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German Aortic Valve RegistrY

Deutsches Aortenklappenregister

Deutsches Aortenklappenregister

Quality of life in 9985 patients following aortic valve replacement: One-year results from the German Aortic Valve Registry

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on behalf of GARY

28th EACTS Annual Meeting
Milan, Italy 11 - 15 October 2014

EACTS European Association For Cardio-Thoracic Surgery
Raising Standards through Education and Training

German **A**orticvalve **R**egistr**Y**

Deutsches Aortenklappenregister

- **Design**:

  Prospective, controlled, multicenter registry

- **Inclusion**:

  All consecutive patients undergoing an invasive therapy for acquired aortic valve disease

- **Exclusion**:

  No informed consent by the patient

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Support / Management / Sponsorship

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Support

German Society for Thoracic Cardiovasc. Surg. (DGTHG)

German Cardiac Society (DGK)

German Heart Foundation (DHS)

Data management

BQS – Institute for Quality & Patient Safety

Sponsorship

Investigator initiated study with unrestricted grants:

Edwards, Medtronic, Jena Valve, Symetis, St Jude, Sorin, Direct Flow

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Quality of Life Measurement

EQ-5D – 3 Level and VAS

Deutsches Aortenklappenregister

EQ-5 Dimensions – 3 Level

Mobility

I have no problems in walking about

I have some problems in walking about

I am confined to bed

Self-Care

I have no problems with self-care

I have some problems washing or dressing myself

I am unable to wash or dress myself

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities

I have some problems with performing my usual activities

I am unable to perform my usual activities

Pain/Discomfort

I have no pain or discomfort

I have moderate pain or discomfort

I have extreme pain or discomfort

Anxiety/Depression

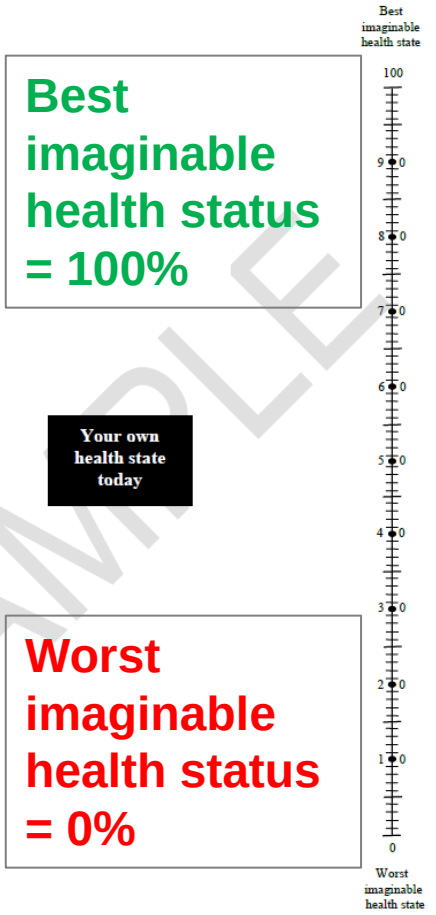
I am not anxious or depressed

I am moderately anxious or depressed

I am extremely anxious or depressed

- no complains
- mild complains
- severe complains

Visual analogue scale (VAS)



SAMPLE

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Quality of Life Measurement

EQ-5D – 3 Level and VAS/pre-OP and 1-year FU

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	Pre-OP	1-Year-FU
Mobility		
I have no problems in walking about	☐	☐ X
I have some problems in walking about	X ☐	☐
I am confined to bed	☐	☐
Self-Care		
I have no problems with self-care	☐	☐
I have some problems washing or dressing myself	☐	X ☐
I am unable to wash or dress myself	X ☐	☐
Usual Activities (*e.g. work, study, housework, family or leisure activities*)		
I have no problems with performing my usual activities	☐	X ☐
I have some problems with performing my usual activities	X ☐	☐
I am unable to perform my usual activities	☐	☐
Pain/Discomfort		
I have no pain or discomfort	☐	☐
I have moderate pain or discomfort	X ☐	☐
I have extreme pain or discomfort	☐	X ☐
Anxiety/Depression		
I am not anxious or depressed	☐	X ☐
I am moderately anxious or depressed	X ☐	☐
I am extremely anxious or depressed	☐	☐

Best imaginable health status = 100%

good
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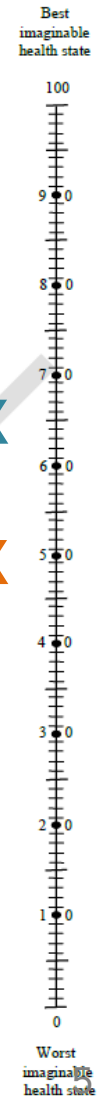
od or

Your own health state today

Worst imaginable health status = 0%



http://www.euroqol.org/fileadmin/user_upload/Documenten/PDF/Products/Sample_UK__English__EQ-5D-3L.pdf

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Patients distribution

Deutsches Aortenklappenregister

53 *cardiac surgery units*

14220 included Patients
01/01/2011– 31/12/2011

n = 360 Ross /David OP

n = 3875 TAVI
(TV and TA)

6523 P (AVR)

3462 P (AVR+CABG)

438 P died

115 P denied FuP

986 P ⦸ compl. EQ-5D

395 P died

73 P denied FuP

524 P ⦸ compl. EQ-5D

EQ-5D completed
Pre- & 1 Year FuP

4984 AVR

2470 AVR & CABG

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Preoperative patient characteristics

Deutsches Aortenklappenregister

	AVR n = 4984	AVR & CABG n = 2470	P-Value
Age [years] Mean ± SD	68.2 ±11.0	72.3 ±7.9	< 0.001
Age >= 75	32.2%	43.8%	< 0.001
Female	38.4%	26.4 %	< 0.001
CAD	18.4%	97.6%	< 0.001
Previous cardiac Surgery	8.5%	6.1%	< 0.001
Pulmonary hypertension	9.8%	9.7%	0.868
Diabetes (insulin dependent)	7.9%	11.6%	< 0.001
Atrial fibrillation	14.8%	13.8%	0.264
COPD requir. medication	5.9%	6.5%	0.356
EF [%] > 50 30-50 < 30	 77.6% 19.7% 2.7%	 68.9% 26.7% 4.4%	< 0.001

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Preoperative patient characteristics

Deutsches Aortenklappenregister

	AVR n = 4984	AVR & CABG n = 2470	P-Value
Active endocarditis	2.7%	1.4%	< 0.001
Peripheral arterial vascular disease	4.0%	11.2%	< 0.001
AÖF [cm²] Mean ± SD	0.86 ±0.67	0.85 ±0.51	< 0.001
Pmean [mmHg] Mean ± SD	44.5 ±19.6	41.7 ±17.4	< 0.001
Pmax [mmHg] Mean ± SD	70.3 ±29.5	66.2 ±26.1	< 0.001
MI ≥2°	13.9%	13.4%	0.561
Log ES Mean ± SD	8.2 ±8.9	10.1 ±9.7	< 0.001
German AV Score Mean ± SD	2.2 ±2.8	2.7 ±3.4	< 0.001

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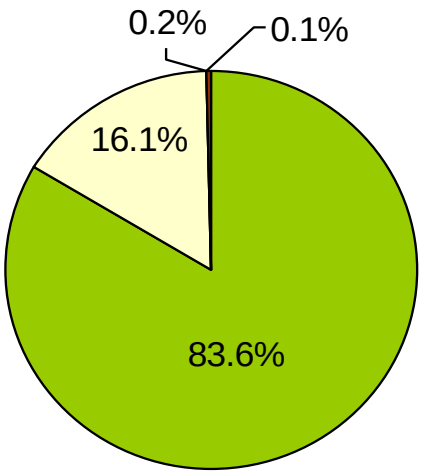
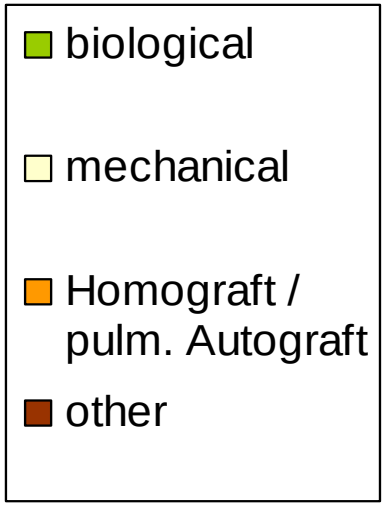
Prosthesis

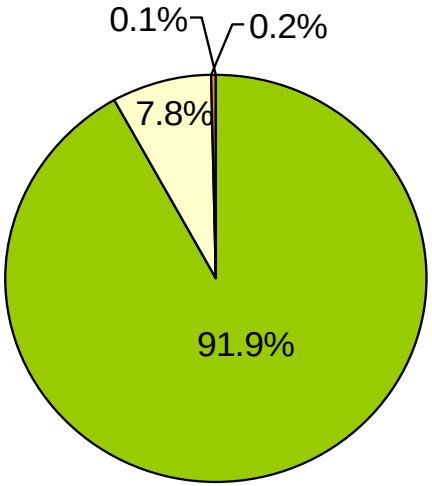
Deutsches Aortenklappenregister



isolated



Surgical AVR



AVR & CABG

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Postoperative patient characteristics

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	AVR n = 4984	AVR & CABG n = 2470	P-Value
TIA	0.9%	1.5%	0.022
Stroke	1.0%	1.4%	0.136
Myocardial infarction	0.3%	0.3%	0.821
New onset Afib	5.4%	5.6%	0.727
New onset pace-maker / aicd implant.	4.4%	3.9%	0.345
Dialysis (new onset)			0.427
temporary	1.9%	2.2%	
chronic	0.1%	0.2%	
PostOP In-hospital stay [days] Mean ± SD	11.8 ±7.2	12.7 ±8.3	< 0.001
PostOP Intensive care [days] Mean ± SD	3.2 ±5.2	4.2 ±6.2	< 0.001

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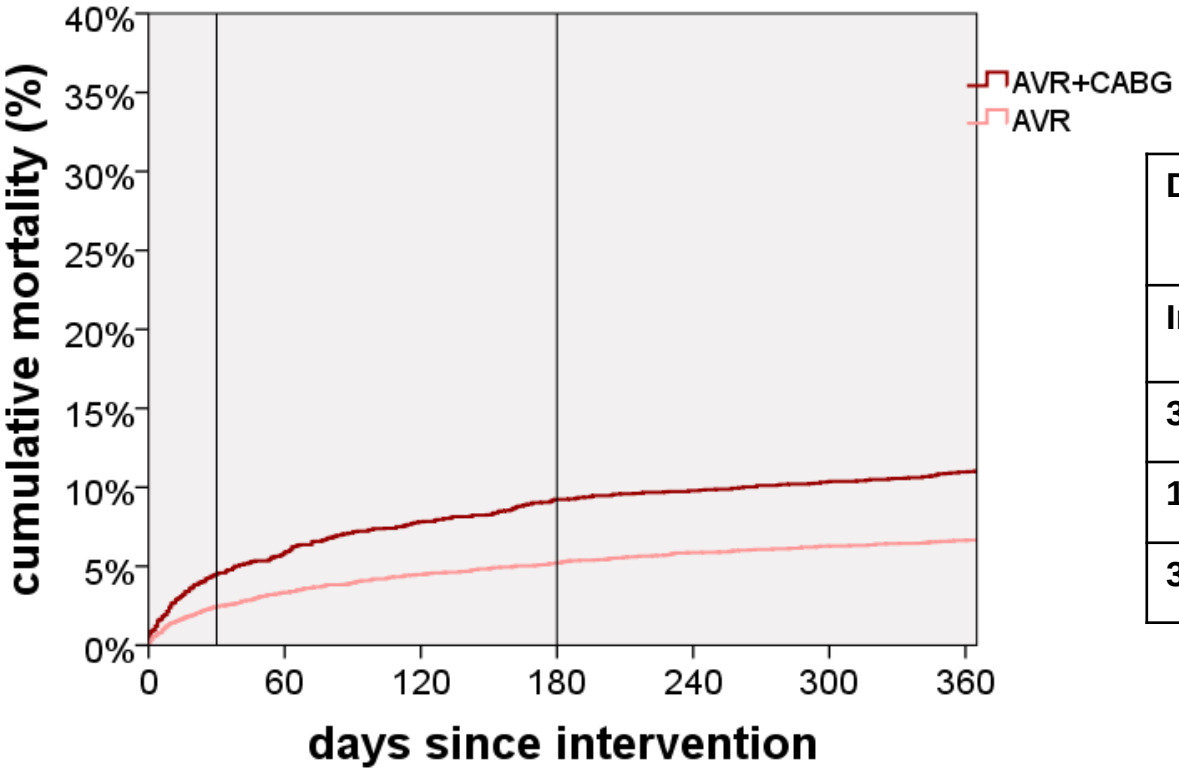
Kaplan-Meier Time-to-Event Curve

Deutsches Aortenklappenregister



Death	AVR	AVR + CABG
In-Hospital	2.1%	4.5%
30 Days	2.4%	4.5%
180 Days	5.2%	9.2%
365 Days	6.7%	11.0%

Cum.Events No. at Risk	Day 0	Day 30	Day 180	Day 365
AVR	12 6523	158 6346	337 6089	430 5982
AVR+CABG	12 3462	157 3293	316 3079	377 3016

log-rank test
p-value: < 0.001

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VAS Score

Comparison: pre-OP → 1-year-Follow Up

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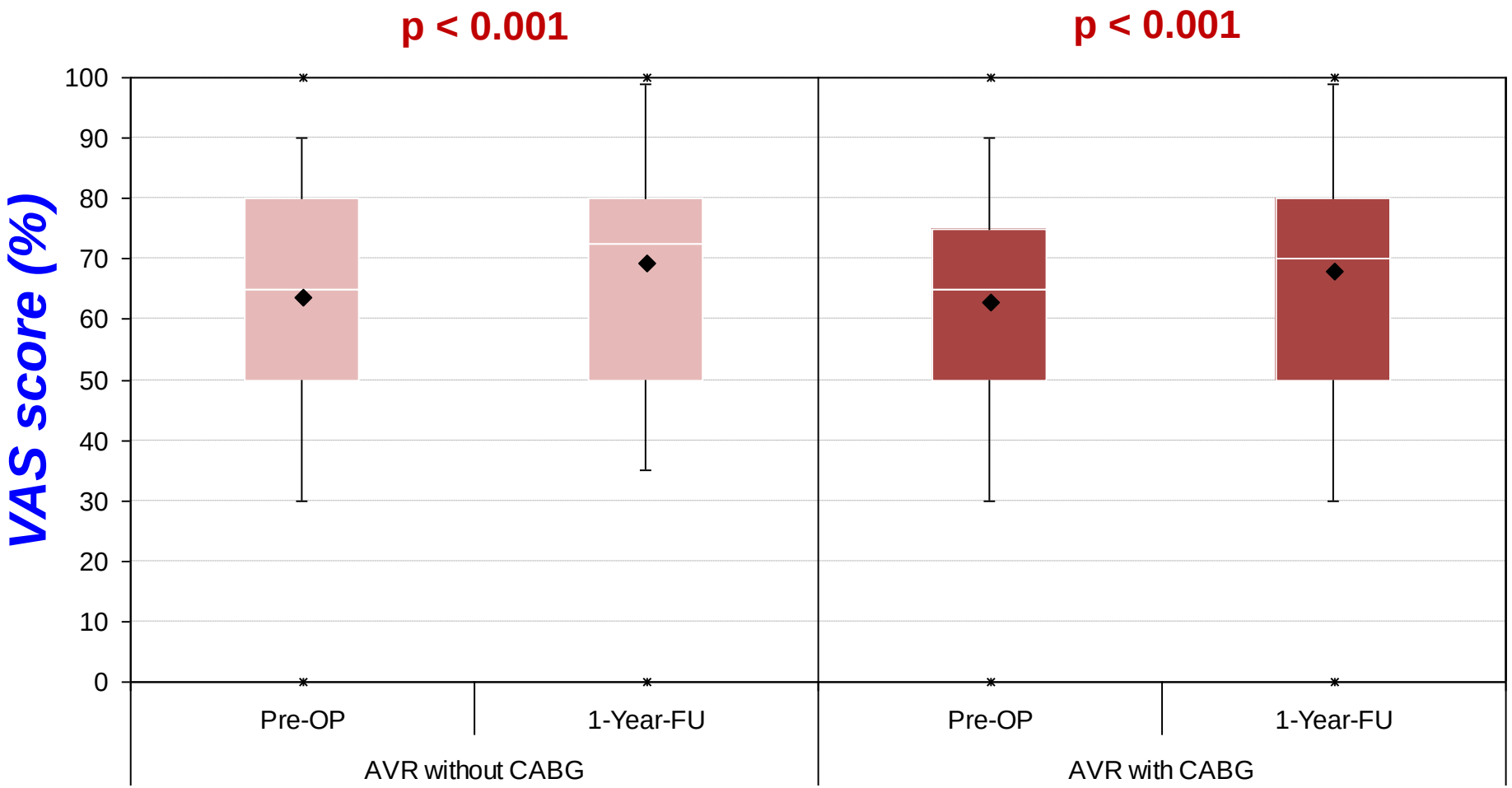

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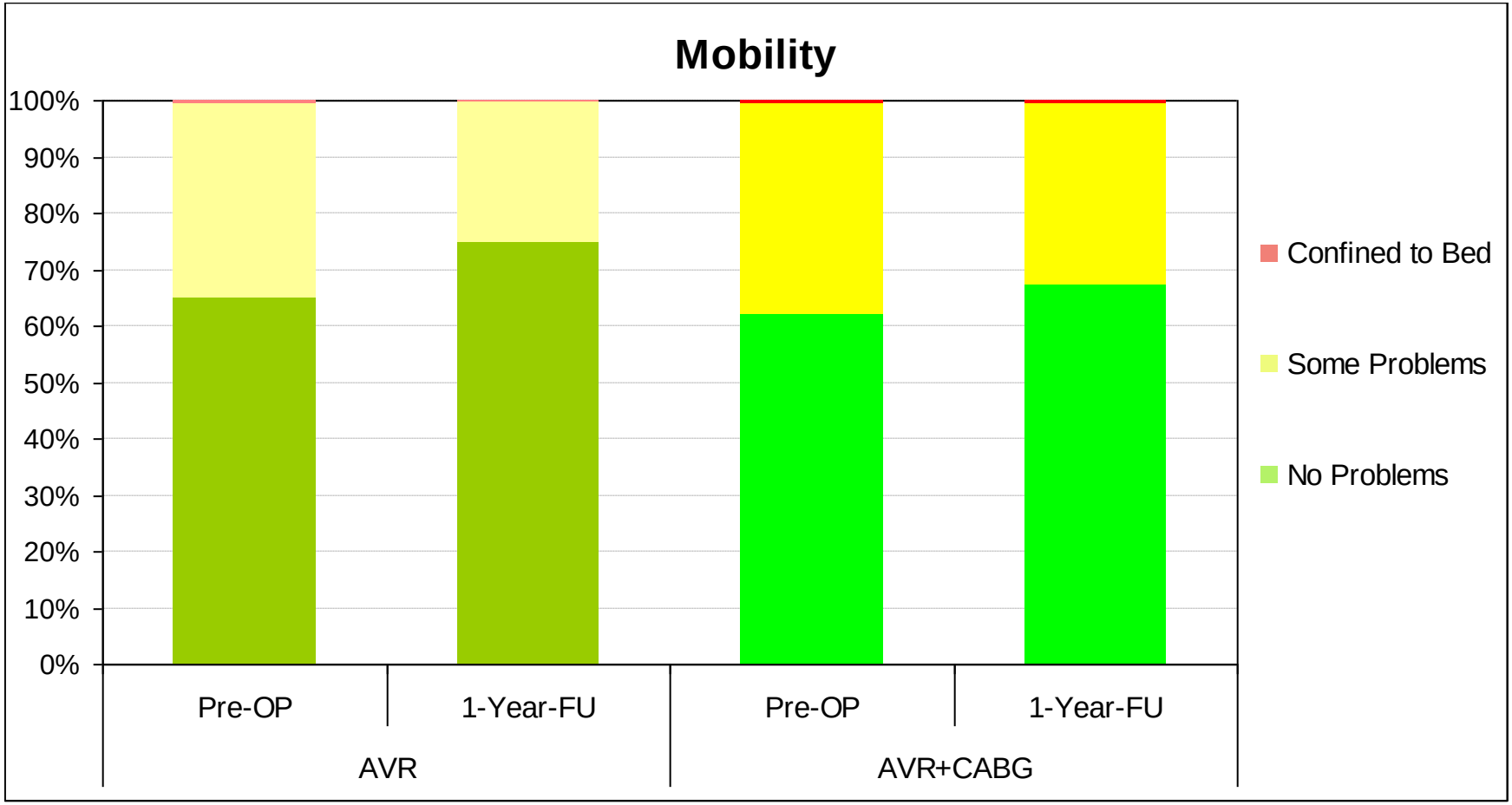
EQ-5D - 3 Level

Deutsches Aortenklappenregister



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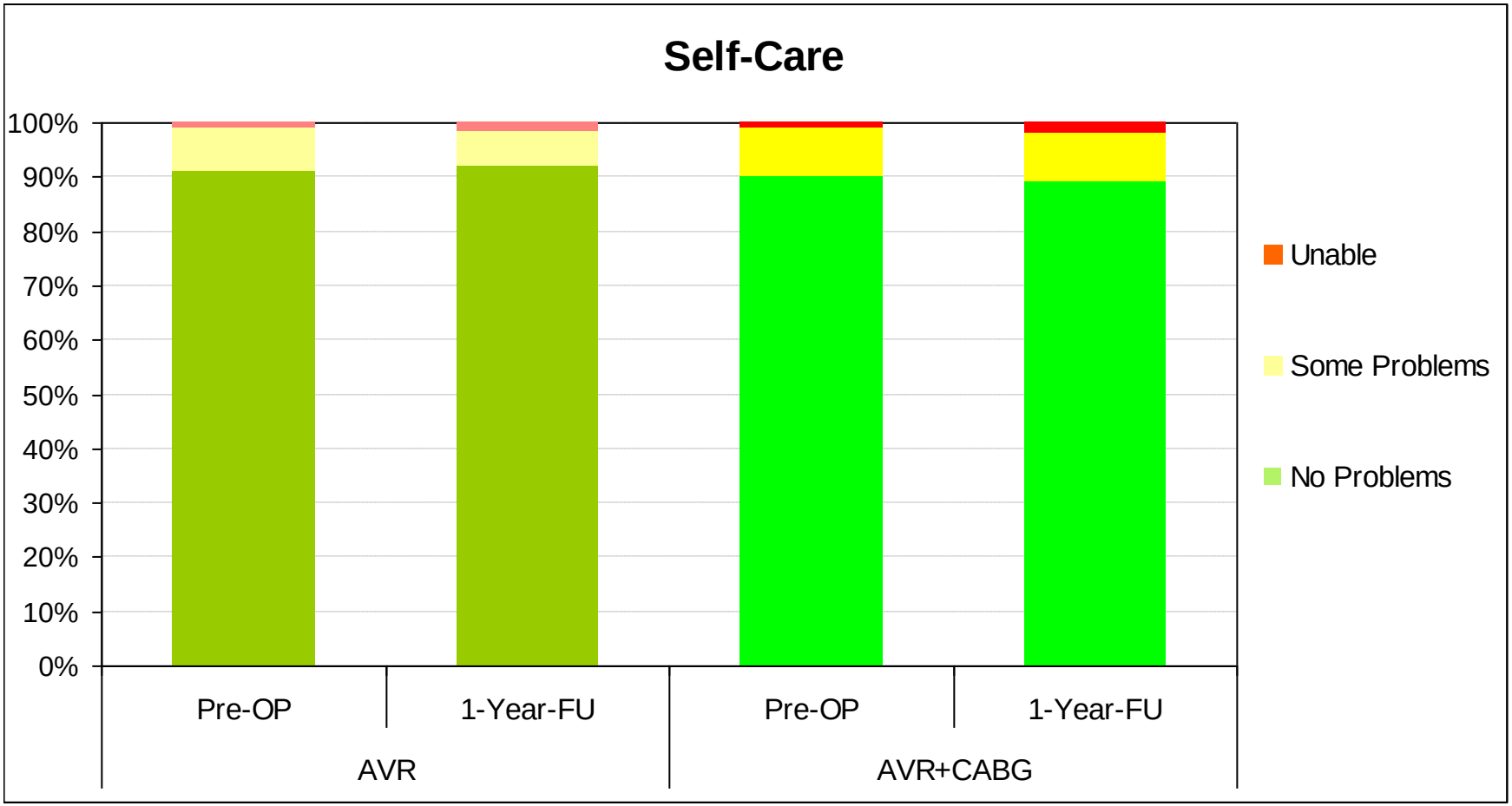
EQ-5D - 3 Level

Deutsches Aortenklappenregister



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EQ-5D - 3 Level

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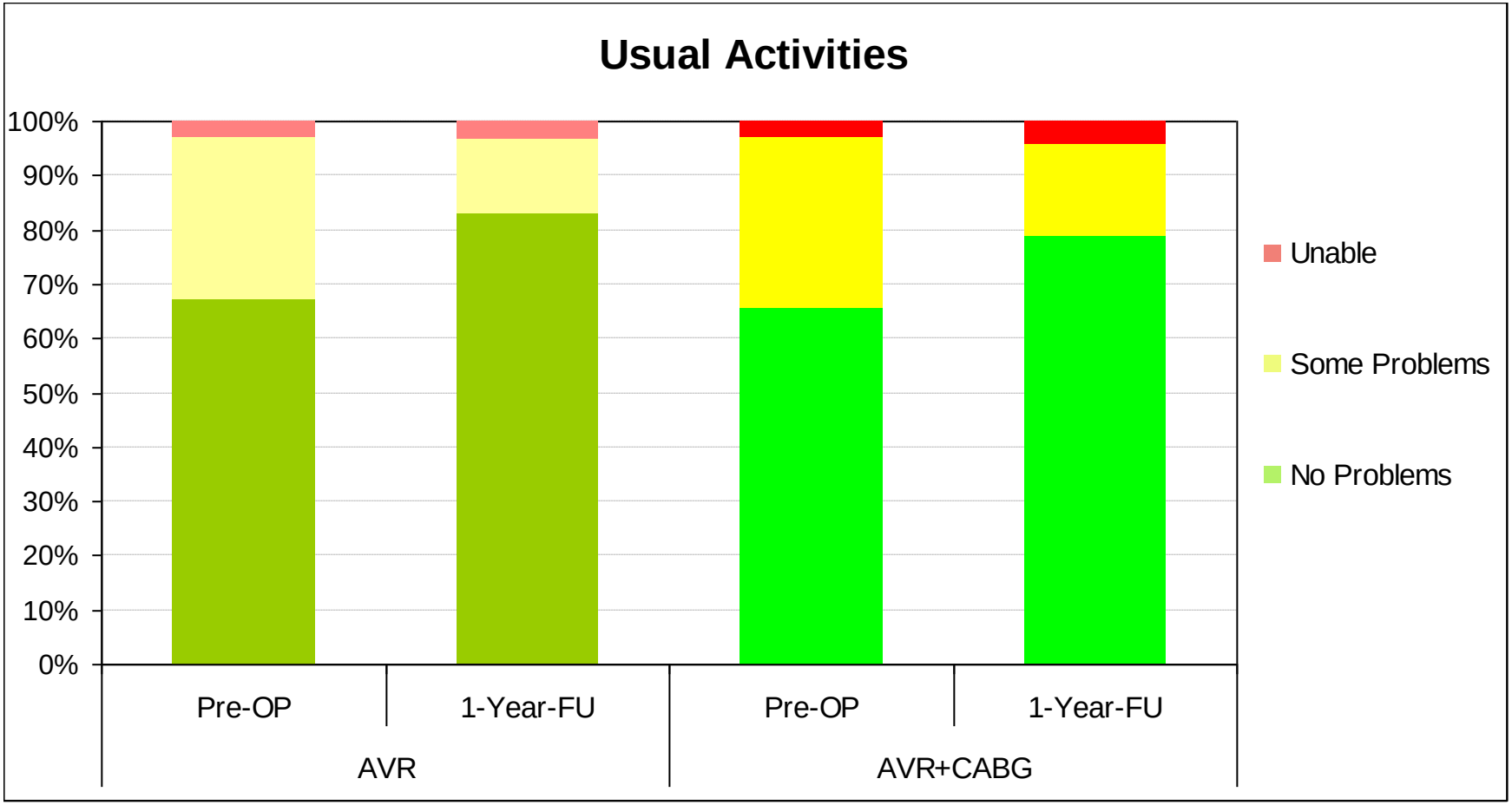

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EQ-5D - 3 Level

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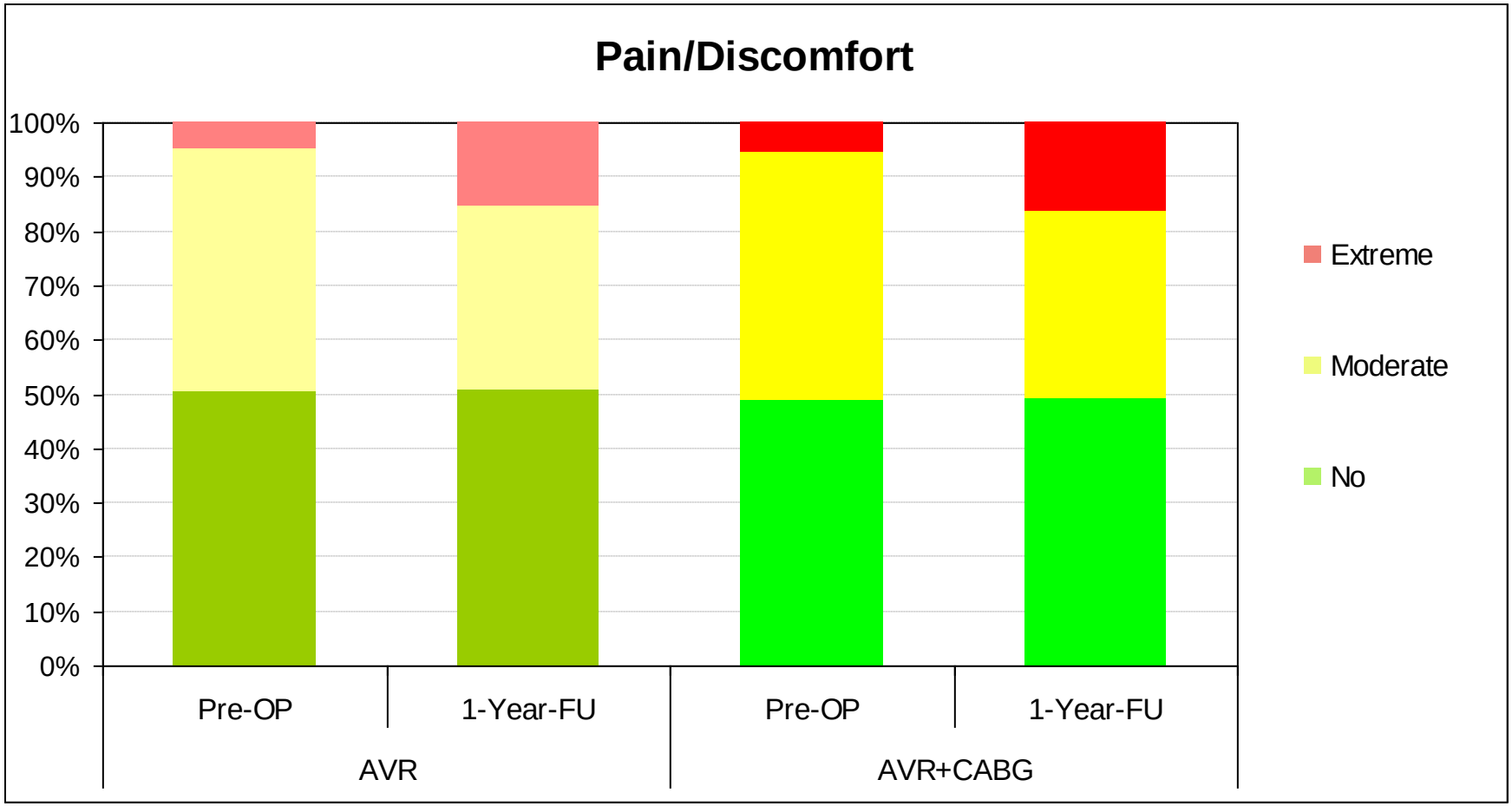

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EQ-5D - 3 Level

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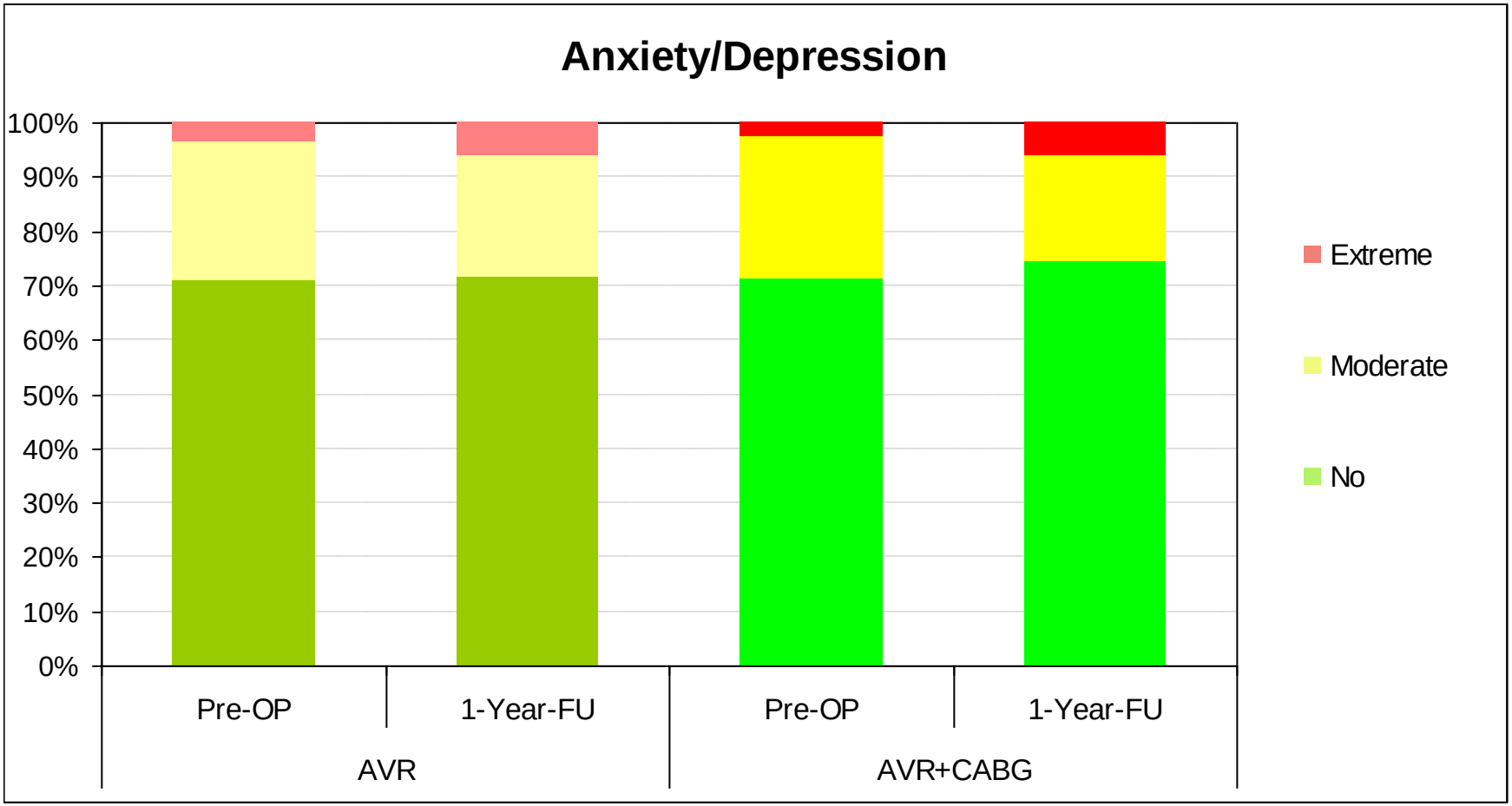

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EQ-5D – 3 Level

Comparison: pre-OP → 1-year-Follow Up

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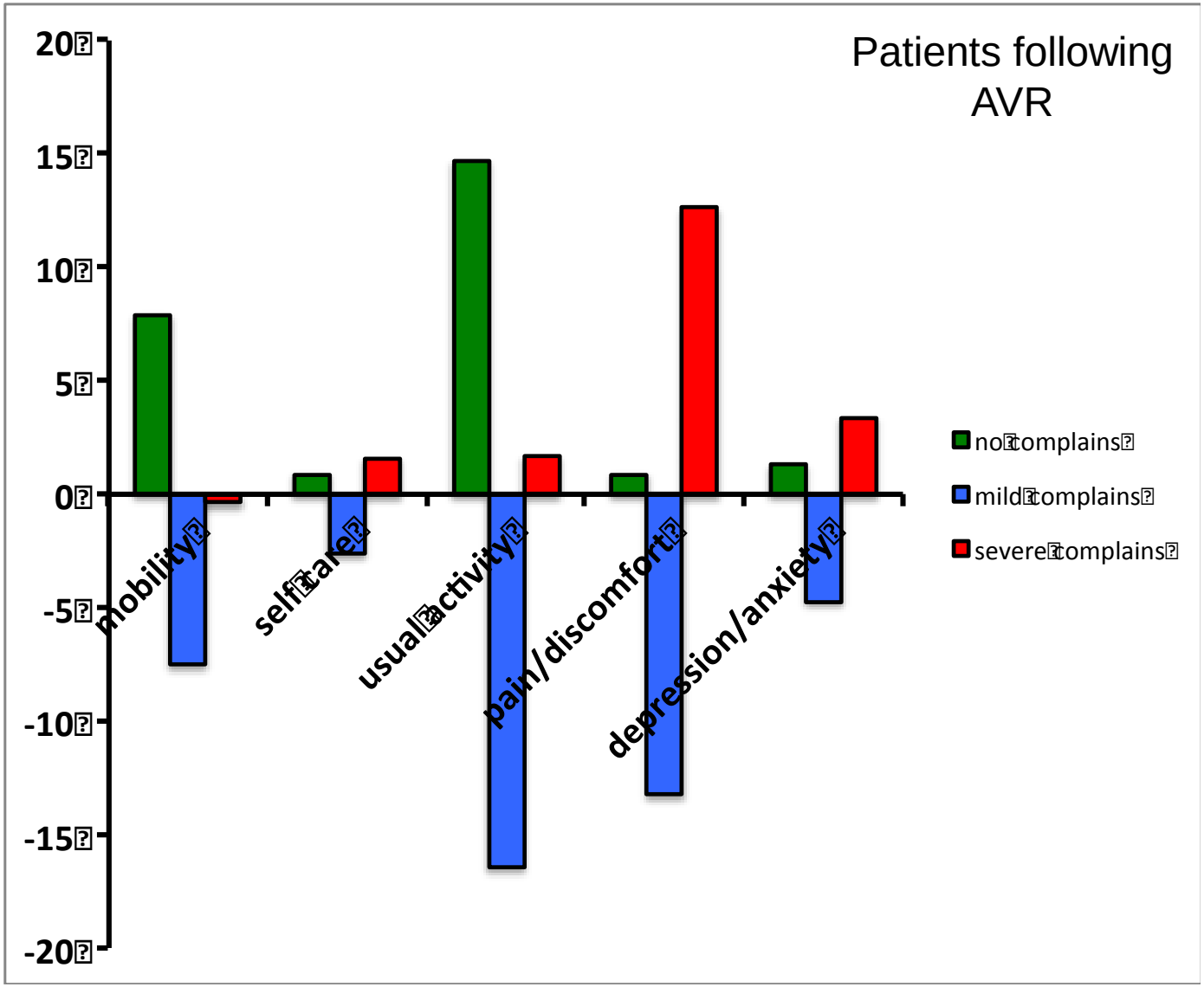

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EQ-5D – 3 Level

Comparison: pre-OP → 1-year-Follow Up

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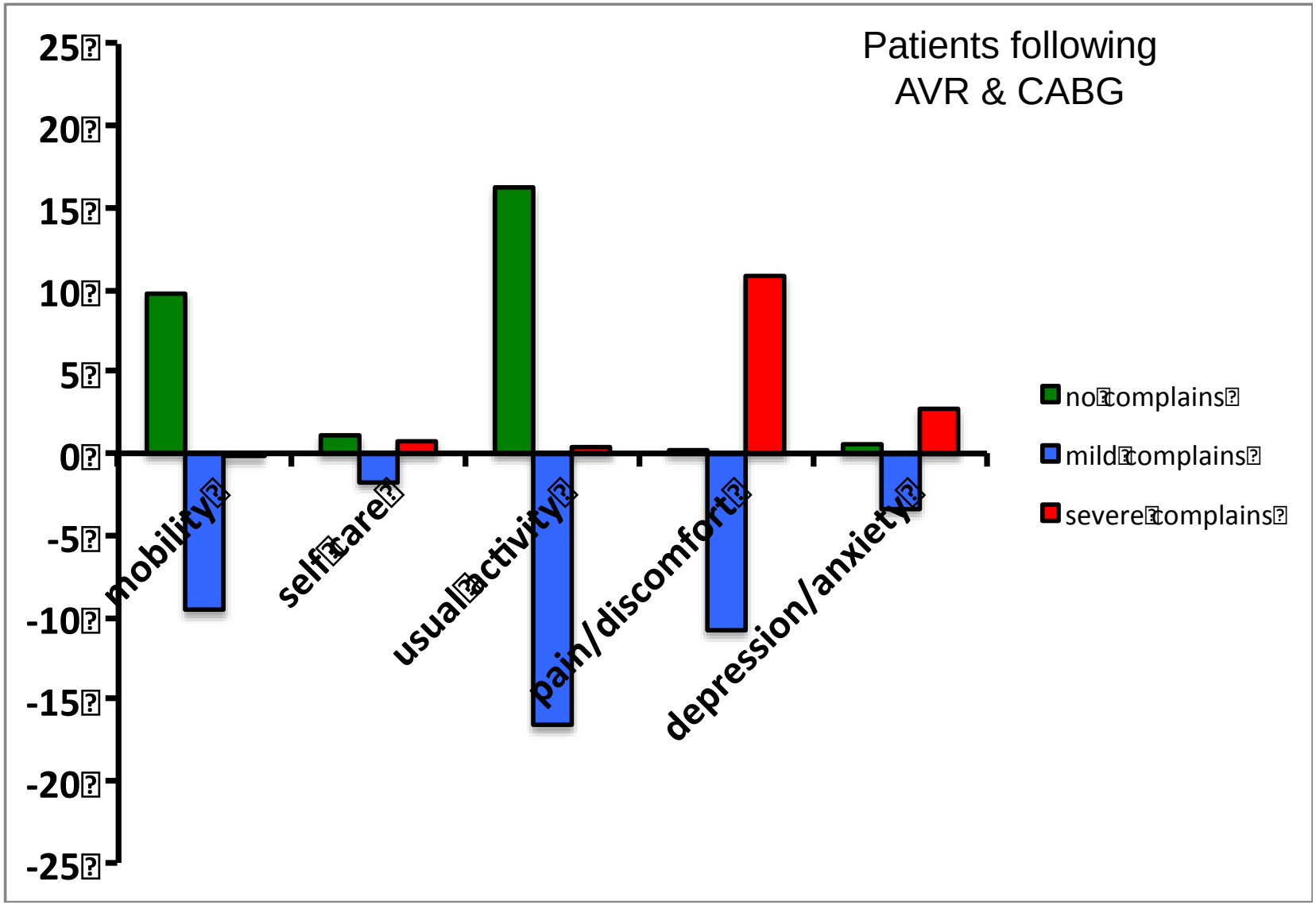

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Conclusions

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- **GARY** engages a **national real world study population** with complete follow-up

- Treatment of patients suffering from aortic valve disease leads to significant **improvement in Quality of Life** shown by
  - **increased** proportions of patients in Level 1 (uncomplicated status) in nearly all dimensions of the EQ-5D, especially in mobility and usual activity.
  - **improved VAS Scores** in the overall group as well as in the isolated AVR and combined AVR + CABG groups

- The dimensions **pain/discomfort** and **anxiety/depression** demonstrate an increase for patient numbers in Level 3 reflecting a **worsening in QoL** in these categories

- Further analysis should be performed to **identify patients** which have **no** treatment **benefit** in terms **o**f an improved **Quality of Life**

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Thank you!

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& PATIENTENSICHERHEIT

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