Radial Access Versus Conventional Femoral Puncture: Outcome and Resource Effectiveness in a Daily Routine. The RAPTOR-Trial

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Background

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-**Less bleeding complications**

-Rapid ambulation

-More economic use of human and hospital resources

-**Higher patient comfort**

-**Possible entry site failure**

-**Occurrence of unsuccessful arterial puncture**

-**Higher radiation doses**

-**Longer procedural times**

-**Occlusion and/or spasm of the radial artery**

Study purpose

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Is it feasible for an interventional site with operators experienced in femoral access to switch ad hoc to radial access as a routine strategy in a real world population with regard towards

- **-Patient safety**
- **-Radiation exposure**
- **-Patient comfort**
- **-Procedural durations**
- **-Staff involvement**
- **-Overall effectiveness**

Methods

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Study design: Prospective, randomized single center trial to compare radial vs. femoral access in a 1:1 ratio in an unpreselected population

Exclusion criteria

- Abnormal Allen Test
- Planned CABG
- ESRD
- Pregnancy
- Hyperthyroidism

Outcome parameters:

Interventional	Peri-/Post interventional
-Access site failure	-Staff involvement (cath lab)
-Procedural time	-Staff involvement (ward)
-Flouroscopy time	-Bleeding complications
-Radiation exposure	-Patient satisfaction

Results

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4/2008 -4/2009: 421 patients included - 410 evaluated

Baseline Characteristics

	Femoral	Radial	P Value
Age	66±9	64±10	0.02
Male (%)	69.6	74.4	0.2
Hight (cm)	169±0.1	171±0.1	0.1
BMI	28±4	28±4	1
Hypertension (%)	53.6	48.8	0.5
Known CAD	21.3	19.2	0.9

Procedures performed

	Femoral	Radial	P Value
gnostic only	152 (73.4%)	152 (74.8%)	0.7
PCI	55 (27%)	51 (25%)	0.7
CABG	12 (6%)	5 (3%)	0.09
Access Failure	8 (3.4%)	8 (3.6%)	0.9
mbulatory Treatment	43 (21%)	53 (26%)	0.5

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Procedural Durations

	Femoral	Radial	Delta	P Value
Puncture	0.9±1.4	3.8±3	2.9±1,6	<0.01
Coronary Angiography	8.4±4	10.9±6	1.8±0.3	<0.01
Coronary Angiography + PCI	37.4±15	33.9±15	3.5	0.2
PCI withSheath Exchange	23.4±15	25.1±15	1.7	0.5
PCI without Sheath Exchange	16.3±13	21±9	4.7±4	0.3

All values given in minutes; p<0.05 considered statistically significant

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Radiation Times

	Femoral	Radial	Delta	P Value
RT Diagnostics	4.4±5	6.4±5	2	<0.01
RT-PCI RCA	8.6±8	6.4±5	2.2±3	0.7
RT-PCI LCA	5.2±3	7±4	1.8±1	0.8

RT = Radiation Time; RCA = right coronary artery; LCA = left coronary artery

All values given in minutes; p<0.05 considered statistically significant

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Radiation Dose (Dose Area Product)

	Femoral	Radial	Delta	P Value
RD Diagnostics	22.6±15	29.7±16	7.1±1	<0.01
RD-PCI RCA	27.1±19	27.8±23	0.7±4	0.5
RD-PCI LCA	31.9±31	25.1±17	5.8±14	0.5

RD = Radiation Dose; RCA = right coronary artery; LCA = left coronary artery

All values given in Gycm²; p<0.05 considered statistically significant

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Involvement of Staff

Diagnostics

	Manual Compression of Access Site	Handling in Cath Lab	Time Nurse Spent with Patient
Femoral	13±40	14.3±5	45.2±27
Radial	0.6±3	17.3±13	31.3±18
Delta	12.4±37	3±7	13.4±9
P Value	<0.01	0.02	0.02

Involvement of Staff

Interventions

	Manual Compression of Access Site	Handling in Cath Lab	Time Nurse Spent with Patient
Femoral	11.6±9	15.7±6	64.4±33
Radial	0±0	16.6±4	30.6±15
Delta	11.6	0.9±2	34±18
P Value	<0.01	0.38	<0.01

All values given in minutes; p<0.05 considered statistically significant

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Economical Impact of Staff Involvement

	Time Diagnostics + Sheath Removal	Time Diagnostics + PCI + Sheath Removal
Femoral	72.5±36	91.7±36
Radial	54.6±14	47.2±12
Time Saved by Radial Access	17.9±30	47.2±24
P Value	<0.01	<0.01

All values given in minutes; p<0.05 considered statistically significant

3000 procedures/year with 1000 PCI △staff involvement = 1383 hours = 36.4 weeks

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Learning progress for radial access

		1. Quartile	4. Quartile	P Value
Operator # 1	Procedure Time	11.9±9	10.3±3	0.6
	Radiation Time	10.7±11	6.1±7	0.02
Operator # 2	Procedure Time	10.6±6	13.3±7	0.3
	Radiation Time	6.9±5	6±4	0.6
Operator # 3	Procedure Time	8.9±6	11.4±6	0.1
	Radiation Time	6.8±5	7.4±5	0.6

Values are given in minutes ± SD

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Adverse events

	Femoral	Radial	P Value
Hematoma	19	4	<0.01
Pseudo Aneurysm	2	0	N/A
AV-Fistula	1	0	N/A
Pain at Back/Puncture Site	43	8	<0.01
Puncture Site Bleedings	18	4	<0.01
Vagal Reactions	19	0	<0.01

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Acces Site Failure

	Femoral	Radial	P Value
Access Site Failure	8	8	N/A

Femoral Group

- Unsuccessful femoral puncture (n=4)
- Kinking of the iliac artery (n=3)
- Acute bleeding at the puncture site (n=1)

Radial Group

- Unsuccessful radial puncture (n=4)
- Tortuosities (n=3)
- Spasm (n=1)

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Quality of Life

No Differences for

-Tolerance of arterial puncture
-Tolerance of procedure itself
-Tolerance of procedural duration

Advantage towards Radial Access for

-Pain due to Compression Device
-Preference of Alternative Access Route

Summary

-Switching to radial access leads to only mild procedural prolongation when diagnostic coronary angiography is performed -Differences in procedural times are no longer significant for PCI -Radiation time and dose are extended for diagnostic angiography, but are similar for interventions

-Using radial approach leads to a more economic use of resources -The procedure is safe and well tolerated by patients

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Conclusion

The RAPTOR Trial demonstrates that experienced invasive cardiologists can easily and rapidly shift their practice towards radial access.

The results of the present trial should therefore encourage interested centers to switch from femoral to radial access as a routine strategy.