;16:168–176.
- van den Berg JC. Three-dimensional image overlay to assist endovascular procedures. Vasc Dis Manag. 2013;10: E179–E184.
- 16. Slim K, Nini E, Forestier D, et al. Methodological index for non-randomized studies (MINORS): Development and validation of a new instrument. ANZ J Surg. 2003;73:712–716.
- 17. Guneyli S, Bozkaya H, Cinar C, et al. The incidence of contrast medium-induced nephropathy following endovascular aortic aneurysm repair: assessment of risk factors. Jpn J Radiol. 2015;33:253–259.
- 18. McNally MM, Scali ST, Feezor RJ, et al. Three-dimensional fusion computed tomography decreases radiation exposure, procedure time, and contrast use during fenestrated endovascular aortic repair. J

Vasc Surg. 2015;61:309-316.

- 19. Stangenberg L, Shuja F, Carelsen B, et al. A novel tool for three-dimensional roadmapping reduces radiation exposure and contrast agent dose in complex endovascular interventions. J Vasc Surg. 2015;62:448–455.
- Tacher V, Lin M, Desgranges P, et al. Image guidance for endovascular repair of complex aortic aneurysms: comparison of two-dimensional and three-dimensional angiography and image fusion. J Vasc Interv Radiol. 2013;24:1698–1706.
- Sailer AM, De Haan MW, Peppelenbosch AG, et al. CTA with fluoroscopy image fusion guidance in endovascular complex aortic aneurysm repair. Eur J Vasc Endovasc Surg. 2014;47:349–356.
- 22. Maurel B, Sobocinski J, Perini P, et al. Evaluation of radiation during EVAR performed on a mobile C-arm. Eur J Vasc Endovasc Surg. 2012;43:16–21.
- Sailer AM, de Haan MW, de Graaf R, et al. Fusion guidance in endovascular peripheral artery interventions: a feasibility study. Cardiovasc Intervent Radiol. 2014;38:314–321.
- 24. Schulz CJ, Schmitt M, Böckler D, et al. Feasibility and accuracy of fusion imaging during thoracic endovascular aortic repair. J Vasc Surg. 2015;63:314–322.
- Kauffmann C, Douane F, Therasse E, et al. Source of errors and accuracy of a two-dimensional/threedimensional fusion road map for endovascular aneurysm repair of abdominal aortic aneurysm. J Vasc Interv Radiol. 2015;26:544–551.
- 26. Fukuda T, Matsuda H, Doi S, et al. Evaluation of automated 2D-3D image overlay system utilizing subtraction of bone marrow image for EVAR: Feasibility study. Eur J Vasc Endovasc Surg. 2013;46:75–81.
- Ahmad W, Gawenda M, Brunkwall S, et al. Endovascular aorto-iliac aneurysm repair with fenestrated stent graft and iliac side branch using image fusion without iodinated contrast medium. Ann Vasc Surg. 2016;33:231.e5–231.e9.
- 28. Alomran F, Desgranges P, Majewski M, et al. Image fusion for hybrid repair of dislocated superior mesenteric branch of a branched endovascular aortic graft. J Vasc Surg. 2013;58:798–801.
- 29. Bargellini I, Turini F, Bozzi E, et al. Image fusion of preprocedural CTA with real-time fluoroscopy to guide proper hepatic artery catheterization during transarterial chemoembolization of hepatocellular carcinoma: a feasibility study. Cardiovasc Intervent Radiol. 2013;36:526–530.
- 30. Chinnadurai P, Duran C, Al-Jabbari O, et al. Value of C-arm cone beam computed tomography image fusion in maximizing the versatility of endovascular robotics. Ann Vasc Surg. 2015;30:138–148.
- Gupta A, Grünhagen T. Live MR angiographic roadmapping for uterine artery embolization: a feasibility study. J Vasc Interv Radiol. 2013;24:1690–1697.
- 32. Ierardi AM, Duka E, Radaelli A, et al. Fusion of CT angiography or MR angiography with unenhanced CBCT and fluoroscopy guidance in endovascular treatments of aorto-iliac steno-occlusion: technical note on a preliminary experience. Cardiovasc Intervent Radiol. 2016;39:111–116.
- Kaladji A, Dumenil A, Castro M, et al. Endovascular aortic repair of a postdissecting thoracoabdominal aneurysm using intraoperative fusion imaging. J Vasc Surg. 2013;57:1109–1112.
- Kaladji A, Dumenil A, Mahé G, et al. Safety and accuracy of endovascular aneurysm repair without preoperative and intra-operative contrast agent. Eur J Vasc Endovasc Surg. 2015;49:255–261.

3

- 35. Kocer N, Kizilkilic O, Babic D, et al. Fused magnetic resonance angiography and 2D fluoroscopy visualization for endovascular intracranial neuronavigation. J Neurosurg. 2013;118:1000–1002.
- Koutouzi G, Hendrikson O, Roos H, et al. EVAR guided by 3D image fusion and CO2 DSA, a new imaging combination for patients with renal insuffiency. J Endovasc Ther. 2015;22:912–917.
- Maurel B, Hertault A, Gonzalez TM, et al. Evaluation of visceral artery displacement by endograft delivery system insertion. J Endovasc Ther. 2014;21:339–347.
- Munich SA, Theessen H, Johnson AK, et al. Contrastless stent-assisted coiling of an A1 aneurysm. J Stroke Cerebrovasc Dis. 2014;23:2283–2286.
- Sadek M, Berland TL, Maldonado TS, et al. Use of preoperative magnetic resonance angiography and the Artis zeego fusion program to minimize contrast during endovascular repair of an iliac artery aneurysm. Ann Vasc Surg. 2014;28:261.e1–261.e5.
- 40. Tacher V, Desgranges P, You K, et al. Feasibility of threedimensional MR angiography image fusion guidance for endovascular abdominal aortic aneurysm repair. J Neuroimaging. 2016;27:188–193.

