TAVI SURVEY

Performed by the ESC Council for Cardiology Practice

BACKGROUND

To evaluate the knowledge and the behaviour of a large community of cardiologists working in different settings, both in hospital and in out of hospital practice, the Council for Cardiology Practice developed a survey based on a questionnaire to submit to cardiologists who have subscribed to the Council's Newsletter and to the Council's E-Journal of Cardiology Practice.

The aims of the survey were:

- To analyse the knowledge and the application of current knowledge about TAVI methodology for aortic valve replacement
- To analyse the behaviour of Cardiologists in Practice on this specific topic
- To understand how cardiologists are seeing the future of TAVI procedures
- To study possible implementation problems and solutions in the application of guidelines on Valvular Heart Disease of the European Society of Cardiology and of suggestions of scientific literature about the topic
- To verify in the future the modification of behaviour with a similar survey in the next years.

METHOD

The questionnaire was sent to 50,840 cardiologists who have subscribed to the E-journal and/or electronic Newsletter of the Council for Cardiology Practice, with a link to the website hosting the questionnaire. Data collected were anonymous.

After the questions regarding the demographic characteristics, data regarding the answers about the scientific contents of the survey from N°6 to N°18, were matched by groups of:

- Age (Under 40 years / From 40 to 50 years / Over 50 years – Groups 1, 2 and 3)
- Professional status (In University or normal hospital / Cardiologist in practice – Groups 4 and 5)
- World region (Africa / Asia + Oceania / Europe / North America + South & Central America – Groups 6, 7, 8 and 9)

to verify possible differences among the answers by these groups and the possible statistic differences.

The data regarding Age and World Regions groups were analyzed versus their complement in the sample.

For the professional status, General Practitioners and other activities were excluded from the statistical analysis: Cardiologist in University and Cardiologist in Hospital group data were compared with the data from Cardiologist in Practice group.

The profile of each group was determined by highlighting significant differences in the answers to questions 6-18.

+++	---	Significant differences => 99% => p-value ≤ 0,01
++	--	Significant differences => 95% => 0,01 < p-value ≤ 0,05
+	-	Significant differences => 90% => 0,05 < p-value ≤ 0,1

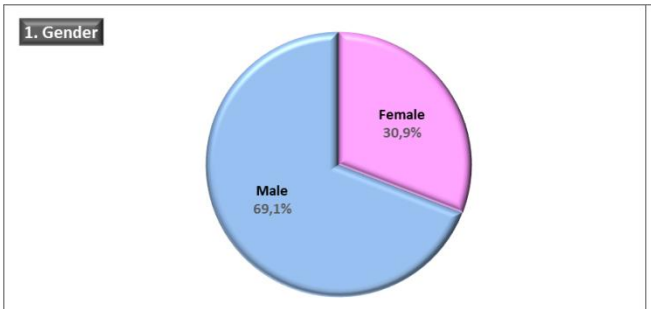
RESULTS AND DESCRIPTIVE ANALYSIS

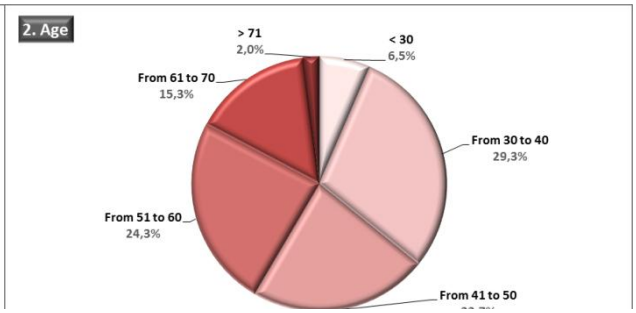
1 425 were the respondents to questions 1-5 (Q1-Q5). The data about the scientific contents were obtained from 1 245 respondents that fully answered to questions 6-18 (Q8-Q18). The statistical analysis concentrated on the sample of these 1 245 questionnaires. The responders of the Syncope Survey of the Council for Cardiology Practice were 1 474 and of the Atrial Fibrillation Survey were 2428.

DEMOGRAPHICS CHARACTERISTICS:

In tables and in graphs 1, 2, 3 and 5 are summarized the demographic characteristics of the sample, with both data about the whole group of responders and the group of responders who completed the answers from Q6 to Q18.

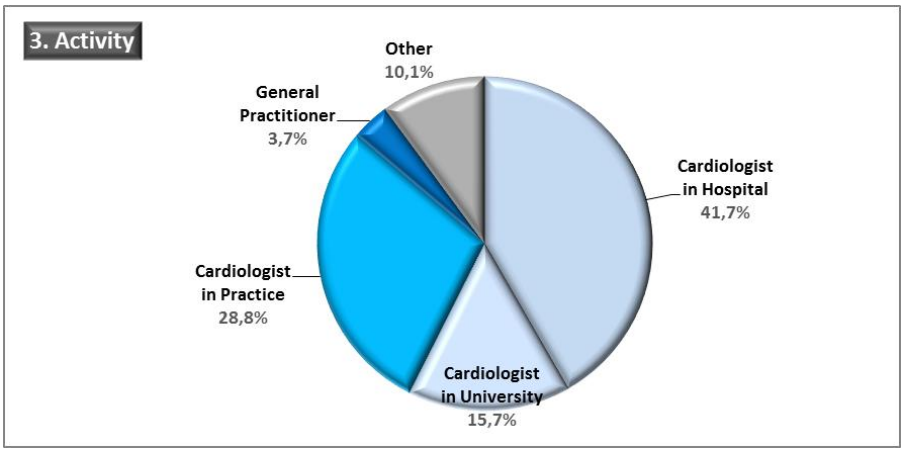
1. Gender	Total	%	Respondent Q6 to Q18	%
Female	**464**	**32,6%**	**385**	**30,9%**
Male	**961**	**67,4%**	**860**	**69,1%**
answered question	**1425**	**100,0%**	**1245**	**100,0%**
skipped question	*0*	*/*	*0*	*/*



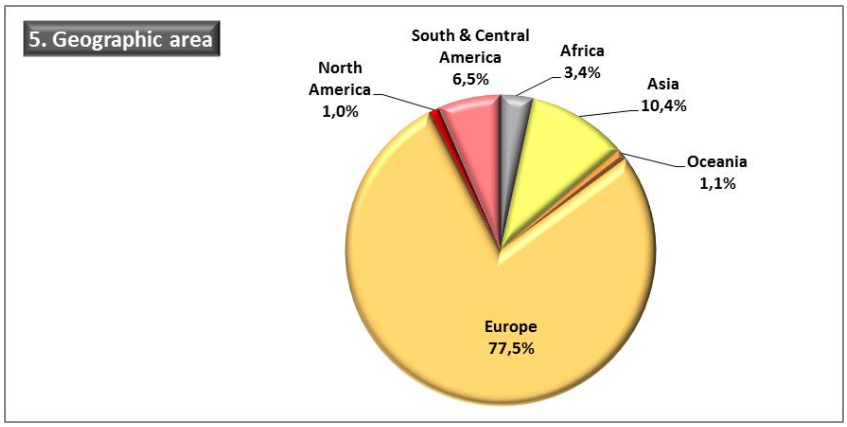


2. Age	Total	%	Respondent Q6 to Q18	%		
Under 30 years	103	7,2%	81	6,5%	35,8%	Group 1
From 30 to 40 years	423	29,7%	365	29,3%		
From 41 to 50 years	321	22,5%	282	22,7%	22,7%	Group 2
From 51 to 60 years	345	24,2%	302	24,3%	41,5%	Group 3
From 61 to 70 years	207	14,5%	190	15,3%		
Over 71 years	26	1,8%	25	2,0%		
answered question	1425	100,0%	1245	100,0%		
skipped question	*0*	*/*	*0*	*/*		

3. Activity	Total	%	Respondent Q6 to Q18	%		
General Practitioner	55	3,9%	46	3,7%		
Cardiologist in University	227	15,9%	196	15,7%	57,4%	Group 4
Cardiologist in Hospital	566	39,7%	519	41,7%		
Cardiologist in Practice	384	26,9%	358	28,8%	28,8%	Group 5
Other	193	13,5%	126	10,1%		
answered question	1425	100,0%	1245	100,0%		
skipped question	*0*	*/*	*0*	*/*		



5. Region	Total	%	Respondent Q6 to Q18	%		
Africa	49	3,4%	42	3,4%	3,4%	**Group 6**
Asia	158	11,1%	130	10,4%	11,6%	**Group 7**
Oceania	18	1,3%	14	1,1%		
Europe	1101	77,3%	965	77,5%	77,5%	**Group 8**
North America	15	1,1%	13	1,0%	7,6%	**Group 9**
South & Central America	84	5,9%	81	6,5%		
answered question	**1425**	**100,0%**	**1245**	**100,0%**		
skipped question	***0***	***/***	***0***	***/***		



The number of responders to the survey was similar to that of the surveys performed by the Council for Cardiology Practice about Cardiology Practice and about Syncope Guidelines, while a higher number of respondents was observed for the survey about antithrombotic treatment in Atrial Fibrillation. The distribution of the responders for:

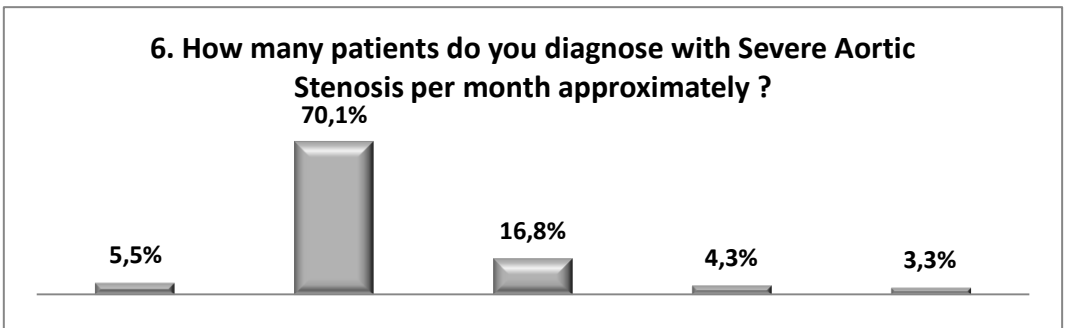
- Sex
- Age
- Hospital vs non-hospital
- Country

was similar to that of the previous surveys of the Council for Cardiology Practice.

RESULTS TO THE SCIENTIFIC QUESTIONS FROM 6 TO 18

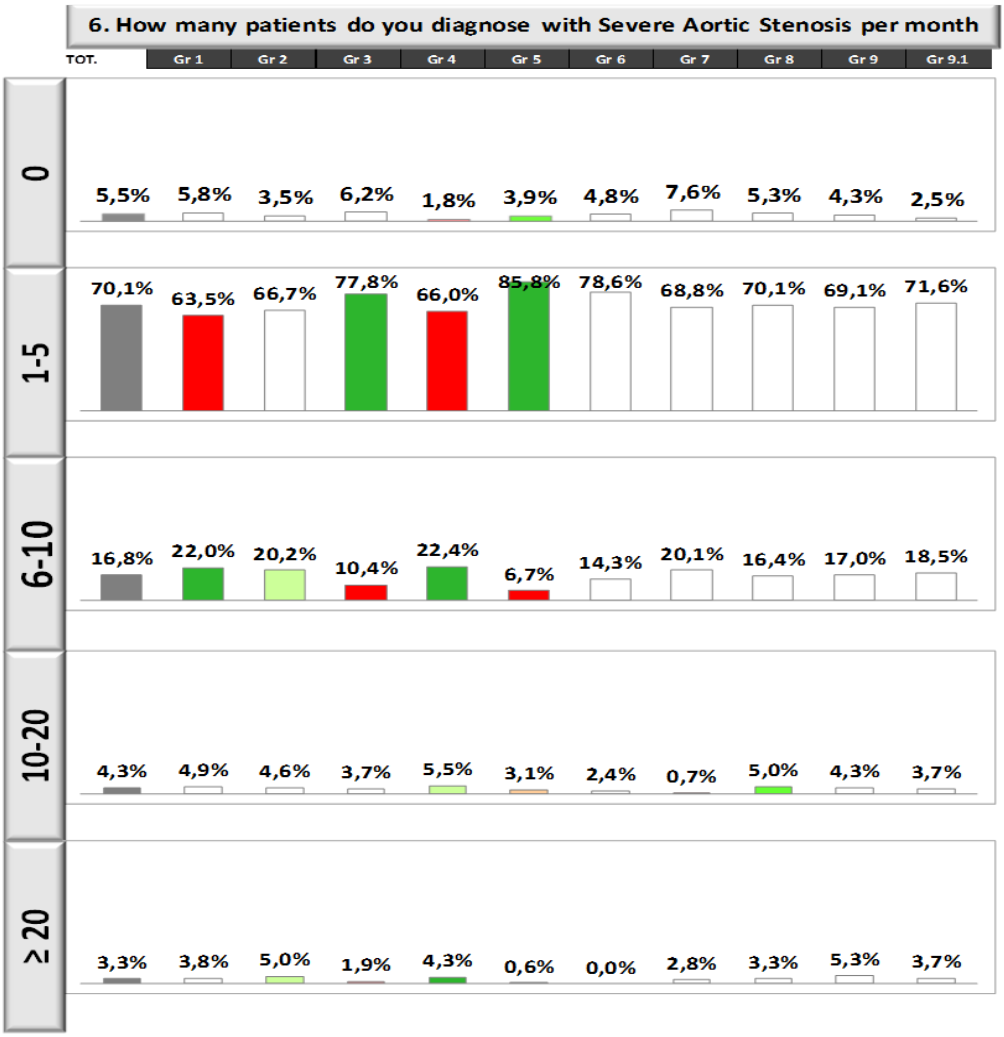
The respondents answering completely to these questions were 1 245 and on these answers is concentrated the analysis.
Here are summarized the results considering the answers to the single questions from 6 to 18 both regarding the total of the answers and the subgroups.
The tables and graphs showing the subgroups data report the total data of the answers to the specific question and the data divided according to the pre-specified subgroups shown in red if the result of that group is significantly under the mean data or in green if the result of that group is significantly higher than the mean data.
Please note that sometimes the red or green color does not necessarily correspond to a "good" or "bad" result – it has only a "mathematic" meaning.

6. How many patients do you diagnose with Severe Aortic Stenosis per month approximately?	**Total**	**%**
0	68	5,5%
1-5	873	70,1%
6-10	209	16,8%
10-20	54	4,3%
>20	41	3,3%
answered question	**1245**	**100,0%**
skipped question	***0***	***/***

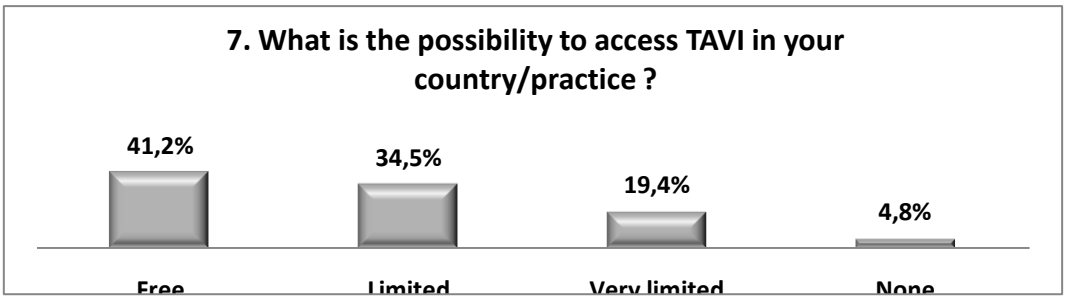


The large majority of the responders are facing a number of patients with severe aortic stenosis per month variable from 1 to 10. Consequently this is a high number of patients who have undergone cardiologic evaluation, who have been diagnosed and who have possible indication to aortic valve replacement and to TAVI procedure,

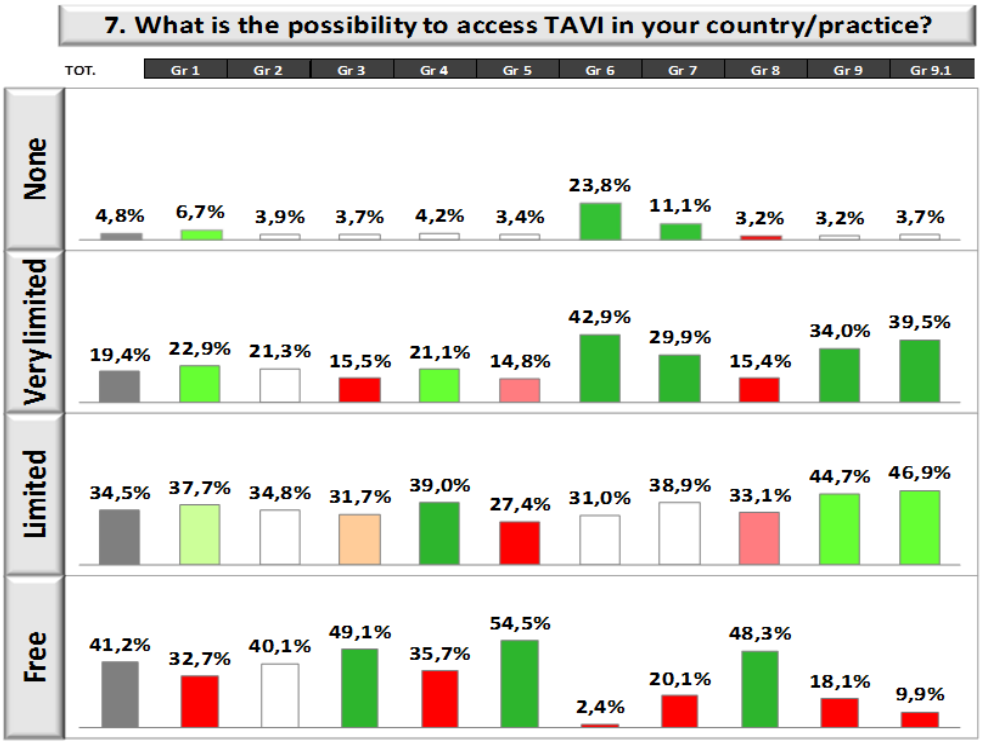
By the groups analysis it seems that young cardiologists and hospital cardiologists have a larger opportunity to diagnose severe aortic stenosis than oldest cardiologists and non-hospital cardiologists, while non–significant differences were observed according to the world regions.


6. How many patients do you diagnose with Severe Aortic Stenosis per month
TOT.
Gr 1
Gr 2
Gr 3
Gr 4
Gr 5
Gr 6
Gr 7
Gr 8
Gr 9
Gr 9.1
0
5,5% 5,8% 3,5% 6,2% 1,8% 3,9% 4,8% 7,6% 5,3% 4,3% 2,5%
1-5
70,1% 63,5% 66,7% 77,8% 66,0% 85,8% 78,6% 68,8% 70,1% 69,1% 71,6%
6-10
16,8% 22,0% 20,2% 10,4% 22,4% 6,7% 14,3% 20,1% 16,4% 17,0% 18,5%
10-20
4,3% 4,9% 4,6% 3,7% 5,5% 3,1% 2,4% 0,7% 5,0% 4,3% 3,7%
≥ 20
3,3% 3,8% 5,0% 1,9% 4,3% 0,6% 0,0% 2,8% 3,3% 5,3% 3,7%

7. What is the possibility to access TAVI in your country/practice?	Total	%
Free	513	41,2%
Limited	430	34,5%
Very limited	242	19,4%
None	60	4,8%
answered question	**1245**	**100,0%**
skipped question	***0***	***/***

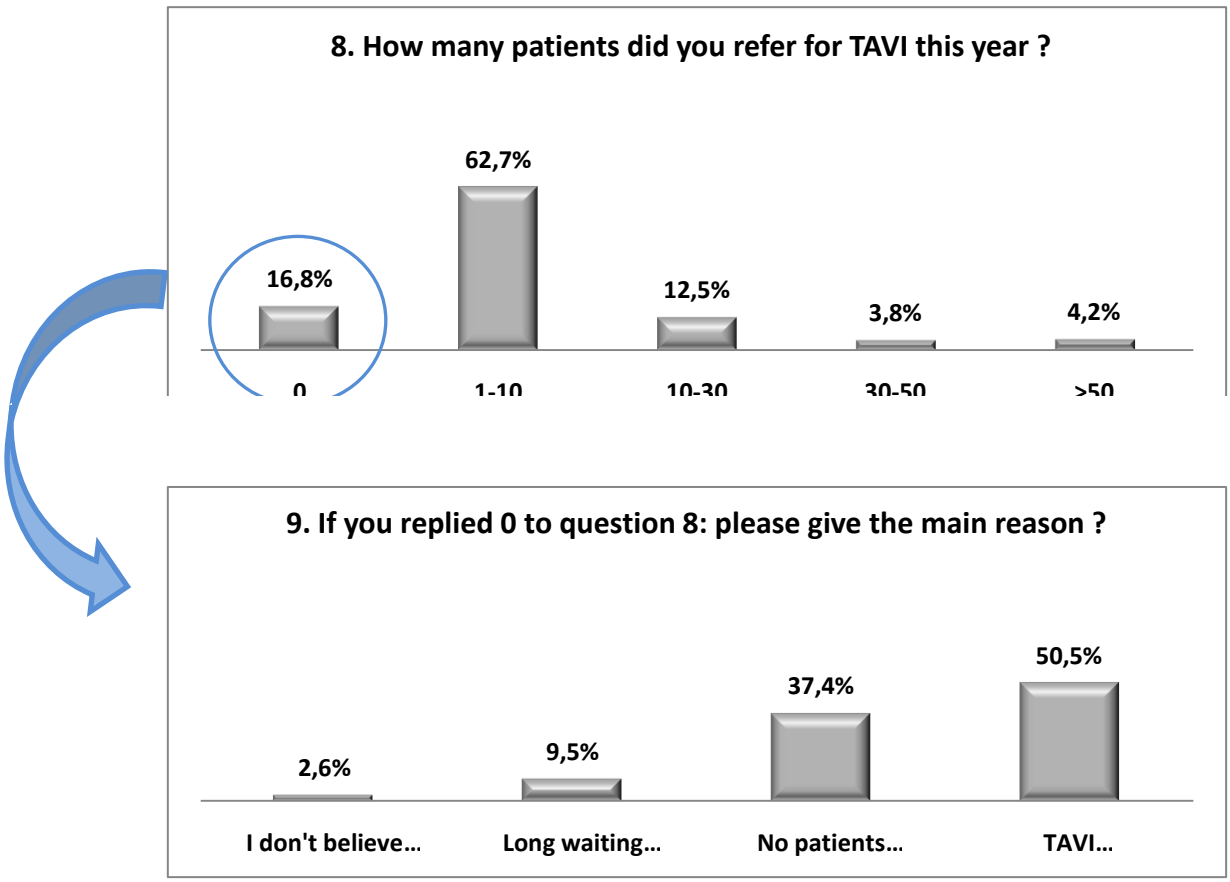


More than 40% of responders have free access to TAVI. It seems a very good result. But the groups analysis shows some expected and some non-expected data: youngest cardiologists and hospital cardiologists seem to have less free access to TAVI than their oldest and non-hospital colleagues. Cardiologists from Africa and Asian countries have less free access than European cardiologists to TAVI.

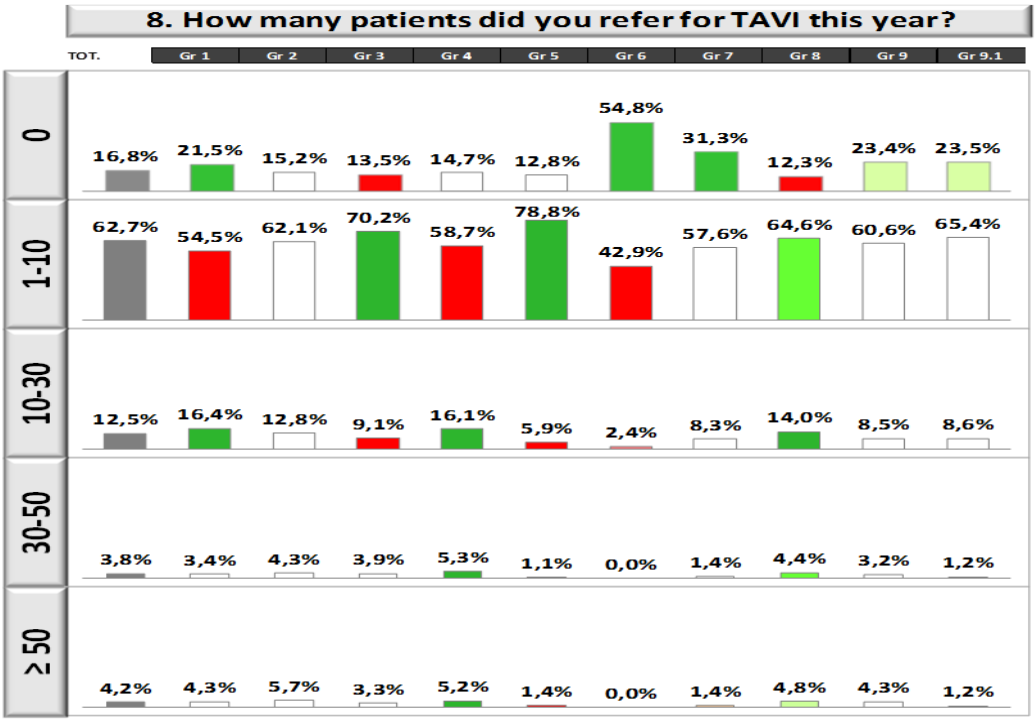

7. What is the possibility to access TAVI in your country/practice?
TOT.
Gr 1
Gr 2
Gr 3
Gr 4
Gr 5
Gr 6
Gr 7
Gr 8
Gr 9
Gr 9.1
None
4,8%
6,7%
3,9%
3,7%
4,2%
3,4%
23,8%
11,1%
3,2%
3,2%
3,7%
Very limited
19,4%
22,9%
21,3%
15,5%
21,1%
14,8%
42,9%
29,9%
15,4%
34,0%
39,5%
Limited
34,5%
37,7%
34,8%
31,7%
39,0%
27,4%
31,0%
38,9%
33,1%
44,7%
46,9%
Free
41,2%
32,7%
40,1%
49,1%
35,7%
54,5%
2,4%
20,1%
48,3%
18,1%
9,9%

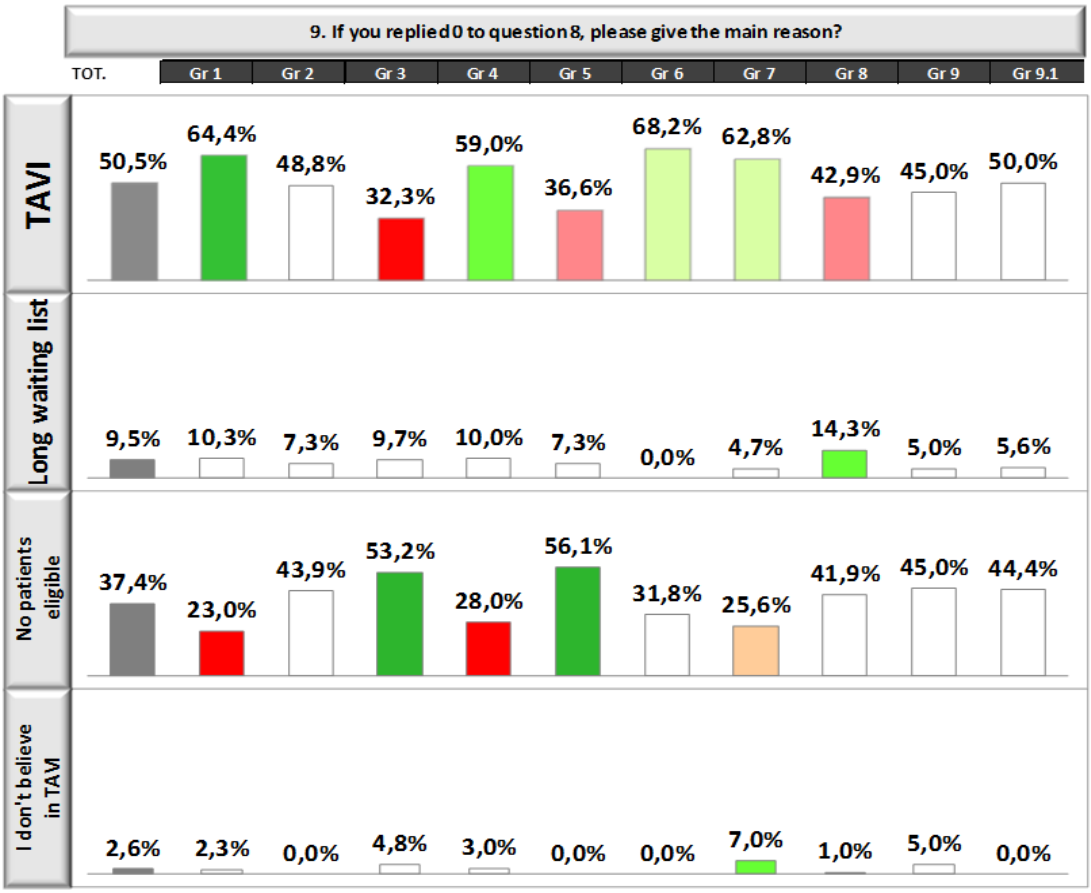
8. How many patients did you refer for TAVI this year?	Total	%
0	209	16,8%
1-10	781	62,7%
10-30	156	12,5%
30-50	47	3,8%
>50	52	4,2%
answered question	**1245**	**100,0%**
skipped question	***0***	***/***

9. If you replied 0 to question 8: please give the main reason? If you did not reply 0 to question 8, please go directly to question 10.	Total	%
I don't believe in TAVI	5	2,6%
Long waiting list	18	9,5%
No patients eligible	71	37,4%
TAVI unavailable	96	50,5%
answered question	**190**	**100,0%**
skipped question	***19***	***/***

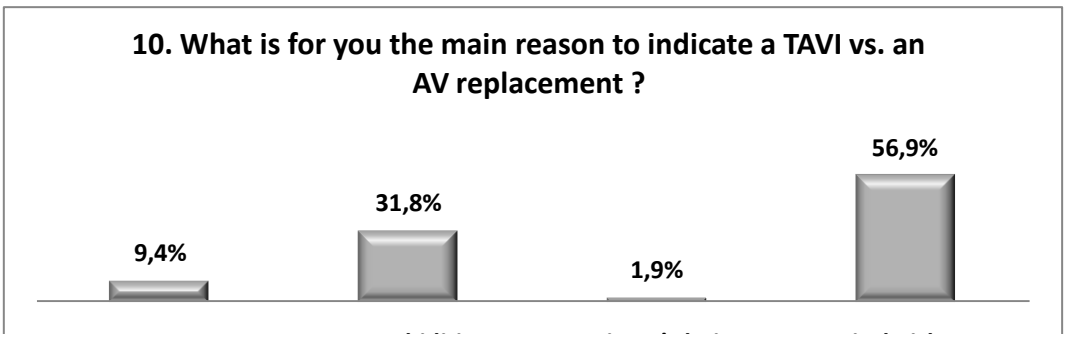


More than 60% of responders referred from 1 to 10 patients for TAVI in the last year. Among the responders the youngest cardiologists were prevalent for the answer " no patients" or "10 to 30 patients" referred for TAVI / year, while responders "1 to 10 patients" were the oldest and the non-hospital cardiologists. Africa and Asian regions have the largest percentage of responders "no patients" referred for TAVI, while the majority of cardiologists responders "1 to 10" and "more patients" referred are coming from Europe. If a cardiologist answered to have no referred patient for TAVI, the reason was not availability of TAVI for youngest and for hospital cardiologists, without clear differences for world regions.

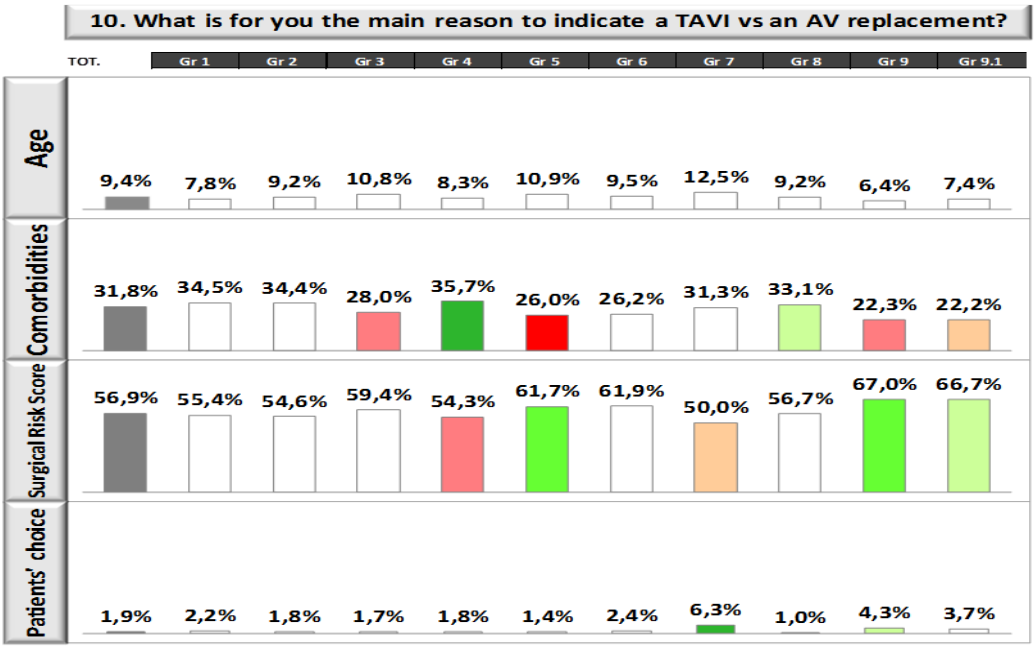

8. How many patients did you refer for TAVI this year?
TOT.
Gr 1
Gr 2
Gr 3
Gr 4
Gr 5
Gr 6
Gr 7
Gr 8
Gr 9
Gr 9.1
0
16,8%
21,5%
15,2%
13,5%
14,7%
12,8%
54,8%
31,3%
12,3%
23,4%
23,5%
1-10
62,7%
54,5%
62,1%
70,2%
58,7%
78,8%
42,9%
57,6%
64,6%
60,6%
65,4%
10-30
12,5%
16,4%
12,8%
9,1%
16,1%
5,9%
2,4%
8,3%
14,0%
8,5%
8,6%
30-50
3,8%
3,4%
4,3%
3,9%
5,3%
1,1%
0,0%
1,4%
4,4%
3,2%
1,2%
≥ 50
4,2%
4,3%
5,7%
3,3%
5,2%
1,4%
0,0%
1,4%
4,8%
4,3%
1,2%



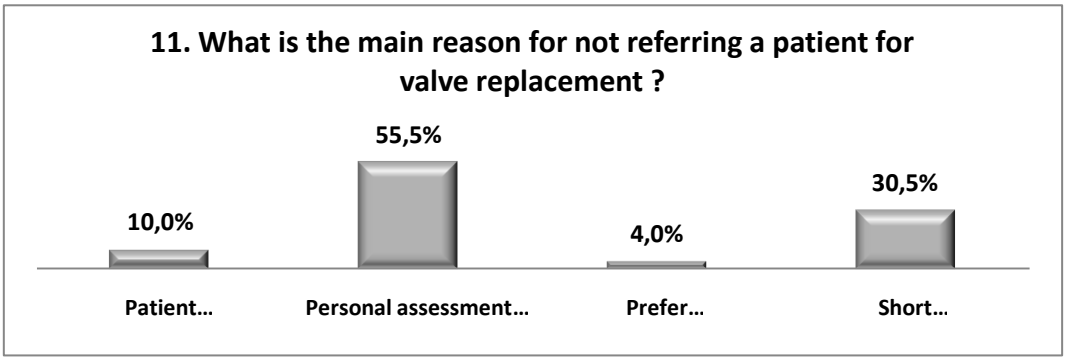
10. What is for you the main reason to indicate a TAVI vs. an AV replacement?	**Total**	**%**
Age	117	9,4%
Comorbidities	396	31,8%
Patients' choice	24	1,9%
Surgical Risk Score	708	56,9%
answered question	**1245**	**100,0%**
skipped question	***0***	***/***



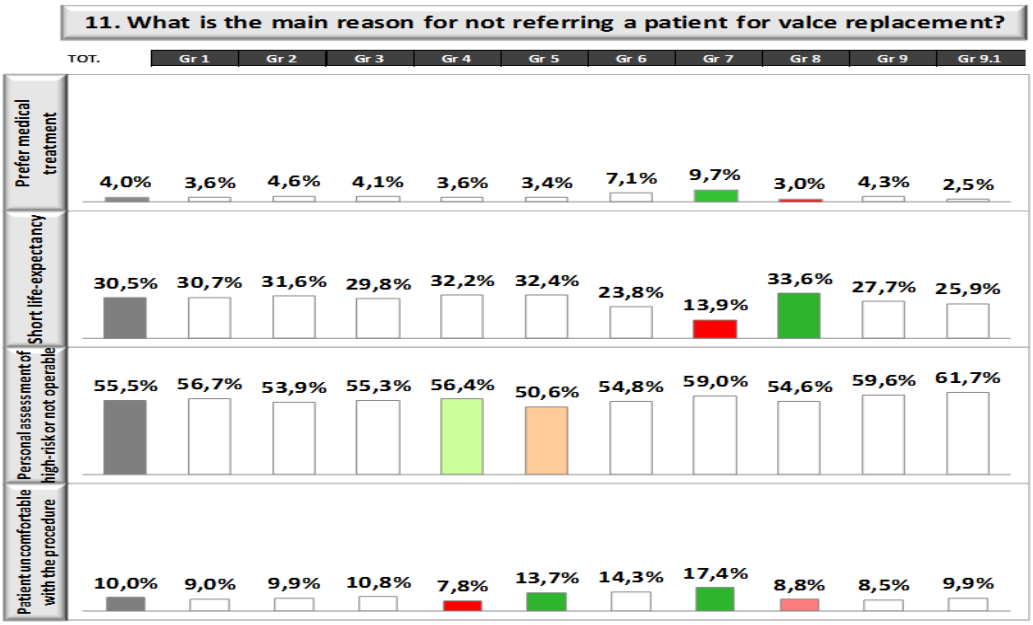
The surgical risk score is the main reason for the indication of a TAVI procedure. Youngest cardiologists seems to prefer TAVI in patients with comorbidities, while for the other reasons there are no significant differences for age and world regions.



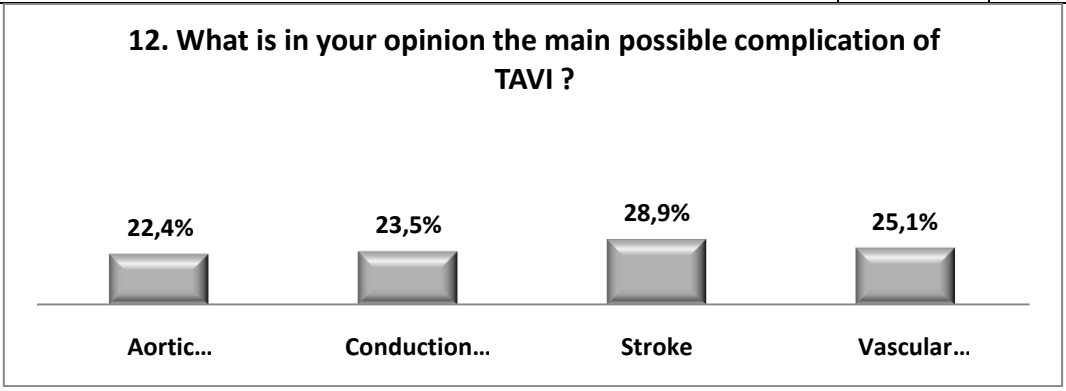
11. What is the main reason for not referring a patient for valve replacement?	Total	%
Patient uncomfortable with the procedure	124	10,0%
Personal assessment of high-risk or not operable patient	691	55,5%
Prefer medical treatment	50	4,0%
Short life-expectancy	380	30,5%
answered question	**1245**	**100,0%**
skipped question	***0***	***/***



A high surgical risk and/or a short life expectancy are the main reasons leading the responders to avoid a valve replacement. No differences according to ages were shown, while non-hospital cardiologists slightly indicate that patients may be uncomfortable with TAVI. The analysis for world regions indicates a significant difference for Asia group, where respondents prefer medical therapy and are thinking that patients may be uncomfortable with TAVI. European cardiologists are significantly less indicating medical treatment.

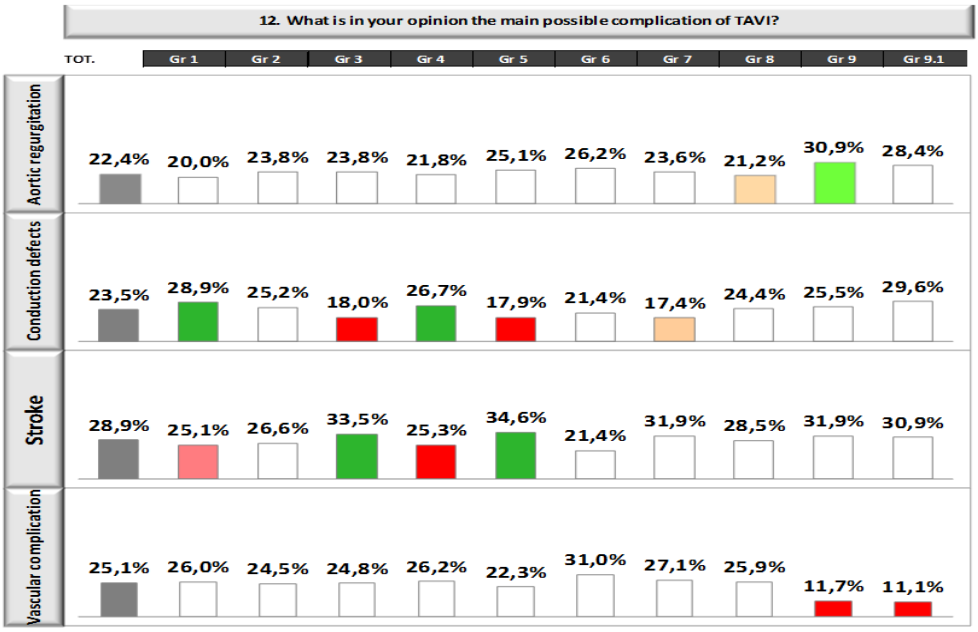


12. What is in your opinion the main possible complication of TAVI?	Total	%
Aortic regurgitation	279	22,4%
Conduction defects	293	23,5%
Stroke	360	28,9%
Vascular complication	313	25,1%
answered question	**1245**	**100,0%**
skipped question	**0**	**/**

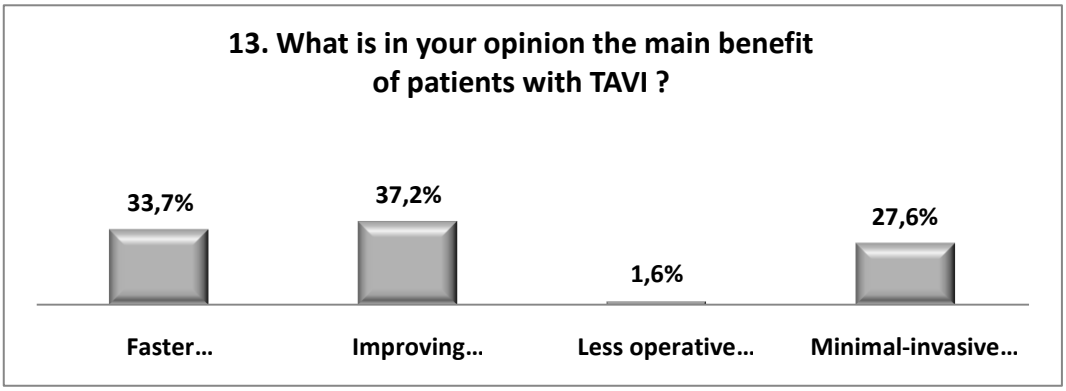


The believed main complications of TAVI are equally distributed among aortic regurgitation, conduction defects, stroke and vascular complication. This last possibility seems to be an occurrence of the past years and not common with the new materials and procedures. Aortic regurgitation

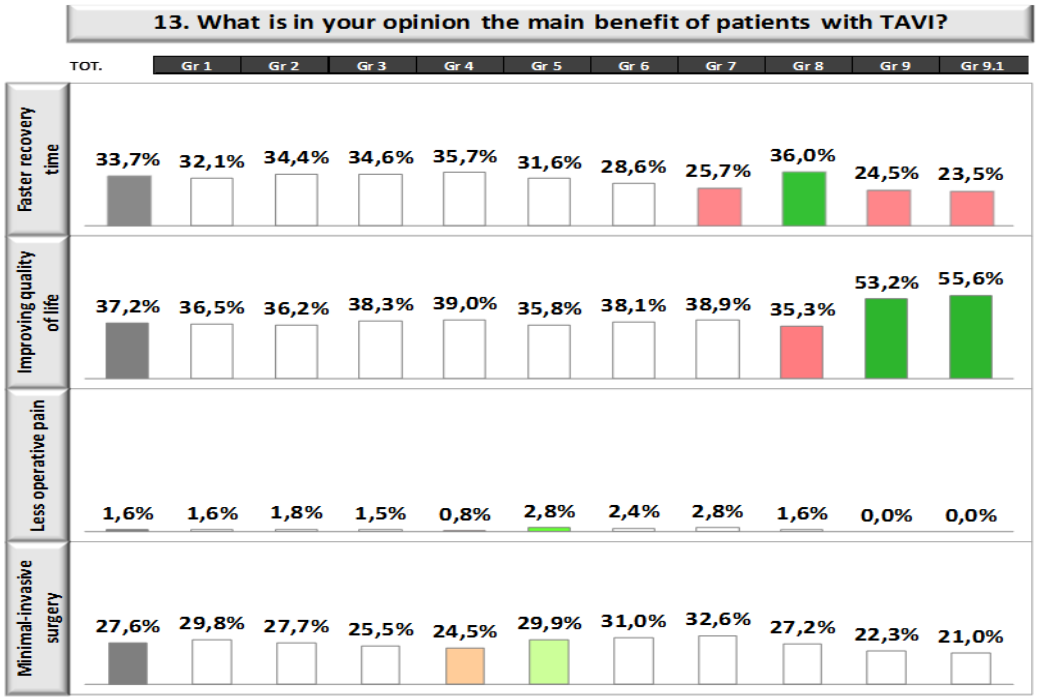
seems to be under-evaluated as possible complication. Youngest and hospital cardiologists are significantly more worried by conduction defects, while oldest and non–hospital cardiologists by stroke. No significant differences were shown by region groups, except for American cardiologists indicating mainly vascular complications as main complication of TAVI.



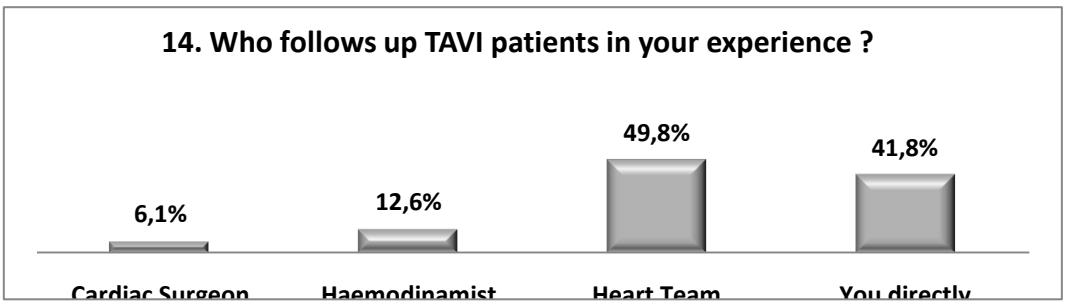
13. What is in your opinion the main benefit of patients with TAVI?	Total	%
Faster recovery time	419	33,7%
Improving quality of life	463	37,2%
Less operative pain	20	1,6%
Minimal-invasive surgery	343	27,6%
answered question	**1245**	**100,0%**
skipped question	**0**	**/**



If the surgical risk is the main reason to prefer TAVI, however the main benefit that cardiologists are expecting is regarding the quality of life and a faster recovery time. These answers were indicated by all age groups and by cardiologists working in or out of hospital. European cardiologists indicate a faster recovery time while American cardiologists a quality of life improvement as main objectives of TAVI.

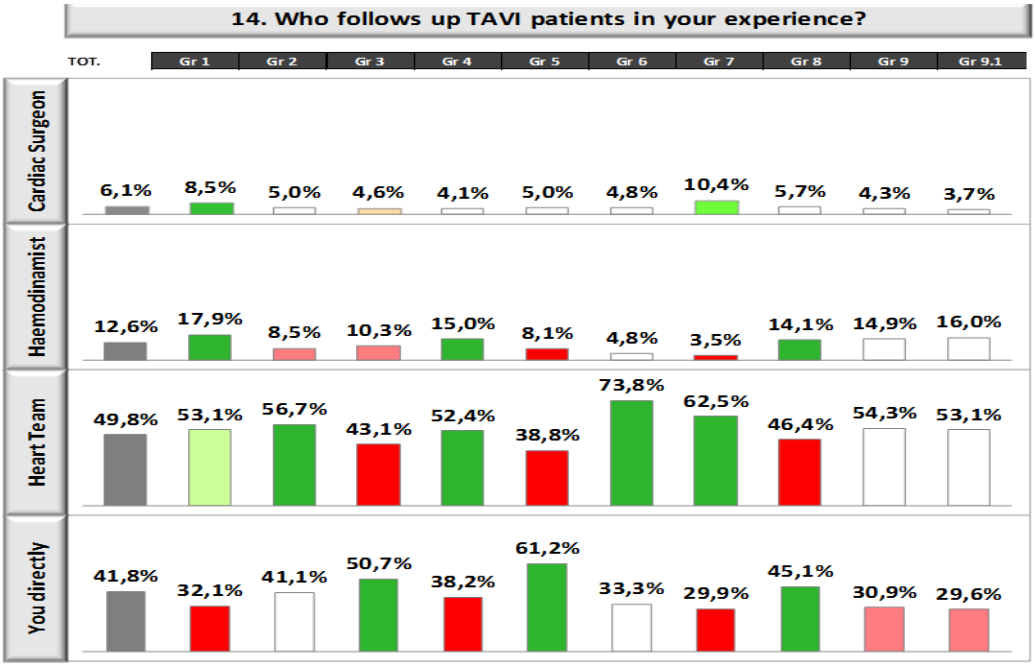


14. Who follows up TAVI patients in your experience?	Total	%
Cardiac Surgeon	76	6,1%
Haemodinamist	157	12,6%
Heart Team	620	49,8%
You directly	521	41,8%
answered question	**1245**	**100,0%**
skipped question	***0***	***/***

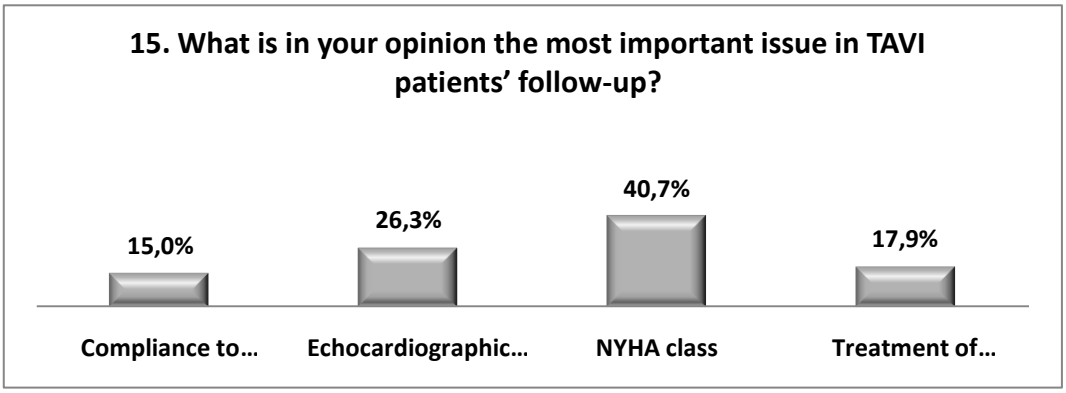


The majority of responders indicate in the Heart Team as responsible for the follow up of a TAVI patient. However some significant differences were shown for every analysis group. Younger

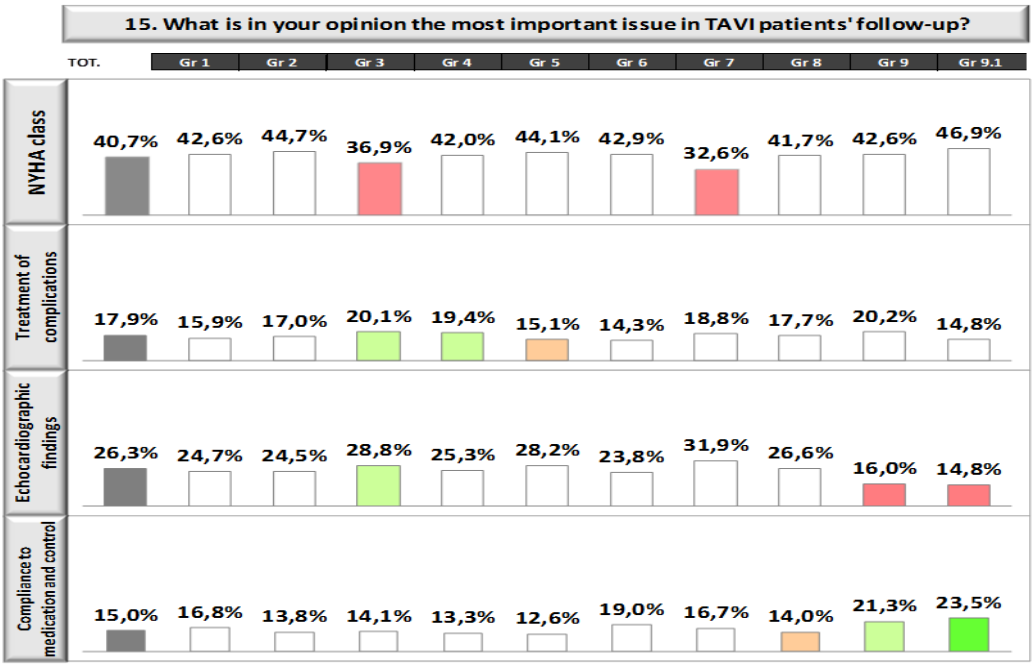
cardiologists and hospital cardiologists seems to follow directly TAVI patients significantly less than their oldest and non-hospital colleagues and to let the patients be followed-up by haemodinamists, and (in hospital) by a Heart Team. This solution is significantly more frequent in Africa and Asian countries, while in Europe cardiologists are choosing more the "you directly" option and less frequently the "Heart Team" option.



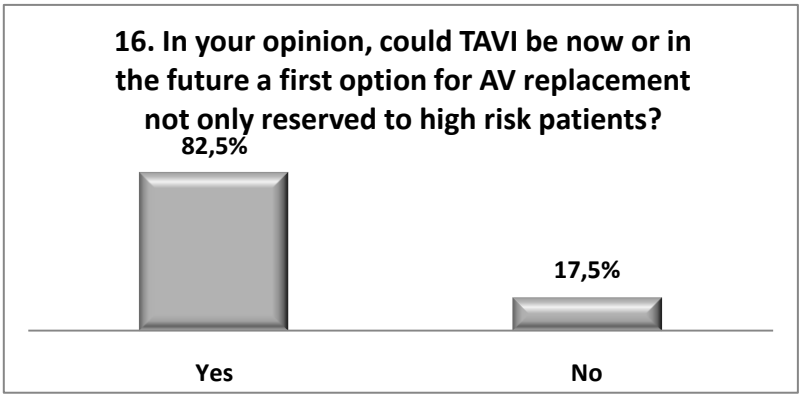
15. What is in your opinion the most important issue in TAVI patients' follow-up?	Total	%
Compliance to medication and control	187	15,0%
Echocardiographic findings	328	26,3%
NYHA class	507	40,7%
Treatment of complications	223	17,9%
answered question	**1245**	**100,0%**
skipped question	***0***	***/***



Most responders indicate NYHA class as the most important issue of TAVI follow-up, without great differences per age, professional status and world regions.

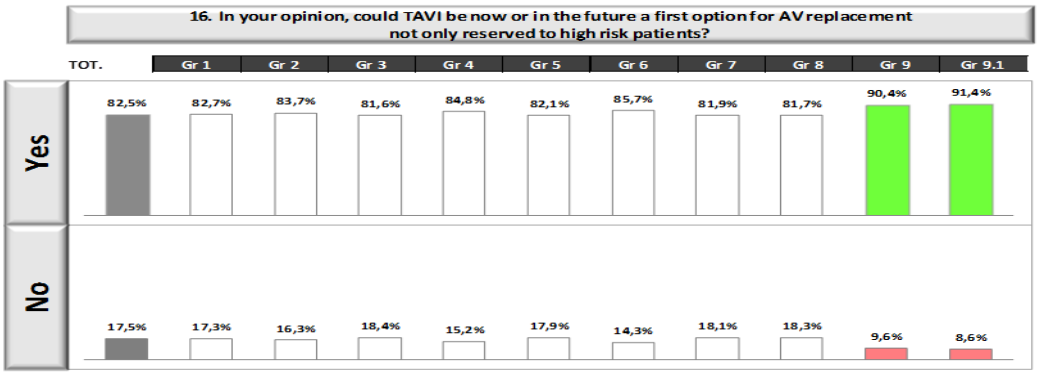


16. In your opinion, could TAVI be now or in the future a first option for AV replacement not only reserved to high risk patients?	Total	%
Yes	1027	82,5%
No	218	17,5%
answered question	**1245**	**100,0%**
skipped question	***0***	***/***

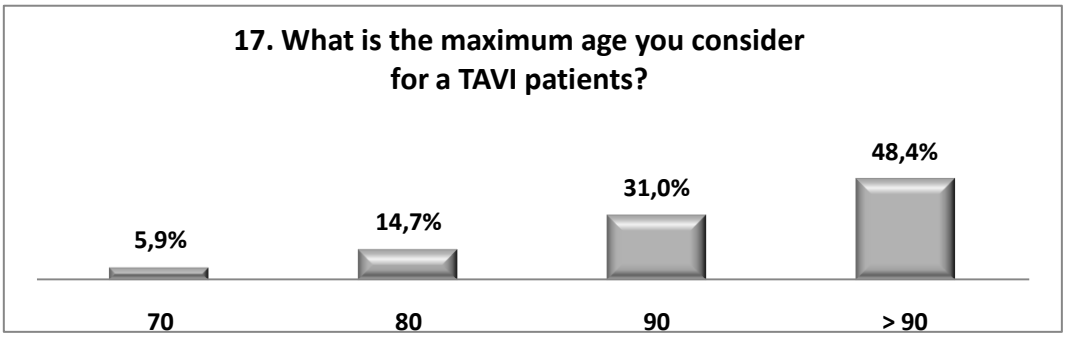


Eight responders in ten are thinking that TAVI procedures may be not only a procedure reserved for high risk patients and will be used more diffusely as first option for aortic replacement. No

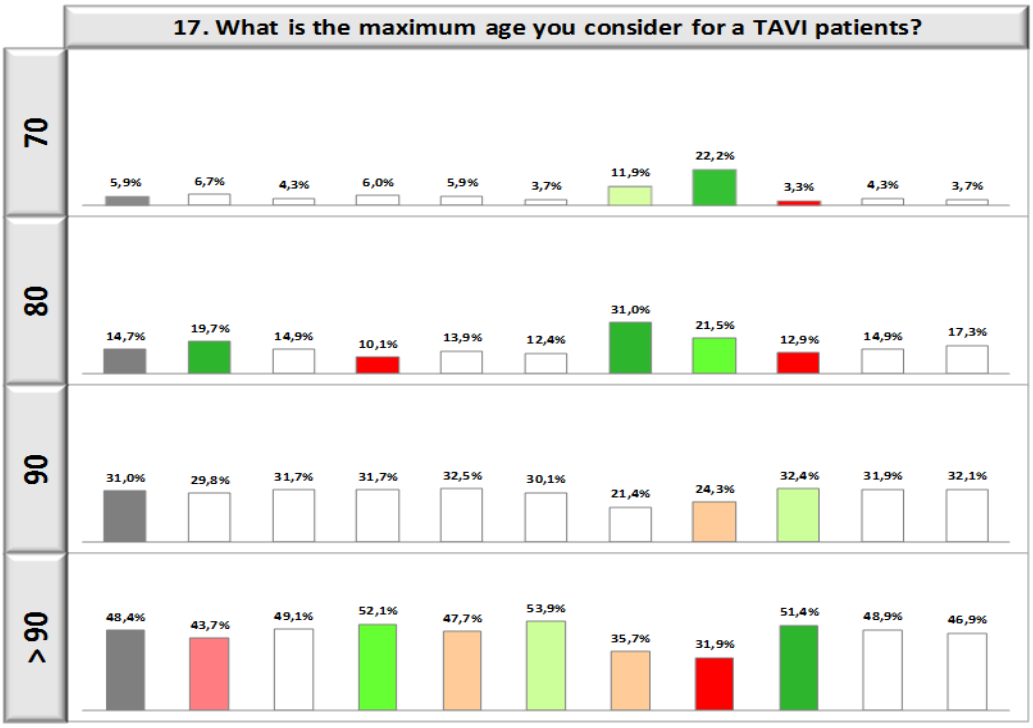
statistically relevant differences were found for any analysis group.



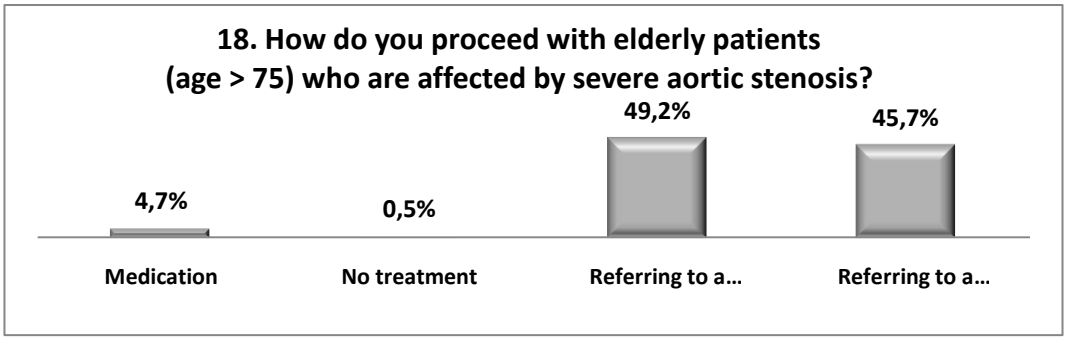
17. What is the maximum age you consider for a TAVI patients?	Total	%
70	73	5,9%
80	182	14,6%
90	385	30,9%
> 90	601	48,3%
answered question	**1241**	**100,0%**
skipped question	***4***	***/***



Nearly fifty percent of responders are indicating a very high age as limit for TAVI indication, but a larger percentage of the young cardiologists are considering 80 years as upper limit of age, and this limit is more indicated by African and Asian cardiologists.

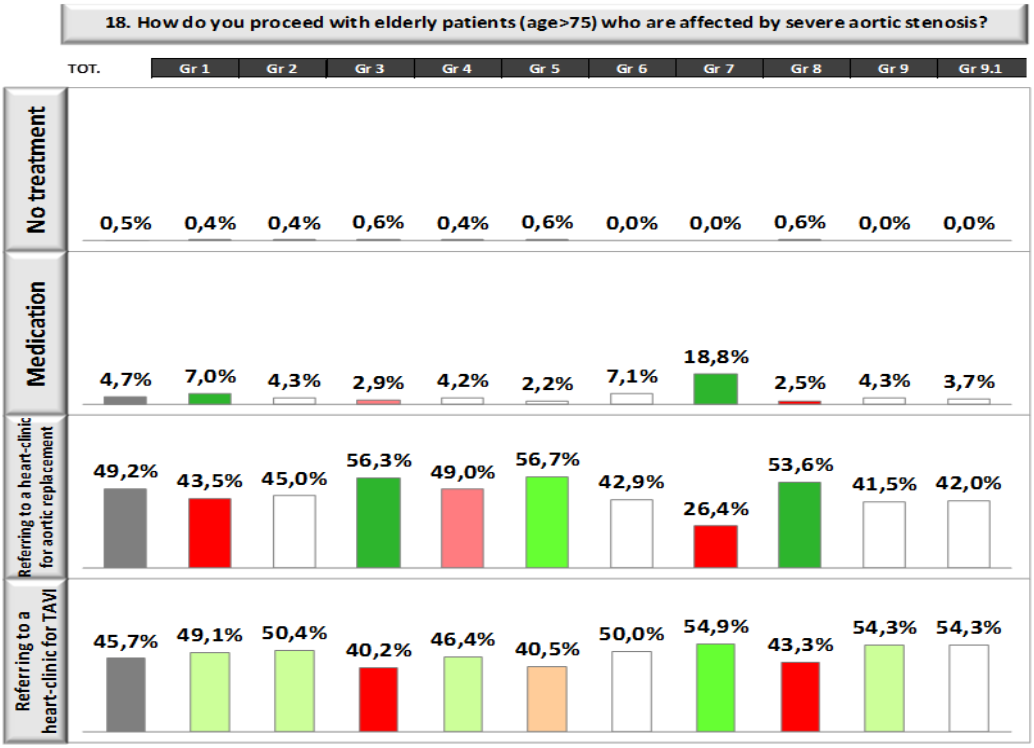


18. How do you proceed with elderly patients (age > 75) who are affected by severe aortic stenosis?	Total	%
Medication	58	4,7%
No treatment	6	0,5%
Referring to a heart-clinic for aortic replacement with a prosthetic valve	612	49,2%
Referring to a heart-clinic for TAVI	569	45,7%
answered question	**1245**	**100,0%**
skipped question	***0***	***/***



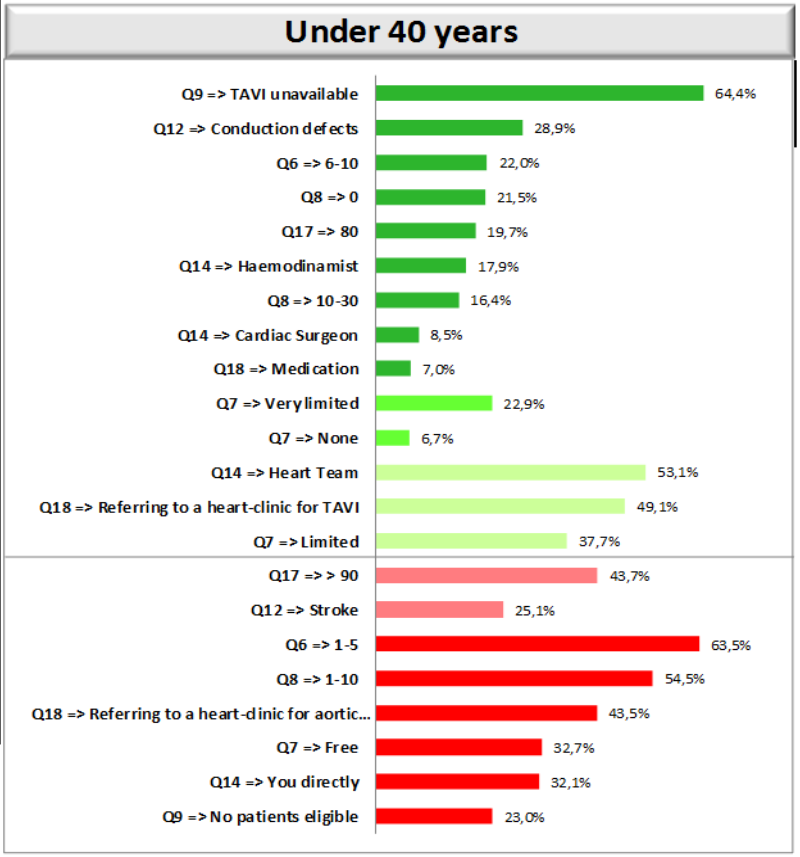
Most responders are sending patients with aortic stenosis in similar percentages to a surgical

prosthetic replacement and to a TAVI replacement. A significant percentage of young cardiologists however is choosing "medication" as possible treatment, while the oldest and non-hospital colleagues seems still prefer the surgical replacement.



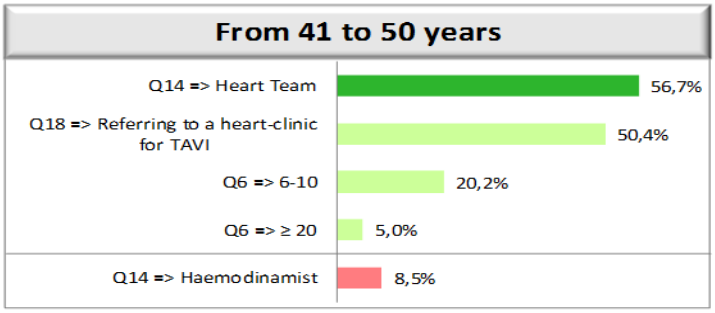
In the following pictures the data are shown in a different way that summarizes the most important findings of every subgroup, underlining the differences in respect to the mean result of the whole number of respondents.

	Group 1 Under 40 years	p-value
Q9 => No patients eligible	23,0%	< 0,001
Q14 => You directly	32,1%	< 0,001
Q7 => Free	32,7%	< 0,001
Q18 => Referring to a heart-clinic for aortic replacement with a prosthetic valve	43,5%	0,003
Q8 => 1-10	54,5%	< 0,001
Q6 => 1-5	63,5%	< 0,001
Q12 => Stroke	25,1%	0,027
Q17 => > 90	43,7%	0,013
Q7 => Limited	37,7%	0,083
Q18 => Referring to a heart-clinic for TAVI	49,1%	0,072
Q14 => Heart Team	53,1%	0,078
Q7 => None	6,7%	0,019
Q7 => Very limited	22,9%	0,022
Q18 => Medication	7,0%	0,004
Q14 => Cardiac Surgeon	8,5%	0,008
Q8 => 10-30	16,4%	0,002
Q14 => Haemodinamist	17,9%	< 0,001
Q17 => 80	19,7%	< 0,001
Q8 => 0	21,5%	0,001
Q6 => 6-10	22,0%	< 0,001
Q12 => Conduction defects	28,9%	0,001
Q9 => TAVI unavailable	64,4%	< 0,001



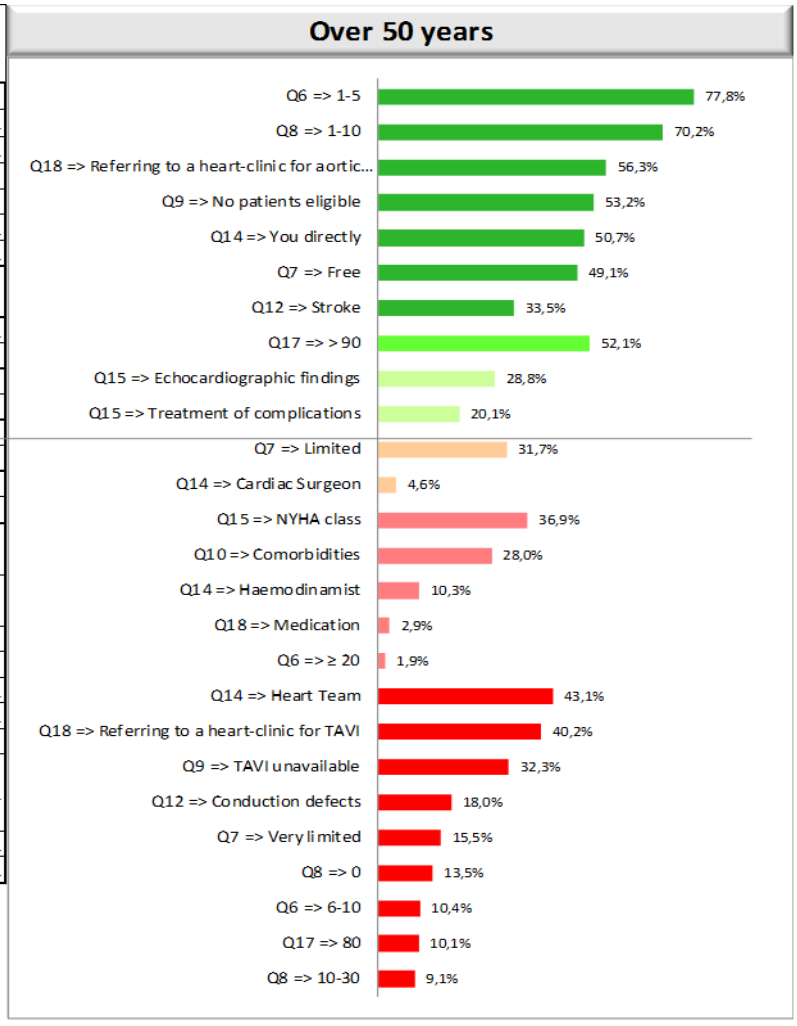
The younger cardiologists seem to have less availability of TAVI, are thinking that the conduction defects are the most important issue of TAVI implant, seem to diagnose an higher number of aortic stenosis, but are referring less patients for TAVI and are using an higher level of medication treatment. Moreover they seem less prone to TAVI in patients with an age over 80 years and after a TAVI less frequently are following directly the patients but are referring them to the haemodinamist or to the surgeon

	Group 2 From 41 to 50 years	p-value
Q14 => Haemodinamist	8,5%	0,018
Q6 => ≥ 20	5,0%	0,074
Q6 => 6-10	20,2%	0,080
Q18 => Referring to a heart-clinic for TAVI	50,4%	0,075
Q14 => Heart Team	56,7%	0,008



The group age from 41 to 50 years offers a level of answers more similar to the mean value of every answer. This group seems to prefer that the follow-up of a TAVI patient will be supervised by the Heart Team.

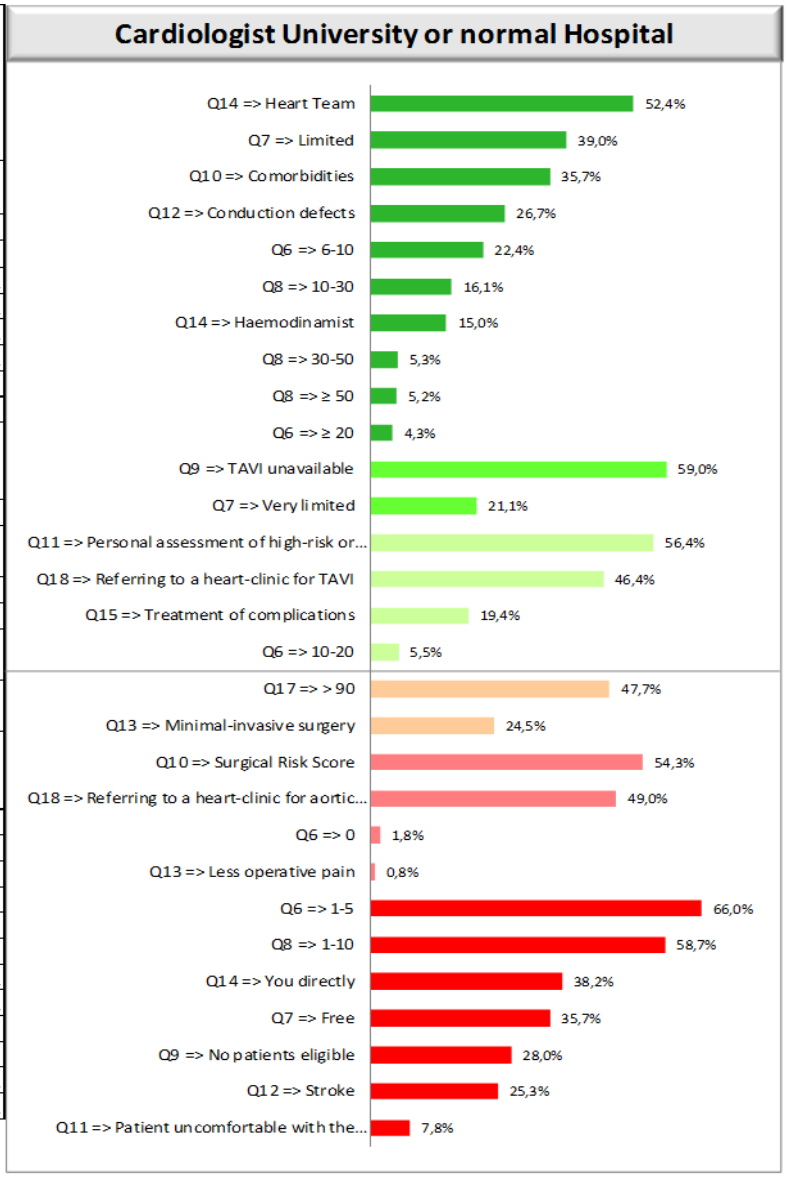
	Group 3 Over 50 years	p-value
Q8 => 10-30	9,1%	0,002
Q17 => 80	10,1%	< 0,001
Q6 => 6-10	10,4%	< 0,001
Q8 => 0	13,5%	0,010
Q7 => Very limited	15,5%	0,003
Q12 => Conduction defects	18,0%	< 0,001
Q9 => TAVI unavailable	32,3%	< 0,001
Q18 => Referring to a heart-clinic for TAVI	40,2%	0,001
Q14 => Heart Team	43,1%	< 0,001
Q6 => ≥ 20	1,9%	0,024
Q18 => Medication	2,9%	0,013
Q14 => Haemodinamist	10,3%	0,035
Q10 => Comorbidities	28,0%	0,016
Q15 => NYHA class	36,9%	0,022
Q14 => Cardiac Surgeon	4,6%	0,069
Q7 => Limited	31,7%	0,078
Q15 => Treatment of complications	20,1%	0,087
Q15 => Echocardiographic findings	28,8%	0,095
Q17 => > 90	52,1%	0,028
Q12 => Stroke	33,5%	0,003
Q7 => Free	49,1%	< 0,001
Q14 => You directly	50,7%	< 0,001
Q9 => No patients eligible	53,2%	0,002
Q18 => Referring to a heart-clinic for aortic replacement with a prosthetic valve	56,3%	< 0,001
Q8 => 1-10	70,2%	< 0,001
Q6 => 1-5	77,8%	< 0,001



The group of cardiologists of older age (> 50 years) diagnose less aortic stenosis (1-5 cases monthly), but are referring a higher number of patients/year for TAVI. However in an old patient

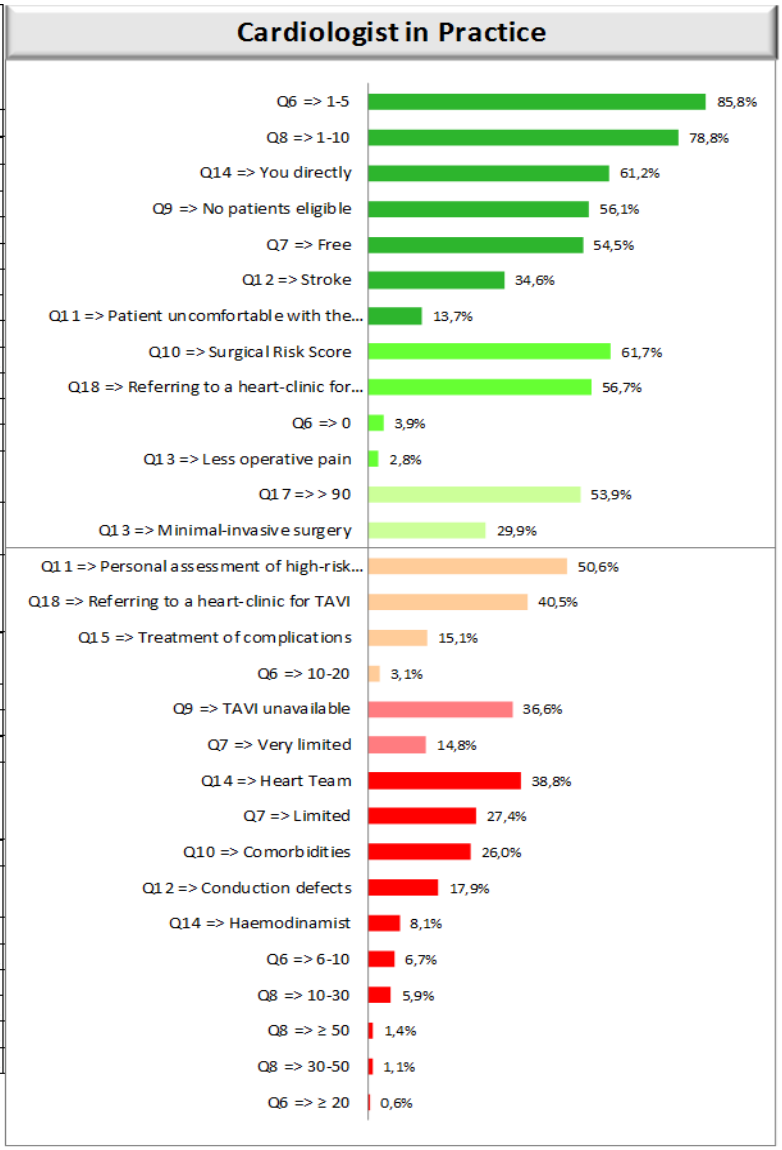
with severe aortic stenosis they seem to prefer to referral to the heart-clinic for aortic replacement. Regarding TAVI, they seem to have more free access than younger colleagues, they are following directly the patients during the follow-up, and during it they are consider stroke as the main issue of complication of TAVI.

	Group 4 Cardiologist University or normal Hospital	p-value
Q11 => Patient uncomfortable with the procedure	7,8%	0,002
Q12 => Stroke	25,3%	0,001
Q9 => No patients eligible	28,0%	0,002
Q7 => Free	35,7%	< 0,001
Q14 => You directly	38,2%	< 0,001
Q8 => 1-10	58,7%	< 0,001
Q6 => 1-5	66,0%	< 0,001
Q13 => Less operative pain	0,8%	0,013
Q6 => 0	1,8%	0,039
Q18 => Referring to a heart-clinic for aortic replacement with a prosthetic valve	49,0%	0,017
Q10 => Surgical Risk Score	54,3%	0,020
Q13 => Minimal-invasive surgery	24,5%	0,058
Q17 => > 90	47,7%	0,054
Q6 => 10-20	5,5%	0,081
Q15 => Treatment of complications	19,4%	0,080
Q18 => Referring to a heart-clinic for TAVI	46,4%	0,065
Q11 => Personal assessment of high-risk or not operable patient	56,4%	0,072
Q7 => Very limited	21,1%	0,013
Q9 => TAVI unavailable	59,0%	0,016
Q6 => ≥ 20	4,3%	0,001
Q8 => ≥ 50	5,2%	0,003
Q8 => 30-50	5,3%	0,001
Q14 => Haemodinamist	15,0%	0,001
Q8 => 10-30	16,1%	< 0,001
Q6 => 6-10	22,4%	< 0,001
Q12 => Conduction defects	26,7%	0,001
Q10 => Comorbidities	35,7%	0,001
Q7 => Limited	39,0%	< 0,001
Q14 => Heart Team	52,4%	< 0,001



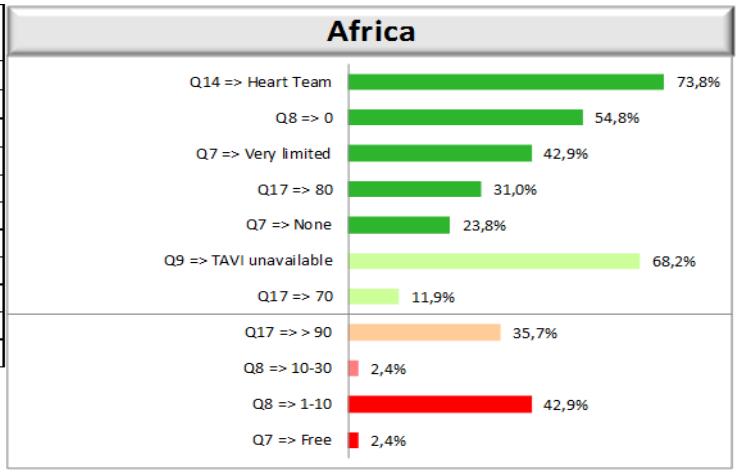
Hospital cardiologists are diagnosing more patients with aortic stenosis than their colleagues, but surprisingly they seem to have less free access to TAVI; at the other end they are referring a higher number of patients for TAVI, considering comorbidities the main reason for this indication and conduction defects as main issues among the possible complications of follow-up. The Heart Team is preferred in this group as responsible for the follow-up of the patients.

	Group 5 Cardiologist in Practice	p-value
Q6 => ≥ 20	0,6%	0,001
Q8 => 30-50	1,1%	0,001
Q8 => ≥ 50	1,4%	0,003
Q8 => 10-30	5,9%	< 0,001
Q6 => 6-10	6,7%	< 0,001
Q14 => Haemodinamist	8,1%	0,001
Q12 => Conduction defects	17,9%	0,001
Q10 => Comorbidities	26,0%	0,001
Q7 => Limited	27,4%	< 0,001
Q14 => Heart Team	38,8%	< 0,001
Q7 => Very limited	14,8%	0,013
Q9 => TAVI unavailable	36,6%	0,016
Q6 => 10-20	3,1%	0,081
Q15 => Treatment of complications	15,1%	0,080
Q18 => Referring to a heart-clinic for TAVI	40,5%	0,065
Q11 => Personal assessment of high-risk or not operable patient	50,6%	0,072
Q13 => Minimal-invasive surgery	29,9%	0,058
Q17 => > 90	53,9%	0,054
Q13 => Less operative pain	2,8%	0,013
Q6 => 0	3,9%	0,039
Q18 => Referring to a heart-clinic for aortic replacement with a prosthetic valve	56,7%	0,017
Q10 => Surgical Risk Score	61,7%	0,020
Q11 => Patient uncomfortable with the procedure	13,7%	0,002
Q12 => Stroke	34,6%	0,001
Q7 => Free	54,5%	< 0,001
Q9 => No patients eligible	56,1%	0,002
Q14 => You directly	61,2%	< 0,001
Q8 => 1-10	78,8%	< 0,001
Q6 => 1-5	85,8%	< 0,001



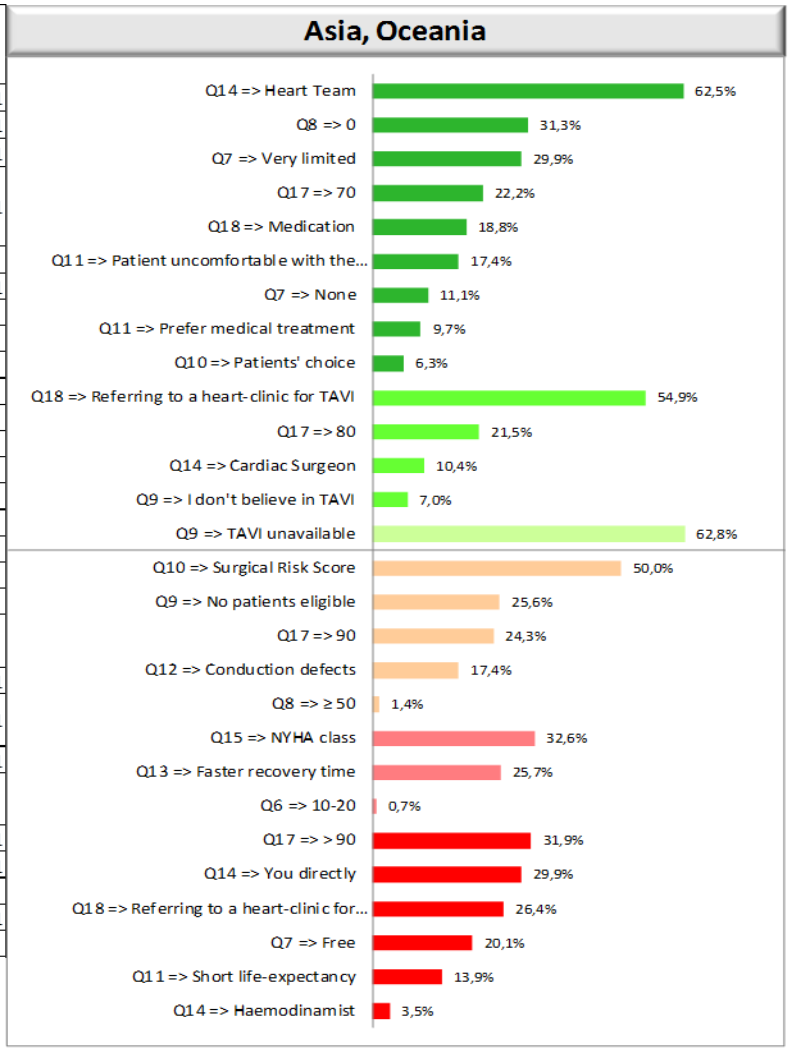
Cardiologists working in out of hospital settings are diagnosing a mean of 1 to 5 patients with aortic stenosis for month and are referring for TAVI from 1 to 10 patients per year; as a paradox they declare to have freer access than their hospital colleagues to TAVI and they feel freer to follow-up directly the patient after a TAVI implant. They are considering stroke as the main complication of TAVI procedure.

	Group 6 Africa	p-value
Q7 => Free	2,4%	< 0,001
Q8 => 1-10	42,9%	0,007
Q8 => 10-30	2,4%	0,043
Q17 => > 90	35,7%	0,093
Q17 => 70	11,9%	0,091
Q9 => TAVI unavailable	68,2%	0,078
Q7 => None	23,8%	< 0,001
Q17 => 80	31,0%	0,002
Q7 => Very limited	42,9%	< 0,001
Q8 => 0	54,8%	< 0,001
Q14 => Heart Team	73,8%	0,002



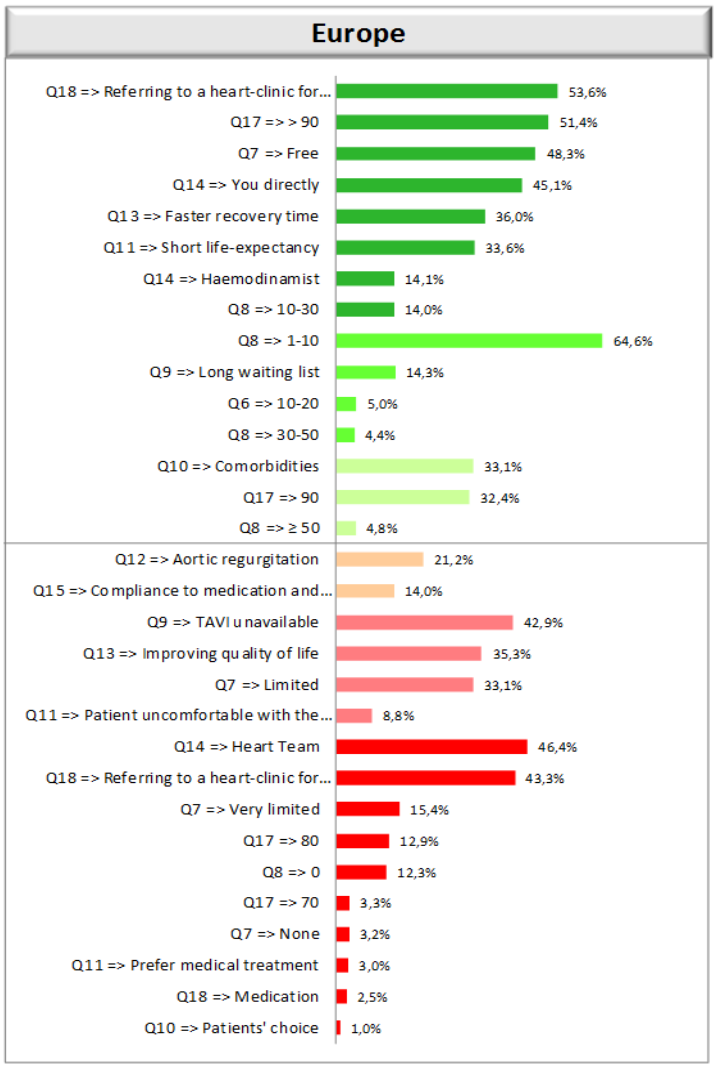
Cardiologists working in Africa, as expected have no or very limited access to TAVI, and frequently have not referred patients for this procedure. They are considering an age of more than 80 years for TAVI and they are considering the Heart Team the most appropriate choice for patient follow-up.

	Group 7 Asia, Oceania	p-value
Q14 => Haemodinamist	3,5%	< 0,001
Q11 => Short life-expectancy	13,9%	< 0,001
Q7 => Free	20,1%	< 0,001
Q18 => Referring to a heart-clinic for aortic replacement with a prosthetic valve	26,4%	< 0,001
Q14 => You directly	29,9%	0,002
Q17 => > 90	31,9%	< 0,001
Q6 => 10-20	0,7%	0,022
Q13 => Faster recovery time	25,7%	0,032
Q15 => NYHA class	32,6%	0,036
Q8 => ≥ 50	1,4%	0,075
Q12 => Conduction defects	17,4%	0,063
Q17 => 90	24,3%	0,064
Q9 => No patients eligible	25,6%	0,069
Q10 => Surgical Risk Score	50,0%	0,077
Q9 => TAVI unavailable	62,8%	0,067
Q9 => I don't believe in TAVI	7,0%	0,043
Q14 => Cardiac Surgeon	10,4%	0,022
Q17 => 80	21,5%	0,013
Q18 => Referring to a heart-clinic for TAVI	54,9%	0,019
Q10 => Patients' choice	6,3%	< 0,001
Q11 => Prefer medical treatment	9,7%	< 0,001
Q7 => None	11,1%	< 0,001
Q11 => Patient uncomfortable with the procedure	17,4%	0,002
Q18 => Medication	18,8%	< 0,001
Q17 => 70	22,2%	< 0,001
Q7 => Very limited	29,9%	0,001
Q8 => 0	31,3%	< 0,001
Q14 => Heart Team	62,5%	0,001



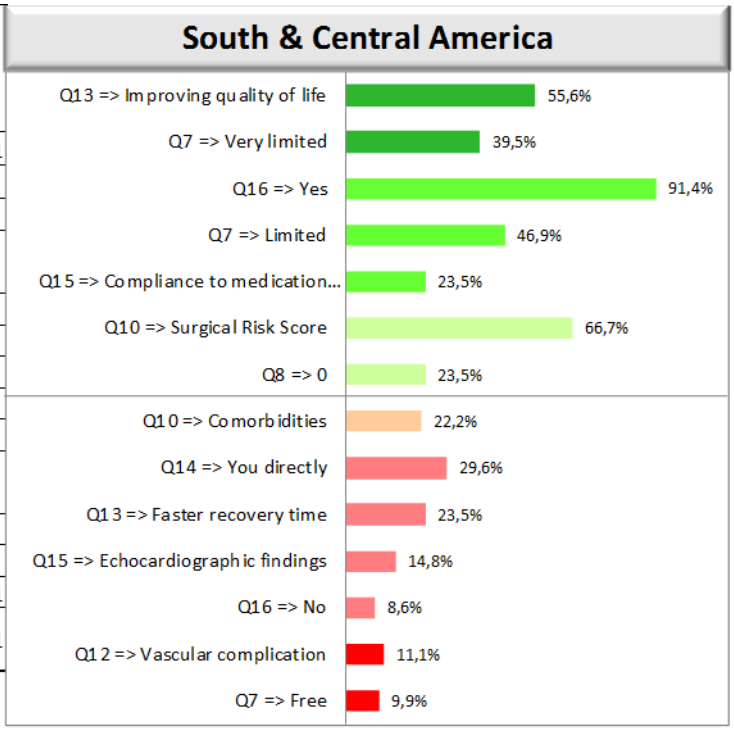
Cardiologists working in the Asia-Oceania area give results similar to that of Africa regarding availability of TAVI and number of patients referred for TAVI; moreover they are still using a medical approach in aortic stenosis and they are considering a very low age (70 years) for the indication of TAVI. Also in this group is preferred the Heart Team for the follow up of the patient after TAVI.

	Group 8 Europe	p-value
Q10 => Patients' choice	1,0%	< 0,001
Q18 => Medication	2,5%	< 0,001
Q11 => Prefer medical treatment	3,0%	0,001
Q7 => None	3,2%	< 0,001
Q17 => 70	3,3%	< 0,001
Q8 => 0	12,3%	< 0,001
Q17 => 80	12,9%	0,001
Q7 => Very limited	15,4%	< 0,001
Q18 => Referring to a heart-clinic for TAVI	43,3%	0,002
Q14 => Heart Team	46,4%	< 0,001
Q11 => Patient uncomfortable with the procedure	8,8%	0,012
Q7 => Limited	33,1%	0,041
Q13 => Improving quality of life	35,3%	0,012
Q9 => TAVI unavailable	42,9%	0,019
Q15 => Compliance to medication and control	14,0%	0,059
Q12 => Aortic regurgitation	21,2%	0,067
Q8 => ≥ 50	4,8%	0,053
Q17 => 90	32,4%	0,059
Q10 => Comorbidities	33,1%	0,079
Q8 => 30-50	4,4%	0,047
Q6 => 10-20	5,0%	0,041
Q9 => Long waiting list	14,3%	0,012
Q8 => 1-10	64,6%	0,013
Q8 => 10-30	14,0%	0,004
Q14 => Haemodinamist	14,1%	0,003
Q11 => Short life-expectancy	33,6%	< 0,001
Q13 => Faster recovery time	36,0%	0,001
Q14 => You directly	45,1%	< 0,001
Q7 => Free	48,3%	< 0,001
Q17 => > 90	51,4%	< 0,001
Q18 => Referring to a heart-clinic for aortic replacement with a prosthetic valve	53,6%	< 0,001



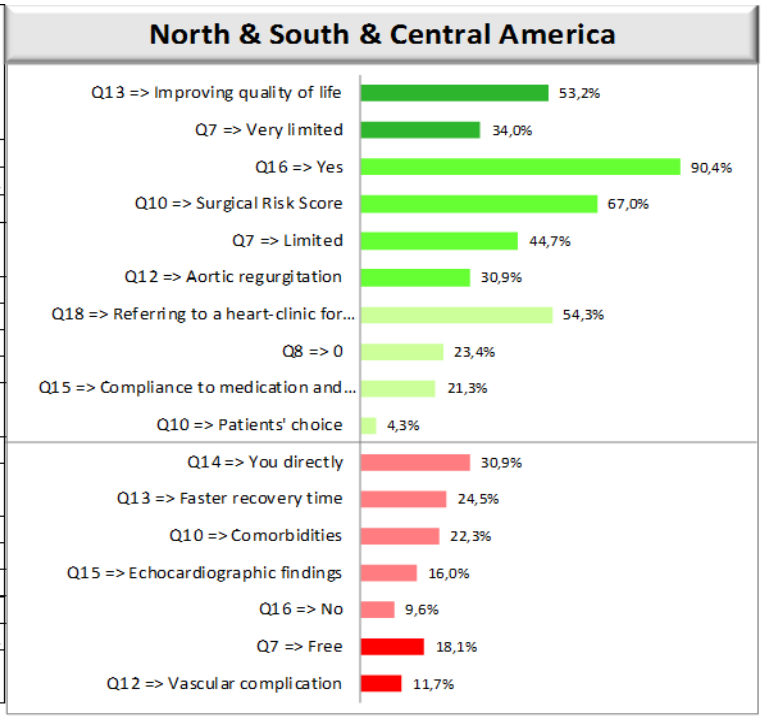
European colleagues seem to have a more free access to TAVI, are following directly or are referring the patient to the heamodinamist after the procedure, are considering TAVI for very old patients for (> 90 years), but in old patients with severe aortic stenosis they prefer to send the patient to an aortic valve replacement.

	Group 9.1 South & Central America	p-value
Q7 => Free	9,9%	< 0,001
Q12 => Vascular complication	11,1%	0,003
Q16 => No	8,6%	0,030
Q15 => Echocardiographic findings	14,8%	0,015
Q13 => Faster recovery time	23,5%	0,045
Q14 => You directly	29,6%	0,021
Q10 => Comorbidities	22,2%	0,055
Q8 => 0	23,5%	0,097
Q10 => Surgical Risk Score	66,7%	0,066
Q15 => Compliance to medication and control	23,5%	0,028
Q7 => Limited	46,9%	0,015
Q16 => Yes	91,4%	0,030
Q7 => Very limited	39,5%	< 0,001
Q13 => Improving quality of life	55,6%	< 0,001



And colleagues from

	Group 9 North & South & Central America	p-value
Q12 => Vascular complication	11,7%	0,002
Q7 => Free	18,1%	< 0,001
Q16 => No	9,6%	0,035
Q15 => Echocardiographic findings	16,0%	0,017
Q10 => Comorbidities	22,3%	0,040
Q13 => Faster recovery time	24,5%	0,050
Q14 => You directly	30,9%	0,025
Q10 => Patients' choice	4,3%	0,088
Q15 => Compliance to medication and control	21,3%	0,077
Q8 => 0	23,4%	0,074
Q18 => Referring to a heart-clinic for TAVI	54,3%	0,083
Q12 => Aortic regurgitation	30,9%	0,041
Q7 => Limited	44,7%	0,031
Q10 => Surgical Risk Score	67,0%	0,039
Q16 => Yes	90,4%	0,035
Q7 => Very limited	34,0%	< 0,001
Q13 => Improving quality of life	53,2%	0,001



gave answers generally not very different from the mean of the responders, except for the "very limited" option for TAVI availability and for the confidence in a better quality of life of TAVI patients.

DISCUSSION

The European Society of Cardiology organized in the past leading surveys about different topics in different settings, for example on prevention like the series of EUROASPIRE or the surveys on heart failure and on atrial fibrillation.
These surveys are generally multi-centre retrospective analysis of the management of a specific aspect of cardiology, realized using data-bases of patients followed in a specific time in selected hospital settings.
The surveys proposed by the Council for Cardiology Practice, unlike the commonly published surveys, are based on the direct interview of a population of cardiologists with a wide dissemination of geographic and professional conditions (mainly hospital setting) and not on data derived from patient databases. This way of collecting information about a clinic topic is somewhat different and in our thinking represents a sort of "intention to treat" questionnaire.
Although with many limitations, due to the characteristics of our sample, not randomized and with many selection bias, but that however is fully obtained on a volunteer basis and can be considered honest and representative of a large general population of cardiologists, working both in hospital (the majority) or in an out-of-hospital setting, the data derived from the TAVI patients survey of the ESC Council for Cardiology Practice gives, in the view of the authors, some interesting information on the knowledge of this topic.
The surveys are intended to offer a snapshot of the current clinical practice about a specific topic and their importance will be increasing over time.
The rate of adherence to this survey on TAVI treatment (<3%) is still low, less than the survey for atrial fibrillation, though in line with surveys on other important topics (i.e. syncope) previously conducted by the Council for Cardiology Practice. Similarly, the distribution of the responders by gender, age, hospital vs non-hospital activity and Countries was similar to that of the previous surveys. This survey mostly included European cardiologists.

Answers were divided by groups based on:

- Age (Under 40 years / From 40 to 50 years / Over 50 years – Groups 1, 2 and 3)
- Professional status (In University or normal hospital / Cardiologist in practice – Groups 4 and 5)
- World region (Africa / Asia + Oceania / Europe / North America + South & Central America – Groups 6, 7, 8 and 9).

The scientific questions numbered 6 to 18 of the questionnaire explored how TAVI issues are felt by the cardiology community and were:

6. How many patients do you diagnose with Severe Aortic Stenosis per month approximately?
7. What is the possibility to access TAVI in your country/practice?
8. How many patients did you refer for TAVI this year?
9. If you replied 0 to question 8: please give the main reason? If you did not reply 0 to question 8, please go directly to question 10.
10. What is for you the main reason to indicate a TAVI vs. an AV replacement?
11. What is the main reason for not referring a patient for valve replacement?

12. What is in your opinion the main possible complication of TAVI?
13. What is in your opinion the main benefit of patients with TAVI?
14. Who follows up TAVI patients in your experience?
15. What is in your opinion the most important issue in TAVI patients' follow-up?
16. In your opinion, could TAVI be now or in the future a first option for AV replacement not only reserved to high risk patients?
17. What is the maximum age you consider for a TAVI patients?
18. How do you proceed with elderly patients (age > 75) who are affected by severe aortic stenosis?

The answers to these questions showed expected results, but also some results that may be debatable and partially unexpected or disappointing and may be summarized as follows:

Question 6. Most cardiologists (87% - especially young and hospital cardiologists) diagnose 1-10 patients/ month with severe aortic stenosis. "Do you diagnose" means a new diagnosis per month and highlights the large population of patients with aortic stenosis and possible indication to aortic valve replacement or TAVI seen by the cardiologist population, working both in hospital or in an out-of-hospital setting.

Question 7. Due to the limited economic resources, we are used to believe that the main limit to TAVI is the restricted access to the procedure. Unexpectedly, more than 40% of responders reported a free access to TAVI. However, this free access mainly involves the oldest cardiologists (and this could be related to a better established and functioning network with TAVI hospitals) and non-hospital colleagues. The latter findings are quite unexpected. A possible explanation is that non-hospital colleagues may refer their TAVI patients to private structures or they have, according to their "freedom" from a specific hospital, a larger network than their hospital colleagues with a larger availability of different public structures.

Questions 8/9. While 4% of cardiologists referred more than 50 patients to TAVI, still a percentage of almost 17% did not refer any patient to TAVI in the current year. The main reason was unavailability of TAVI (50.5%).
Still a 2.6% of cardiologists do not believe in TAVI, despite the striking results of large randomized trials. Spreading of a state-of-the-art TAVI culture has a critical role, especially for the youngest and non-hospital cardiologists, and contributes to extend the eligibility criteria.
Cardiologists from Africa and Asian Countries, as expected, have less access and referral to TAVI than European cardiologists.

Question 10. The main reason for TAVI preference over aortic valve replacement (AVR) was considered the surgical risk score, then comorbidities, age and lastly patient's choice. This sounds evidence-based, though it is important to remember that risk scores often do not include patient's frailty. Also, results from large trials in intermediate risk patients favour TAVI over AVR, and there is a current debate on extending TAVI to low risk patients also.

Question 11. An unexpected surprising data was the still present, though limited (4%), percentage

of cardiologists who would prefer medical treatment over AVR, against all the evidence and against the common indications of Guidelines. This result is mainly coming from the Asian and African regions, and probably related to the poor situation of the National Health Systems of those countries. Only a very short life-expectancy and/or a prohibitive risk should be criteria for not referring a patient with severe aortic stenosis to either AVR or TAVI.

Question 12. Disappointingly, although stroke is not a frequently reported complication after TAVI, and all trials have shown a lower risk with TAVI as compared to AVR, still 28.9% of cardiologists reported it as the main possible complication of TAVI. Vascular complications decrease with the learning curve and prosthesis profile. Conduction defects are prosthesis related. Aortic regurgitation, though common, is often mild, especially with modern prostheses.

Question 13. The most important benefit felt after TAVI is considered to be the improvement of quality of life. The bibliography about TAVI seems to show that both AVR and TAVI have a similar impact on quality of life, while the main TAVI benefits are considered to be inferior invasiveness, less pain and faster recovery.

Question 14. The heart team should take in charge post TAVI patients for almost 50% of the responders. This is a good sign, but a centralized follow-up may be difficult for all TAVI patients and should coexist with the possibility for the cardiologist to directly follow those patients. Hopefully, more than 40% of cardiologists directly follow the patients after TAVI. This happens especially in Europe, maybe as a consequence of a more extensive culture regarding TAVI aspects.

Question 15. Low emphasis was put on compliance to medication and controls in post TAVI patients, while the majority of focus was on NYHA class. This may highlight an under-treatment of post TAVI patients, while this should be mandatory considering their complexity.

Question 16. It is encouraging to note the high percentage of cardiologists for which TAVI may become an option also for mean or low risk patients in the treatment of aortic stenosis. In the near future TAVI will be offered more extensively, and there is great concordance on this opinion also in the literature.

Question 17. Results of TAVI are also good in patients >90 years old, but not all responders believe an high age compatible with TAVI (oddly for younger cardiologists). Actually, more than age, life expectancy > 1 year should be the real limit for the indication to TAVI.

Question 18. An almost equal percentage of cardiologists would refer a patient on the sole basis of his age to AVR or TAVI. This means that there is not a definite approach and the indications of treatment are not clear if age category is considered the main issue and when surgical risk or comorbidities are not the decisive issues. Probably TAVI will be considered as the standard approach following current trials results. Unfortunately there is still a ~5% who would propose medical treatment (or nothing!).

CONCLUSIONS

The findings of the survey highlight several important issues:

- The population of patients of aortic stenosis is important and increasing.
- The main strategy to increase TAVI access may be the creation of functional networks involving single out-of-hospital cardiologists, hospitals with and without TAVI, eventually including private for those patients with private insurances or with some reimbursement possibility.
- Strategies to increase TAVI referral are important, since the main reason of missed access to TAVI was still its unavailability (50.5%). However the diffusion of knowledge regarding TAVI (trial results, technical aspects) plays a pivotal role.
- TAVI indication should be guided not only by surgical risk scores
- There is no evidence of any benefit of medical treatment for aortic stenosis patients and TAVI is a comfortable procedure even in elderly patients. Still the knowledge of TAVI features should play a pivotal role for the right choice of treatment of these patients.
- The most frequent complication after TAVI is different from the most feared one. There is still some confusion regarding the occurrence of stroke and vascular complications after TAVI, and scientific societies should improve the knowledge about this issue among cardiologists.
- AVR and TAVI have a similar impact on quality of life. The main TAVI benefits (thus the preference criterion) regard less invasiveness and pain and faster recovery
- Post TAVI follow-up by the heart team seems to be the favourite choice, however a widespread knowledge of post TAVI issues may extend the portion of cardiologists who will directly follow post TAVI patients in the future.
- Clinical status post TAVI should be monitored and periodically re-assessed to prevent worsening of the NYHA class: NYHA class is not the target but the expected result of a good follow-up.
- The main opinion is that TAVI will become a first option therapy in the near future and is already considered as a therapeutic option even in patients aged > 90 years old; this is an encouraging finding about the correct treatment of aortic stenosis.
- Further trials will better clarify the correct approach in patients > 75 years with no other preferential policy for TAVI or AVR.

TAVI is perceived to become a first option therapy in the near future. However, despite results from large randomized and observational trials, there are still some problems regarding a correct

knowledge of the feasibility and safety of the TAVI procedure, and of its complications.