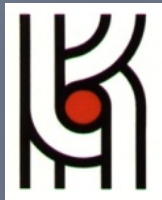


# TAVI: EXTENSION DES INDICATIONS?



Martin Heimeshoff  
Klinik für Herzchirurgie Karlsruhe  
Für das TAVI Team Karlsruhe



Biarritz 5 Juin 2013



Je n'ai pas de liens d'intérêt potentiels liés à ma présentation à déclarer



# TAVI: Pose d'Indication

- ▣ Indications formelles
  - Guidelines et recommandations
- ▣ Indications spécifiques
  - Contre-indications
  - Sclérose aortique, déformation thoraciques, suites d'irradiation thoracique
  - Intervention après pontage coronarien
  - Procédures valve-in-valve
- ▣ Aspects particuliers
  - TAVI: planning
  - Résultats (Voies d'Access, TAVI versus SAVR)
  - Karlsruhe Algorithme TAVI: pose d'indication



European Heart Journal (2012) 33  
doi:10.1093/eurheartj/ehs109

## Guidelines on transcatheter aortic valve replacement (TAVR)

The Joint Task Force of the European Association for Cardio-Thoracic Surgery (EACTS) and the Society for Cardiovascular Intervention (SCAI)

Authors/Task Force Chairperson: (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (14) (15) (16) (17) (18) (19) (20) (21) (22) (23) (24) (25) (26) (27) (28) (29) (30) (31) (32) (33) (34) (35) (36) (37) (38) (39) (40) (41) (42) (43) (44) (45) (46) (47) (48) (49) (50) (51) (52) (53) (54) (55) (56) (57) (58) (59) (60) (61) (62) (63) (64) (65) (66) (67) (68) (69) (70) (71) (72) (73) (74) (75) (76) (77) (78) (79) (80) (81) (82) (83) (84) (85) (86) (87) (88) (89) (90) (91) (92) (93) (94) (95) (96) (97) (98) (99) (100) (101) (102) (103) (104) (105) (106) (107) (108) (109) (110) (111) (112) (113) (114) (115) (116) (117) (118) (119) (120) (121) (122) (123) (124) (125) (126) (127) (128) (129) (130) (131) (132) (133) (134) (135) (136) (137) (138) (139) (140) (141) (142) (143) (144) (145) (146) (147) (148) (149) (150) (151) (152) (153) (154) (155) (156) (157) (158) (159) (160) (161) (162) (163) (164) (165) (166) (167) (168) (169) (170) (171) (172) (173) (174) (175) (176) (177) (178) (179) (180) (181) (182) (183) (184) (185) (186) (187) (188) (189) (190) (191) (192) (193) (194) (195) (196) (197) (198) (199) (200) (201) (202) (203) (204) (205) (206) (207) (208) (209) (210) (211) (212) (213) (214) (215) (216) (217) (218) (219) (220) (221) (222) (223) (224) (225) (226) (227) (228) (229) (230) (231) (232) (233) (234) (235) (236) (237) (238) (239) (240) (241) (242) (243) (244) (245) (246) (247) (248) (249) (250) (251) (252) (253) (254) (255) (256) (257) (258) (259) (260) (261) (262) (263) (264) (265) (266) (267) (268) (269) (270) (271) (272) (273) (274) (275) (276) (277) (278) (279) (280) (281) (282) (283) (284) (285) (286) (287) (288) (289) (290) (291) (292) (293) (294) (295) (296) (297) (298) (299) (300) (301) (302) (303) (304) (305) (306) (307) (308) (309) (310) (311) (312) (313) (314) (315) (316) (317) (318) (319) (320) (321) (322) (323) (324) (325) (326) (327) (328) (329) (330) (331) (332) (333) (334) (335) (336) (337) (338) (339) (340) (341) (342) (343) (344) (345) (346) (347) (348) (349) (350) (351) (352) (353) (354) (355) (356) (357) (358) (359) (360) (361) (362) (363) (364) (365) (366) (367) (368) (369) (370) (371) (372) (373) (374) (375) (376) (377) (378) (379) (380) (381) (382) (383) (384) (385) (386) (387) (388) (389) (390) (391) (392) (393) (394) (395) (396) (397) (398) (399) (400) (401) (402) (403) (404) (405) (406) (407) (408) (409) (410) (411) (412) (413) (414) (415) (416) (417) (418) (419) (420) (421) (422) (423) (424) (425) (426) (427) (428) (429) (430) (431) (432) (433) (434) (435) (436) (437) (438) (439) (440) (441) (442) (443) (444) (445) (446) (447) (448) (449) (450) (451) (452) (453) (454) (455) (456) (457) (458) (459) (460) (461) (462) (463) (464) (465) (466) (467) (468) (469) (470) (471) (472) (473) (474) (475) (476) (477) (478) (479) (480) (481) (482) (483) (484) (485) (486) (487) (488) (489) (490) (491) (492) (493) (494) (495) (496) (497) (498) (499) (500) (501) (502) (503) (504) (505) (506) (507) (508) (509) (510) (511) (512) (513) (514) (515) (516) (517) (518) (519) (520) (521) (522) (523) (524) (525) (526) (527) (528) (529) (530) (531) (532) (533) (534) (535) (536) (537) (538) (539) (540) (541) (542) (543) (544) (545) (546) (547) (548) (549) (550) (551) (552) (553) (554) (555) (556) (557) (558) (559) (560) (561) (562) (563) (564) (565) (566) (567) (568) (569) (570) (571) (572) (573) (574) (575) (576) (577) (578) (579) (580) (581) (582) (583) (584) (585) (586) (587) (588) (589) (590) (591) (592) (593) (594) (595) (596) (597) (598) (599) (600) (601) (602) (603) (604) (605) (606) (607) (608) (609) (610) (611) (612) (613) (614) (615) (616) (617) (618) (619) (620) (621) (622) (623) (624) (625) (626) (627) (628) (629) (630) (631) (632) (633) (634) (635) (636) (637) (638) (639) (640) (641) (642) (643) (644) (645) (646) (647) (648) (649) (650) (651) (652) (653) (654) (655) (656) (657) (658) (659) (660) (661) (662) (663) (664) (665) (666) (667) (668) (669) (670) (671) (672) (673) (674) (675) (676) (677) (678) (679) (680) (681) (682) (683) (684) (685) (686) (687) (688) (689) (690) (691) (692) (693) (694) (695) (696) (697) (698) (699) (700) (701) (702) (703) (704) (705) (706) (707) (708) (709) (710) (711) (712) (713) (714) (715) (716) (717) (718) (719) (720) (721) (722) (723) (724) (725) (726) (727) (728) (729) (730) (731) (732) (733) (734) (735) (736) (737) (738) (739) (740) (741) (742) (743) (744) (745) (746) (747) (748) (749) (750) (751) (752) (753) (754) (755) (756) (757) (758) (759) (760) (761) (762) (763) (764) (765) (766) (767) (768) (769) (770) (771) (772) (773) (774) (775) (776) (777) (778) (779) (780) (781) (782) (783) (784) (785) (786) (787) (788) (789) (790) (791) (792) (793) (794) (795) (796) (797) (798) (799) (800) (801) (802) (803) (804) (805) (806) (807) (808) (809) (810) (811) (812) (813) (814) (815) (816) (817) (818) (819) (820) (821) (822) (823) (824) (825) (826) (827) (828) (829) (830) (831) (832) (833) (834) (835) (836) (837) (838) (839) (840) (841) (842) (843) (844) (845) (846) (847) (848) (849) (850) (851) (852) (853) (854) (855) (856) (857) (858) (859) (860) (861) (862) (863) (864) (865) (866) (867) (868) (869) (870) (871) (872) (873) (874) (875) (876) (877) (878) (879) (880) (881) (882) (883) (884) (885) (886) (887) (888) (889) (890) (891) (892) (893) (894) (895) (896) (897) (898) (899) (900) (901) (902) (903) (904) (905) (906) (907) (908) (909) (910) (911) (912) (913) (914) (915) (916) (917) (918) (919) (920) (921) (922) (923) (924) (925) (926) (927) (928) (929) (930) (931) (932) (933) (934) (935) (936) (937) (938) (939) (940) (941) (942) (943) (944) (945) (946) (947) (948) (949) (950) (951) (952) (953) (954) (955) (956) (957) (958) (959) (960) (961) (962) (963) (964) (965) (966) (967) (968) (969) (970) (971) (972) (973) (974) (975) (976) (977) (978) (979) (980) (981) (982) (983) (984) (985) (986) (987) (988) (989) (990) (991) (992) (993) (994) (995) (996) (997) (998) (999) (1000)

Kardologie 2011; 53:666-671  
DOI 10.1007/s12181-011-9369-4  
Online published: 2 September 2011  
© Springer-Verlag 2011

## 2012 ACCF/AATS/SCAI/STS expert consensus document on transcatheter aortic valve replacement: Executive summary

Arvind Agnihotri, MD

### INTRODUCTION

The American Association for Thoracic Surgery (AATS), along with 11 other professional societies, participated in the writing and approval of a consensus document on transcatheter aortic valve replacement (TAVR), which was recently published in the *Journal of the American College of Cardiology* in March 2012 (and also published online in its entirety on the JTCVS and AATS Web sites). The 55-page document provides a review of the current status of TAVR, including patient evaluation, decision making regarding treatment options, implantation details, postoperative considerations, and future directions. The work serves as a reference for practitioners directly involved in TAVR, and also as a resource for the larger group of physicians seeking to understand this technology and its role in the treatment of aortic stenosis (AS).

### AORTIC STENOSIS

With the onset of symptoms, the natural history of AS is poor. Medically managed inoperable patients in the Placement of Aortic Transcatheter Valve (PARTNER) trial had a 50% 1-year mortality rate, yet there are many patients who are not treated because of elevated risk. Diagnosis is generally made by echocardiography, with severe stenosis defined as a peak velocity of greater than 4 m/s OR a valve area of  $<1 \text{ cm}^2$  when systolic function is normal (indexed  $<0.6 \text{ cm}^2/\text{m}^2$ ). Diagnostic challenges exist in the presence of significant aortic regurgitation, upper septal hypertrophy, and in the failing ventricle. Patients with low gradient AS most likely to benefit from treatment are those with contractile reserve (as shown by dobutamine infusion), limited coronary disease, and a mean gradient of  $\geq 20 \text{ mm Hg}$ .

### OPEN SURGERY

Open surgical replacement (AVR) remains the only effective treatment considered a class I recommendation by the ACCF/AHA guidelines in adults with severe symptomatic AS. Current data from the Society of Thoracic Surgeons (STS) Registry documents a mortality rate that is 2.6% for

all patients undergoing AVR, and in patients with minimal comorbidity, mortality and major morbidity rates are under 1% each in many centers. Surgical AVR for most patients is a proven low-risk therapy for AS and remains the gold standard.

### PATIENT SELECTION

Indications for treatment in AS are well established by guidelines; however, decisions at the extreme of risk can be complex and is facilitated by use of risk models. The STS and logistic EuroSCORE are the most commonly used mechanisms for mathematical estimation of surgical risk. Along with consideration of the patient's nonrepresented risk (risk not accounted for in the models), the patient might be declared "prohibitive risk," "extreme risk" or "inoperable," but it is acknowledged that these terms are used with some subjectivity.

The alternatives to surgical AVR are limited to medical therapy and percutaneous balloon valvuloplasty. Percutaneous balloon valvuloplasty is known to often result in hemodynamic improvement, but this does not translate in to survival benefit and, as such, its role is strictly palliative or, in rare circumstances, as a bridge toward more definitive therapy.

### TAVR BACKGROUND

In the 1990s, investigators began evaluation of stent-based porcine bioprosthesis delivered to various aortic sites in animal models. In 2000, a percutaneous heart valve was placed in a child's pulmonary arterial conduit, and in 2002, the first human TAVR was performed. Since then, multiple devices have been evaluated, but most human data comes from 2 valve designs: The Sapien valve (Edwards Lifesciences, Inc, Irvine, Calif) and the CoreValve (Medtronic, Inc, Minneapolis, Minn). The Sapien is available in 23- and 26-mm sizes; the CoreValve in 23, 26, and 29 mm. The Sapien valve is mounted within a balloon-expandable cobalt chromium stent, whereas the CoreValve is self-expanding with a nitinol frame. Initial delivery systems required 22- or 24-French sheaths, but recent iterations have decreased this to 18 French. Both valves are preferentially placed via a transfemoral arterial (TF) approach. The Sapien valve is also implantable via a transapical (TA) route, using a specialized delivery system (Ascendra; Edwards Lifesciences).

### CLINICAL EVIDENCE: REGISTRIES

Initial evidence regarding the outcomes of TAVR with Sapien and CoreValve come from registry data. The patients

# Feuille de Route DGK 2009

- ▣ Collaboration étroite entre cardiologie et chirurgien cardiaque
- ▣ Risque procédural élevé – pose d'indication au sein d'un team
- ▣ Participation au Deutsches Aortenklappenregister (GARY) recommandé

| Positionspapier                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Kardiologie 2009 · 3:199–206<br/>DOI 10.1007/s12181-009-0183-4<br/>© Deutsche Gesellschaft für Kardiologie – Herz- und Kreislaufforschung e.V.<br/>Published by Springer Medizin Verlag<br/>all rights reserved 2009</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>H.R. Figulla · J. Cremer · T. Walther · U. Gerckens · R. Erbel · A. Osterspey · R. Zahn</p> <h2>Positionspapier zur kathetergeführten Aortenklappenintervention</h2>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <p><b>Positionspapier zur kathetergeführten Aortenklappenintervention</b></p> <p>Im Auftrag der DGK in Zusammenarbeit mit der Deutschen Gesellschaft für Herz-, Thorax- und Gefäßchirurgie</p> <p>Korrespondenzadresse:<br/>Prof. Dr. H.R. Figulla<br/>Klinik für Innere Medizin I,<br/>Universitätsklinikum Jena,<br/>Erlanger Allee 101, 07740 Jena,<br/>Hans.Figulla@med.uni-jena.de</p> <p>Dieses Positionspapier ist eine Stellungnahme der Deutschen Gesellschaft für Kardiologie – Herz- und Kreislaufforschung (DGK), die den gegenwärtigen Erkenntnisstand wiedergibt und allen Ärzten und ihren Patienten die Entscheidungshilfe erleichtern soll. Es werden bisher publizierte, relevante Studien herangezogen, gekürzte Fassungen beantwortet und ungeklärt aufgezogen. Es wird eine Empfehlung abgegeben, für welche Patienten das vorgestellte (diagnostische und/oder therapeutische) Verfahren infrage kommt. Der Zusammenhang zwischen der jeweiligen Empfehlung und dem zugehörigen Evidenzgrad ist gekennzeichnet. Das Positionspapier ersetzt nicht die ärztliche Evaluation des individuellen Patienten und die Anpassung der Diagnostik und Therapie an dessen spezifische Situation.</p> <p>Prof. Dr. H.R. Figulla ist federführender Autor dieses Positionspapiers.</p> | <p><b>Einkleitung</b></p> <p>Wärum ein Positionspapier zu Aortenklappeninterventionen?</p> <p>Die erfreuliche Zunahme der Lebenserwartung in Deutschland geht einher mit einer zunehmenden Prävalenz von signifikanten Aortenklappenstenosen [1]. Der zunehmenden Inzidenz dieser Klappenkrankungen steht seit 2002 ein neues Therapiekonzept gegenüber, welches kathetergeführte Aortenklappenimplantation (Kath-AKI) genannt wird und seit 2005 in Deutschland eingesetzt wird [2, 3]. Die neue Therapieform wird gegenwärtig weltweit am häufigsten in Deutschland angewandt. Die Therapie ist einzigartig, da sie</p> <ol style="list-style-type: none"><li>1. den Klappenring bzw. die Klappenimplantation für Patientengruppen ermöglicht, die bislang wegen Komorbiditäten nicht in Betracht kamen,</li><li>2. eine ganz neue und viel engere Interaktion zwischen Kardiologen und Herzchirurgen erfordert,</li><li>3. besondere periprozedurale Komplikationen aufweist, die ein spezielles Komplikationsmanagement erfordern (Tab. 1) [4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15],</li><li>4. eine Geräustattung verlangt, die am besten in den sog. Hybrid-OPs realisiert werden kann (d. h. OP-Standards hinsichtlich Sterilität, Herz-Lungen-Maschinen-Einsatz möglich sowie Herzkatheterlaborstandard hinsichtlich Bildgebung) [16],</li><li>5. ein intensives interventionelles Training erfordert, um die Einarbeitung zu beschleunigen und die Lernkurve flach zu halten [15].</li></ol> <p>Die Deutsche Gesellschaft für Kardiologie-, Herz- und Kreislaufforschung sieht es deswegen als ihre Aufgabe an, die neue Therapieform durch ein nationales Positionspapier zu begleiten und Standards für die Anwendung zu erarbeiten, ergänzend zu europäischen und US-amerikanischen Positionspapieren [17, 18].</p> <p><b>Methodik</b></p> <p>Der Erstellung des Positionspapiers liegen zugrunde:</p> <ol style="list-style-type: none"><li>1. Informationen aus der veröffentlichten Literatur,</li><li>2. Informationen von Kongressen (insbesondere TCT in Washington vom 10.10. bis 12.10.2008),</li><li>3. Angaben der Industrie (Stand Oktober 2008 (CoreValve, Edwards)).</li></ol> <p>Für die Empfehlungs- und Evidenzgrade der Therapieverfahren wird die Klassifikation der Präambel benutzt (Tab. 2, 3).</p> <p><b>Hauptteil</b></p> <p><b>Welche kathetergeführten Herzklappenimplantationen gibt es gegenwärtig?</b></p> <ol style="list-style-type: none"><li>1. Die Pulmonalklappenimplantation Melody-Prothe sP (Medtronic) oder Edwards-Sapien-Prothe sP (Edwards) bei Jugendlichen und jungen Erwachsenen mit voroperierten Pulmonalklappen [19].</li></ol> <p><sup>1</sup> Der Einsatz der Edwards-Sapien-Klappe in Pulmonalposition, Mitralklappenposition oder in degenerierten Bioprothesen ist nicht zertifiziert und entspricht einer „off-label-use“.</p> |

# Feuille de Route ALKK 2011

- „TAVI-Team“ comprenant cardiologue, chirurgien cardiaque, personnel paramédical spécialisé
- Equipement adéquat
- Diagnostique exact
- Suivi péri- et postinterventionnel

| Interventionelle Kardiologie                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Kardiologie 2011 · 5366-371<br/>DOI 10.1007/s12181-011-0369-4<br/>Online publiziert: 2. September 2011<br/>© Springer-Verlag 2011</p> | <p>H. Mudra<sup>1</sup>, S. Sack<sup>2</sup>, M. Haud<sup>3</sup>, U. Gerdken<sup>4</sup>, K.-H. Kuck<sup>5</sup>, R. Hambrecht<sup>6</sup>,<br/>H. Siwert<sup>7</sup>, G. Richard<sup>8</sup>, V. Schächinger<sup>9</sup>, C. Naber<sup>10</sup>, U. Sechtem<sup>11</sup>, R. Zahn<sup>12</sup>,<br/>J. Brachmann<sup>13</sup></p> <p><sup>1</sup> Klinik für Kardiologie, Pneumologie und Internistische Intensivmedizin, Städtisches<br/>Klinikum München, Klinikum München GmbH, Klinikum Neuperlach, München; <sup>2</sup> Klinik<br/>für Kardiologie, Pneumologie und Internistische Intensivmedizin, Städtisches Klinikum<br/>München GmbH, Klinikum Schwabing, München; <sup>3</sup> Medizinische Klinik I, Lukas-<br/>Krankenhaus, Neuss; <sup>4</sup> Abteilung für Innere Medizin und Kardiologie,<br/>Gemeinschaftskrankenhaus Bonn, Bonn; <sup>5</sup> Abteilung Kardiologie, Asklepios<br/>Klinik St. Georg, Hamburg; <sup>6</sup> Klinik für Kardiologie und Angiologie, Klinikum<br/>Links der Weser, Bremen; <sup>7</sup> CardioVasculäres Centrum Frankfurt, St. Katharinen<br/>Krankenhaus, Frankfurt am Main; <sup>8</sup> Herzzentrum, Segeberger Kliniken GmbH,<br/>Bad Segeberg; <sup>9</sup> Medizinische Klinik I, Klinikum Fulda AG, Fulda; <sup>10</sup> Klinik für<br/>Kardiologie und Angiologie, Elisabeth-Krankenhaus, Essen; <sup>11</sup> Abteilung für<br/>Kardiologie, Robert-Bosch-Krankenhaus, Stuttgart; <sup>12</sup> Medizinische Klinik B<br/>(Kardiologie, Rhythmologie, Pneumologie), Ludwigshafen; <sup>13</sup> Medizinische<br/>Klinik (Kardiologie, Angiologie, Pneumologie), Klinikum Coburg, Coburg</p> <p><b>Strukturelle und organisatorische<br/>Voraussetzungen zur Durchführung<br/>des Transkatheter-Aorten-<br/>klappenersatzes (TAVI)</b></p> <p><b>Ein Positionspapier der Arbeitsgemeinschaft<br/>Leitende Kardiologische<br/>Krankenhausärzte (ALKK) e.V.</b></p> <p>Dieses Positionspapier soll eine Orientierungshilfe für Kliniken sein, die ein Programm zur kathetergestützten Aortenklappenimplantation (TAVI) in ihrer Klinik durchführen möchten. Es lehnt sich ausdrücklich an das gemeinsame Positionspapier der DGK und DGTHG [1] an, das die bislang einzige im Konsens formulierte Empfehlung von DGK und DGTHG darstellt und bis zu einer eventuellen Überarbeitung weiterhin uneingeschränkt Gültigkeit hat. Durch die nicht allgemein konsentierten Abfassung von Meinungsäußerungen einzelner Interessengruppen, zuletzt z. B. in der Form eines sog. Ordinariatspapiers, verfasst durch Meinungsbildner der DGTHG und einige kardiologische Ordinarien [2], wird einerseits der falsche Eindruck erweckt, als handele es sich hierbei um eine Aktualisierung des gemeinsamen Positionspapiers der DGK und DGTHG, andererseits zwingt es die anderen Gruppierungen innerhalb der Fachgesellschaften, sich dezidiert von derartigen interessengesteuerten Statements zu distanzieren.</p> <p>Das vorliegende Papier soll insbesondere vor dem Hintergrund derartiger Stellungnahmen einzelner Interessengruppen auch für die Kliniken bzw. Krankenhäuser mit ausreichender Infrastruktur, die keine sog. „institutionalisierte Herzchirurgie“ am Haus vorhalten, die notwendigen personellen und apparativen Voraussetzungen zusammenfassen, die nach Ansicht der Autoren in Übereinstimmung mit dem gemeinsamen Positionspapier der DGK und DGTHG zu einer heutigen</p> <p>Qualitätsstandard genügt TAVI-Behandlung erforderlich sind.</p> <p>Dazu wurden die Analyse und Interpretation von Registerdaten und der Publikationen der PARTNER-Studien (Kohorte B und A) herangezogen.</p> <p>Die Bildung eines „Herzklappenteams“, bestehend aus Kardiologen, Herzchirurgen, Echo- und CT-Spezialisten, Gefäßchirurgen und Kardi-Anästhesisten, die in einem strukturierten und sich kontinuierlich weiterentwickelnden Programm zusammenarbeiten, ist auch nach unserer Überzeugung eine Grundvoraussetzung für die optimale Durchführung der Transkatheter-Aortenklappenintervention.</p> |

# Recommendations 2012

- ▣ TAVI: pour les patients inopérables une option thérapeutique
- ▣ Consensus minimum
  - STS > 10 ou Euroscore > 20
  - Age > 75 ans



# ESC/EACTS Guidelines 2012

## TAVI: Indications

- ❑ Team interdisciplinaire
- ❑ Presence d'une unité de chirurgie cardiaque
- ❑ Indication TAVI
  - Sténose aortique sévère, symptomatique
  - Espérance de vie > 1 an
  - Patients au risque élevé avec contre-indication pour l'opération conventionnelle
  - Amélioration de la qualité de vie anticipée
- ❑ Décision individuelle



European Heart Journal (2012) 33, 2451–2496  
doi:10.1093/eurheartj/ehs109



### Guidelines on the management of valvular heart disease (version 2012)

**The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)**

**Authors/Task Force Members:** Alec Vahanian (Chairperson) (France)\*, Ottavio Alfieri (Chairperson)\* (Italy), Felicia Andreotti (Italy), Manuel J. Antunes (Portugal), Gonzalo Barón-Esquivias (Spain), Helmut Baumgartner (Germany), Michael Andrew Borger (Germany), Thierry P. Carrel (Switzerland), Michele De Bonis (Italy), Arturo Evangelista (Spain), Volkmar Falk (Switzerland), Bernard Iung (France), Patrizio Lancellotti (Belgium), Luc Pierard (Belgium), Susanna Price (UK), Hans-Joachim Schäfers (Germany), Gerhard Schuler (Germany), Janina Stepinska (Poland), Karl Swedberg (Sweden), Johanna Taldenberg (The Netherlands), Ulrich Otto Von Oppell (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain), Marian Zembala (Poland)

**ESC Committee for Practice Guidelines (CPG):** Jeroen J. Bax (Chairperson) (The Netherlands), Helmut Baumgartner (Germany), Claudio Cecconi (Italy), Veronica Dorian (France), Christl Diason (UK), Robert Fagard (Belgium), Christian Funck-Brentano (France), David Hassdai (Israel), Arno Hoes (The Netherlands), Paulus Kirchhof (United Kingdom), Juhani Knuuti (Finland), Philippe Kolh (Belgium), Theresa McDonagh (UK), Cyril Moulin (France), Bogdan A. Popescu (Romania), Zeljko Reiner (Croatia), Udo Sechtem (Germany), Per Anton Simonsen (Norway), Michael Tendera (Poland), Adam Torbicki (Poland), Alec Vahanian (France), Stephan Windecker (Switzerland)

**Document Reviewers:** Bogdan A. Popescu (ESC CPG Review Coordinator) (Romania), Ludwig Von Segesser (EACTS Review Coordinator) (Switzerland), Luigi P. Badano (Italy), Matjaz Bunc (Slovenia), Marc J. Claeys (Belgium), Nilsa Drinkovic (Croatia), Gerasimos Filippatos (Greece), Gilbert Habib (France), A. Pieter Kappetein (The Netherlands), Roland Kasseab (Lebanon), Gregory Y.H. Lip (UK), Neil Moat (UK), Georg Nickenig (Germany), Catherine M. Otto (USA), John Pepper (UK), Nicolo Piazza (Germany), Petronella G. Pieper (The Netherlands), Raphael Rosenheck (Austria), Naltin Shulka (Albania), Ehud Schwammenthal (Israel), Juerg Schwitler (Switzerland), Pilar Tornos Mas (Spain), Pedro T. Trindade (Switzerland), Thomas Walther (Germany)

The disclosure forms of the authors and reviewers are available on the ESC website [www.escard.org/guidelines](http://www.escard.org/guidelines)

Online published ahead of print 24 August 2012

\* Corresponding authors: Alec Vahanian, Service de Cardiologie, Hôpital Bichat AP-HP, 46 rue Henri Huchard, 75018 Paris, France. Tel: +33 1 40 25 67 60; Fax: +33 1 40 25 67 32. Email: [alec.vahanian@bichatp.fr](mailto:alec.vahanian@bichatp.fr)  
 Ottavio Alfieri, S. Raffaele University Hospital, 20132 Milan, Italy. Tel: +39 02 26437109; Fax: +39 02 26437125. Email: [ottavioalfieri@hsr.it](mailto:ottavioalfieri@hsr.it)  
 To other ESC entities having participated in the development of this document:  
 Association European Association of Echocardiography (EAE), European Association of Percutaneous Cardiovascular Interventions (EAPCI), Heart Failure Association (HFA), Working Group Acute Cardiac Care, Cardiovascular Surgery, Valvular Heart Disease, Thrombosis, Grown-up Congenital Heart Disease  
 Council of Cardiology Practice, Cardiovascular Imaging  
 The content of these European Society of Cardiology (ESC) Guidelines has been published for personal and educational use only. No commercial use is authorized. No part of the ESC Guidelines may be translated or reproduced in any form without written permission from the ESC. Permission can be obtained upon submission of a written request to Oxford University Press, the publisher of the European Heart Journal, and the party authorized to handle such permissions on behalf of the ESC.  
 Disclaimer: The ESC/EACTS Guidelines represent the views of the ESC and the EACTS and were arrived at after careful consideration of the available evidence at the time they were written. Health professionals are encouraged to take them fully into account when exercising their clinical judgment. The guidelines do not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patients in consultation with that patient and, where appropriate and necessary, the patient's guardian or carer. It is also the health professional's responsibility to verify the rules and regulations applicable to drugs and devices at the time of prescription.  
 © The European Society of Cardiology 2012. All rights reserved. For permissions please email: [journals.permissions@oup.com](mailto:journals.permissions@oup.com)

# ESC/EACTS Guidelines

## TAVI: Contre-indications

### ▣ Clinique

- Esperance de vie < 1 an
- Amélioration de la qualité de vie non anticipée à cause de comorbidités
- Pathologie signifiante d'une autre valve

### ▣ Anatomique

- Diamètre annulaire inadéquat
- Thrombus intra-ventriculaire
- Endocardite active
- Risque notable d'obstruction coronaire
- Formation de plaques sclérotiques dans la crosse aortique ou dans l'arc de l'aorte

# ESC/EACTS Guidelines

## TAVI: Contre-indications Relatives

- ▣ Valve bicuspide ou non calcifiée?
- ▣ Sclérose coronaire significative?
- ▣ Hémodynamique instable?
- ▣ LV-EF < 20%?
- ▣ Situation d'urgence?

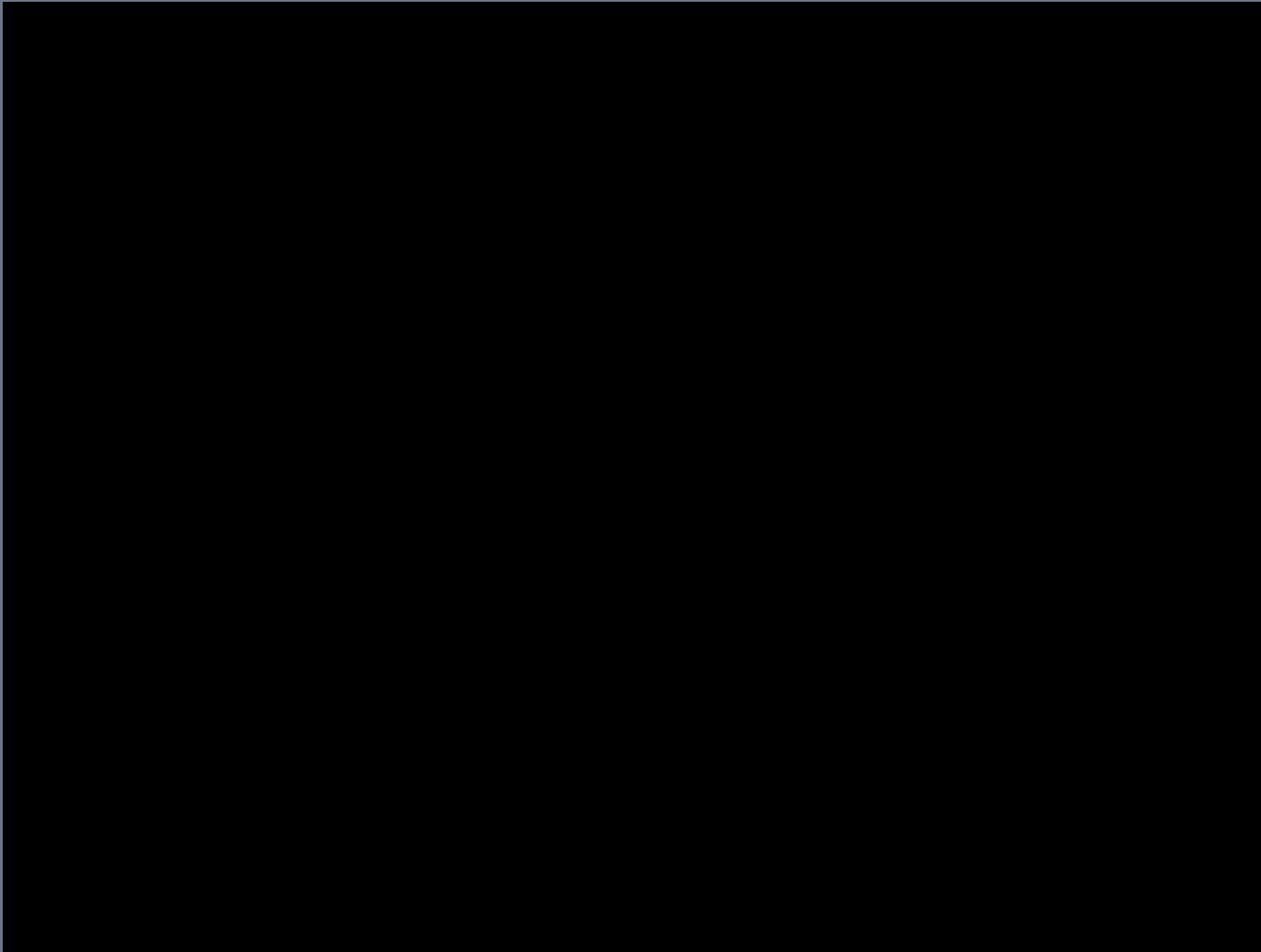
# TAVI: Pose d'Indication

- ▣ Indications formelles
  - Guidelines et recommandations
- ▣ Indications spécifiques
  - Contre-indications
  - Sclérose aortique, déformation thoraciques, suites d'irradiation thoracique
  - Intervention après pontage coronarien
  - Procédures valve-in-valve
- ▣ Aspects particuliers
  - TAVI: planning
  - Résultats (Voies d'Access, TAVI versus SAVR)
  - Karlsruhe Algorithme TAVI: pose d'indication

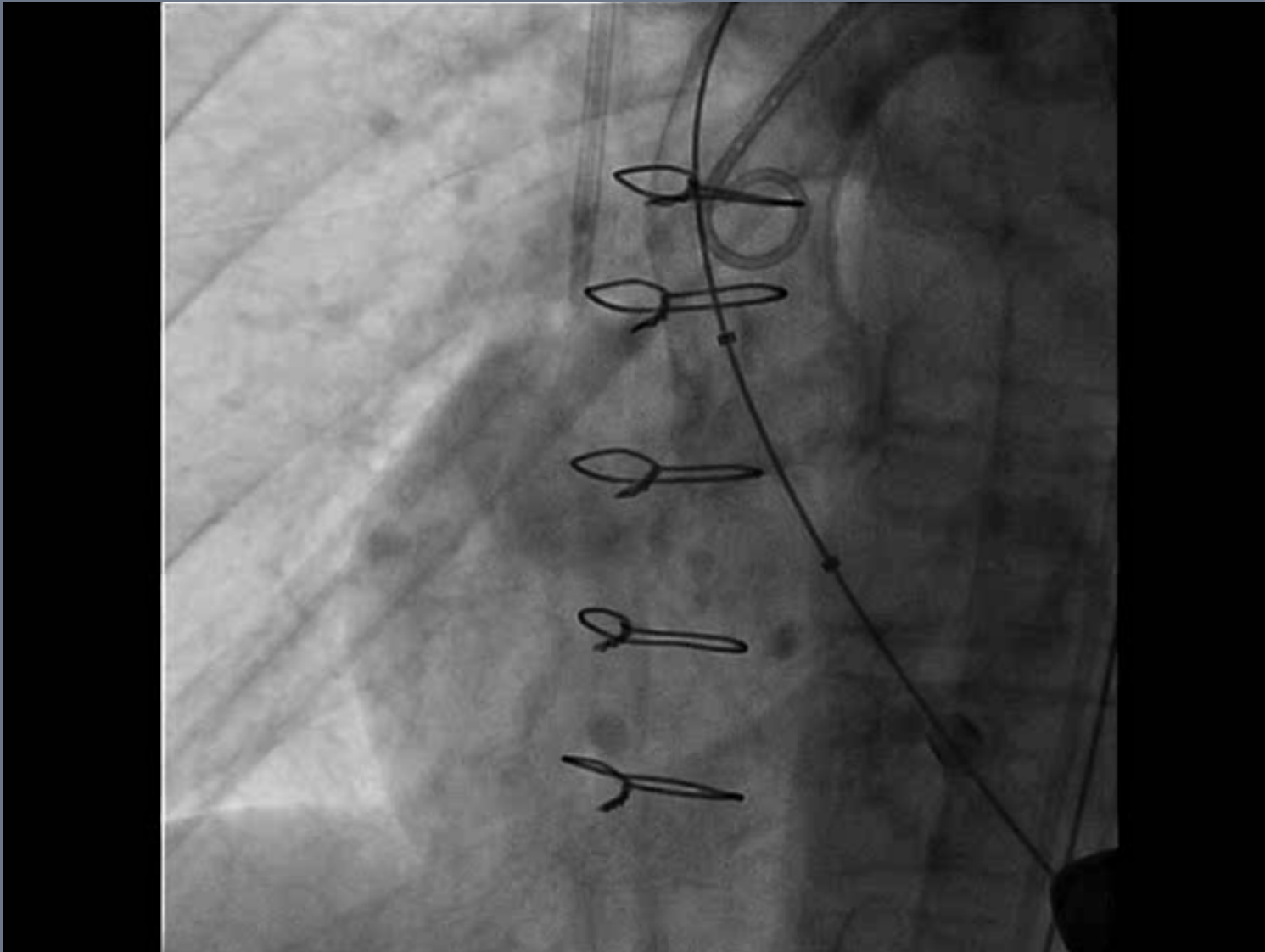
# Contre-Indication

- ▣ Patient G.,M.; \*12.01.1931
- ▣ Sténose aortique (0,7 cm<sup>2</sup>,  $\Delta p_{\max}$  22 mm Hg)
  - Low flow – low gradient
  - Echocardiographie de stress
    - ▣ augmentation faible du gradient transvalvulaire
    - ▣ Croissance faible de la fraction d'éjection ventriculaire
  - LV-EF 15%
  - RV-EF réduite, hypertonie pulmonaire (80 mm Hg)
  - Redo après pontage coronarien, défaillance rénale, hémodialyse, artériopathie oblitérante
  - Euroscore 1: 80,1 %
  - Euroscore 2: 41,6%

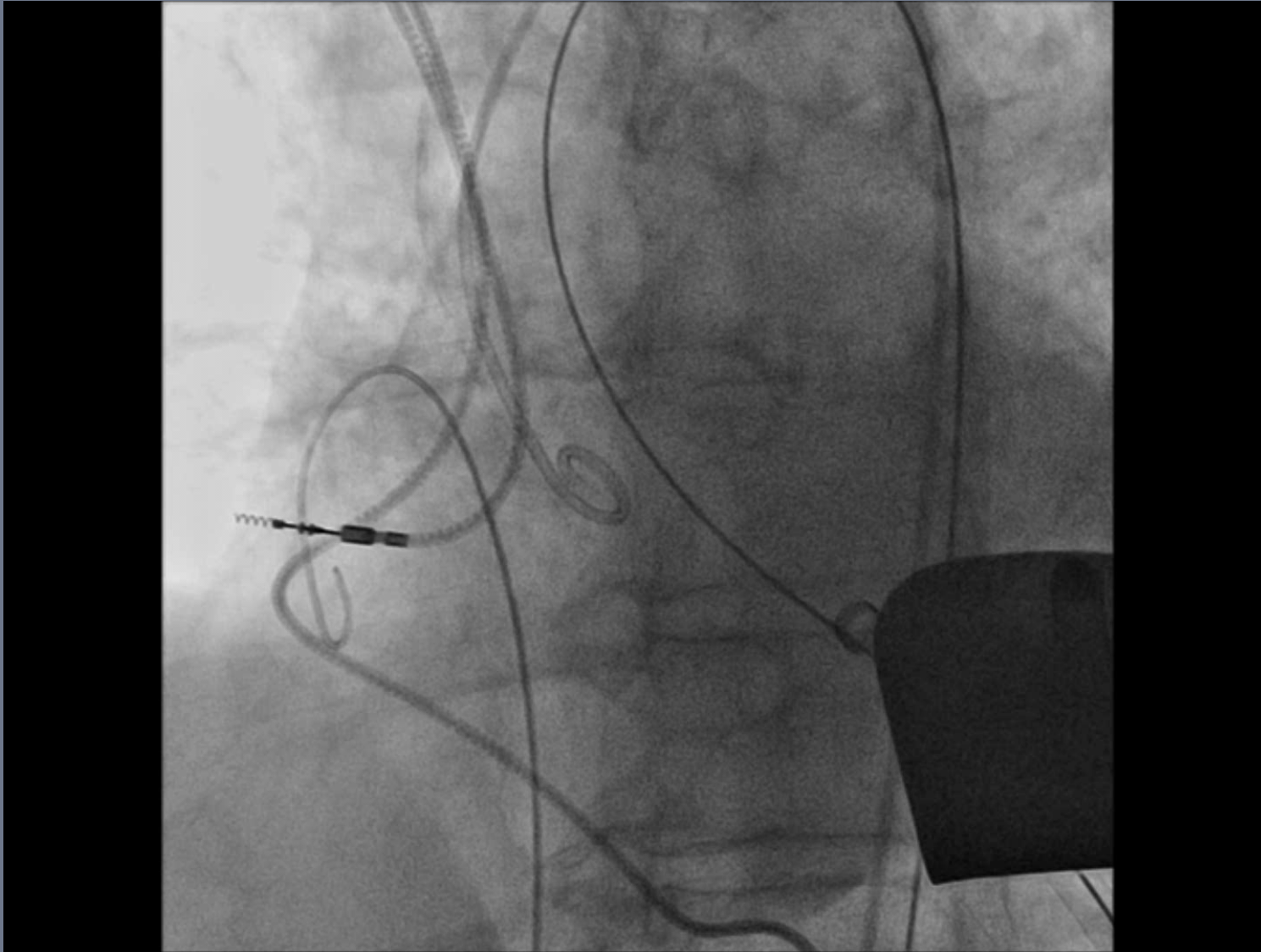
# Contra-Indication



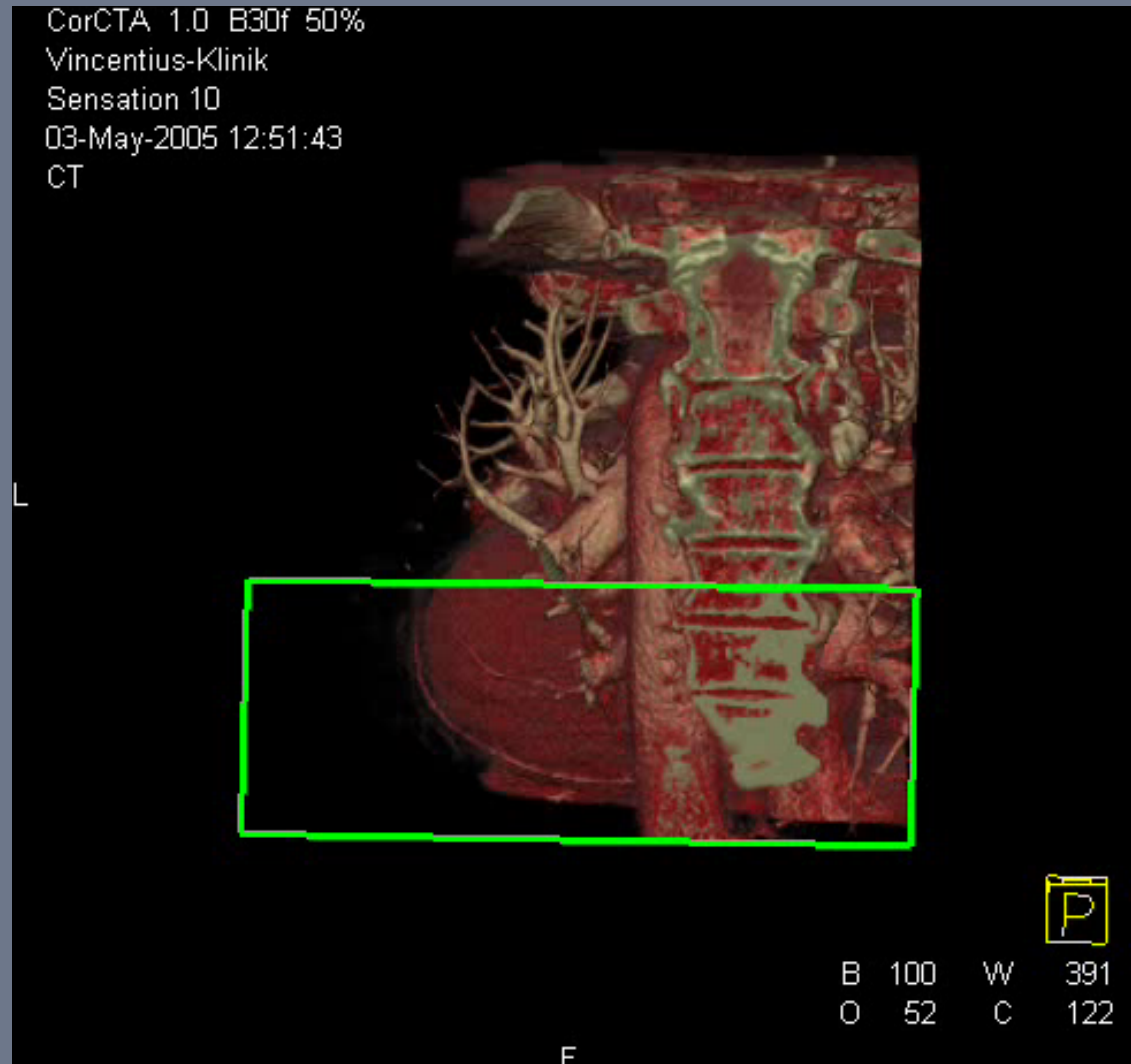
# Aorte en porcelaine



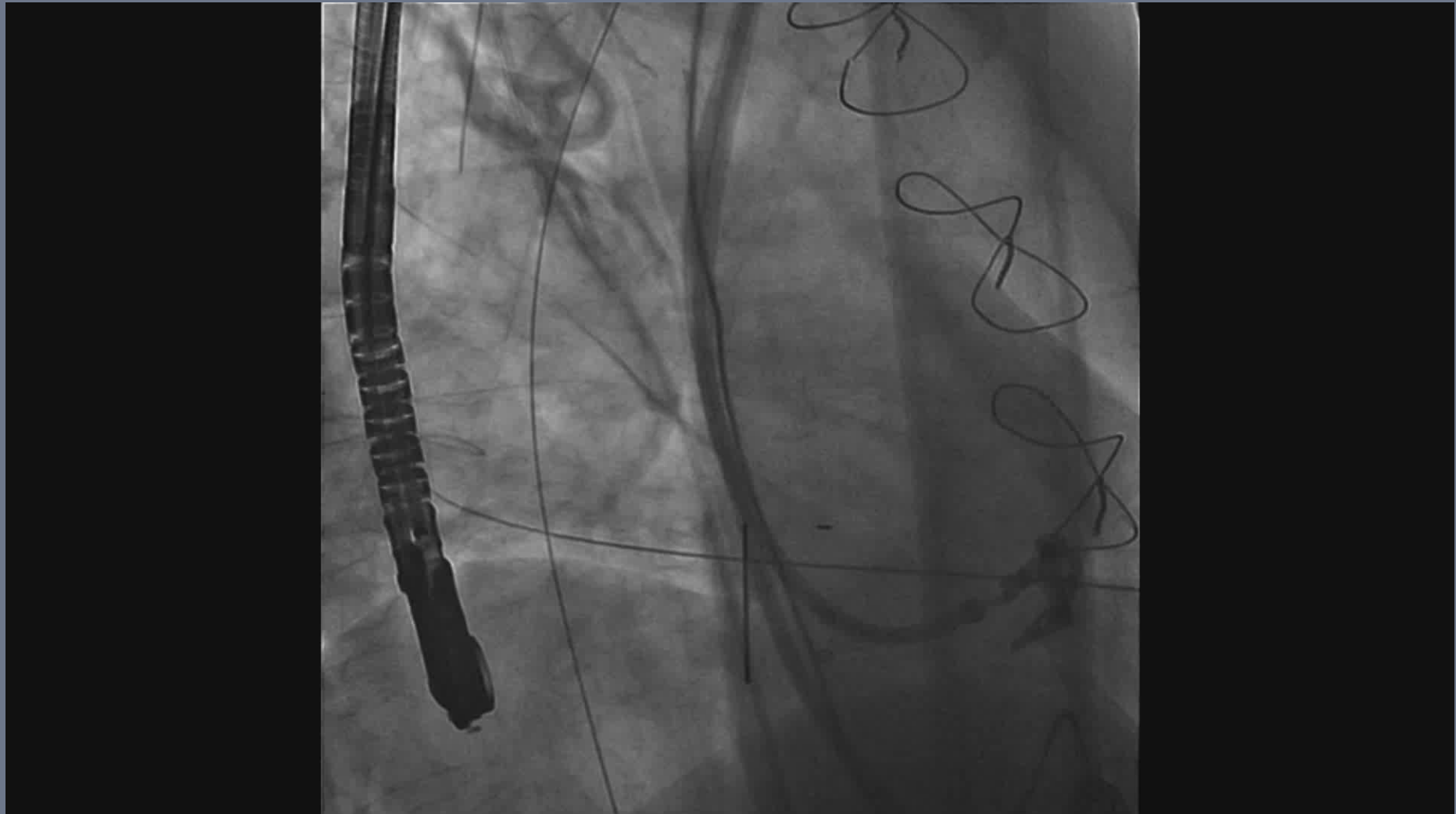
# Aorte en Porcelaine



# Redo après pontage coronarien



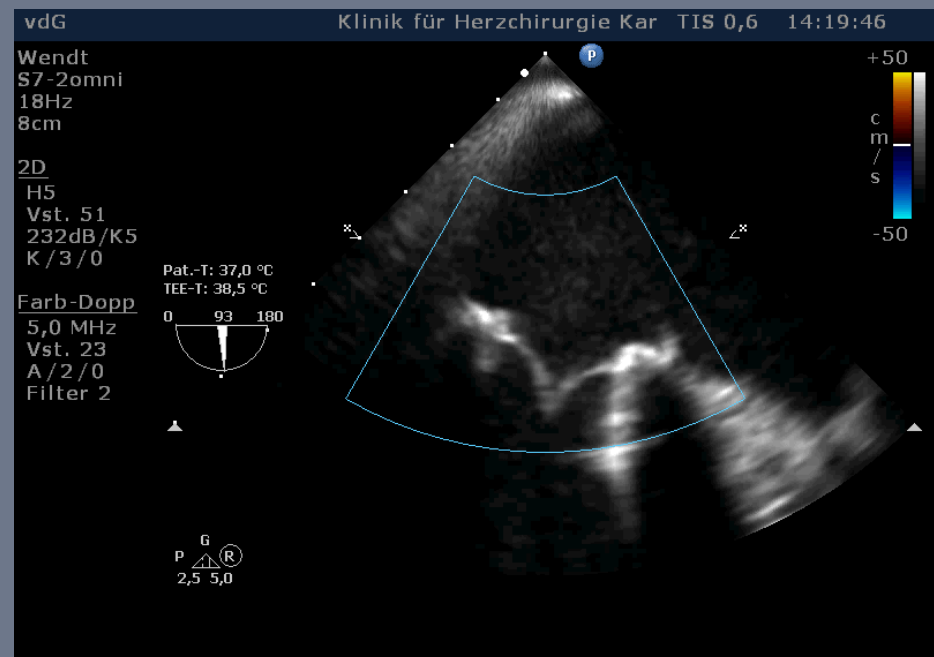
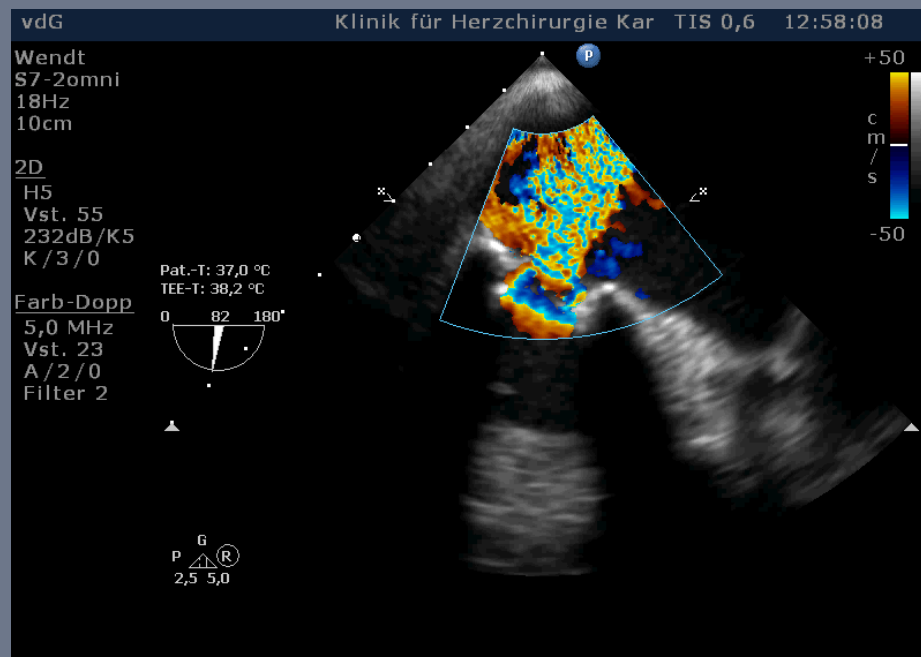
# Valve-in-Valve en position mitrale



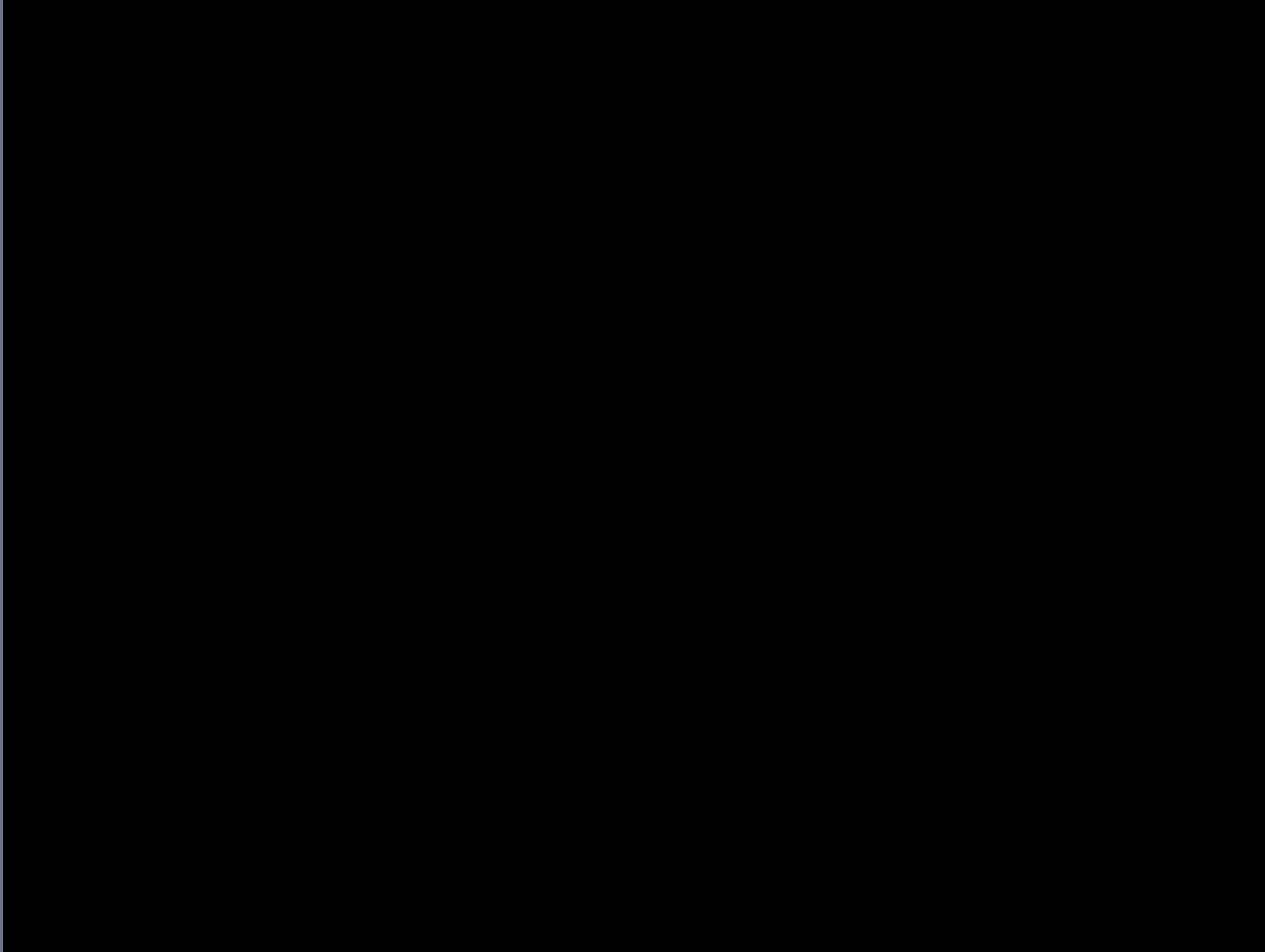
# Valve-in-Valve en Position Mitrale

ETO PRE

ETO POST



# AV et MV Valve-in-Valve



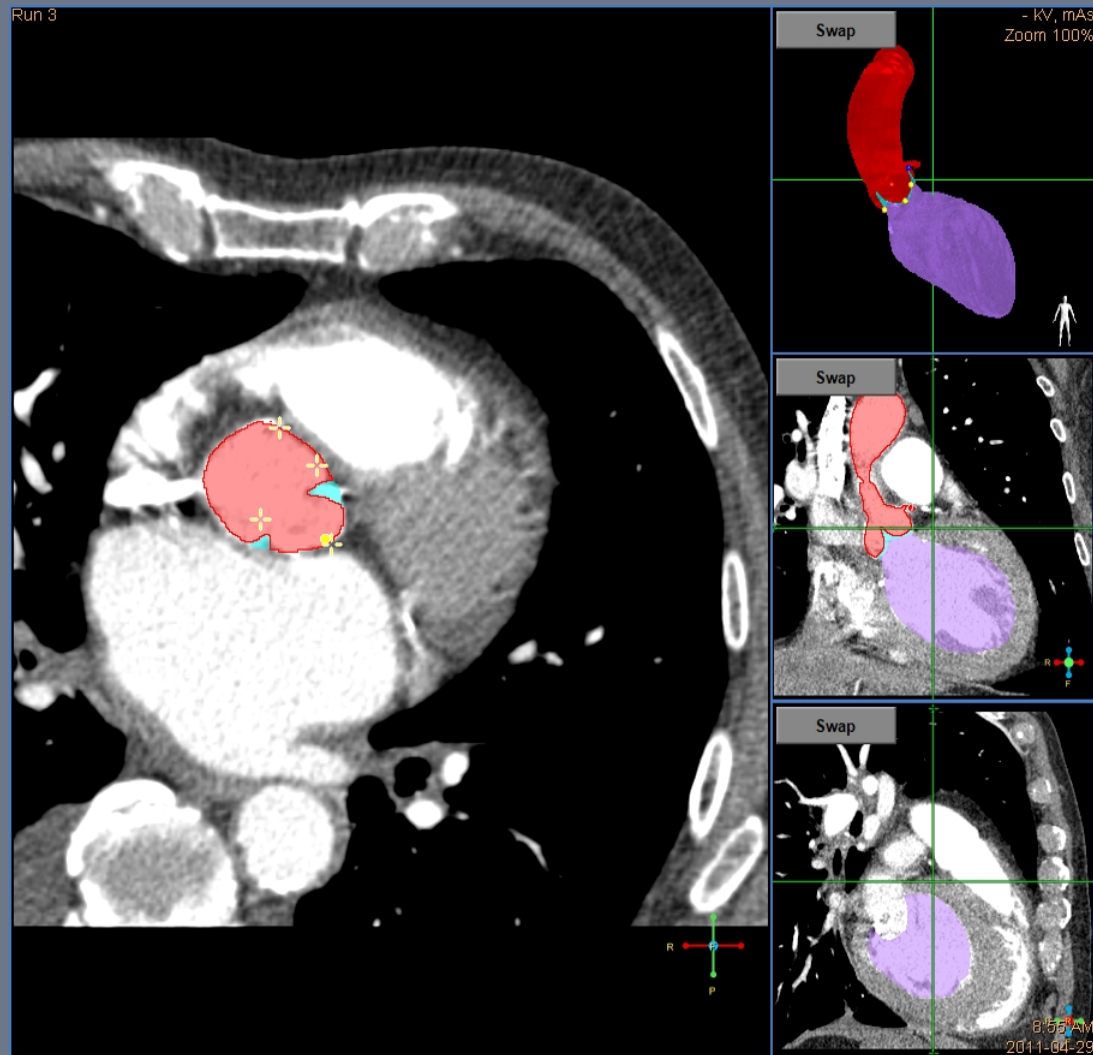
# TAVI: Pose d'Indication

- ▣ Indications formelles
  - Guidelines et recommandations
- ▣ Indications spécifiques
  - Contre-indications
  - Sclérose aortique, déformation thoraciques, suites d'irradiation thoracique
  - Intervention après pontage coronarien
  - Procédures valve-in-valve
- ▣ Aspects particuliers
  - TAVI: planning
  - Résultats (Voies d'Access, TAVI versus SAVR)
  - Karlsruhe Algorithme TAVI: pose d'indication

# TAVI: Planification

- ▣ CT-Angiographie du thorax
- ▣ Système de Navigation
  - HeartNavigator® sur base d'un Angio-CT
    - ▣ Planning virtuel: TAVI faisable?
    - ▣ Type et diamètre de prothèse
    - ▣ Distributions des calcifications
    - ▣ Voie d'accès
- ▣ Echocardiographie transoesophagienne

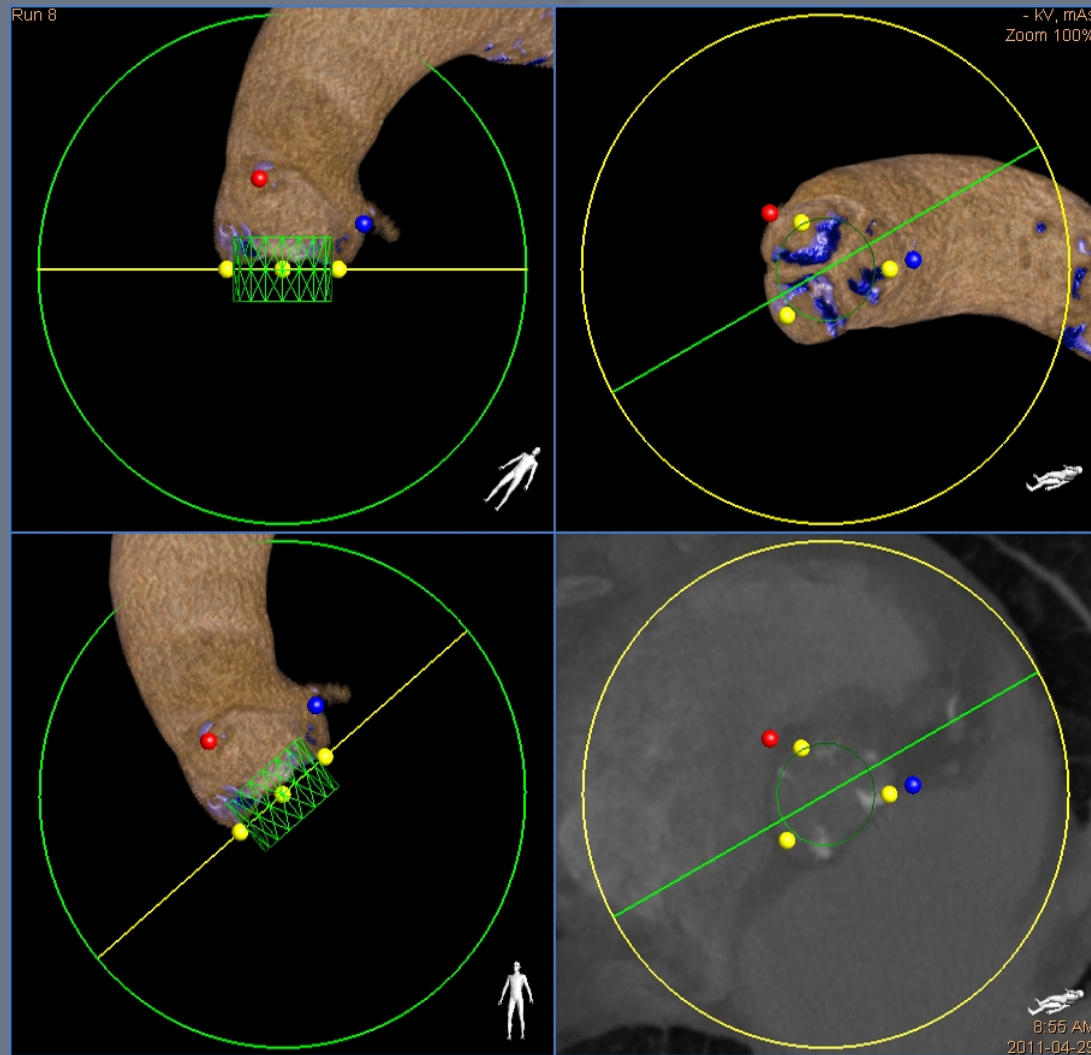
# Segmentation



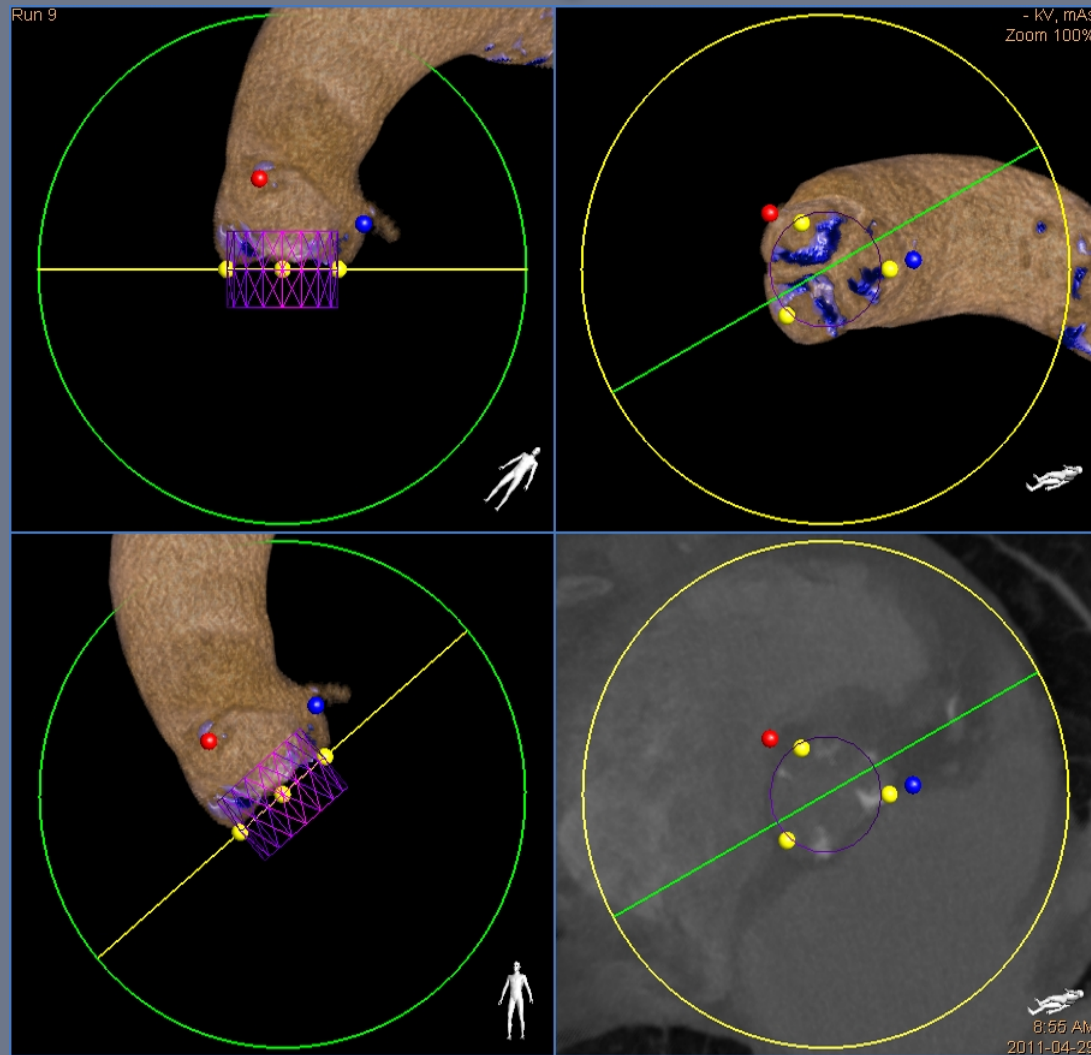
# Reconstitution 3D



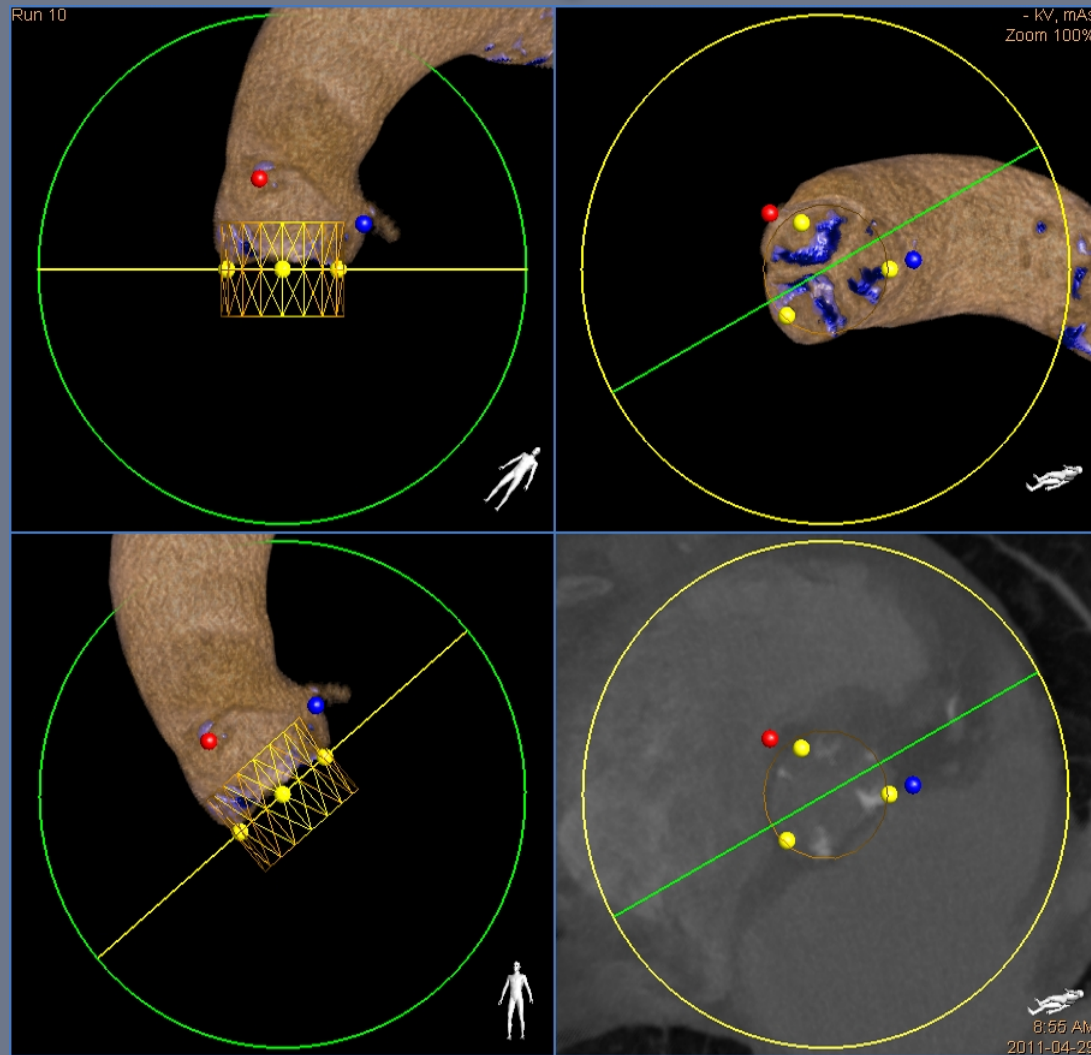
# Edwards Sapien 23 mm



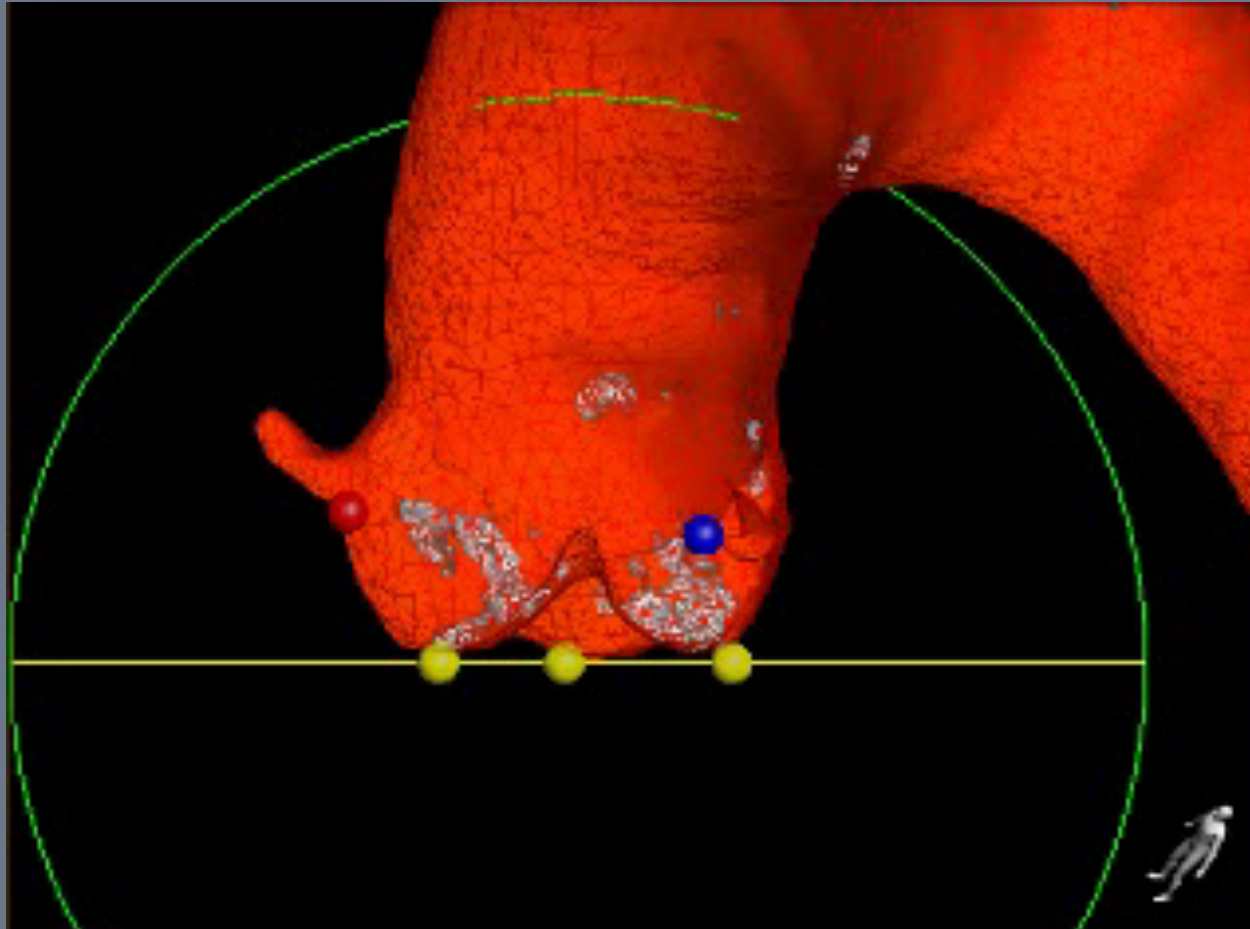
# Edwards Sapien 26 mm



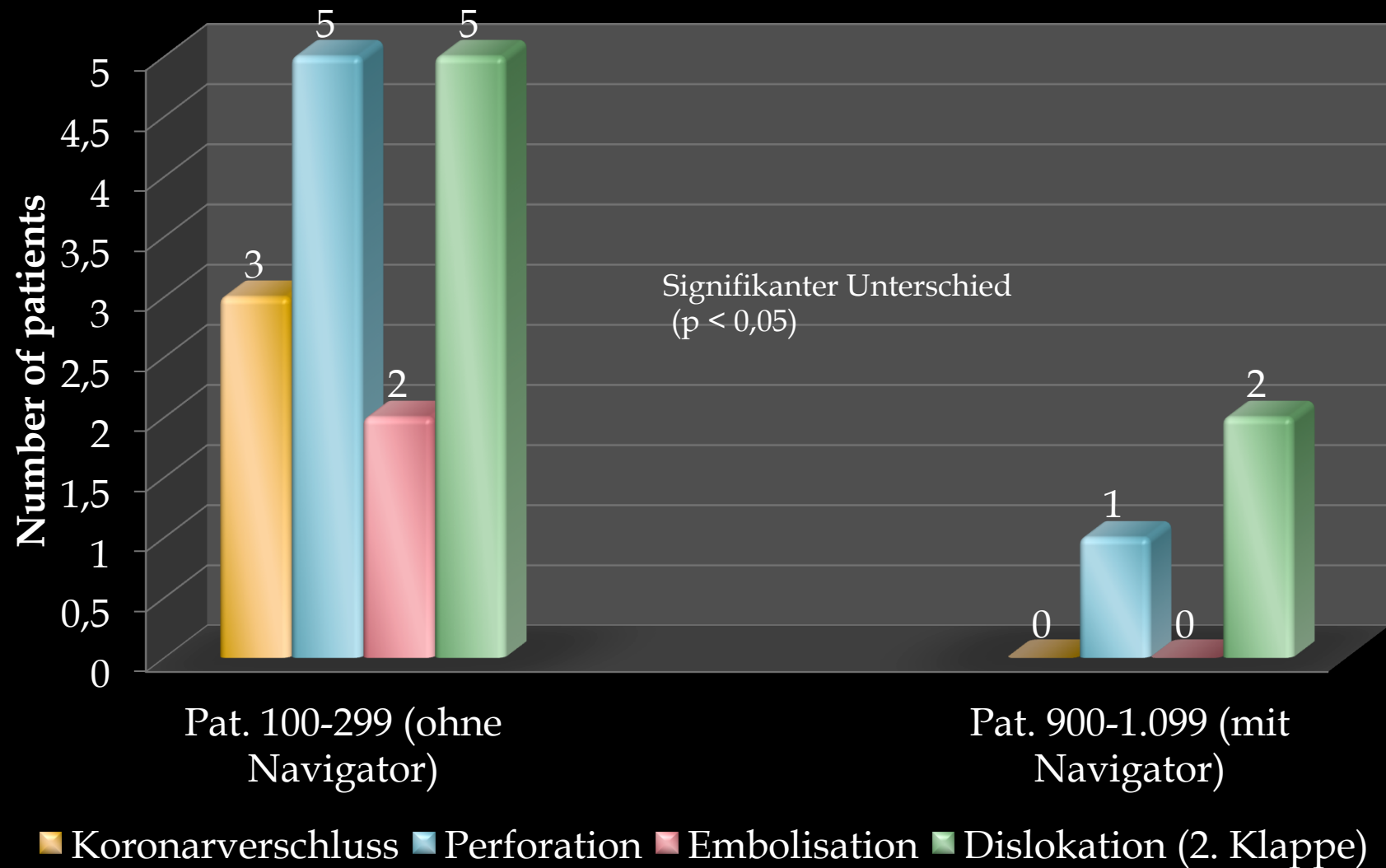
# Edwards Sapien 29 mm



# Surface Rendering



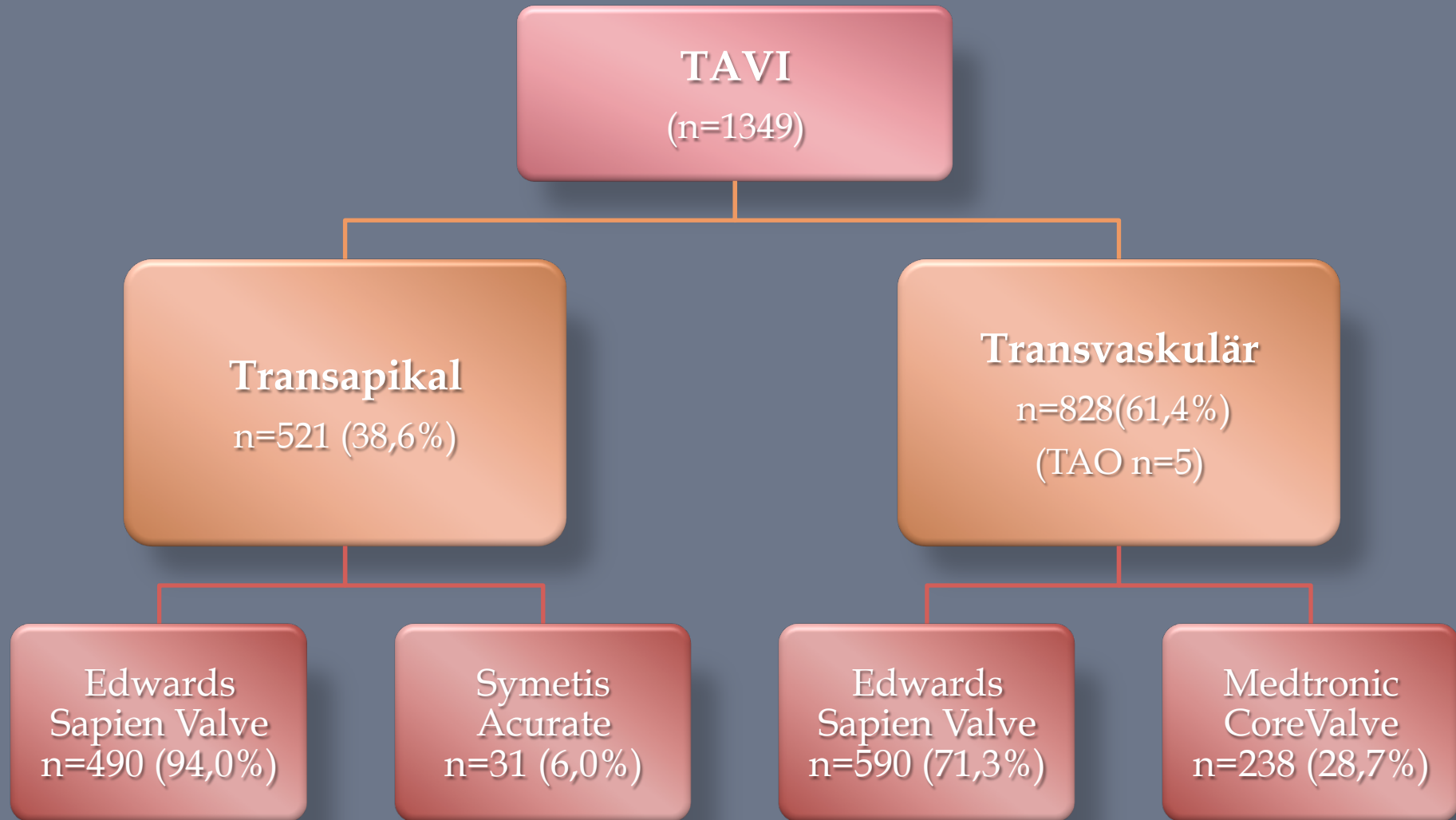
# Analyse rétrospective: Complications sévères



# TAVI: Résultats du TAVI Team Karlsruhe

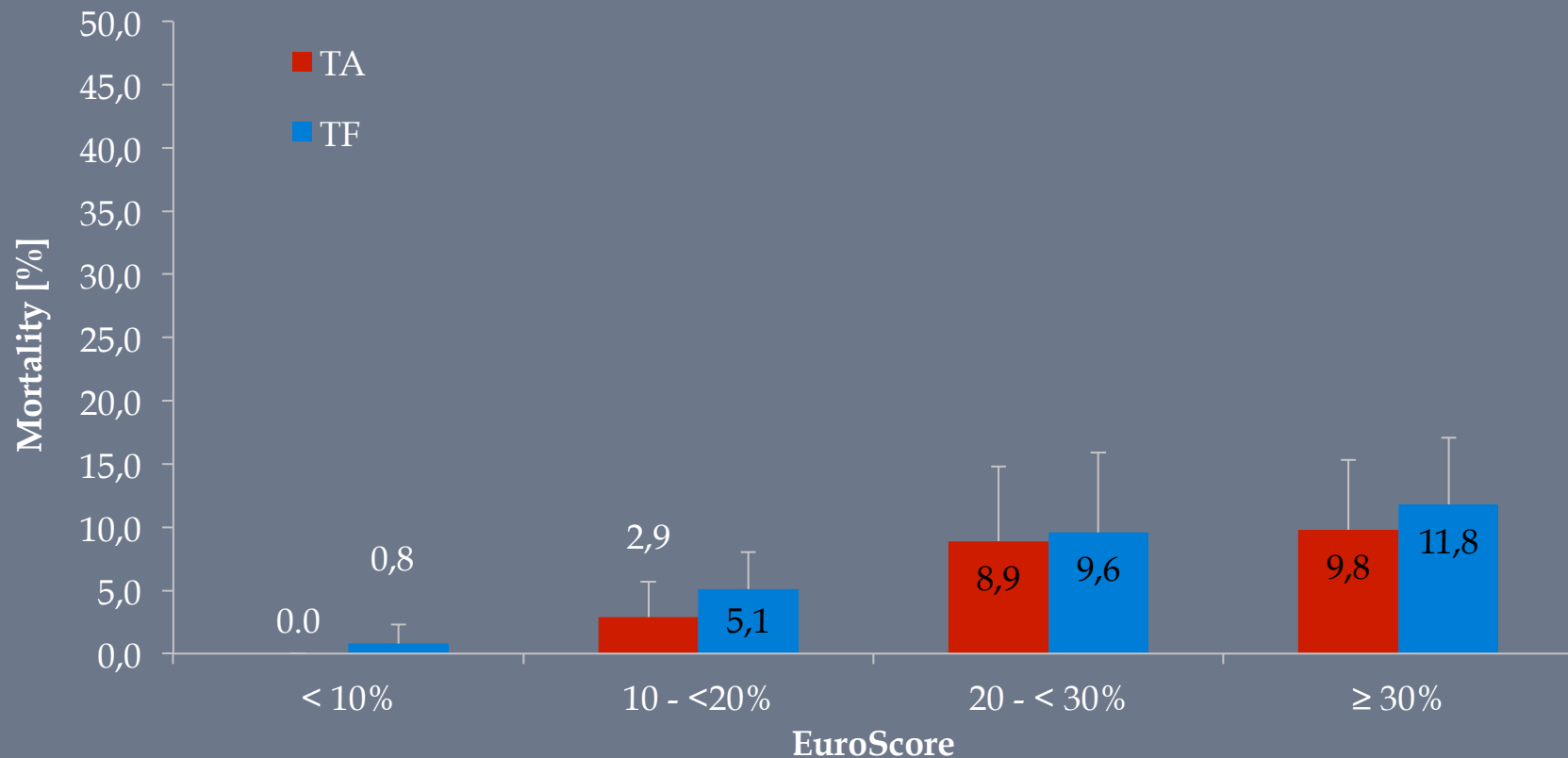
# TAVR Implantationen Karlsruhe

## 30. April 2008 – 22. März 2013



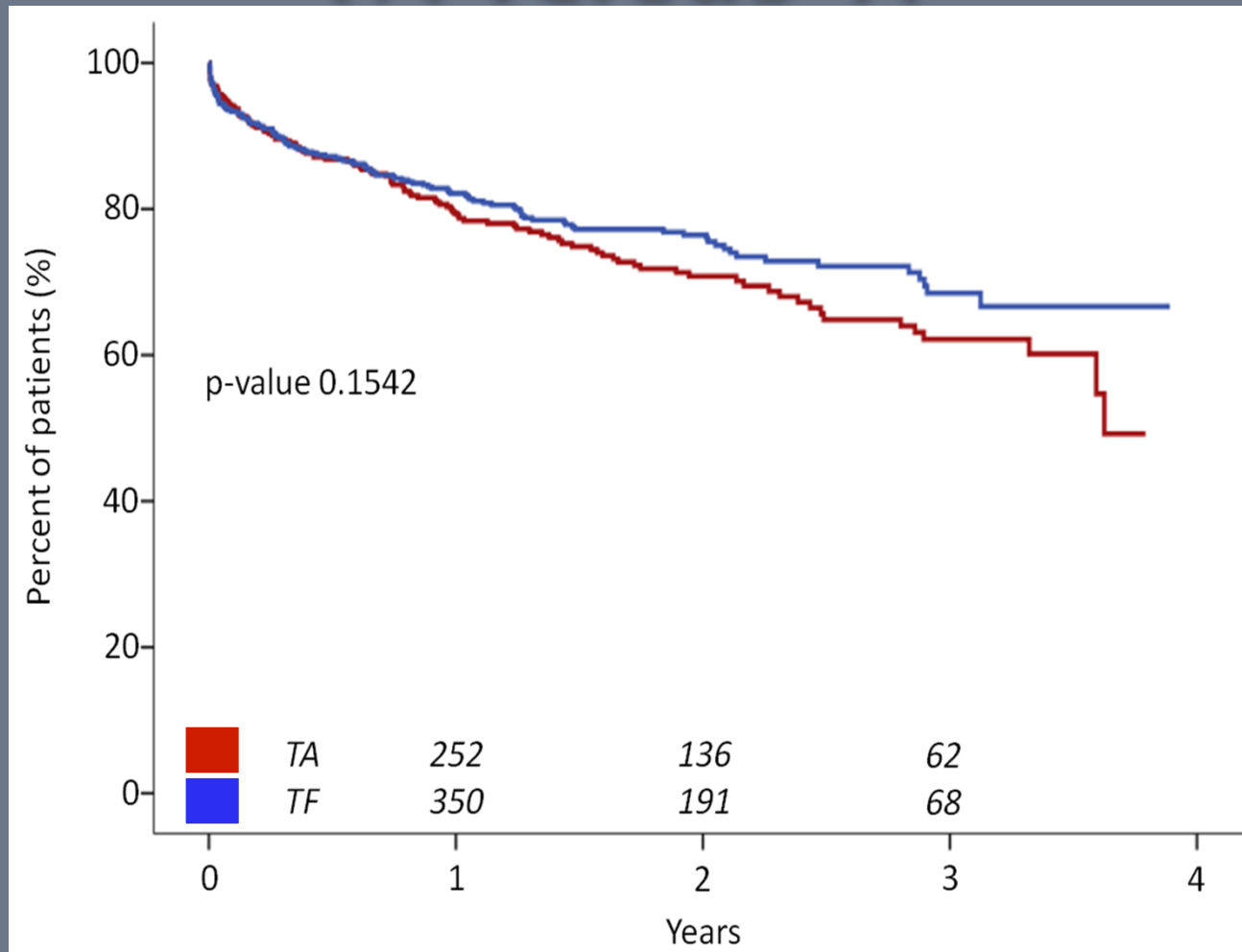
# Accès transvasculaire ou transapical?

# All Cause Mortalité (30 jours) TA versus TF



Schymik et al.: TAVI – 3 Years results of transapical versus transfemoral approach in a real world population of 1.000 patients with severe aortic stenosis

# TAVI: Survie après 3 ans TA versus TF

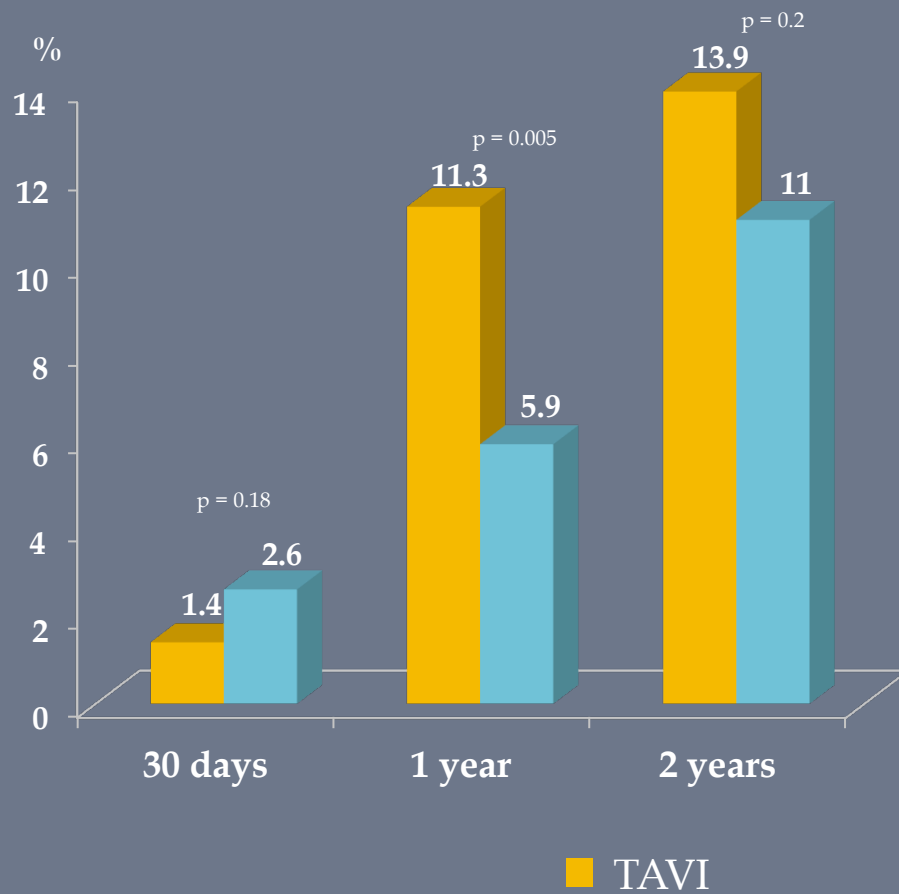


Schymik et al.: TAVI – 3 Years results of transapical versus transfemoral approach in a real world population of 1.000 patients with severe aortic stenosis

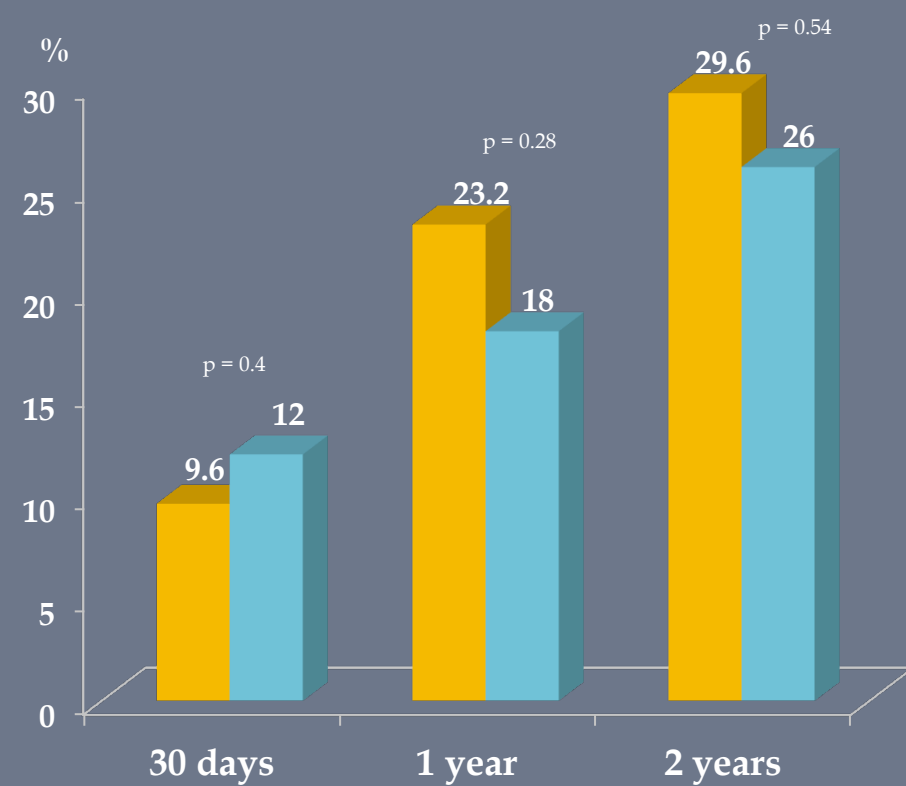
## Results V

# Mortality: TAVI vs. SAVR

EuroSCORE I < 15



EuroSCORE I ≥ 15



# Resultats principaux, Conclusions

Fondé sur les données «real world» de plus de 1300 patients à Karlsruhe

- ▣ TA vs TF: au sein d'un heart team expérimenté, la mortalité ne diffère pas d'une manière statistiquement significative entre l'accès transapical ou transfemoral
- ▣ TAVI vs. SAVR: La mortalité après 2 ans est plus importante parmi les patients TAVI que parmi les patients SAVR à cause de la comorbidité de base plus importante des patients.
- ▣ TAVI et SAVR: La mortalité après 30 jours ne diffère pas entre le groupe à risque intermédiaire (Euroscore < 15) et le groupe à risque élevé (Euroscore  $\geq$  15). La mortalité après 30 jours de 1.4 % pour le groupe TAVI à risque intermédiaire est modérée.
- ▣ Analyse multivariate
  - Prédicteurs de mortalité à long terme
    - ▣ EuroSCORE logistique
    - ▣ Insuffisance aortique après procédure
  - La mortalité TAVI ne diffère pas de la mortalité SAVR après 30 jours et 1 an

# Pose d'indication au sein du TAVI Team Karlsruhe

- ▣ Indications pour TAVI: évolution au cours des années passées
- ▣ Patients > 75 ans: TAVI comme option de traitement
- ▣ Décision prise conjointement (cardiologue, chirurgien cardiaque, patient) après discussion détaillée
  - Aspects cliniques (profil de risque individuel, indications particulières, frailty)
  - Aspects anatomiques (faisabilité après planning)
  - Desiderata, directives anticipées

# TAVI – Indications

- ▣ Indication certain
  - Patients considérés comme à haut risque
  - Indications spécifiques
- ▣ Indication relative
  - Patients à risque intermédiaire
  - Patients à risque bas
  - Redo
  - Patients âgés, fragiles
- ▣ Contre-indications
  - Patients à risque très élevé
  - Patients < 75 ans





## Klinik für Herzchirurgie Karlsruhe GmbH