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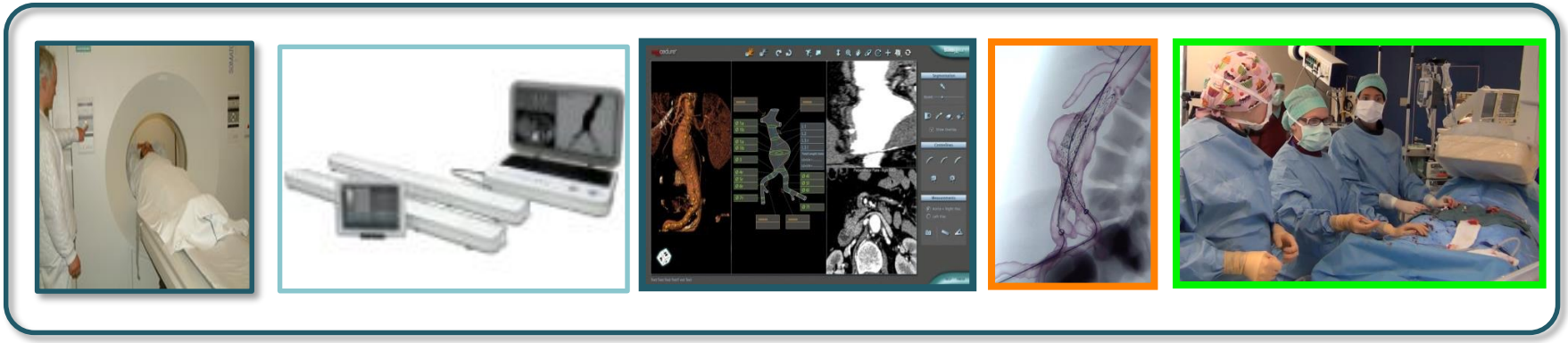
*Should **WE** Simulate to Improve **OUR** Practice?*



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Research Foundation – Flanders

Disclosures

I, Isabelle Van Herzeele, have the following potential conflicts of interest to report:

X Research contracts:

- Simbionix, Cleveland, Ohio, USA
- W.L. Gore & Associates, Inc., Flagstaff, USA
- Medtronic Academia, Tolochenaz, Swiss

X Consulting:

- Silk Road Medical, Sunnyvale, CA, USA
- Medtronic Academia, Tolochenaz, Swiss

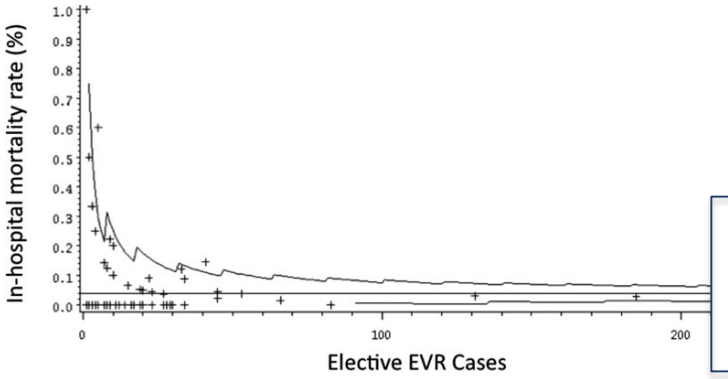
Anatomic severity grading score predicts technical difficulty, early outcomes, and hospital resource utilization of endovascular aortic aneurysm repair

Ahanchi *et al. J Vasc Surg 2011;54(5):1266-72.*

Table IV. Statistically significant predictors of 30-day mortality after EVAR.

Risk factor	*Parameter*	*Odds ratio and 95% CL*	*P value*
Renal failure w/ dialysis	1.95	7.06 [5.23-9.53]	<.0001
LE ischemia	1.27	3.55 [2.65-4.75]	<.0001
Age ≥ 85 years	1.13	3.10 [1.57-2.37]	<.0001
Liver disease	0.93	2.52 [1.54-4.12]	.0002
CHF	0.80	2.23 [1.89-2.64]	<.0001
Renal failure w/o dialysis	0.65	1.91 [1.45-2.51]	<.0001
Age 80-84 years	0.65	1.92 [1.56-2.36]	<.0001
Female	0.52	1.68 [1.42-1.99]	<.0001
Neurological	0.45	1.59 [1.29-1.94]	.0001
Chronic pulmonary	0.45	1.57 [1.35-1.83]	<.0001
Hospital annual vol <7	0.37	1.45 [1.18-1.80]	.0005
Age 75-79 years	0.34	1.40 [1.14-1.71]	0.001
Surgeon EVAR vol <3	0.26	1.30 [1.04-1.62]	.002

Fig 3. The distribution of mortality rates for EVAR (n1645).



Effect of Endovascular Aneurysm Repair on the Volume–Outcome Relationship in Aneurysm Repair

Holt *et al. Circ Cardiovasc Qual Outcomes 2009;2(6):624-32.*

Advanced Endovascular Aortic Workshop 2016; CHRU Lille

" Do EVAR to decrease mortality

Standardise

EVAR = TEAM sport

Errors should be original "

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GENERIC SIMULATION

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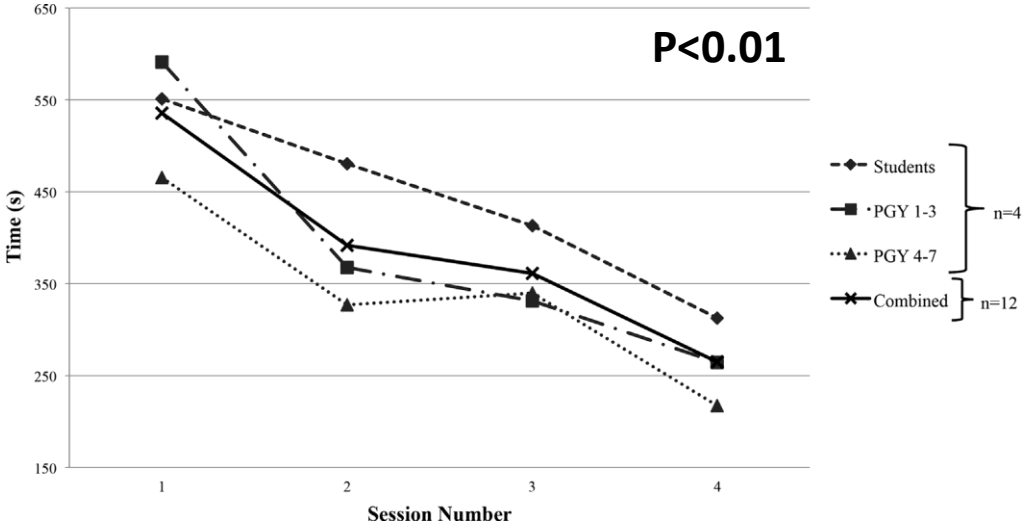
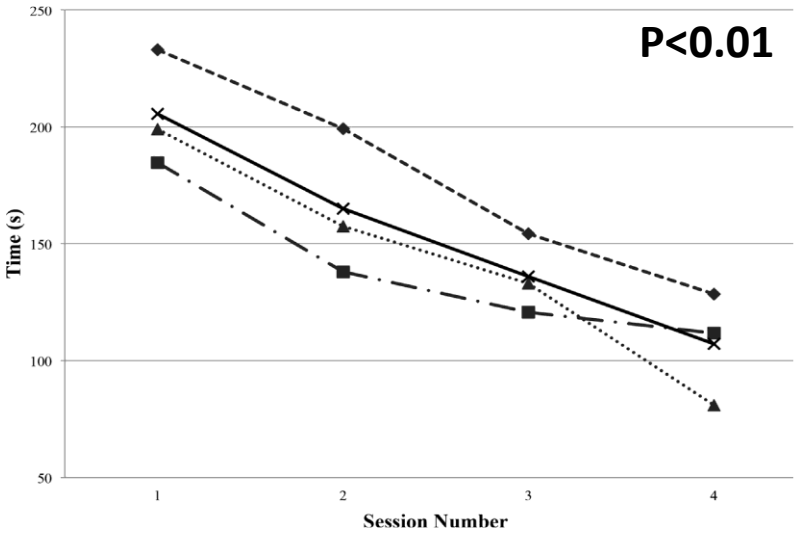
Endovascular Simulation Leads to Efficiency and Competence in Thoracic Endovascular Aortic Repair Procedures

DE Kendrick et al. *J Surg Educ* 2015; 72: 1158-64

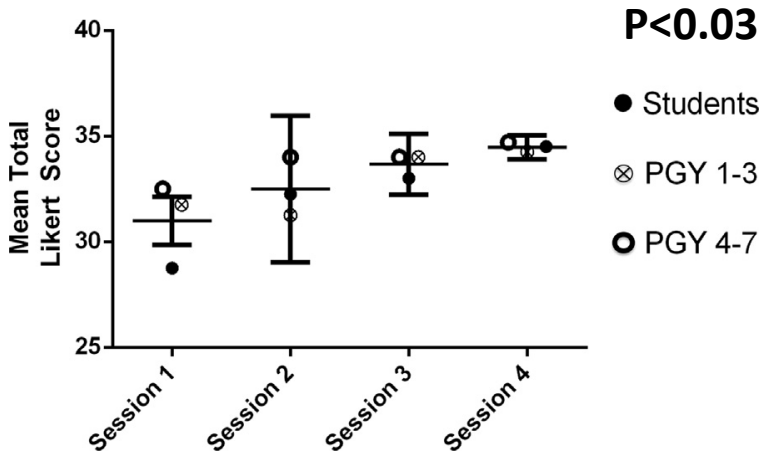
Total procedure time (secs)



Total fluoroscopy time (secs)

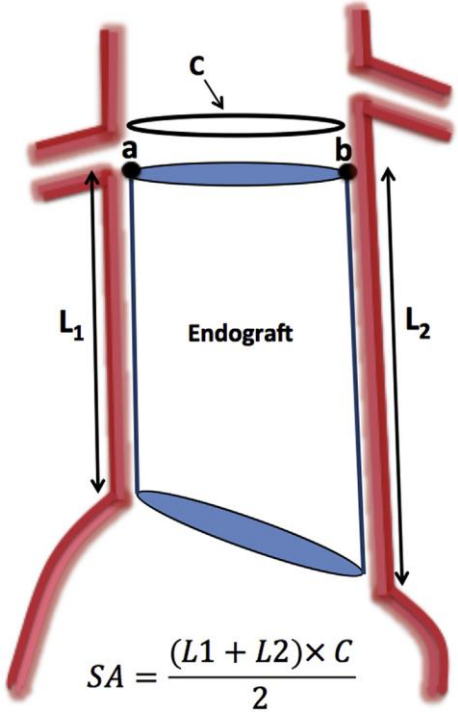


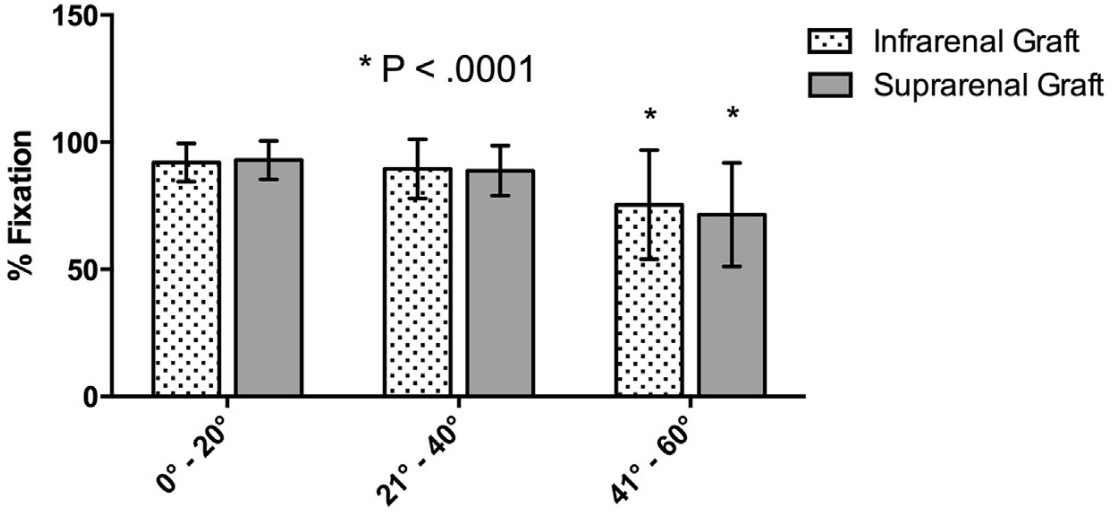
Overall mean performance score

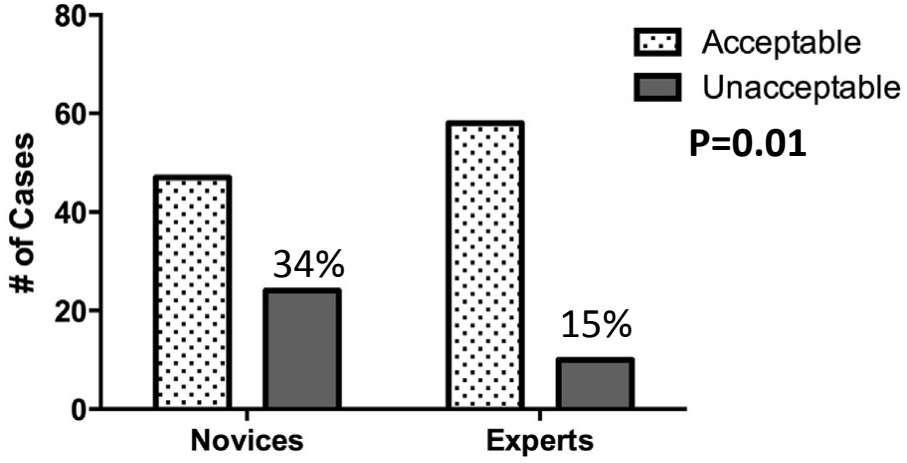


Endovascular aneurysm repair simulation can lead to decreased fluoroscopy time and accurately delineate the proximal seal zone

AH Kim et al. *J Vasc Surg* 2016 In Press







Acceptable (score 1 or 2)
- Partial renal artery coverage <= 2 mm OR
- <= 2-4 mm distal to the renal artery orifice

Unacceptable (score 3 or 4)

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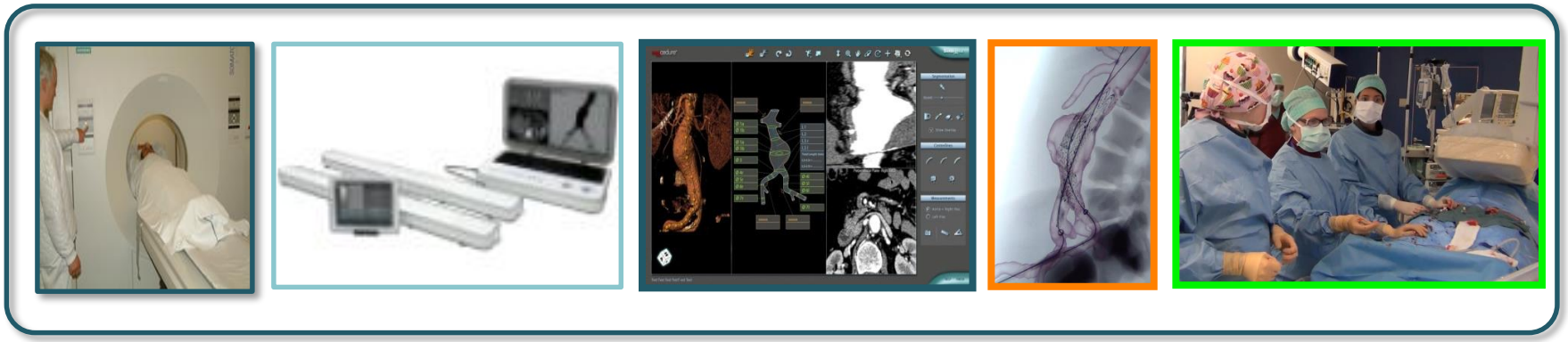
PATIENT-SPECIFIC SIMULATION - REHEARSAL



Desender L et al. *Eur J Vasc Endovasc Surg 2013; 45(6): 639-47*
Live Cases *EuroPCR 2004, ICCA 2009-2010, TCT 2012-2013, LINC 2014*

- Procedure Rehearsal Studio (PRS)

Simbionix, Cleveland, Ohio, USA

- VIST Case-it

Mentice, Gothenburg, Sweden

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Pilot study

n=10
n=9: infrarenal AAA > 55mm
n=1: iliac aneurysm (50mm)

n =10
Procedure rehearsal

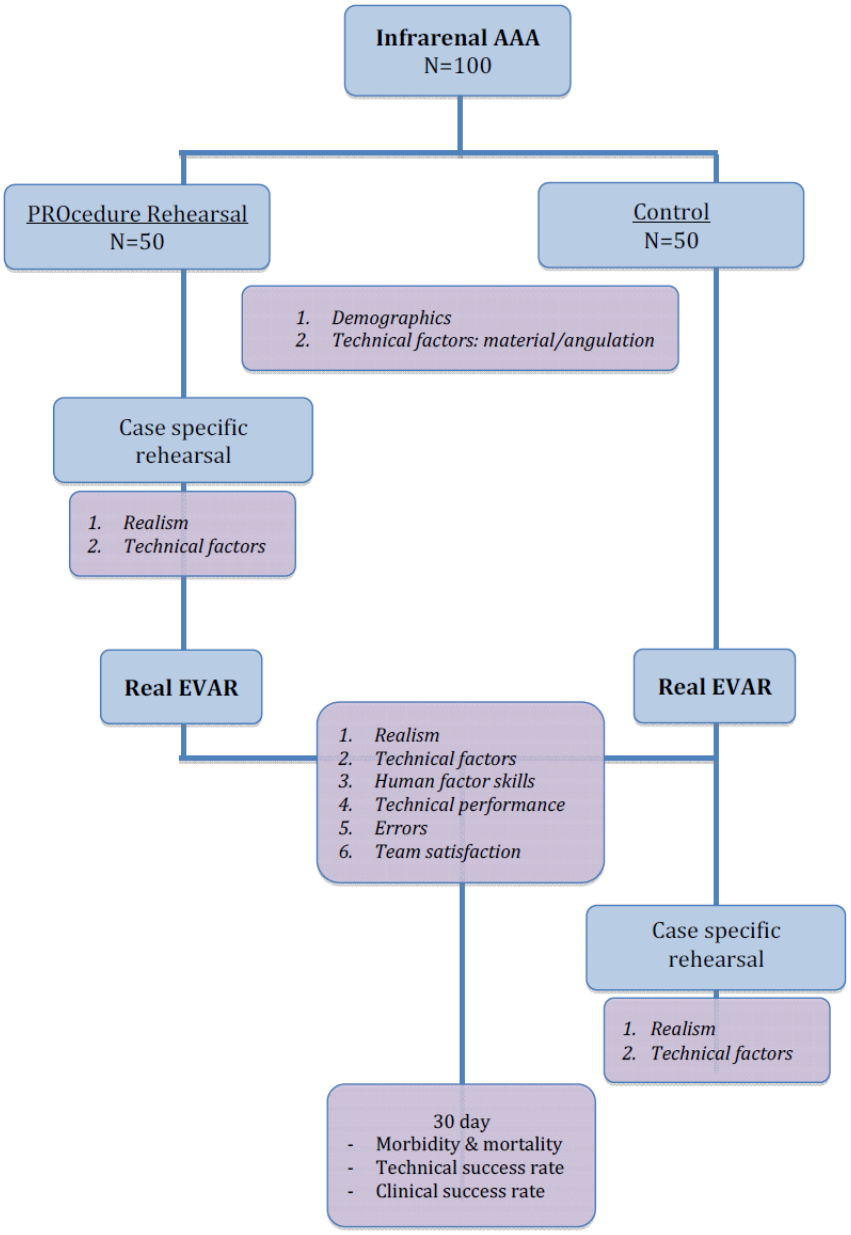
n=9
Real case

- Selection
  - Case
  - Device


- Planning -Technical
  - C-arm angulation
  - Sequence
  - Pitfalls


- Human factor skills

Desender L et al. *Eur J Vasc Endovasc Surg 2013; 45(6): 639-47*



FACULTEIT GENEESKUNDE EN GEZONDHEIDSWETENSCHAPPEN

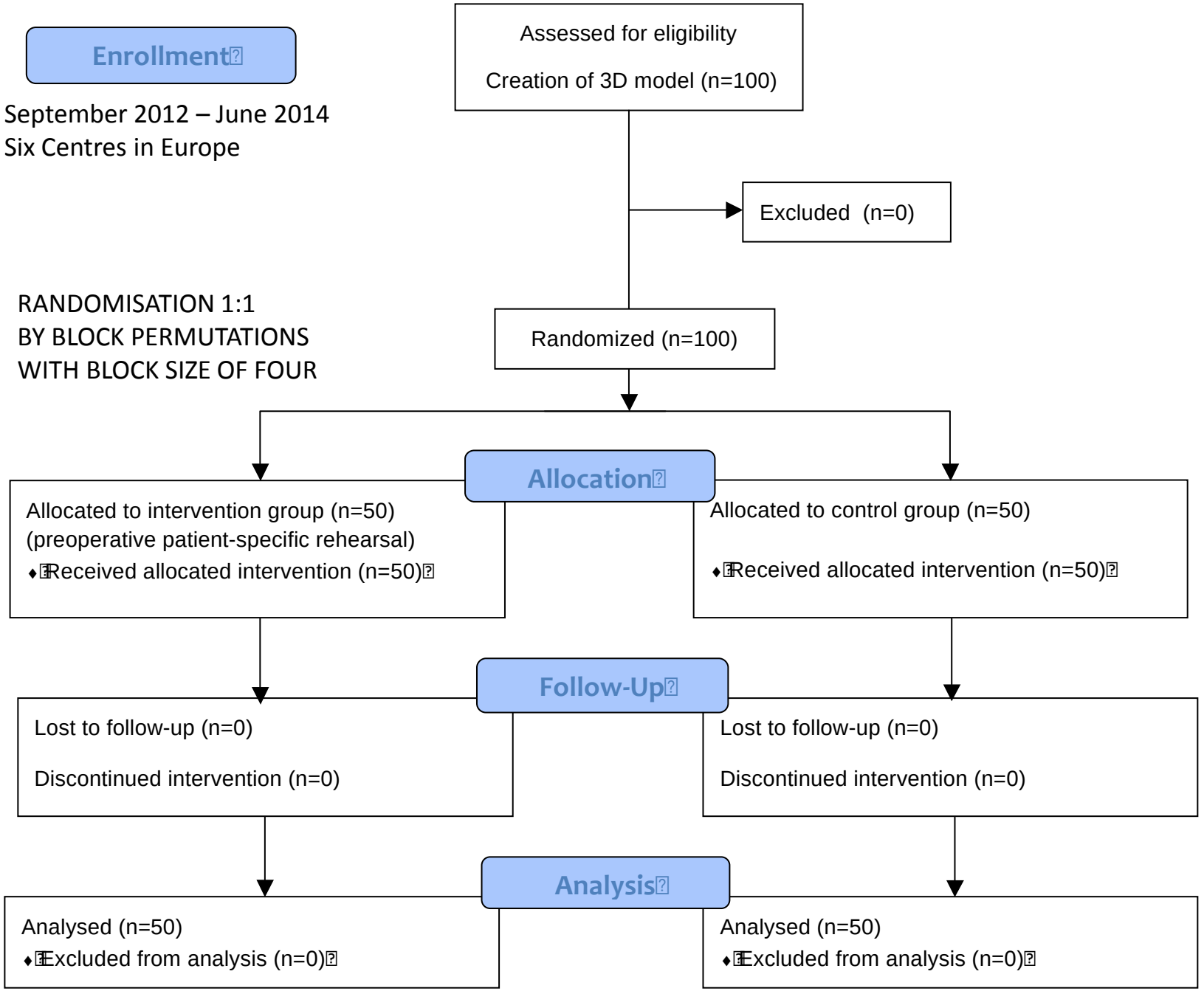
RCT NCT 01632631

- ***Primary* objectives**
  - Technical parameters
  - Number of errors (ICECAP)

Desender L et al. *Ann Surg* 2016 In Press

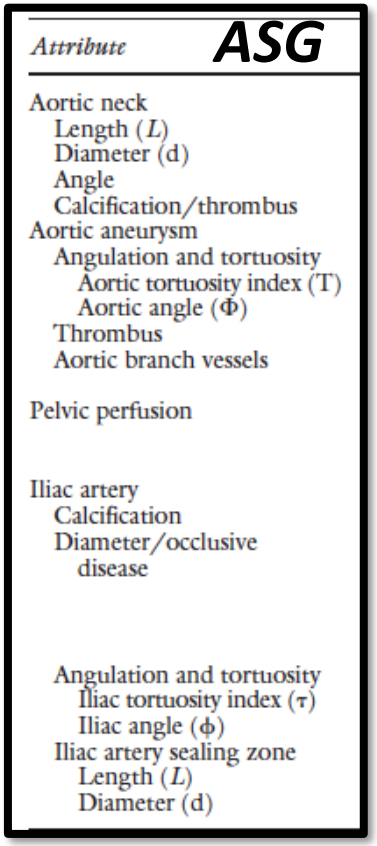
- *Secondary* objectives
  - Technical and non-technical performances
  - Deviation of treatment plan
  - Technical and initial clinical success

Whilst patient is prepared in Hybrid Angiosuite or OR


Enrollment
September 2012 – June 2014
Six Centres in Europe
Assessed for eligibility
Creation of 3D model (n=100)
Excluded (n=0)
RANDOMISATION 1:1
BY BLOCK PERMUTATIONS
WITH BLOCK SIZE OF FOUR
Randomized (n=100)
Allocation
Allocated to intervention group (n=50)
(preoperative patient-specific rehearsal)
♦ Received allocated intervention (n=50)
Allocated to control group (n=50)
♦ Received allocated intervention (n=50)
Follow-Up
Lost to follow-up (n=0)
Discontinued intervention (n=0)
Lost to follow-up (n=0)
Discontinued intervention (n=0)
Analysis
Analysed (n=50)
♦ Excluded from analysis (n=0)
Analysed (n=50)
♦ Excluded from analysis (n=0)

Baseline characteristics - Patient

Variable	PRS n= 50	Control n= 50
Age (years)	72 (11)*	68 (20)*
Male sex	43 (86%)	47 (94%)
ASA classification		
II	22 (44%)	22 (44%)
III	28 (56%)	26 (52%)
IV	0	2 (4%)
Max aortic diameter (mm)	59 (14)*	57 (9)*
ASG score	27 (7)*	27 (7)*



* Mean (SD)

ASG = Anatomic Severity Grading

Chaikof E. *et al. J Vasc Surg 2002; 35(5): 1061-6*

Baseline characteristics – Technical/Team

- N= 27 — ALGEMEEN ZIEKENHUIS SINT MAARTEN
- N= 5 — catharina ziekenhuis
- N= 5 — Imperial College London
- N= 7 — St. Elisabeth Ziekenhuis
- N= 28 — UniversitätsSpital Zürich
- N= 28 — Universitair Ziekenhuis Gent

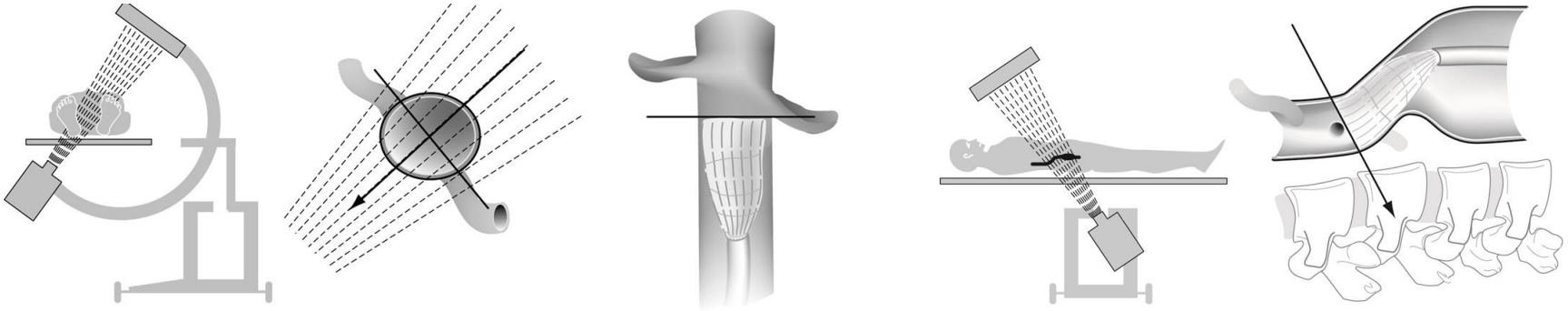
Variable	PRS n=50	Control n=50
Within IFU	35 (70%)	28 (56%)
Hybrid angiosuite	30 (60%)	28 (56%)
Academic Centre	29 (58%)	32 (64%)
Experienced team	32 (64%)	36 (72%)
Device type		
Gore Excluder	32 (64%)	29 (60%)
Medtronic Endurant	18 (36%)	21 (40%)

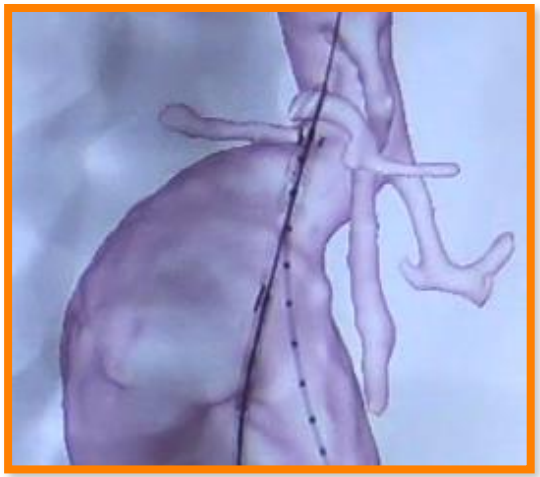
PRIMARY: TECHNICAL PARAMETERS

Technical parameters	PRS Median	CONTROL Median	Difference PRS vs. Control 95% Confidence Interval	P value
Total endovascular procedure time (min)	52,1	54,6	-4.6% -19.6 to 13.2%	0.589
Fluoroscopy time (sec)	916	864	6.0% -18.1% to 37.3%	0.656
Contrast volume (ml)	81	93	-12.8% -25.3 to 1.7%	0.081
Number of angiograms to deploy main body prox.	2.2	2.8	-23.1% -35.8 to -7.8%	**0.005**
Number of angiograms to deploy entire device	4.3	5.4	-20.5% -32.0 to -7.1%	**0.004**
Total number of angiograms	6.5	7.5	-12.6% -24.1 to 0,7%	0.062
DAP ($Gycm^2$)	103,951	112,943	-8.0% -36.8 to 34.1%	0.663

Proximal landing zone

Elimination of the parallax





CRAN 18°

RAO 30°

COMPLEXITY of Aneurysm repair
Anatomic Severity Grading Score

Outcome variable (Log)	P
Total endovascular procedure time (min)	**0.0013**
Fluoroscopy time (min)	**0.0019**
Contrast volume (ml)	**0.0010**
Number of angiograms to deploy main body prox.	**0.0273**
Number of angiograms to deploy entire device	**0.0015**
Total number of angiograms	**0.0039**
DAP (Gycm^2)	**0.0393**

Chaikof E. *et al. J Vasc Surg 2002; 35(5): 1061-6*

N= 100

Total ASG score
20

Total ASG score
41

TEAM Experience

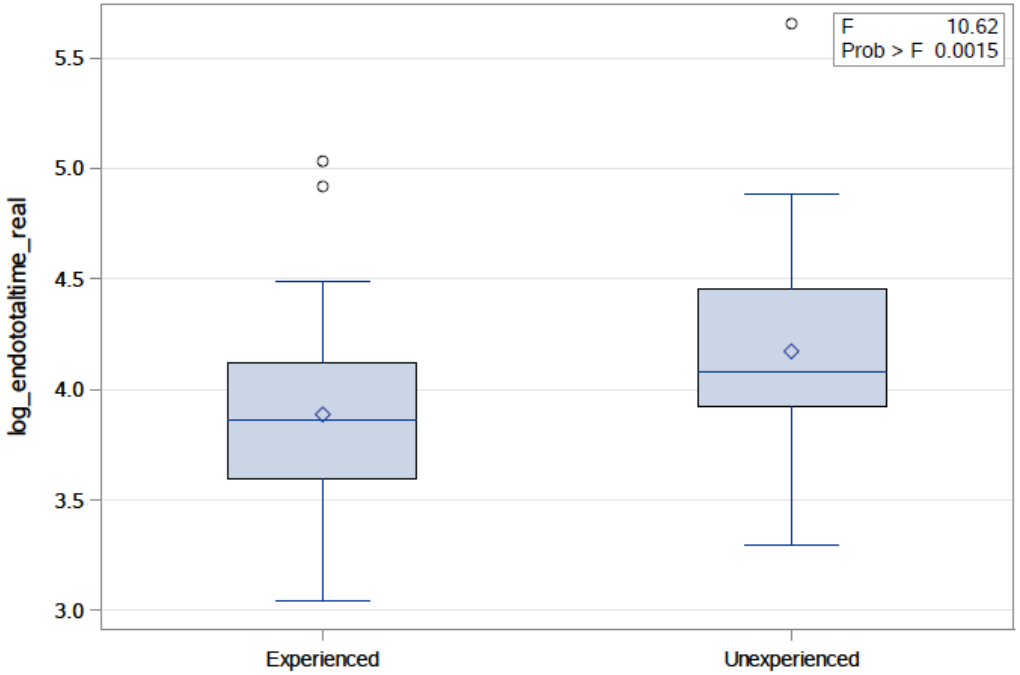
Team= Lead implanter + Assistant implanter + Scrub nurse

Experienced Team member > 50 EVAR

Experienced Team = ≥ 2 experienced team members

Outcome variable (Log)	P
Total endovascular procedure time (min)	**0.0015**
Fluoroscopy time (min)	**0.0132**
Contrast volume (ml)	0.8750
Number of angiograms to deploy main body prox.	0.4764
Number of angiograms to deploy entire device	0.8320
Total number of angiograms	0.9039
DAP (Gycm²)	**0.0120**

N= 100



Technical operative metrics

Variable	PRS n=50	Control n=50	Difference PRS vs. Control	p-value*	p-value multivariate analysis #
Endovascular procedure time (min)	52.1	54.6	-4.6%	0.59	0.48
Fluoroscopy time (sec)	916	864	6.0%	0.66	0.66
Contrast medium use (ml)	81	93	-12.8%	0.08	0.10
Number of angiograms till deployment of main body	2.2	2.8	-23.1%	0.005	**0.007**
Number of angiograms till deployment of all stentgrafts	4.3	5.4	-20.5%	0.004	**0.005**
Total number of angiograms	6.5	7.5	-12.6%	0.06	0.07
Radiation dose (DAP) ($Gycm^2$)	103,951	112,943	-8.0%	0.66	0.57

* Two-sample t-test

Multiple linear regression with correction for aneurysm difficulty and team experience

PRIMARY: ERRORS

Term	Definition
Error	Any event that prevented the operation progressing in an ideal manner (from knife-to-skin to final suture).
Minor error	Error that causes minimal or no disruption to the operation (<15 mins delay), does not cause harm directly
Major error	Error that causes major disruption to the operation (> 15 mins delay), causes harm directly, or has the potential to cause harm in the majority of circumstances.

Reason J Qual Health Care 1995; 4(2): 80-9

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ICECAP (Imperial College Error CAPture) **Record for Vascular Surgery** **OBSERVER** Imperial College London

Date: *Start time:* *End time:* *Total time:* *Hospital:* *No. team members present:* *Completed by:*
Surgery:

Error Category	Equipment Radiological, Surgical, Anaesthetic, Drugs /Medication, Other		Communication	Procedure – Indep Pressures	Technical	Safety	Patient	Other	Details	*Delay*	*Resol*
	U -Unavailable F -Failure/Fault C -Configuration D -Desterilised		M -Misleading L -Lack of D -Discord H -Does not hear/ misheard	A -Absence D -Distraction E -External pressures	Psy –Psychomotor Unf –Unfamiliar with - Procedure - Equipment - Technique	C -Checks not done V -Violation	A -Anatomy P -Physiology C -Compliance		Provide further information including people, item involved and/or circumstance	*(1-5)*	*(1-5)*
Time :	☐ Ra ☐ S ☐ An ☐ Dr / Med ☐ Oth	☐ U ☐ F ☐ C ☐ D	☐ M ☐ L ☐ D ☐ H	☐ A ☐ D ☐ E	☐ Psy ☐ Unf ☐ Proc ☐ Equip ☐ Tech	☐ C ☐ V	☐ A ☐ P ☐ C	☐			
: :	☐ Ra ☐ S ☐ An ☐ Dr / Med ☐ Oth	☐ U ☐ F ☐ C ☐ D	☐ M ☐ L ☐ D ☐ H	☐ A ☐ D ☐ E	☐ Psy ☐ Unf ☐ Proc ☐ Equip ☐ Tech	☐ C ☐ V	☐ A ☐ P ☐ C	☐			

Mason S.L. et al EJVES 2013; 45(3): 248-54

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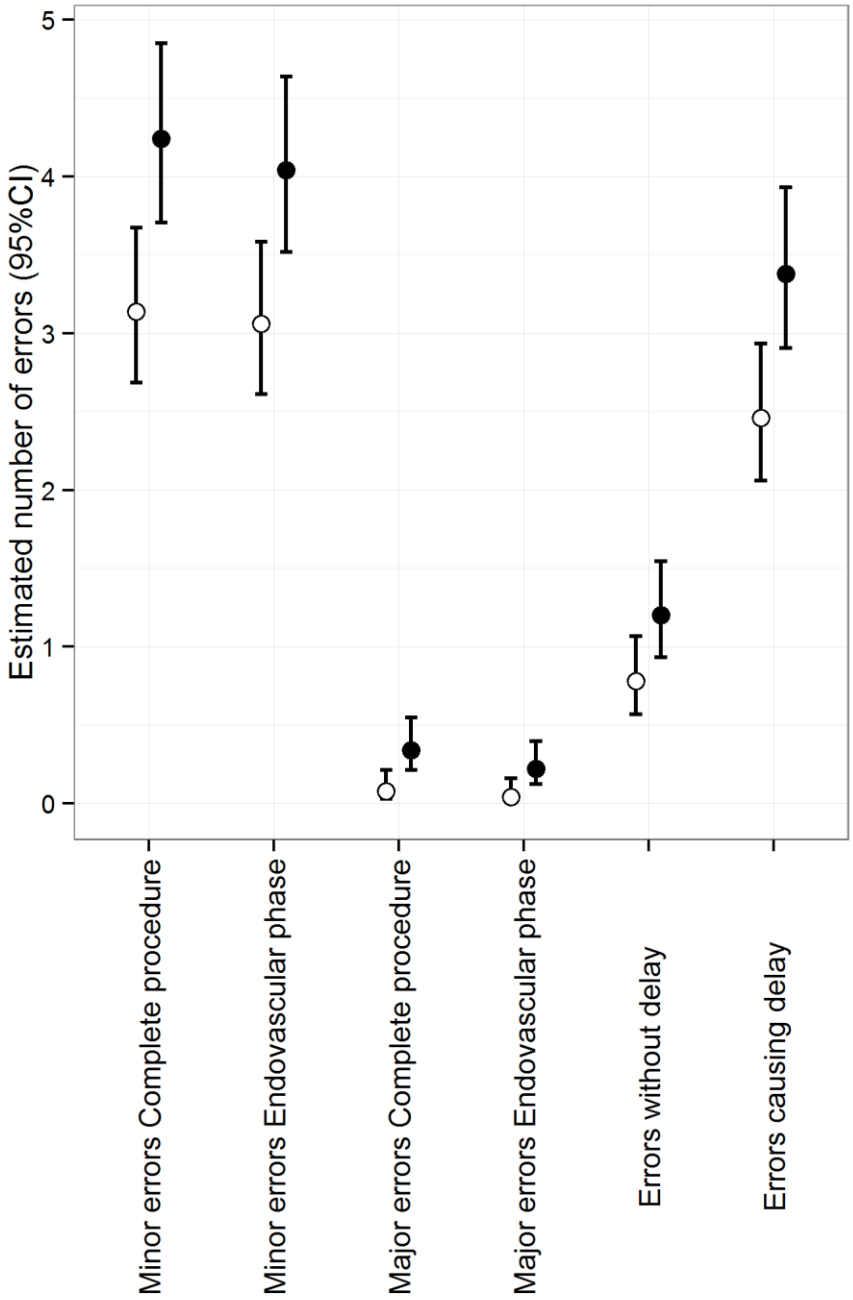
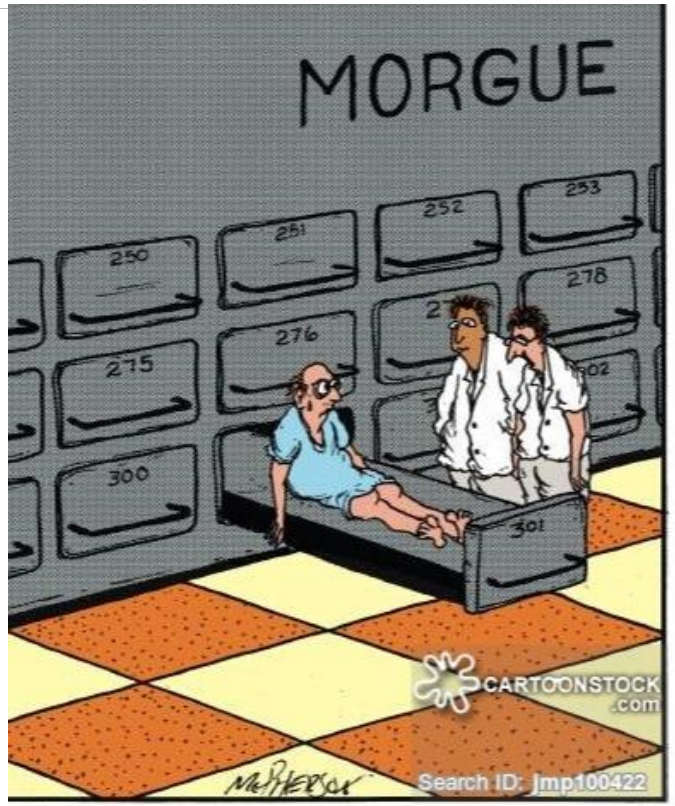


- Errors noted by real-time observer
- Categorized by 2 independent blinded investigators using ICECAP
- 2/100: NO errors

Group ○ Intervention ● Control



"Anyway, to make a long story short, the medical examiner who performed your autopsy was fired."

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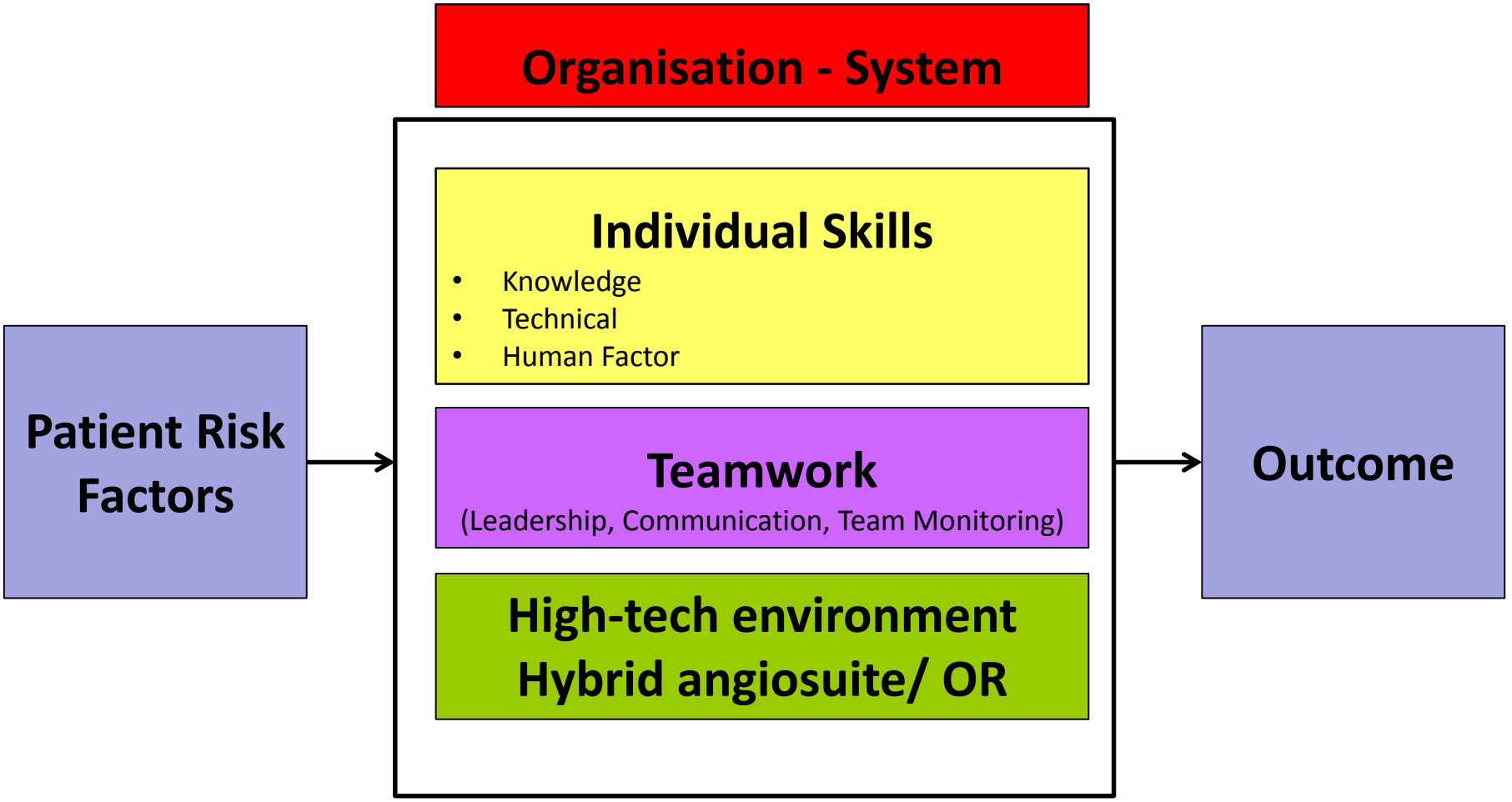
Categories of Error

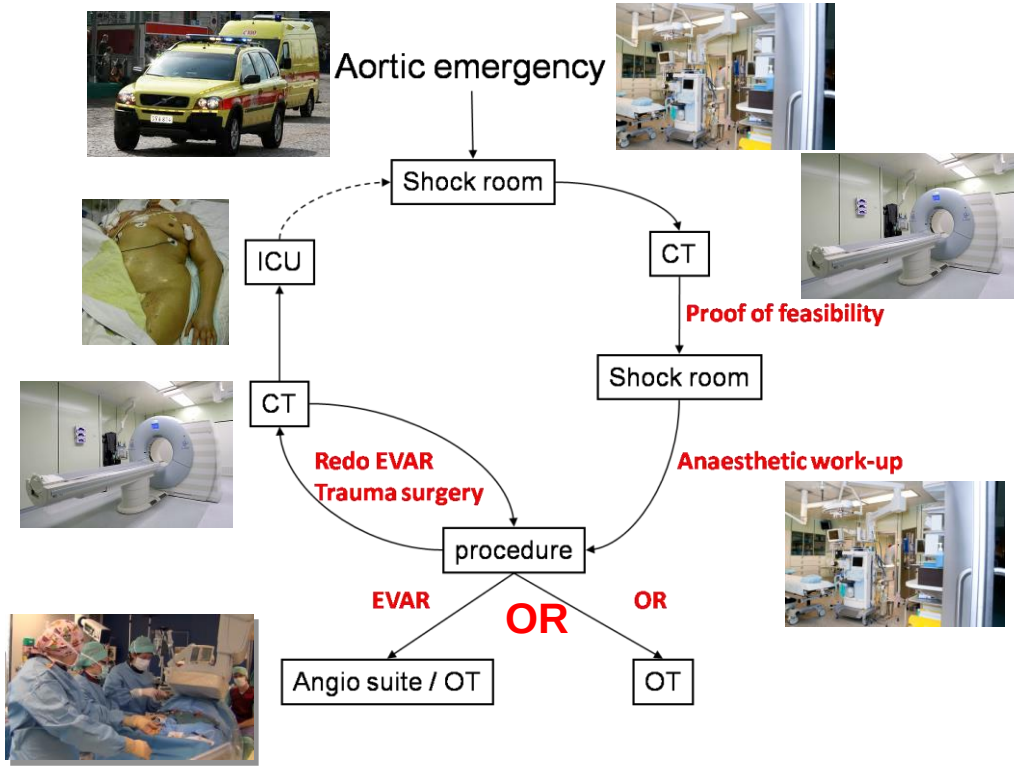
Variable	Number of errors (%) n= 390	Errors PRS	Errors Control	Difference PRS vs. control	95% confidence interval	p-value*
Technical issues	***122 (31%)***	0.78	1.64	-52.4%	-67.5 to -30.4%	**< 0.001**
Minor	108/368 (29%)	0.70	1.46	-52.1%	-68.0% to -28.3%	**< 0.001**
Major	14/22 (64%)	0.08	0.18	-55,6%	-86,4% to 44,3%	0.18
PIP	92 (23%)	0.86	0.98	-12.2%	-41.7 to 32.2%	0.53
Equipment	83 (21%)	0.84	0.84	0.0%	-34.8 to 53.4%	1.0
Communication	***76 (19%)***	0.60	0.92	-34.8%	-58.8 to 3.3%	0.07

* Univariate Poisson Regression


Organisation - System
Individual Skills
• Knowledge
• Technical
• Human Factor
Teamwork
(Leadership, Communication, Team Monitoring)
High-tech environment
Hybrid angiosuite/ OR
Patient Risk Factors
Outcome

SOP IN CRISIS SCENARIO: RAAA

- Patient
- Centre/Country
- ***SOP***
  - Hemodynamics
  - Imaging
  - Logistics
    - *Tool kit*
    - **TRAINED TEAM**
      - A&E
      - Anesthetic care
      - Ad Hoc
      - "Business as usual"?
      - Intra-aortic balloon
      - ACS
      - Debriefing
      - Level III Intensive Care



Courtesy of ***M. Lachat***, University Hospital Zurich

Van Herzeele I et al.

J Cardiovasc Surg (Torino) 2014; 55(2): 193-206

DEBRIEFING - CASE MULTIPLICATION - ERROR REDUCTION

Debriefing checklist	
Communication clear?	☑
Roles and responsibilities understood?	☑
Situation awareness maintained?	☑
Workload distribution?	☑
Did we ask or offer assistance?	☑
Were errors made or avoided?	☑
What went well, what can improve?	☑

Rudarakanchana N et al.
Cardiovasc Intervent Radiol 2014; 37(4): 920-7

Conclusion

Simulation improves ***TEAM Performance*** in EVAR

- Patient specific rehearsal reduces
  - Number of angiograms to deploy device
  - Number of perioperative errors
  - Procedural delay

  Independent of team experience or difficulty of aneurysm repair
- SOP implementation

Simulation ***CAN*** and ***SHOULD*** be part of (R)EVAR programs

i-MEET

NEXT GENERATION

Multidisciplinary European Endovascular Therapy

JUNE 2-3 2016

Nice, France