

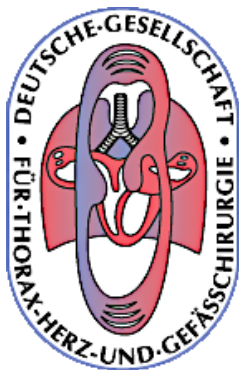
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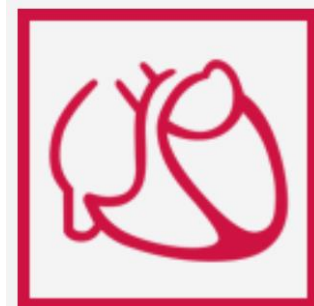
Deutsches
Aortenklappenregister

Peri-operative results and complications in 15,964 transcatheter aortic valve implantations from the German Aortic valve RegistrY (GARY)

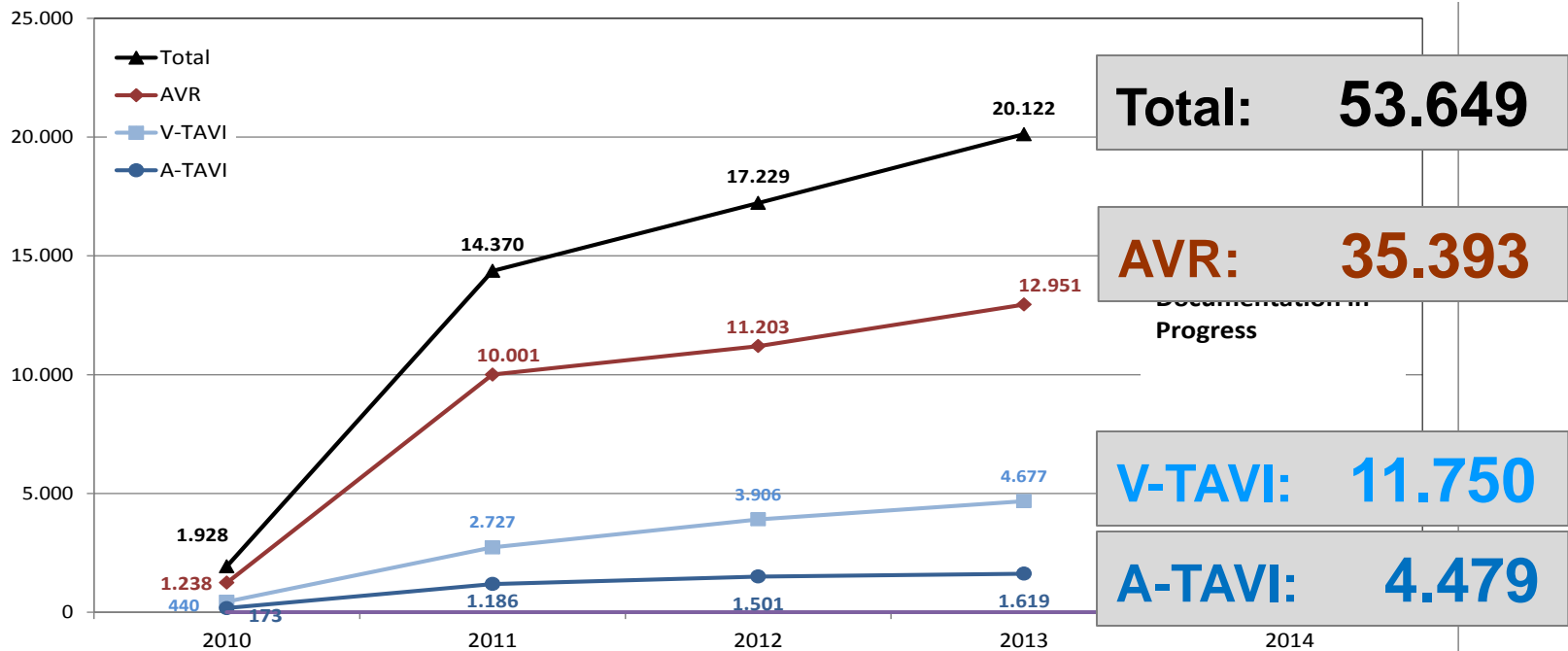
Thomas Walther, Christian W. Hamm, Gerhard Schuler, Alexander Berkowitsch, Joachim Kötting,
Norman Mangner, Harald Mudra, Andreas Beckmann, Jochen Cremer, Armin Welz,
Rüdiger Lange, Karl-Heinz Kuck, Friedrich W. Mohr, and Helge Möllmann
on behalf of the GARY executive board

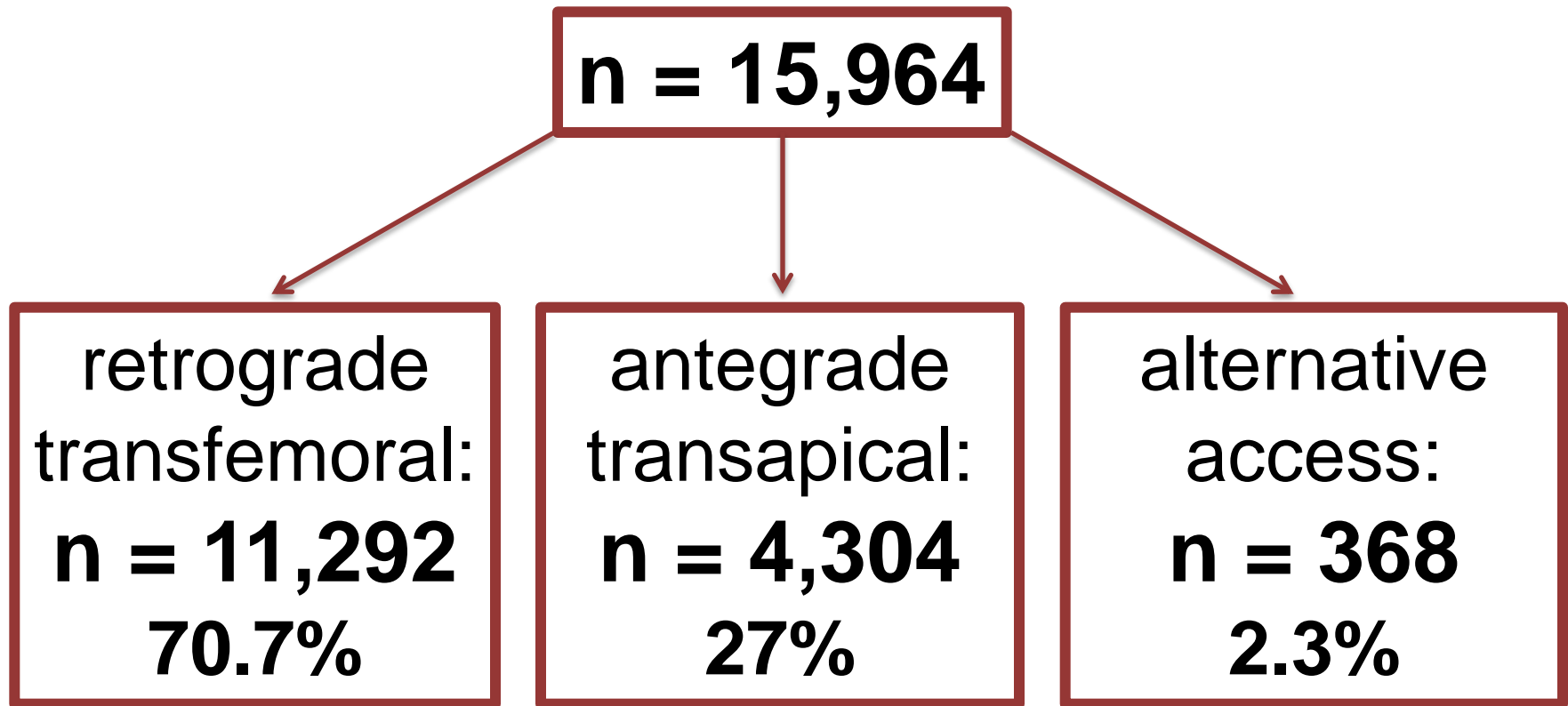


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- nationwide registry on AVR + T-AVI
- 93 active hospitals; 82,577 consented pat. 12/14
- 25,710 consented patients in 2014





- In-hospital outcome data were analyzed.

Valves implanted

T-AVI 2011 - 2013



n = 15,964

**Balloon
expandable**

(SAPIEN XT™,
SAPIEN 3™)

52.6%

n = 8,390



**Self
expandable**

(Corevalve™)

37.7%

n = 6,026



**Self
expandable
and Other**

9.7%

n = 1,548



- **Severe vital complications (SVC):**
death on day of intervention, conversion to sternotomy, acute PCI, low cardiac output requiring mechanical circulatory support, cardiac tamponade requiring treatment, aortic dissection, annular rupture
- **Technical complications of the procedures (TCO):**
repositioning or retrieval of valve prosthesis, valve-in-valve procedure, valve embolization, closure of a paravalvular leak
- **Other complications:**
aortic regurgitation, new-onset pacemaker implantation, stroke, major vascular complications, major bleeding
- **Conversion to sternotomy**
- **In-hospital death**

Baseline data

T-AVI 2011 - 2013, n = 15,964



	Total
Patients	100 %
Female	54 %
Age [years]	81 ±6
Euroscore [Median]	18.3
GER AV Sc. [Median]	5.6
STS Score [Median]	5.0
NYHA III – IV	86 %

* indicates $p < 0.01$ versus all other patients

Baseline data

T-AVI 2011 - 2013, n = 15,964



	Total	SVC	TCO	Sternotomy	Death
Patients	100 %	5.0%	4.7%	1.3%	5.2%
Female	54 %				
Age [years]	81 ±6				
Euroscore [Median]	18.3				
GER AV Sc. [Median]	5.6				
STS Score [Median]	5.0				
NYHA III – IV	86 %				

* indicates $p < 0.01$ versus all other patients

Baseline data

T-AVI 2011 - 2013, n = 15,964



	Total	SVC	TCO	Sternotomy	Death
Patients	100 %	5.0%	4.7%	1.3%	5.2%
Female	54 %	59.5% *	47.6% *	59.2%	53.4% *
Age [years]	81 ±6	81.0 ±6.2	81.0 ±6.0	80.5 ±5.6	81.6 ±6.3
Euroscore [Median]	18.3	21.0 *	21.5 *	20.6	24.7 *
GER AV Sc. [Median]	5.6	6.1 *	6.1 *	5.8 *	8.1 *
STS Score [Median]	5.0	5.7 *	5.5 *	5.5 *	6.9 *
NYHA III – IV	86 %	88.0%	86.1%	88.6%	90.2% *

* indicates $p < 0.01$ versus all other patients

Baseline data (b)

T-AVI 2011 - 2013, n = 15,964



	Total	SVC	TCO	Sternotomy	Death
Patients	100%	5.0%	4.7%	1.3%	5.2%
CAD	55.1%	58.0%	58.2%	50.2%	61.8% *
Previous card. Surgery	21.0%	23.0%	25.1% *	19.4%	23.3%
Pulmonary hypertension	35.7%	35.6%	35.9%	34.2%	45.4% *
COPD requ.med.	14.2%	12.8%	13.8%	11.9%	16.2%
EF < 30%	9.5%	12.8% *	13.6% *	8.5%	16.3% *
Renal repl. tx.	5.0%	4.8%	5.2%	5.5%	8.2% *
Peripheral vasc. disease	19.5%	22.3% *	19.7%	22.4%	30.1% *

* indicates $p < 0.01$ versus all other patients

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Procedural data

T-AVI 2011 - 2013, n = 15,964



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	Total	SVC	TCO	Sternotomy	Death
Patients	15,964	792	748	201	828
In-hospital mortality	5.2%	40.8% *	17.1% *	42.3% *	100%

* indicates $p < 0.01$ versus all other patients

Procedural data

T-AVI 2011 - 2013, n = 15,964



	Total	SVC	TCO	Sternotomy	Death
Patients	15,964	792	748	201	828
In-hospital mortality	5.2%	40.8% *	17.1% *	42.3% *	100%
CPB used	2.4%	28.7% *	13.9% *	56.7% *	13.6% *
Conversion open heart surgery	1.3%	25.4% *	12.0% *	100.0% *	10.3% *
Cardiac tamponade	1.0%	20.7% *	3.9% *	31.5% *	8.0% *
Transfemoral approach	70.7%	66.3% *	79.0% *	67.7%	58.6% *
Transapical approach	27.0%	31.3% *	20.2% *	30.3%	37.6% *

* indicates $p < 0.01$ versus all other patients

Other complications

T-AVI 2011 - 2013, n = 15,964



	Total	SVC	TCO	Sternotomy	Death
Patients	15,964	792	748	201	828
Residual AR $\geq 2^\circ$	5.8%	10.7% *	12.8% *	16.7% *	12.0% *
New-onset pacer implant	17.5%	13.3% *	25.2% *	12.8%	13.9% *
Stroke	1.5%	4.2% *	4.1% *	3.5% *	6.3% *
Major vasc. complication	4.1%	8.0% *	10.3% *	7.0% *	8.0% *
Major bleeding #	26.3%	54.7% *	40.3% *	70.1% *	59.8% *

* indicates $p < 0.01$ versus all other patients

VARC II definition, ≥ 2 RBC units

Predictors for death

T-AVI 2011 - 2013, n = 15,964



	OR	95% conf. interval		p
Residual aortic regurgitation $\geq 2^\circ$	1.885	1.372	2.588	0.000
Peripheral vascular disease	1.443	1.156	1.800	0.001
Mitral regurgitation $> 2^\circ$	1.324	1.079	1.624	0.007
Ejection fraction $< 30\%$	1.573	1.184	2.092	0.002
Pulmonary hypertension	1.353	1.106	1.655	0.003
NYHA class IV	1.288	0.999	1.661	0.051
Body mass index < 22	1.586	1.227	2.049	0.000
Sternotomy	2.078	1.208	3.573	0.008
Low cardiac output	8.850	6.039	12.971	0.000
Cardiogenic shock	1.952	1.296	2.941	0.001
Tamponade	3.743	2.121	6.606	0.000
Aortic dissection	5.594	2.023	15.470	0.001
Annular rupture	7.058	3.202	15.559	0.000
PCI due to complications	2.841	1.253	6.439	0.012
Technical complications	1.638	1.155	2.323	0.006
Post-operative stroke	3.574	2.301	5.550	0.000
Post-operative new-onset dialysis	10.519	8.137	13.599	0.000
Post-operative myocardial infarction	23.146	10.877	49.251	0.000
Post-operative ischemia	2.101	1.085	4.068	0.028
Bleeding	5.005	3.961	6.325	0.000

**Severe
vital
complications
(SVC)**

multivariate
analysis

Predictors for SVC

T-AVI 2011 - 2013, n = 15,964



	OR	95% conf. interval		p
Female gender	1.37	1.16	1.62	<i>0.0002</i>
NYHA class IV	1.46	1.19	1.79	<i>0.0003</i>
LVEF ≤ 30 %	1.33	1.05	1.70	<i>0.0183</i>
i.v. Inotropes	3.88	2.92	5.16	<i>0.0000</i>
Arterial vascular disease	1.23	1.04	1.45	<i>0.0159</i>
Higher degree of calcification	1.28	1.07	1.52	<i>0.0059</i>
Higher degree of aortic stenosis	1.36	1.14	1.62	<i>0.0007</i>

Predictors for TCO

T-AVI 2011 - 2013, n = 15,964



	OR	95% conf. interval		p
Year of procedure	.882	.803	.969	0.009
Male gender	1.287	1.106	1.499	0.001
LVEF ≤ 30 %	1.39	1.11	1.74	0.005
Neurological dysfunction	1.43	1.17	1.74	0.000
Cardiac decompensation	1.21	1.04	1.41	0.015
i.v. Inotropes	2.22	1.59	3.11	0.000

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Predictors for Sternotomy

T-AVI 2011 - 2013, n = 15,964



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	OR	95% conf. interval	<i>p</i>
none			

Regression in risk profiles

T-AVI 2011 - 2013, n = 15,964



	Total	2011	2012	2013	p
	100%	24.7%	34.6%	40.6%	
Log ES [mean / median]	23.3 18.3	25.4 20.2	23.5 18.6	21.9 16.9	< 0.001
German AV Score [mean / median]	7.7 5.6	8.4 5.8	7.7 5.6	7.2 5.2	< 0.001
STS Score [mean / median]	6.4 5.0	6.7 5.2	6.3 5.0	6.4 4.9	< 0.001

<i>in %</i>	Total	SVC	TCO	Sterno- tomy	Death
Patients	100	5.0	4.7	1.3	5.2
2011	100	6.8	5.3	1.6	5.9
2012	100	4.9	5.0	1.2	5.0
2013	100	3.9	4.0	1.1	4.9
<i>p</i>	-	< 0.001	0.003	0.133	0.078

SVC = severe vital complication

TCO = technical complication

- **T-AVI is safe** with acceptable complication rates, all-comers and high-risk population (**n= 15,964**)
- Decrease in complications over years:
(learnings, screening+selection, technical progress)
- **Severe vital complications + TCO remain ~ 4 %.**
- Independent predictors for complications ($p < 0.01$):
(gender, reduced ejection fraction, arterial vascular disease)
- **Sternotomy** stable at ~ **1.2 %**, **no predictors**
- In-hospital **death rate ~ 5 %**, no change

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Thank you !



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Thomas Walther, M.D.¹, Christian W. Hamm, M.D.², Gerhard Schuler, M.D.³, Alexander Berkowitsch, M.D.², Joachim Kötting, Dipl. Stat.⁴, Norman Mangner, M.D.³, Harald Mudra, M.D.⁵, Andreas Beckmann, M.D.⁶, Jochen Cremer, M.D.⁷, Armin Welz, M.D.⁸, Rüdiger Lange, M.D.⁹, Karl-Heinz Kuck, M.D.¹⁰, Friedrich W. Mohr, M.D.¹¹, and Helge Möllmann, M.D.² *on behalf of the GARY executive board*