Aus der Klinik für Herzchirurgie des Universitätsklinikums Bonn
(Ärztlicher Direktor: Prof. Dr. med. Farhad Bakhtiary)

UMHABILITATION

Modifikationen der Reimplantationstechnik bei Aortenwurzelaneurysmata

Fachgebiet Herzchirurgie

als

HABILITATIONSSCHRIFT

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PD Dr. med. Nadejda Monsefi
aus Abadan, Iran

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Inhaltsverzeichnis

1 Zugrunde liegende Originalarbeiten der kumulativen Habilitation

Der vorgelegten kumulativen Habilitationsschrift liegen folgende Originalarbeiten zugrunde:

Bakhtiary F*, **Monsefi N***, Herrmann E, Trendafilow M, Aybek T, Miskovic A, Moritz A.
Long-term results and cusp dynamics after aortic valve resuspension for aortic root aneurysms. Ann Thorac Surg 2011;91:478-84. *contributed equally. DOI:10.1016/j.athoracsur.2010.09.076.
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2 Einleitung

Veränderungen sowohl im Bereich der Aortenklappe als auch der Aortenwurzel, können zur Insuffizienz der Aortenklappe und strömungsphysikalischen Beeinträchtig des Flussverhaltens führen. Die Pathologie der strukturellen Elemente kann eine Erweiterung des Aortenanulus-Durchmessers, eine Segelveränderung (Perforation, Prolaps, Verschmelzung) oder eine Erweiterung des sinotubulären Durchmessers mit/ohne Erweiterung (Aneurysma) der Aorta ascendens sein. Jede dieser Pathologien kann das dynamische Gleichgewicht in der Aortenwurzel beeinflussen. Primäres Ziel der Therapie der Aorteninsuffizienz ist in der Regel die Rekonstruktion. Denn so kann auf eine lebenslange Antikoagulation, wie sie bei dem mechanischen Aortenklappenersatz benötigt wird, verzichtet werden. Liegt zusätzlich zu der pathologisch veränderten Klappe eine Erweiterung der Aorta ascendens vor, muss der aneurysmatische Bereich der Aorta mittels Prothese ersetzt werden. Erste Rekonstruktionstechniken der Aortenklappe wurden in den 1950er und 1960er Jahren vorgestellt [1, 2]. Einhergehend mit der technischen Verbesserung in der Echokardiographie konnte der Mechanismus der Aortenklappeninsuffizienz (AI) präziser diagnostiziert werden, um so eine erfolgreiche Rekonstruktion unter Beachtung geometrischer Verhältnisse der Aortenwurzel zu erlangen. Schließlich wird die endgültige Entscheidung, ob eine insuffiziente Aortenklappe rekonstruierbar ist, intraoperativ durch Inspektion getroffen. Hier ist die Segelbeschaffenheit von besonderer Bedeutung. Im Idealfall weist eine gut rekonstruierbare Klappe keine endokarditischen Auflagerungen oder destruierte Segel auf.

Folgende chirurgische Rekonstruktionsmöglichkeiten ergeben sich je nach Pathologie der Aortenklappe bzw. Aortenwurzel: Segelplikatur bei Prolaps eines Segels [3], eine Ringverstärkung (Anuloplastie) mittels externer Stabilisierung, zum Beispiel mit einem Ring nach Lansac [4] oder eine zirkuläre Naht mit Polytetrafluoräthylen (PTFE) [5].

Eine weitere Möglichkeit der Rekonstruktion bei Prolaps besteht in der triangulären Resektion oder Plikatur des prolabierenden Segels [6].

Nach wie vor gibt es Debatten darüber, was die beste Therapie für Patienten mit Aneurysma der Aorta ascendens und gleichzeitig bestehender Aortenklappeninsuffizienz ist. In den 90er Jahren wurde unter anderem die Rekonstruktion nach Tirone David vorgestellt, bei der der Aortenklappenanulus mit einzelnen Basisnähten zirkulär verstärkt wird und gleichzeitig die erweiterte Aorta ascendens durch eine Prothese ersetzt wird. Die Abgänge der Herzkranzgefäße werden zuvor aus der erweiterten Aorta herauspräpariert und in die Prothese reimplantiert. Das wird kurz als Reimplantation bezeichnet [7]. Dieser Innovation gegenüber stand der „Goldstandard" des Aortenwurzelersatzes mittels klappentragender Prothese (Bentall-Operation), bei der die Aortenklappe inklusive der Wurzel und der Aorta ascendens ersetzt wird. Beim Ersatz kommt entweder eine biologische oder mechanische,

klappentragende Prothese (Conduit) zum Einsatz [8]. Die prothesenassoziierten Komplikationen wie Endokarditis und Blutungen bei Dauerantikoagulation stellen nach wie vor ein diffiziles Problem dar.
Seit den 90er Jahren entwickelte sich die rekonstruktive Technik der Aortenwurzel rasant. Es kamen verschiedene Modifikationen der David-Technik hinzu, unter anderem mit dem Ziel der Optimierung der Segeldynamik und der Geometrie, die im Folgenden näher aufgeführt werden. Bei allen rekonstruktiven Techniken an der Aortenwurzel, die ein sehr komplexes Feld sind, ist ein wesentlicher Faktor, den man nicht unterschätzen sollte, die Erfahrung des Operateurs.

3 Themenstellung

In der vorliegenden Habilitationsschrift wurden folgende Themen bearbeitet:

- Untersuchung der Langzeitergebnisse und der Segeldynamik von Tirone David Operationen bei Patienten mit Aortenwurzelaneurysma. Klinische und echokardiographische Datenlage [12]

- Die Anwendung der modifizierten David Technik bei Patienten mit bikuspiden, undichten Aortenklappen durch Einsatz von Perikardflicken [16]

- Lanzeitergebnisse der David Technik bei Patienten mit akuter Typ A Dissektion der Aorta. Der Einsatz der David Technik in Notfallsituationen [22]

- Operateursbezogene Ergebnisse der David-Operation: Ein Vergleich der Operationsergebnisse zwischen Ausbilder und Auszubildenden in der Herzchirurgie [29]

4 Zusammenfassende Darstellung der Einzelarbeiten

4.1 Untersuchung der Langzeitergebnisse und der Segeldynamik von Tirone David Operationen bei Patienten mit Aortenwurzelaneurysma

Die ursprüngliche Reimplantationstechnik nach David war und bleibt weiterhin eine Innovation in der Herzchirurgie, da durch die Rekonstruktion eine undichte trikuspide Aortenklappe repariert und eine aneurysmatische Aorta mittels Rohrprothese ersetzt wird [7]. Wie in jeder neuen Errungenschaft steckt auch in der David-Methode eine kleine Schwäche: Die Segel der Aortenklappe, die sich nach der Rekonstruktion in einer Rohrprothese befinden, berühren beim Öffnungs- und Schließvorgang der

Aortenklappe jedes Mal die Prothesenwand und sind durch die Reibung der Flächen gegeneinander einem erhöhten physikalischen Stress ausgesetzt, der in einer normalen Aortenwand nicht vorliegt [9]. Seit Einführung der Aortenklappenrekonstruktion kam es zu interessanten Lösungsvorschlägen: De Paulis entwickelte 2001 eine neue Prothese mit einer Wölbung im Anfangsteil, die den Sinus Valsalva der Aorta ähnelte, sodass die Aortenklappensegel die Prothesenwand beim Öffnungs- und Schließvorgang nicht mehr berührten [9]. In unserer Klinik wurde 2005 die Pseudosinus-Technik vorgestellt, bei der die Basis der Rohrprothese durch drei Raffnähte (je 5 mm greifende dreiecksförmige Nähte) geformt wurde (s. Abb. 1B), um eine physiologischere Form (ähnlich der nativen Aorta) der Rohrprothese zu schaffen [10]. Es konnte gezeigt werden, dass die Öffnungsgeschwindigkeit der Aortenklappensegel geringer war als bei der Standard-David-Technik [10], was einen geringeren mechanischen Stress auf die Segel bedeutete. In den Folgejahren wurde eine weitere Modifikation entwickelt, bei der drei zusätzliche Raffnähte an der Rohrprothese auf Höhe der Kommissuren gesetzt wurden, um eine physiologischere Form der Prothese zu schaffen. Diese ähnelten der Sinus Valsalva , der sogenannten Neosinus-Modifikation der David-Operation (s. Abb. 1C) [11]. Die Geometrie der Aortenwurzel konnte so bewahrt werden. Die Fragestellung der ersten Arbeit [12] war der Vergleich verschiedener David-Modifikationen, die im Hinblick auf die Segeldynamik in unserer Klinik entwickelt wurden. Die retrospektive und prospektive Erfassung der klinischen und echokardiographischen Langzeitergebnisse der Patienten, die sich von 1996 bis 2009 einer David-Operation unterzogen haben, war Teil der Arbeit. Bei 151 Patienten mit einem Durchschnittsalter von 59±13 Jahren wurde in dem o.g. Zeitraum die David-Operation durchgeführt. Die Majorität (90%) der Patienten hatte eine mittelgradige oder schwere Aortenklappeninsuffizienz. Der Durchmesser der Aorta ascendens lag im Schnitt bei 6,0 cm. Die Standard-David-Operation wurde bei 54 Patienten (36%), die Pseudosinus-Modifikation bei 42 Patienten (28%) und die Neosinus-Modifikation bei 55 Patienten (36%) angewandt. Ein zusätzlicher Teilbogen oder Aortenbogeneingriff wurde bei 59 Patienten durchgeführt (39%). Begleitend erhielten 28 Patienten (19%) eine aortokoronare Bypassoperation und 7 Patienten (5%) eine Mitralklappenrekonstruktion. Es zeigten sich keine signifikanten Unterschiede perioperativer Ergebnisse der Patienten mit unterschiedlicher David-Modifikation. Die im-Krankenhaus Mortalität betrug 3,9%. Die echokardiographischen Untersuchungen im mittleren Nachuntersuchungszeitraum von fünf Jahren zeigten bei der Mehrheit der Patienten eine unauffällige Klappenfunktion. Lediglich 6% der Patienten hatten eine AI Grad 2 und 2% eine AI Grad 3. Das 10-Jahres-Überleben betrug im gesamten Kollektiv 65%. Die 10-Jahres-Freiheit von Reoperation betrug 90%, was den in der Literatur beschriebenen Daten anderer Kliniken entspricht [13, 14]. Unter den reoperierten Patienten waren keine mit Neosinus-Modifikation. Eine echokardiographische Subgruppenanalyse der verschiedenen Modifikationen zeigte interessante Beobachtungen: Betrachtet man die Segeldynamikergebnisse, fällt auf, dass die Öffnungsgeschwindigkeit (VOV = valve opening velocity) der Aortenklappensegel in der Neosinus-Gruppe (48,4±10,7 cm/sec) deutlich geringer war als in der Pseudosinus-Gruppe (56,4 ±21,1 cm/sec), p=0,11 und der Standard-David-Gruppe (71,7±10 cm/sec), p<0,001. Der Unterschied der Öffnungsgeschwindigkeiten zwischen Pseudosinus und Standard-David-Gruppe war ebenfalls signifikant (p=0,008). Dies unterstützt frühere Beobachtungen unserer Arbeitsgruppe, die damals altersgleiche Patienten mit normaler Aortenwurzel verglichen [10]. Die Ergebnisse der Segeldynamik erhärten die Theorie, dass durch Schaffung einer Sinusformation (Neosinus) an der Rohrprothese der Stress der Aortenklappensegel durch niedrigere Öffnungsgeschwindigkeit reduziert wird und sich dem Öffnungsgeschwindigkeitswert der Aortenklappe eines gesunden Menschen (Kontrollgruppe, mit VOV 28±1,3 cm/sec) annähert.

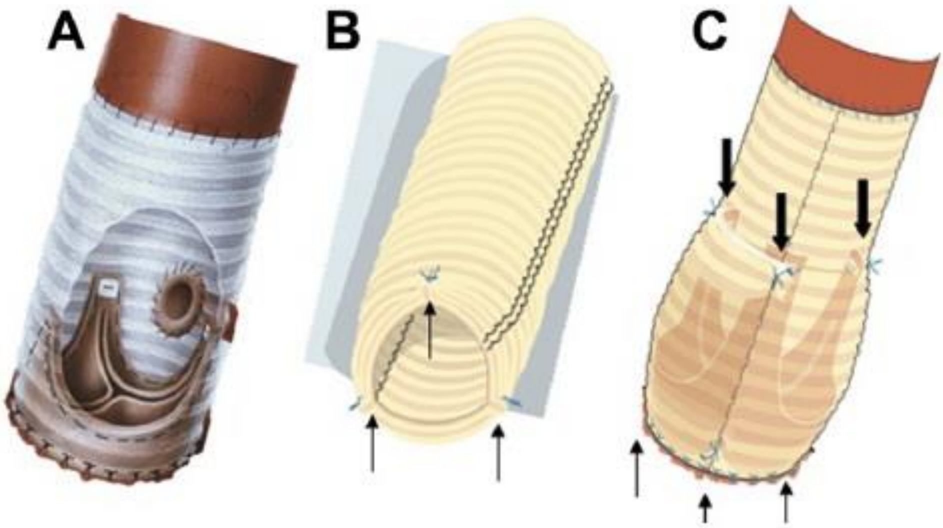

Abbildung 1: *A: Standard David-Technik; B: Pseudosinus-Technik; die drei Pfeile deuten auf die Raffnähte an der Prothesenbasis; C: Neosinus-Technik; die drei dick markierten Pfeile deuten auf die drei zusätzlichen Raffnähte an der Prothese in Höhe der Kommissuren [12].*

4.2 Die Anwendung der modifizierten David-Technik bei Patienten mit bikuspiden, undichten Aortenklappen durch Einsatz von Perikardflicken

Die bikuspide Anomalie der Aortenklappe geht häufig mit einem Prolaps des kongenital fusionierten Segels oder einer anulären Dilatation einher [15]. Bereits die präoperative Echokardiographie kann durch Analyse der Komponenten, Wurzel und Klappe, die Planung der Operation erleichtern. Schließlich wird die endgültige Entscheidung zur Rekonstruktion intraoperativ bei Inspektion der Aortenklappe getroffen. Hier können Messinstrumente wie eine Schublehre (Caliper) zur Bestimmung der effektiven Höhe u.a. eingesetzt werden, um einen Segelprolaps (effektive Taschenhöhe < 10 mm) zu verifizieren [16]. Im Grunde genommen ist die Rekonstruktion der bikuspiden ähnlich der trikuspiden Klappe, je nachdem, welche Komponenten betroffen sind. Die David-Prozedur wurde anfangs für die Rekonstruktion von trikuspiden Aortenklappen beschrieben [7]. Die Thematik der zweiten Arbeit [17] handelt vom Einsatz von autologen Perikardflicken zur Rekonstruktion bikuspider Aortenklappen im Rahmen der David-Operation: Im Zeitraum 1999 bis 2007 unterzogen sich 14

Patienten mit bikuspider Aortenklappe einer David-Operation. Klinische und echokardiographische Daten wurden retrospektiv und prospektiv ausgewertet. Das Durchschnittsalter betrug 58±5 Jahre. Etwa 79% der Patienten hatten eine mittelschwere bis schwere Aortenklappeninsuffizienz. Der Diameter der Aorta ascendens betrug im Schnitt 4,8±1,5 cm. Intraoperativ wurde bei Vorliegen einer zarten Segelstruktur die endgültige Indikation zur Reimplantationstechnik nach David getroffen. Die Basis der Prothese wurde leicht angeschrägt, um sich dem unebenen Anulus, wie sie bei bikuspiden Klappen häufig vorkommt, anzupassen [17]. Wie bei der David-Operation erfolgten die üblichen Schritte wie Freipräparation der Aortenwurzel, Exzision der Sinus mit Belassen eines ca. 5 mm breiten Saumes, Exzision der Koronarostien als „button“, Setzen von subanulären filzarmierten U-Nähten, die später durch die Gefäßprothese geführt und geknotet wurden [7]. Die Modifikation der David-Methode bestand darin, zunächst die mediane Raphe zu mobilisieren und ggf. verdicktes Gewebe davon zu resezieren. Danach wurde ein vorbereitetes Stück Perikardflicken (autolog, halbmondförmig zugeschnitten), das vorher 10 Minuten in 0,6 %iger Glutharaldehyd Lösung eingelegt wurde, an den freien Rand des fusionierten Segels fortlaufend angenäht (s. Abb. 2). Schließlich wurden die Kommissuren in der Prothese mit U-Nähten fixiert und der Saum der Sinus fortlaufend an die Prothese genäht. Die Koronarostien wurden dann in die Prothese reimplantiert und der distale Teil der Prothese an die Aorta anastomosiert. In dieser Arbeit wurde bei 65% der Patienten zusätzlich ein Bogenersatz bei aneurysmatischer Aorta durchgeführt. Perioperativ gab es keine Reoperation an der Aortenklappe. Die im-Krankenhausmortalität betrug null. Zum Zeitpunkt der Entlassung hatten alle Patienten entweder keine oder maximal eine triviale AI, was sich auch im mittleren Nachuntersuchungszeitraum bestätigte. Es konnten keine klappenbezogenen Komplikationen beobachtet werden. In großen klinischen Studien konnten ebenfalls sehr gute Resultate der rekonstruierten, bikuspiden Aortenklappen im Kurzzeitverlauf präsentiert werden [18, 19]. Jedoch zeigen publizierte Langzeitdaten eine relevante Reoperationsrate nach fünf Jahren [19, 20]. Zusammenfassend kann man sagen, dass die modifizierte David-Operation mit der Perikardpatchaugmentation bei der bikuspiden Klappe Sicherheit in der Stabilität bietet und klappenbezogene Komplikationen in dieser Arbeit nicht zu beobachten waren. Jedoch muss man die Daten im Langzeitverlauf abwarten.

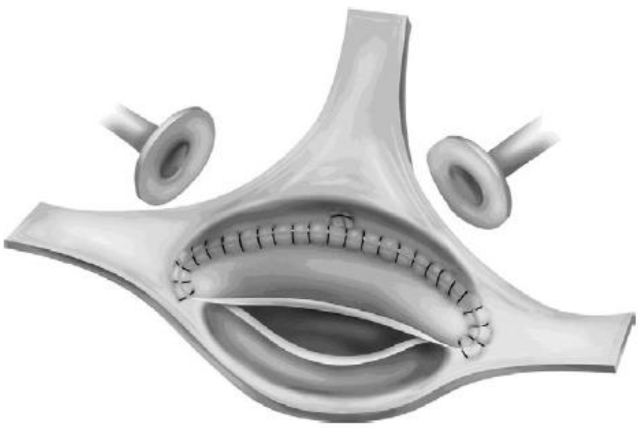

Abbildung 2: *Der autologe Perikardflicken ist am freien Rand des fusionierten Segels fortlaufend angenäht [12].*

4.3 Lanzeitergebnisse der David-Technik bei Patienten mit akuter Typ A Dissektion der Aorta. Der Einsatz der David-Technik in Notfallsituationen

Die akute Typ A Dissektion führt - unbehandelt - in ca. 50% der Fälle innerhalb von 48 Stunden nach Symptombeginn zum Tod [21]. Eine begleitende relevante Aortenklappeninsuffizienz oder eine Ausweitung der Dissektion bis in den Wurzelbereich erfordert fast immer einen Aortenwurzelersatz, zum Beispiel mittels Conduit [8]. Die David-Operation stellt hier eine mögliche Indikation dar, wenn der Patient in stabilem Zustand und jung ist und ein erfahrenes Operations-Team die Prozedur durchführt. In dieser dritten Arbeit [22] wurde die Thematik behandelt, wie die klinischen und echokardiographischen Langzeitdaten von Patienten sind, die im Rahmen einer akuten Typ A Dissektion zwischen 1996 und 2011 eine modifizierte David-Operation in der Herzchirurgie des Universitätsklinikums Frankfurt erhalten haben. Hierzu wurden die Daten von 23 Patienten analysiert. Das Durchschnittsalter des Kollektivs betrug 49±15 Jahre, und bei 87% der Patienten lag eine mittelschwere bis schwere Aortenklappeninsuffizienz vor. Nach orientierender transösophagealer Echokardiographie erfolgte der endgültige Entschluss zur David-Operation bei der Inspektion der Aortenklappe, die eine zarte Segelstruktur aufweisen sollte. Die standardisierte Vorgehensweise unserer Klinik in Bezug auf Kanülierung, Perfusion und Temperaturmanagement bei Eingriffen am Aortenbogen ist in vorangegangenen Arbeiten vorgestellt worden. Dabei wurde die Kombination aus milder Hypothermie, mit selektiv antegrader Hirnperfusion über die rechte Arteria axillaris als günstig für das perioperative Outcome identifiziert [23, 24]. Von den 23 David-Eingriffen wurde in 20 Fällen (87%) ein Teilbogen oder kompletter Bogenersatz durchgeführt. Die Neosinus-Modifikation der David-Operation [11] wurde in 39% der Fälle durchgeführt. Die 30-Tage-Mortalität betrug null. Perioperativ erlitt nur ein Patient einen Schlaganfall. Zum Zeitpunkt der Entlassung zeigten alle Patienten eine regelrechte Aortenklappenfunktion ohne bzw. mit trivialer Insuffizienz. Auch die Langzeitdaten (mittleres Follow up 7,7±3 Jahre) waren akzeptabel. Das 10-Jahres-Überleben war 88%, und die 10-Jahres-Freiheit von Reoperation betrug 81%. Die Rate an neurologischen Ereignissen (Schlaganfall) betrug 0,6%/pt-yr. In zwei Fällen (1,1%/pt-yr) traten Blutungskomplikationen auf (nicht antikoagulationsbezogen). Nur zwei Patienten hatten eine Aortenklappeninsuffizienz Grad 2. Die Mehrzahl der Patienten (74%) befand sich im New York Heart Association (NYHA) Stadium I bzw. 26% in NYHA Klasse II. Zusammenfassend kann man sagen, dass die 10-Jahres-Überlebensrate dieses Kollektivs mit der anderer David-Serien vergleichbar ist, die zwischen 83% und 92% variiert [13, 14]. Die linearisierte Rate von Schlaganfall und Tod betrug in unserem Kollektiv 2,8%/pt-yr, was vergleichbar ist mit den publizierten Bentall-Daten von Dr. Etz und Mitarbeitern (5,6%/pt-yr) [25]. Auch die linearisierte Blutungsrate unserer Serie mit 1,1%/pt-yr liegt im Rahmen; als Vergleich hierzu ist die einer anderen großen Bentall-Serie mit 1,8%/pt-yr zu erwähnen [26]. Hinsichtlich der niedrigen klappenbezogenen Komplikationen unseres Kollektivs ist in der Zusammenschau die David-Operation eine mögliche Option, um selektierte, junge Patienten mit Typ A Dissektion und begleitender Aortenklappeninsuffizienz zu behandeln. Ein erfahrenes Operations-Team und ein stabiler Zustand des Patienten sind in diesen Notfall-Operationen unabdingbar.

4.4 Operateursbezogene Ergebnisse der David-Operation: Ein Vergleich der Operationsergebnisse zwischen Ausbilder und Auszubildenden in der Herzchirurgie

Die David-Prozedur, die eine komplexe, chirurgische Rekonstruktion ist, wird weltweit in vielen herzchirurgischen Zentren angewandt. Es stellt sich die Frage, inwieweit die Erfahrung des Operateurs in Bezug auf die postoperativen Ergebnisse und Aortenklappenfunktion eine Rolle spielt. Dazu gibt es kaum Literatur in der Disziplin Herzchirurgie. Es existieren lediglich Studien, die die postoperativen Ergebnisse bei laparoskopischen Eingriffen und Hüftoperationen beschreiben [27, 28]. Die Ergebnisse der modifizierten David-Technik (von 1991 bis 2011) in der Uniklinik Frankfurt wurden in dieser vierten Arbeit [29] näher untersucht. Dabei wurde folgender Aspekt berücksichtigt: Es wurden die klinischen und echokardiographischen Ergebnisse retrospektiv und prospektiv im Langzeit Follow up zwischen zwei Gruppen verglichen. In Gruppe 1 (n=130) befanden sich die Patienten, die vom Ausbilder selbst oder von erfahrenen Operateuren unter seiner Aufsicht operiert wurden. Die Patienten, die in Gruppe 2 (n=79) waren, wurden von erfahrenen Operateuren ohne Aufsicht des Ausbilders operiert. Alle erfahrenen Operateure wurden primär vom Ausbilder geschult. Um die Unterschiede der präoperativen Parameter zwischen den zwei Gruppen zu minimieren, wurde ein „propensity matching“ durchgeführt, sodass in jeder Gruppe jeweils 68 Patienten mit vergleichbaren Voraussetzungen verblieben. Das Durchschnittsalter betrug 61±12 Jahre in Gruppe 1 und 61±13 Jahre in Gruppe 2. Auch hinsichtlich Geschlecht, Alter und Anzahl der Typ A Dissektionen gab es keine signifikanten Unterschiede zwischen den beiden Gruppen. Die perioperativen Ergebnisse zeigten keine signifikanten Unterschiede hinsichtlich angewandten Begleitprozeduren wie aortocoronare Bypassoperation (35% in Gruppe 1 vs. 36% in Gruppe 2, p=0,9), Segelplikatur (65% vs. 50%, p=0,1) oder Klemmzeit (143±36 min vs. 150±32 min, p=0,2). Die im-Krankenhausmortalität betrug 3% bzw. 4% (p=0,9). Was die chirurgischen Prozeduren betrifft, fiel auf, dass die Anzahl der Neosinus-Modifikationen in Gruppe 1 (n=37) signifikant größer waren als in Gruppe 2 (n=18), p=0,001. Die Pseudosinus-Technik war in beiden Gruppen ähnlich verteilt (n=15 bzw. n=18, p=0,7) und die Standard-David-Prozedur wurde häufiger in Gruppe 2 (n=32) im Vergleich zu Gruppe 1 (n=16), p=0,01, durchgeführt. Zum Zeitpunkt der Entlassung hatten nur drei Patienten aus Gruppe 2 (5%) eine Aortenklappeninsuffizienz Grad 2. Alle anderen Patienten aus beiden Gruppen hatten keine bzw. eine triviale Aortenklappeninsuffizienz (p=0,2). Anhand der Daten kann man zusammenfassen, dass es keine signifikanten Unterschiede zwischen den zwei Gruppen im postoperativen Outcome gab. Betrachtet man die Langzeitdaten (mittleres Follow up 5±4 Jahre) der zwei Gruppen (nach „propensity matching“) gab es keine signifikanten Unterschiede hinsichtlich 9-Jahres-Überleben (78% in Gruppe 1 bzw. 76% in Gruppe 2, p=0,3). Die neurologischen Ereignisse im Follow up waren in beiden Gruppen ähnlich verteilt (n=1 in Gruppe 1 und n=4 in Gruppe 2, p=0,13). Ebenfalls nicht signifikant war die Anzahl der Endokarditiden (n=3 vs. n=1, p=0,45). Nur ein Patient (aus Gruppe 2) hatte eine Blutungskomplikation (gastrointestinal). Die linearisierte Rate an neurologischen Ereignissen (Schlaganfall) betrug insgesamt 0,42%/pt-yr. Zwischen den zwei Gruppen gab es keinen signifikanten Unterschied (n=1 vs. n=4, p=0,13). Die 9-Jahres-Freiheit von Reoperation betrug in Gruppe 1 95% und in Gruppe 2 88%, p=0,04. Von den reoperierten Patienten hatte zum Zeitpunkt der Entlassung aus dem Krankenhaus keiner eine Aortenklappeninsuffizienz > 1°. Der Grund für Reoperationen an der Aortenklappe waren Endokarditiden in Gruppe 1 und Prolaps der Segel bzw. Segelperforation in Gruppe 2. Zum Zeitpunkt der letzten Nachuntersuchung hatten sechs Patienten aus Gruppe 2 eine Aortenklappeninsuffizienz Grad 2. In Gruppe 1 war kein Patient mit AI Grad 2 zu beobachten (p=0,03). Die 10-Jahres-Freiheit von Reoperation und Aortenklappeninsuffizienz $\geq$ 2° fiel zugunsten von Gruppe 1 aus (s. Abb. 3). Zusammenfassend kann man aus dieser Arbeit schließen, dass die David-Ergebnisse des Ausbilders signifikant besser sind als die der Auszubildenden. Das betrifft die Reoperationsfreiheit ebenso wie die Aortenklappeninsuffizienz im Langzeit Follow up. Aber im Vergleich zu der 9-Jahres-Reoperationsfreiheit von anderen Zentren (81-98%) [13] sind die Ergebnisse der Auszubildenden immer noch im Rahmen (88% in Gruppe 2). Insgesamt sind die klappenbezogenen Komplikationen in beiden Gruppen niedrig, unabhängig von der Erfahrung der Operateure. Trotzdem ist der Grundgedanke berechtigt, gerade solche komplexen Operationen nur sehr erfahrenen Operateuren oder Zentren mit langjähriger Erfahrung zu überlassen.

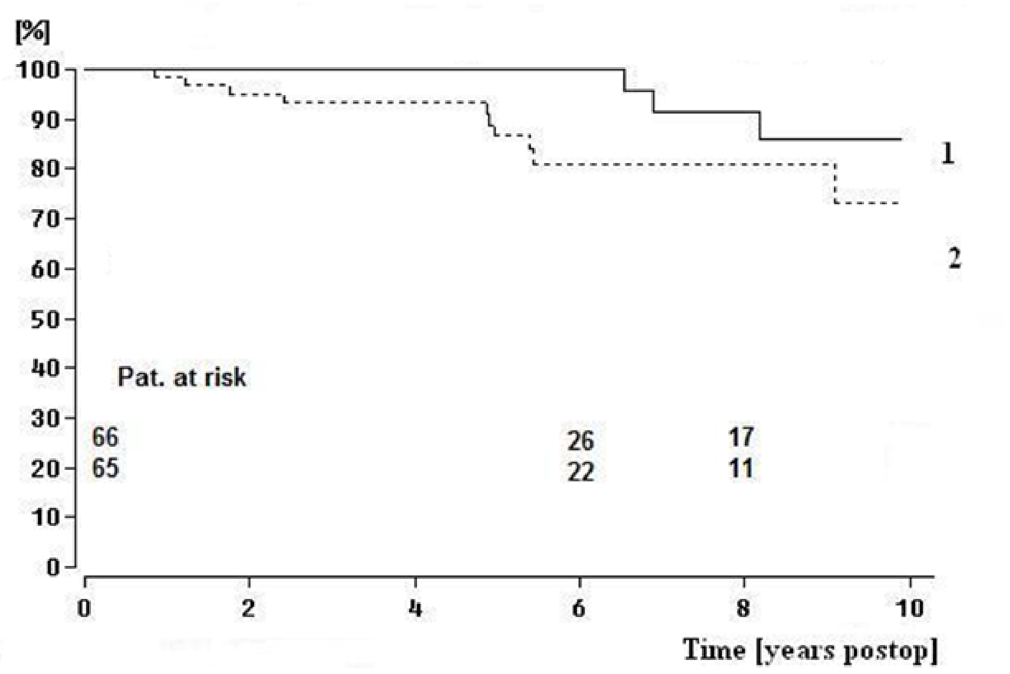

Abbildung 3: *Kaplan-Meier Kurve für Freiheit von Reoperation und Aortenklappeninsuffizienz $\geq$2° nach „propensity matching“. 1: Gruppe 1; 2: Gruppe 2. Log rank Test zwischen 1 und 2: p= 0,02 [29].*

5 Zusammenfassung

Die Therapie der Aorteninsuffizienz liegt vorzugsweise in der Rekonstruktion, da so auf eine lebenslange Antikoagulation, wie sie bei dem mechanischen Aortenklappenersatz benötigt wird, verzichtet werden kann [15]. Auch nachteilige hämatologische Veränderungen können so umgangen werden: Wir konnten in einer klinischen Studie zeigen, dass im mittleren Nachuntersuchungszeitraum von 4±3 bzw. 6±3 Jahren bei David-operierten Patienten geringere Anzeichen für Hämolyse zu verzeichnen waren als bei Patienten mit mechanischem Conduit. Die signifikanten Unterschiede zwischen den zwei Gruppen waren in den Parametern Lactatdehydrogenase und Haptoglobin zu beobachten [30].
Es ist ebenso bekannt, dass die Häufigkeit klappenassoziierter Komplikationen bei allen Formen der Aortenklappenrekonstruktion gering ist [31]. Mit einem systematischen Vorgehen gelingt es, die zugrundeliegende Pathologie zu identifizieren und korrigieren [15]. Die David-Technik bietet eine gute Lösung bei zugrundeliegender Aortenwurzeldilatation, da der Anulus verstärkt wird, um eine erneute Erweiterung im Verlauf zu verhindern. Seit den 90er Jahren wurde die David-Technik variiert. Mit der Entwicklung der Neosinus-Technik [11] mit drei zusätzlichen Raffnähten an der Rohrprothese in Höhe der Kommissuren konnte anhand der Analyse der Segeldynamik gezeigt werden, dass eine weitere Reduktion der Öffnungsgeschwindigkeit der Aortenklappe erzielt wird [12]. Die Neosinus-Modifikation ähnelt optisch und geometrisch der Sinus Valsalva. Sie ist technisch einfach zu reproduzieren und kostengünstiger im Vergleich zur Valsalva-Prothese. Mit einer 10-Jahres-Freiheit von Reoperation von 90% sind die Ergebnisse der modifizierten David-Technik [12] akzeptabel und sind vergleichbar mit denen anderer Kliniken [13, 14]. Die Ergebnisse der David-Operation belegen, dass sie in routinierten Händen eine sehr gute Langzeit-Haltbarkeit hat [29]. Die Reoperationsrate ist vergleichbar mit der von publizierten Conduit-Eingriffen [25]. Reoperationsgründe sind meistens Endokarditiden oder Degenerationen, selten jedoch geometrische Veränderungen [29]. Das gilt auch für die schwierige Gruppe der Typ A Dissektionen [22] und für bikuspide Klappen [16], bei denen technische Modifikationen zur Optimierung der Geometrie notwendig sind. Insgesamt zeigen sich wenig klappenbezogene Komplikationen und auch Veränderungen im Blut, wie z.B. Hämolyse [30]. Es ist dennoch anzumerken, dass Zentren mit langjähriger Erfahrung solche komplexe Operationen durchführen sollten, um bestmöglichste Ergebnisse zu erzielen.

Im nachfolgenden Literaturverzeichnis sind die in die kumulative Habilitation eingehenden Originalarbeiten **hervorgehoben**.

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7 Anlage

Ausdrucke der Originalarbeiten

Long-Term Results and Cusp Dynamics After Aortic Valve Resuspension for Aortic Root Aneurysms

Farhad Bakhtiary, MD, PhD,* Nadejda Monsefi, MD,* Eva Herrmann, PhD, Maria Trendafilow, MD, Tayfun Aybek, MD, PhD, Aleksandra Miskovic, MD, and Anton Moritz, MD, PhD

Departments of Thoracic and Cardiovascular Surgery and Biomedical Statistics, Johann-Wolfgang-Goethe University, Frankfurt/Main, and Department of Cardiac Surgery, Leipzig Heart Centre, University of Leipzig, Leipzig, Germany

Background. **This study reports our 10-year experience with the David technique and technical modifications to create neosinuses.**

Methods. **From January 1996 to February 2009, the David procedure was performed in 151 consecutive patients in our department. Mean age was 59 ± 13 years (range, 22 to 78 years). All patients had ascending aortic aneurysm (mean diameter, 6.0 ± 1.1 cm); 59 patients had additional arch aneurysm. Fifty-dour patients underwent the standard David procedure, with a pseudosinus created in 42 patients (28%) and neosinuses in 55 patients (36%) by plicating the base and sinotubular junction of the tube graft. Patients were followed up prospectively and had echocardiography studies before discharge and at follow-up. Mean follow-up was 5 years (584 patient-years).**

Results. **There were 6 in-hospital and 16 late deaths. Reexploration for bleeding was necessary in 27 patients (17%). Three patients had perioperative neurologic events, and 2 patients experienced them during follow-up. Five patients required late aortic valve replacement. Cardiovascular events were the cause of late death in 6 patients. Valve gradients were low, with only 2 patients having significant valve incompetence remaining. Echocardiography results showed a more physiologic, reduced velocity of cusp movement in the neosinus group compared with the conventional technique.**

Conclusions. **Aortic valve resuspension is a durable procedure. Only 4.8% experienced a relevant valve dysfunction. Other valve-related complications were minimal, with three observed neurologic events and one endocarditis. Creation of the neosinus lead to more physiologic leaflet dynamics and facilitated geometric adaptation.**

(Ann Thorac Surg 2011;91:478–84)

Aneurysms of the aortic root are frequently associated with severe aortic valve incompetence, despite preserved leaflet structure [1, 2]. For many years composite graft replacement of the aortic valve and the proximal aorta was the standard procedure in these patients [2, 3]. David and associates [4–8] described an aortic valve-sparing procedure with resuspension of the valve within a prosthetic vascular graft in the early 1990s. The geometry of the aortic root and aortic valve is restored as originally described by reimplantation of the aortic valve in a cylindrical tube graft (David I). This procedure has been shown to be associated with certain drawbacks, particularly increased leaflet stress during opening and closing and possible abrasion of the leaflets as they touch the prosthetic wall [9, 10].

This study describes our long-term results and clinical experience with this technique and modifications by creating a pseudosinus and finally anatomically adapted neosinuses.

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*Doctors Bakhtiary and Monsefi contributed equally.

Address correspondence to Dr Bakhtiary, Department of Cardiac Surgery, Leipzig Heart Centre, University of Leipzig, Leipzig, Germany; e-mail: farhad@bakhtiary.de.

Patients and Methods

From January 1996 to February 2009, 151 consecutive patients (44 female, 107 male) with ascending aortic aneurysm and aortic valve insufficiency (AI) had replacement of the ascending aorta and resuspension of the aortic valve in our department. One hundred thirty-six patients presented with moderate or severe aortic incompetence. In 14 cases we modified the David procedure for reconstruction of incompetent bicuspid aortic valves [11]. Mean age was 59 ± 13 years (range, 22 to 78 years). Six (4%) patients had Marfan syndrome. Table 1 contains patient characteristics.

The leaflet dynamics were examined in four groups: 10 patients with standard David technique, 10 with pseudosinus, 16 with neosinus technique, and 10 age-matched persons without cardiac disease with mean age of 59 ± 15 years.

The study was approved by the university ethics committee; individual consent for the study was waived.

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ADULT CARDIAC

Table 1. Patient Characteristics

Characteristic	Result
Number	151
Age (y)	59 ± 13, range (22–78)
Male	107
Female	44
Hypertension	86
Marfan syndrome	6
Aortic valve regurgitation ≥2°	136
Diameter of the ascending aorta (cm)	6.0 ± 11
Type A dissection	20

Operative Procedure

In an effort to improve reliability, three modifications of aortic valve-sparing operations were performed: reimplantation of the aortic valve in a polyethylene terephthalate (Hemashield, Maquet, Germany) graft as described by David and colleagues [5–8] in 54 patients (David I, Fig 1A), creation of a pseudosinus (Fig 1B) by plicating the Dacron graft at the base in 42 patients, or aortic root remodeling with creation of a neosinus (Fig 1C) in a "6-stitches technique" as described before in 55 patients [12, 13]. The decision to preserve the native aortic valve was made intraoperatively after root and valve leaflet inspection. The base of the aortic root was then dissected circumferentially for adequate exposure. After excision of the coronary buttons the sinuses of Valsalva were excised, leaving approximately 4 to 5 mm of aortic wall adjacent to the insertion line of the leaflets. In acute dissection, the wall layers of the aortic root were reconstructed at this point with gelatin-resorcin-formol surgical glue (Colle chirurgicale, Cardial, St Etienne, France) or by sutures. In 50 patients, leaflet prolapse was reconstructed with resection of the excess leaflet tissue and 5-0 continuous suture (Cardionyl, Peters Lab, Bobigny-Cedex, France), or later by central plication of the closing edge. Thirty-eight patients had single leaflet reconstruction, 8 patients had 2 leaflets reconstructed, and 4 patients had all 3 leaflets reconstructed.

We initially sized the grafts according to the formula (leaflet height in mm $\times$ 1.5) + 2 mm. The graft is slightly bevelled to account for the septal muscle extension at the commissure between the right and left coronary base. Transmural mattress sutures are placed just below the leaflet insertion to the aortic wall. These sutures are then passed through the graft and tied.

To avoid distortion of the right coronary cusp, the deepest or "central" stitch at the right sinus was placed supraannularly as the prosthesis cannot be brought down below the annulus owing to the septal muscle shelf [14].

The valve was resuspended with pledgeted polypropylene sutures above the commissures. Sinus wall remnants were fixed to the prostheses with 4-0 continuous mattress sutures. Coronary arteries were reimplanted as buttons.

To prevent the leaflets from touching the prosthesis and to compensate for the frequently observed second-

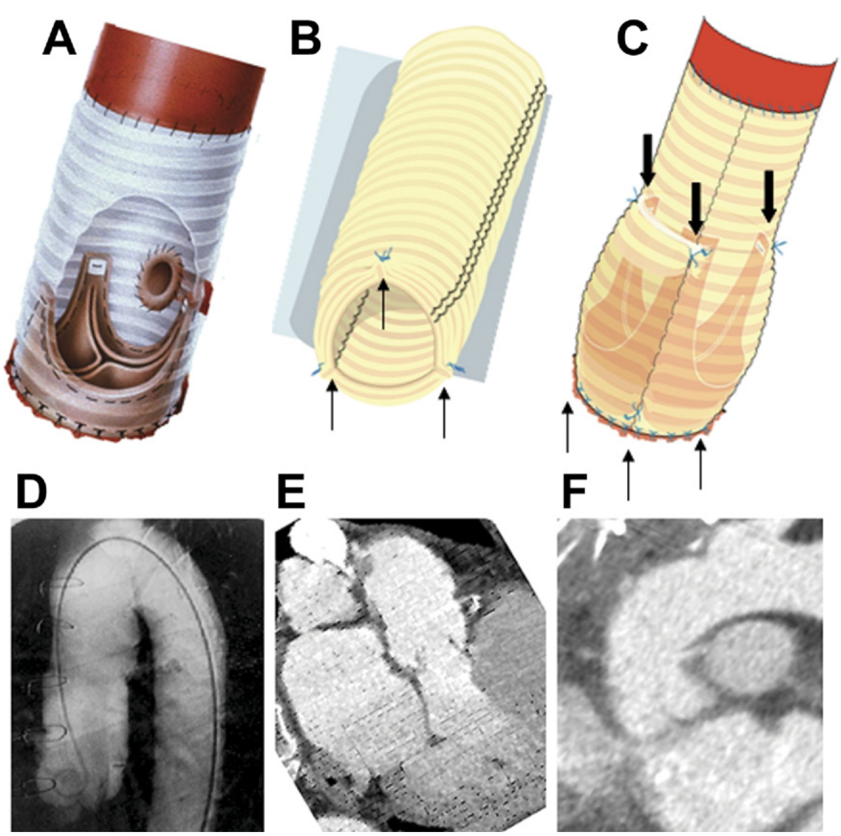

Fig 1. (A) Standard David technique. (B) Pseudosinus technique; arrows show three stitches (5-mm triangular bites) at the base of the prosthesis with 4-0 braided polyester sutures. (C) Neosinus technique; bold arrows show the additional three stitches (5-mm triangular bites) at the top of each commissure perpendicular to the lower edge of the prosthesis (light arrows). (D) Angiography (of the standard David technique). (E) Computed tomographic scan of the heart, pseudosinus technique. (F) Computed tomographic scan of the heart, neosinus technique.

ary elongation of the leaflet edges, a pseudosinus was created later in the series. For this we took a graft size with a diameter twice the leaflet height. In patients with a normal, nondilated annulus, graft size is calculated by the annular diameter, adding about 2 mm for aortic wall thickness and an additional 5 mm to create the pseudosinus. At the base of each commissure, 5-mm triangular bites were passed parallel and perpendicular to the lower edge of the prosthesis [13].

Lately neosinuses were shaped by plicating the base and the sinotubular junction of the graft with three 4-0 braided polyester sutures. At the base of each commissure, 5- to 7-mm bites are passed parallel to the lower edge of the prosthesis. The second bite of the same suture is passed perpendicularly to the first to catch 5 mm of prosthesis height. Placing three stitches at the base in such fashion reduces the diameter and local height of the base and creates a more physiologic protrusion of the graft. Bites for resuspension of the commissures are taken 5 to 7 mm wider at the prosthesis. This creates the anatomic diameter reduction of the sinotubular junction. Again, three 4-0 stitches are placed at the outside to reinforce the diameter reduction, and the perpendicular bites again reduce the height at the commissures to increase the bulge of the sinuses. Frequently a tubular segment of the sinotubular junction was created by plicating the prosthesis with three mattress stitches a few millimeters above the commissures.

Leaflet correction was performed after resuspension with the valve in the new geometric position to ensure sufficient coaptation with belly-shaped leaflets and to avoid prolapse.

In the case of bicuspid aortic valves the David procedure was modified. The raphe was mobilized, thickened closing edges of the leaflets were shaved, and a patch of glutaraldehyde- fixed autologous pericardium was fashioned and sewn to the free edge of the fused leaflet with a 5-0 Cardionyl running suture. The aortic graft was trimmed to match the displacement of the noncoronary base toward the left ventricular outflow tract. Sutures were passed through the aorta and the graft in the usual manner [11].

Table 2 contains all concomitant procedures and operative data.

Table 2. Perioperative Results and Surgical Procedures

Variable	Result
Neosinus/pseudosinus/standard	55/42/54
Isolated ascending aorta replacement	92
Ascending aorta + hemiarch replacement	45
Ascending aorta + complete arch replacement	9
Arch and elephant trunk	5
Concomitant procedures	
Coronary artery bypass grafting	28
ASD closure	3
Mitral valve repair	7
Tricuspid valve repair	3
Leaflet plication of the aortic valve	50
Perioperative data	
CPB time (min)	193 ± 41[a]
Myocardial ischemic time (min)	142 ± 30[a]
Intensive care unit stay (days)	2 ± 3
Ventilation time (h)	33 ± 18
Need for reexploration	27 (Neo 6, Pseudo 6, Std 15)
Temporary neurologic deficit	1 (Neo 1)
Permanent neurologic deficit	2 (Pseudo 1, Std 1)
In-hospital mortality	6 (3.9%) (Neo 1, Pseudo 1, Std 4)
Follow-up data	
Late mortality	16 (2.7%/pt-yr) (Neo 2, Pseudo 6, Std 4)
Endocarditis	1 (0.2%/pt-yr) (Pseudo 1)
Late neurologic events (stroke)	2 (0.34%/pt-yr) (Pseudo 1, Std 1)
Reoperation	5 (0.9%/pt-yr) (Pseudo 2, Std 3)
Valve failure	7 (1.3%/pt-yr) (Neo 1, Pseudo 2, Std 4)

[a] There were no significant differences among the three patient groups (neosinus/pseusodinus/standard).

ASD = atrial septum defect; CPB = cardiopulmonary bypass; Neo = neosinus; Pseudo = pseudosinus; pt-yr = patient-year; Std = standard.

Postoperative Evaluation and Management

Patients were contacted prospectively and invited for clinical and echocardiography evaluation. Patients who were not seen personally were contacted by letter or phone. Results of echocardiographies were then retrieved from referring cardiologists.

No oral anticoagulants were administered to the patients after operation. Use of platelet antiaggregating agents in the follow-up period was left to the discretion of the attending cardiologist.

Adequate function of the aortic valve was ascertained intraoperatively with transesophageal echocardiography after weaning from cardiopulmonary bypass. Transthoracic M-mode, two-dimensional, color-flow, and Doppler echocardiograms were obtained before discharge from the hospital and at follow-up (total follow-up was 584 patient-years, 5 years mean). Seven patients were lost to follow-up (95% complete). The severity of aortic regurgitation (AR) was measured using a modification of the method of Perry and colleagues [15], in which the ratio of the width of the jet of regurgitation to the diameter of the left ventricular outflow tract just below the level of the valve annulus is determined.

All data except those for cusp dynamics were acquired at discharge and at follow-up. Dynamic data were evaluated in the transthoracic echocardiography study of best quality during follow-up. This technique of measurement has been described before by our group [9, 12]. Briefly, the purpose of this additional study was to analyze any possible intermittent systolic contact of an

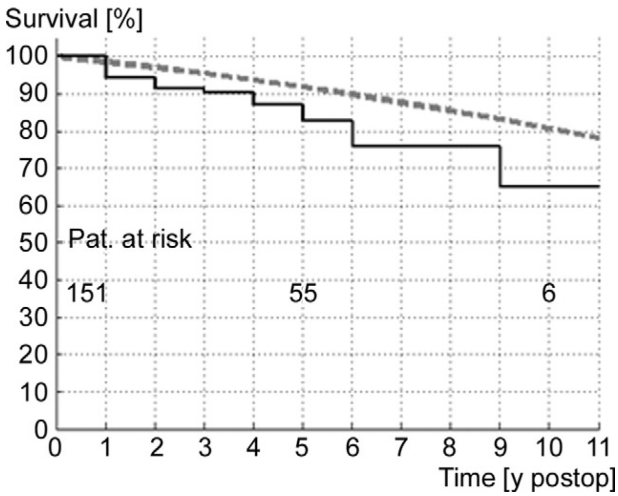

Fig 2. Kaplan-Meier curve for survival compared with an age- and sex-matched German population (dotted line). (Pat = patient; postop = postoperative.)

aortic cusp with the aortic wall, as well as monitoring the speed and dynamics of cusp opening and closing movements. Only views with the leaflet coaptation at the midline of the aortic root and a symmetric appearance of the valve motion were analyzed. All measurements were averaged from three cardiac cycles. The leaflet opening and closing characteristics using M-mode echocardiography were measured as follows: rapid valve opening and closing time and velocity, leaflet displacement after rapid valve opening and before rapid valve closing, and slow-closing leaflet displacement were determined [10]. Slow-closing leaflet displacement was calculated as $(D1 - D2)/D1 \times 100$, where D1 indicates the maximal leaflet displacement and D2, leaflet displacement before rapid valve closing. The leaflet dynamics were examined in four groups (10 patients with standard David technique, 10 with pseudosinus, 16 with neosinus, and 10 age-matched persons without cardiac disease with a mean age of 59 ± 15 years). The data obtained were transferred to an external computer (Power Macintosh G4 800 MHz; Apple, Inc, Cupertino, CA) and digitally analyzed (Echo Pac Software, Vingmed System Five; General Electric Medical Systems, Fairfield, CT).

Statistical Analysis

All statistical analyses were performed with the BIAS 9.05 software (Frankfurt, Germany). Categorical variables are expressed as frequencies. Continuous variables are expressed as mean ± standard deviation and were compared with age- and sex-matched German population. Variables describing the aortic valve function were compared with the Kruskal-Wallis test and corresponding post-hoc analysis. Long-term survival, freedom from reoperation, and freedom from moderate or severe AI were calculated according to Kaplan-Meier method. Perioperative mortality was defined as death within 30 days of operation. The mean follow-up time was 5 years (584 patient-years at total follow-up). Statistical significance was defined as a probability value less than 0.05. The follow-up was 95% completed.

Results

Operative Mortality and Morbidity

There were 6 in-hospital deaths: 2 patients died of low-output syndrome, 3 patients died of multiorgan failure, and 1 died of rupture of an abdominal aortic aneurysm. Three patients experienced postoperative neurologic events (1 a temporary neurologic deficit, 2 prolonged neurologic deficits) like critical illness polyneuropathy. Reexploration for bleeding was necessary in 27 patients (17%). Table 2 contains operative data and surgical procedures.

Late Morbidity and Mortality

There were 16 late deaths. Cardiovascular events were the cause of death in 3 patients: 1 patient died of cardiac decompensation owing to exsiccosis (dehydration) 6 years postoperatively, 1 died of sudden cardiac death 4 years postoperatively (without history of cardiomyopathy), and 1 died of myocardial infarction 2 years postoperatively. One patient died because of lung cancer 2 years postoperatively, 2 died of gastrointestinal bleeding 6 years postoperatively, and 1 of rupture of an abdominal aneurysm. One patient committed suicide at 2 years postoperatively. In 8 patients the cause of death was unknown.

Two patients (0.34%/patient-year) had late focal neurologic events with complete reversible neurologic impairment. Except for one case of endocarditis leading to reoperation, no other valve-related complications other than late dysfunction were observed.

At latest follow-up 112 patients were in New York Heart Association functional class I, 8 patients were in class II, and 2 patients in class III. The Kaplan-Meier curves for survival, freedom from reoperation, and relevant AI (AI ≥ 2°) are illustrated in Figures 2 and 3.

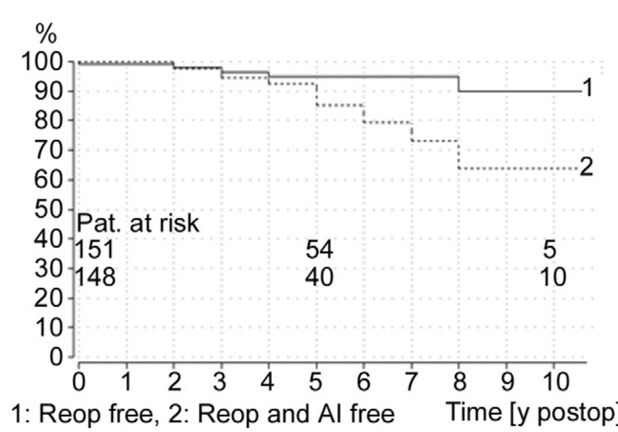

Fig 3. Kaplan-Meier curves of rates for freedom from reoperation (line 1; corresponding to 1 − cumulative incidence of first reoperation), and of rates for freedom from reoperation or aortic valve insufficiency (AI) ≥ 2° (2; corresponding to 1 − cumulative incidence of first occurrence of reoperation or moderate to severe aortic valve insufficiency).

Table 3. Echocardiographic Data

Variable	Preoperative (n = 151)	Postoperative (n = 148)	Latest Follow-up (n = 122)
LVEF	0.59 ± 0.13	0.62 ± 0.12	0.56 ± 0.10
LVEDD (mm)	58 ± 11	54 ± 8	58 ± 5
P mean (mm Hg)	7.8 ± 4	8 ± 5	4.6 ± 3
P max (mm Hg)	14 ± 6	15 ± 7.4	9 ± 5
Moderate AR (2°)	74	3	8[a]
Severe AR (3°)	62	0	2[b]

[a] Pseudosinus 4, Standard 4. [b] Neosinus 1, Standard 1.

AR = aortic valve regurgitation; LVEDD = left ventricular end-diastolic diameter; LVEF = left ventricular ejection fraction; P = pressure.

Aortic Valve Function

The latest follow-up, echocardiography results showed no relevant AR in 112 patients, moderate AR (grade 2) in 8 patients, and severe AR (grade 3 or 4) in 2 patients.

In 36 patients cusp dynamics were measured by echocardiography at 4 years' mean follow-up. Sixteen patients with neosinus technique (group A), 10 patients with pseudosinus technique (group B), and 10 patients with standard David technique (group C) were compared for cusp dynamic data with 10 age-matched persons without cardiac disease with a mean age of 59 ± 15 years.

In the neosinus group significantly lower valve opening velocity and higher systolic closing displacement were observed compared with the patients with pseudosinus or conventional reimplantation technique. Opening was more physiologic in the neosinus group; however, the difference did not reach significance.

Tables 3 and 4 depict all conventional echocardiography data and cusp dynamics.

Reoperation

Five patients (3.4%) required aortic valve replacement because of severe aortic valve insufficiency in 4 patients (1 as a result of endocarditis, 2 for leaflet prolapse, and 1 because of leaflet perforation) and aortic valve stenosis in 1 patient.

Thus a total of 7 of 145 (4.8%) patients experienced severe aortic valve dysfunction, which was attributable to endocarditis in 1, caused by a too small prosthesis (20 mm) in another, and technical errors or late degeneration in 5. This occurred in 1 neosinus, 2 pseudosinus, and 4 standard technique patients.

Among the patients who underwent reoperation, there were 2 with type A dissection. Only 2 patients after leaflet plication had to be reoperated on, 1 for endocarditis and 1 for prolapse. No patients with Marfan syndrome or bicuspid valves needed reoperation.

Comment

Replacement of the aortic root and aortic valve with a composite valve graft incorporating a mechanical prosthesis has been the standard operation for patients with aortic root disease and AR [1, 2]. During the last 20 years, valve-sparing aortic root replacement has become popular in selected patients [4–8, 12, 16].

Reimplantation of the aortic valve is a complex operation because of the fact that the aortic valve and the aortic root act as a geometric and functional unit. Aortic valve incompetence may develop as a consequence of aortic root aneurysm by spreading the commissures or by annular dilatation. The sinuses of Valsalva and their flow dynamics have an important influence on cusp dynamics and probably coronary flow. Analysis of results after reimplantation and remodeling methods indicates that the reimplantation method is more hemostatic, provides more reliable annular stabilization, and might be associated with better long-term durability [4, 5, 7, 17].

Modifications of the original David operation have been described to create a bulge at the sinus level to avoid leaflet abrasion at the conduit wall [5, 10, 18]. Placing two sets of plication sutures and reducing the height and diameter at the annular and sinotubular level allows the generation of a neoaortic root better resembling the natural trilobed geometry. In addition, there is no need for a special

Table 4. Echocardiography and Cusp Dynamics of 46 Patients

Variable	Co: Control (n = 10)	Group A: Neosinus (n = 16)	Group B: Pseudosinus (n = 10)	Group C: Standard (n = 10)	*p* Value: Co vs A	*p* Value: Co vs B	*p* Value: Co vs C
Pmax (mm Hg)	4.6 ± 2	8.2 ± 4	10.9 ± 10.3	6.0 ± 3.6	0.03	0.08	0.52
Pmean (mm Hg)	1.9 ± 0.7	4.6 ± 2.7	6.2 ± 6.1	2.8 ± 1.5	0.001	0.003	0.17
LVEF	0.57 ± 0.06	0.58 ± 0.119	0.53 ± 0.18	0.44 ± 0.06	0.85	0.65	0.01
LVEDD (mm)	44 ± 5	44.7 ± 13.7	49.5 ± 8.2	50 ± 9.9	<0.001	<0.001	<0.001
VOV (cm/s)	28 ± 1.3	48.4 ± 10.7	56.4 ± 21.1	71.7 ± 10	0.003	<0.001	<0.001
VOT (s)	0.04 ± 0	0.03 ± 0.01	0.03 ± 0.1	0.02 ± 0.01	0.03	0.001	<0.001
VCV (cm/s)	26.8 ± 1	57.3 ± 16.6	60 ± 22.2	65.4 ± 11.5	0.002	0.001	<0.001
VCT (s)	0.04 ± 0	0.027 ± 0.01	0.03 ± 0.01	0.02 ± 0.01	0.003	0.004	0.001
SCD (%)	27 ± 1.9	17.8 ± 8.07	12.3 ± 5.3	8.1 ± 4	0.01	<0.001	<0.001

LVEDD = left ventricular end-diastolic diameter; LVEF = left ventricular ejection fraction; Pmax = maximal pressure; Pmean = mean pressure; SCD = systolic closing displacement; VCT = valve closing time; VCV = valve closing velocity; VOT = valve opening time; VOV = valve opening velocity.

Table 5. Probability Values Among Groups

Comparison	VOV (cm/s)	VOT (s)	VCV (cm/s)	VCT (s)	SCD (%)
Group A vs group B	0.11	0.07	0.7	0.92	0.04
Group A vs group C	<0.001	0.001	0.2	0.37	<0.001
Group B vs group C	0.008	0.09	0.43	0.48	0.04

Group A = neosinus technique (n = 16); Group B = pseudosinus technique (n = 10); Group C = standard David technique (n = 10); SCD = systolic closing displacement; VCT = valve closing time; VCV = valve closing velocity; VOT = valve opening time; VOV = valve opening velocity.

graft or a second, smaller tube graft above the sinotubular junction [17, 19]. In addition, adaptation of the tube graft to the sometimes asymmetric changes of the aortic valve is facilitated. This modified technique is reproducible, easily done, and potentially more durable than the procedure as it was originally described [13].

In the present study, the dynamics of valve opening and closing after valve-sparing operations using the technique described as standard David procedure, pseudosinus, and neosinus technique were analyzed and compared with a matched cohort of patients. The neosinus technique was developed primarily to avoid cusp abrasion and to accommodate for the elongation of cusp edges in chronic aneurysms. The conventional technique may overcorrect the valve. This neosinus technique has the potential to improve valve durability by reducing cusp stress [9, 10, 20].

Our echocardiography findings demonstrated that opening and closing times are reduced and cusp velocities are decreased in the neosinus group compared with the standard or pseudosinus technique. The dynamics in the neosinus group were closest to the control group, albeit still not physiologic (Table 5). Not all differences between classic and neosinus techniques did reach significance. These findings, however, prove that dynamic stress acting on the valve is altered. An impact on the durability of the repair, however, could not be proven as only a small number of failures have been observed for any technique. Achievement of optimal valve geometry appears to be dominant over reduced leaflet stress with respect to long-term durability. This simple modification with creation of sinuses of Valsalva may not only reduce stress on the valve leaflets but also avoid interaction between the leaflets and the aortic wall.

We could not observe a negative impact of cusp repair on long-term valve function like others [21]. Only 2 of 50 patients who had received leaflet plication were reoperated on because of endocarditis and leaflet prolapse. In contrast, as a result of secondary changes of leaflet geometry during aortic root dilatation, cusp geometry must be corrected to avoid sagging.

Based on our experience, sparing of the aortic valve in cases of AI with normal leaflet structure is an excellent alternative to procedures that require mechanical valve replacement as the observed rate of valve-related complications is low. We believe, for patients with aortic root aneurysms and relatively normal aortic valves, that this modified aortic valve-sparing operation is the procedure of choice.

Our data support the low valve-related complication rate after aortic valve reimplantation. Thromboembolic risk is low as the natural valve is preserved, anticoagulation is unnecessary, endocarditis is rare, and incidence of late degenerative valve failure is low (1.1%/patient-year). From retrospective studies, clinical outcome is improved with this technique compared with the conduit root replacement [16]. Long-term survival after aortic valve-sparing operations was comparable with that of a matched population in our patients (Fig 2, Kaplan-Meier curve for survival).

In conclusion, our series supports the observations of others that aortic valve reimplantation in the case of ascending aortic aneurysms and aortic incompetence does not increase surgical risk. Long-term valve competence and complication rates are low, resulting in a favorable rate of valve-related complications. Modifications of the technique with creation of neosinuses may improve the long-term durability of the aortic valve by creating more physiologic cusp dynamics.

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INVITED COMMENTARY

This 10-year experience in valve-sparing procedures reports excellent results in line with others in the literature. The overall survival is comparable with a normal population, and the article documents not only a low operative risk, but also an extremely low morbidity for this procedure [1].

Once it is established that a valve-sparing procedure is a safe and reproducible operation, the focus changes to the long-term durability of the spared valve. In fact, avoiding residual valve insufficiency that sooner or later will require a second operation is the second important objective to be achieved. In this respect, the remodeling technique seems inferior because it lacks reliable annular stabilization, and for mainly this reason, the reimplantation procedure is becoming more and more popular. However, the lack of sinuses of Valsalva in the classic reimplantation procedure has prompted creation of new grafts and new technical modifications aimed at re-creation of neo-sinuses. Indeed, this article shows how the authors have modified their technique over the years, from no-sinuses to pseudo-sinuses to neo-sinuses, to achieve a more anatomical root reconstruction. Although they did not find any difference in terms of durability among the three different techniques, and although there is insufficient scientific evidence that the lack of sinuses decreases leaflet durability, it is well-established that the presence of sinuses guarantees physiologic leaflet dynamics. Ironically, the remodeling technique that provides optimal sinus reconstruction has shown the most physiologic leaflet dynamics, whereas the classic reimplantation technique significantly and negatively affects the opening and closing characteristics of the aortic cusps.

Normal dynamics of the aortic cusp depends on several different factors. First, a proper shape and dimension of the sinuses of Valsalva; second, a narrowing at the level of the ST junction; and, third and most importantly the normal distensibility of the aortic root at all levels. By using various techniques, we can tailor a graft to obtain neo-sinuses, but we lose the elasticity of the wall. A perfect anatomical reconstruction will only partially compensate for this problem. Both opening and closing the aortic valve velocities depends on normal physiology of the aortic root. However, the diastolic phase, represented by slow closing leaflet displacement and closing velocity better indicates, with all the limits of a stiff wall, how well the root geometry has been reproduced.

Although the authors report progressive improvement in slow closing displacement going from classical to pseudo-sinuses to neo-sinuses techniques, the closing velocities are not different among the three techniques that were significantly different from the normal controls. This indicates that eddy current formations inside the sinuses prevented smooth valve closure. I believe that the technique of using a larger graft pinched down at the base and then at the level of the ST segment elevation junction, even though it creates neo-sinuses, may have some disadvantages. The method lacks the ability to straighten up the commissural posts to place them on an inner plane with respect to the rest of the root. It is also difficult to obtain egg-shaped sinuses of proper dimensions. Finally, pinched grafts are technically more demanding, and may reduce the chance of obtaining consistent results by different surgeons. Nevertheless, it has not yet been demonstrated that a less than perfect root reconstruction has a significant impact on cusp longevity.

Ruggero De Paulis, MD

Cardiac Surgery Department
European Hospital, Rome, Italy
via Portuense 700
Rome, 00149 Italy
e-mail: depauli@tin.it

Reference

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Modification of the David Procedure for Reconstruction of Incompetent Bicuspid Aortic Valves

Farhad Bakhtiary, MD, PhD, Nadejda Monsefi, MD, Maria Trendafilow, Thomas Wittlinger, MD, PhD, Mirko Doss, MD, PhD, and Anton Moritz, MD, PhD

Department of Thoracic and Cardiovascular Surgery, Johann Wolfgang Goethe University, Frankfurt–Main, Germany

The David procedure was described primarily to treat tricuspid valves. The asymmetry of the bicuspid root asks for modifications to achieve a competent bicuspid valve. The most common feature of the bicuspid valve is the presence of left and right coronary rudimentary cusps. In this case usually the base of the noncoronary cusp is displaced toward the left ventricular outflow tract. The uneven plane of this type of bicuspid aortic annulus has to be compensated for when a rigid prosthesis is wrapped around the aortic root. We describe the modification of the David technique in 14 patients who underwent a valve-sparing aortic root replacement in presence of a bicuspid valve. This technique increases the coaptation surface and provides reliable early and mid-term competence of the reconstructed bicuspid aortic valves.

(Ann Thorac Surg 2009;88:2047–9)

FEATURE ARTICLES

Valve repair for aortic insufficiency may provide an alternative to aortic valve replacement in selected patients. Advantages of aortic valve repair in comparison with aortic valve replacement include avoidance of anticoagulation and prosthetic valve-related complications. David and associates [1] described an aortic valve-sparing procedure with reimplantation of the valve within a prosthetic vascular graft in the early 1990s. This article describes our experience with the modification of the David procedure, particularly in patients with a bicuspid aortic valve.

Technique

Access to the heart was gained through a median sternotomy (7 patients through a partial upper sternotomy, 7 patients through a total sternotomy). We routinely used aortoatrial cannulation for extracorporeal circulation, antegrade and retrograde cold blood cardioplegia, CO_2 insufflation of the operative field, and moderate hypothermia (32°C). The aortic valve was approached through a transverse aortotomy. After the placement of three stay sutures, the bicuspid valve was examined. The most common appearance of bicuspid valves is the fusion of the left and right coronary rudimentary cusps (Fig 1). In this case the base of the noncoronary cusp is displaced down into the left ventricular outflow tract. The uneven plane of the annulus of bicuspid valves has to be compensated for when a rigid prosthesis is wrapped around the aortic root.

The aortic wall remnants are trimmed to a rim of 5 to 7 mm, and the remaining root is dissected off adventitia down to the annular plane. In most cases the annulus is not severely dilated, and simple sizing of the annulus gives the measure for the size of the prosthesis. As we create neosinuses in the prosthesis, 7 mm of diameter are added to the desired annular diameter [2]. A Dacron vascular prosthesis (DuPont, Wilmington, DE) is then trimmed, and a tongue-shaped extension is created to compensate for the deeper position of the noncoronary base. The area of the muscular septum is compensated for by using a scalloped incision. Then the positions of the true commissures are marked at the prosthesis. Their position varies between a 120° or more (up to 180°) spacing. The prosthesis is constricted at the base of the true commissures with a triangular stitch that crimps the prosthesis in circumference and height, thereby creating the base of the neosinuses. In the area of the pseudo commissure, this stitch is placed with a lesser extent of constriction. Then the usual subannular stitches with 4.0 Ethibond (Ethicon, Somerville, NJ) are placed. As we described for the conventional repair of bicuspid valve [3, 4], the raphe is mobilized and thickened closing edges of the leaflets are shaved, and a patch of glutharaldehyde-fixed autologous pericardium is fashioned and sewn to the free edge of the fused leaflet with a 5.0 Cardionyl running suture (Peters Laboratorys, Bobigny, France) (Fig 2). At completion of the suture line of the patch, the last stitches are placed just above the commissures and slightly deviated toward the neighboring cusp. This is done to safeguard the coaptation of the leaflets at this level.

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Address correspondence to Dr Bakhtiary, Department of Thoracic and Cardiovascular Surgery, Johann Wolfgang Goethe University, Theodor Stern Kai 7, Frankfurt-Main, 60590, Germany; e-mail: farhad@bakhtiary.de.

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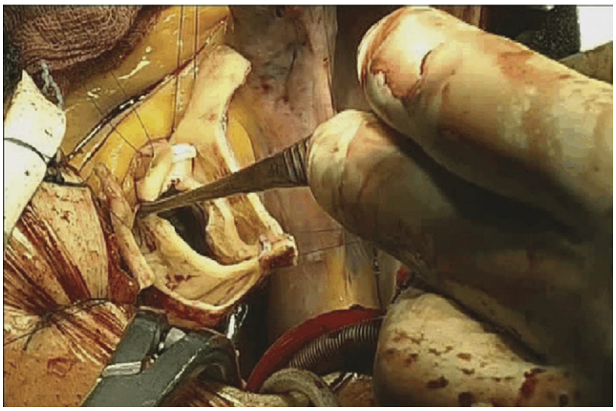

Fig 1. Intraoperative view of a bicuspid aortic valve after resection of the aortic wall. The pledget-armed stay sutures are at the tip of the true commissures. The forceps are showing the fused aortic valve leaflet.

The pledget-armed stay sutures at the tip of the commissures are pulled through the prosthesis. The subannular sutures are passed through the base of the prosthesis and the prosthesis is tied in place (Fig 3). Then the tips of the commissures are positioned within the prosthesis to match the geometry of the reconstructed valve. Tension is put on the commissures, but not on the prosthesis. The commissural sutures are passed at corresponding height through the prosthesis, but taking more prosthesis width to constrict this area to recreate a sinotubular ridge when tying. For complete restoration of the sinuses, an additional triangular stitch is placed outside just below the tip of each commissure, constricting circumference and height to create a sinus bulge [2]. The aortic wall remnants are then sewn to the prosthesis with running 4.0 Prolene mattress sutures (Ethicon).

By approximating the tips of the commissures, the leaflets free edges are relatively elongated and tend to sag into the outflow tract. In most cases, geometric reconstruction of the aortic valve is completed by plication of the free edge of the nonfused leaflet with a 5.0 Cardionyl u-stitch (Peters Laboratorys) and another figure-eight stitch across the closing edge.

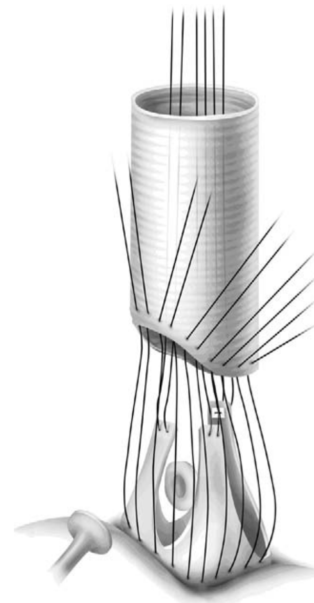

Fig 3. The aortic graft is trimmed to match the displacement of the noncoronary base toward the left ventricular outflow tract. Sutures are passed through the aorta and the graft in the usual manner.

The procedure is completed in the usual way by re-implanting the coronary ostia and performing the distal graft to aorta anastomosis (Fig 4).

Tables 1 and 2 summarize patient characteristics and clinical outcome. Overall survival was 100%. The degree of aortic regurgitation was none to trivial for all patients at last follow-up. There was no echocardiographic evidence of valve incompetence. We observed neither a case of endocarditis nor any neurologic event. The mean effective orifice area (EOA) was 2.9 ± 1.2 cm^2. Mean aortic gradients were 5.2 ± 2.6 mm Hg, and the mean height of coaptation surface was 12.3 ± 3.1 mm.

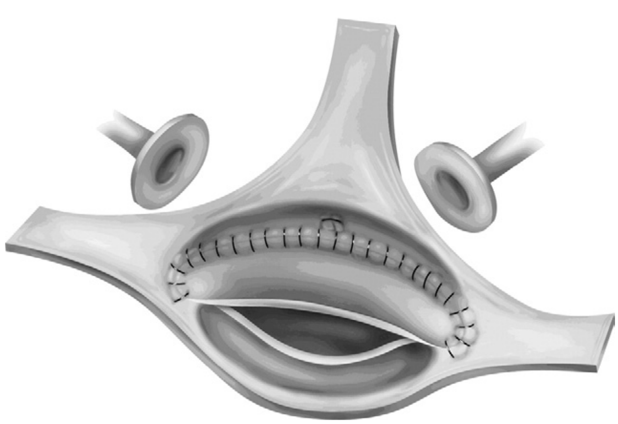

Fig 2. After mobilizing the raphe and shaving of thickened leaflet edges, a patch of glutaraldehyde-fixed autologous pericardium is fashioned and sewn to the free edge of the fused leaflet with a running suture.

Fig 4. Completed repair showing the preserved asymmetry of the aortic root and the bulge of the neosinuses.

FEATURE ARTICLES

Comment

Reimplantation of the aortic valve is a complex operation due to the fact that the aortic valve and the aortic root act as a geometric and functional unit [1]. Aortic valve incompetence may develop as a consequence of ascending aortic or aortic root aneurysm by spreading the commissures or annular dilatation [2]. In bicuspid aortic valves (BAV), prolapse of the fused cusps is seen as a frequent cause of failure. Sparing the aortic valve in selected cases of aortic insufficiency may be a reliable alternative to mechanical valve replacement. One of the major causes of aortic regurgitation is BAV [3], which seems to predominantly affect the young population [5] in whom one is reluctant to use a heterograft valve or to expose the patient to the risk of anticoagulation. It is not surprising that BAV repair is increasingly considered a reasonable option [2, 3, 5].

In large clinical series, excellent early results were reported for bicuspid repair [3, 5]. However, midterm results show a significant rate of reoperations within the first 5 years [5]. Apart from triangular cusp resection, no specific risk factor for failure was identified. With a modification of the technique by augmenting the fused leaflet with a pericardial patch, we were able to eliminate the risk of intraoperative revision and of reoperations at midterm [4]. However, the long-term results of cusp extension with glutaraldehyde fixed autologous pericardium remain unknown [6].

Repair of bicuspid aortic valves may bear the risk of subsequent dilatation of the ascending aorta [4, 7]. Aggressive aortoplasty of the ascending may prevent a secondary dilatation of the ascending aorta and aortic root [4]. Judgement of whether aortoplasty will be sufficient in the long term is difficult. In 40 patients we relied on this technique [4]; however in the 14 patients reported in this series, the aortic wall was deemed to be too thin and was enlarged for repair.

Table 1. Patient Characteristics

Number	14
Age (mean) (y)	58 ± 5
Male	13
Hypertension	7
Aortic valve regurgitation < II°	3
Aortic valve regurgitation II–IV	11
Ejection fraction (%)	40.5 ± 14.3
LVEDD (mm)	64 ± 18
Ascending aorta (cm)	4.8 ± 1.5
Reoperation	0

LVEDD = left ventricular end diastolic diameter.

Table 2. Perioperative Results and Surgical Procedures

Cardiopulmonary bypass time (min)	205 ± 34
Myocardial ischemic time (min)	168 ± 32
Ascending aorta plus hemi-arch replacement	9
Coronary artery bypass grafting	1
Other concomitant procedures	0
Intensive care unit stay (days)	3 ± 1
Ventilation time (hours)	21 ± 16
Re-exploration for bleeding	2
Endocarditis	0
Operative death	0
In-hospital death	0
Late death	0

The geometric peculiarity of a bicuspid aortic root complicates repair. We were able to achieve this with the described modification of the resuspension technique by a special trim of the prostheses, correct spacing of the commissures, and patch augmentation of the fused leaflet.

In summary, our results are encouraging and prove that by a geometric modification of the David procedure, bicuspid aortic valves can be effectively repaired. Adapting the shape of the prostheses to the asymmetric aortic root, augmenting the deficit in height of the fused leaflet, and generous plication of the nonfused leaflet increased the height of coaptation, which gave the reconstruction an additional margin of safety, which increases reliability. This technique is associated with low rates of valve-related complications.

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Original research

Long-term results of the David Procedure in patients with acute type A aortic dissection

Nadejda Monsefi*, Aleksandra Miskovic, Anton Moritz, Andreas Zierer

Department of Thoracic- and Cardiovascular Surgery of Goethe University Hospital, Frankfurt a.M., Germany

HIGHLIGHTS

- Surgery for acute type A aortic dissection (AAD) represents a surgical challenge.
- AAD with aortic root pathology demands complex surgical treatment.
- The David Procedure was performed in 23 patients with AAD in our department.
- The performance of the David technique is also feasible in emergency cases.

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ABSTRACT

Introduction: The David Procedure may provide an attractive alternative to aortic root replacement in patients with aortic valve insufficiency (AI) even in the emergency setting of an acute type A aortic dissection (AAD).

Methods: From 1996 to 2011 the David Procedure was performed in 23 patients with AAD in our department. Patients' mean age was 49 ± 15 years and 70% (n = 16) were male. Concomitant hemiarch replacement was performed in 19 patients while the remaining 4 patients underwent full arch replacement. Additional leaflet prolapse was corrected by plication in 5 cases. A modification of the classic David technique was performed by creating a pseudosinus in 6 patients (26%) and a neosinus in 9 patients (39%). Mean follow up was 7.7 ± 3 years.

Results: Thirty-day mortality was zero. There were 4 late deaths (17%). One patient suffered a perioperative neurologic event (4%). One further patient suffered a late stroke during follow up (0.6%/pt-yr). Three patients (1.7%/pt-yr) required aortic valve reoperation during follow up: in 2 cases leaflet perforation was observed, and one patient had to undergo valve replacement because of endocarditis with severe AI. There were two cases of bleeding events (1.1%/pt-yr) at follow up. The linearized rate for recurrent AI≥2° was 1.1%/pt-yr.

Discussion: The David Procedure certainly provides a challenging option to treat selected young patients with AI in the presence of AAD. However, current data suggest that it is safe and feasible.

Conclusions: Long-term valve-related events of the David Procedure applied in emergency cases are rare and aortic valve function remains stable for many years.

1. Introduction

Aortic dissection is the most frequently diagnosed lethal condition of the aorta with an estimated worldwide prevalence of 0.5–2.9 per 100,000 per year [1]. Fifty percent of patients suffering AAD die within 48 h after onset of symptoms without surgery [2]. In cases of additional aortic valve insufficiency the recommended surgical treatment for these patients has been composite graft replacement of the aortic valve and the ascending aorta, as described by Bentall and DeBono [3]. This technique has yielded excellent long-term results but the known complications of prosthetic valve replacement make an effective technique for preserving the native valve a superior alternative [4]. David and associates described an aortic valve sparing procedure with reimplantation of the valve within a prosthetic vascular graft in the early 1990's [5].

* Corresponding author. Department of Thoracic- and Cardiovascular Surgery, Goethe University Hospital, Frankfurt a.M., Theodor-Stern-Kai 7, 60590 – Frankfurt a. M., Germany.

E-mail address: nadi037@aol.com (N. Monsefi).

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We report herein early postoperative results and long-term outcome of the David procedure and its modifications in 23 patients with AAD.

2. Material and methods

2.1. Patient population and selection

Between 1996 and 2011 twenty-three patients with Stanford type A aortic dissection underwent emergent surgery in our institution. Patients' mean age was 49 ± 15 years. The patients' preoperative characteristics are summarized in Table 1. All patients underwent the David procedure with replacement of the ascending aorta or complete arch with coated woven polyester grafts (Intergard, Maquet, Rasstatt, Germany or Vacutek, Inchinnan, Scotland, UK).

In cases of significant aortic valve insufficiency (AI≥2°) and/or root dilatation (>4 cm) with no signs of valve stenosis in the transesophageal echocardiography (TEE) at admission in the operative room we aimed to perform valve sparing procedure with the David technique. The final decision to preserve the native aortic valve was made intraoperatively after root and valve leaflet inspection. Leaflet-calcifications, -vegetation or - rupture were exclusion criteria for David type repair. Patients with Marfan syndrome with root dilatation (>4 cm) and/or AI≥2° also received the David procedure. Aortic valve conduit was implanted in cases of destructed or calcified leaflets, in elderly patients and in patients with critically unstable preoperative conditions in order to reduce operative times.

2.2. Anesthetic consideration and cardiopulmonary bypass (CPB) management

Our standardized perfusion and temperature management protocol for aortic surgery has been previously described in detail [6,7]: Briefly, all patients had intravenous anesthesia with propofol, sufentanil and cisatracurium. The left radial artery was cannulated for continuous blood pressure monitoring. Transesophageal echocardiography was performed for confirmation of aortic dissection and evaluation of aortic valve function. Temperature probes were placed for esophagopharyngeal and rectal or bladder temperature monitoring. The patient was positioned on the operating table in supine position. After systemic heparinization (300 IU/kg), the right subclavian artery (n = 18), the left femoral artery (n = 2) or distal ascending aorta (n = 3) were directly cannulated (18F–22F flexible arterial cannula; Edwards Lifesciences, Irvine CA). The right atrium was cannulated with double-stage venous cannula (Edwards Lifesciences, Irvine CA). Our standard CPB circuit included a membrane oxygenator (Avant Physio, Dideco Stöckert, Munich, Germany) and heat exchanger (Jostra AG, Hirrlingen, Germany). Before aprotinin was withdrawn from the european market in 2007 our protocol for aprotinin usage was the "Hammersmith dose". This consisted of administering 2 million kallikrein inhibitor units added to the CPB circuit prime solution immediately after anesthetic induction and continuous infusion of 500,000 kallikrein inhibitor units during the operation. Aprotinin acid-base balance was maintained with alpha-stat method. The CPB was started, and the heart was arrested with intermittent retrograde and selective antegrade cold-blood cardioplegia. Cooling was limited to 28 °C rectal or bladder temperature. In cases of right subclavian artery cannulation with arch replacement the innominate and left carotid artery were snared with silicone elastomere loops and occluded at the time of initiation of antegrade cerebral perfusion (ACP). After opening the aortic arch the left subclavian artery was blocked by insertion of a Fogarty catheter to obtain a bloodless operative field. At this time the elastomer loop, snared around the left common carotid artery, was temporarily loosened and an arterial line was placed inside the vessel for additional perfusion of the left hemisphere. This arterial line was simply connected as a side branch to the arterial CPB cannula. ACP was conducted with a perfusate temperature of 30 °C in a pressure-controlled manner. Perfusion pressure was controlled on the pump unit and kept at 75 mmHg, which allowed for a mean flow of 1380 ± 170 ml/min. At this point the arch resection or repair was performed.

Table 1
Patients characteristics at time of surgery.

Characteristics	
n	23
Age (years)	49 ± 15, median 50(31;74)
Male	16 (70%)
Female	7 (30%)
AAD	23 (100%)
AI≥2°	20 (87%)
Aortic diameter	61 ± 8 (mm), median 60 (52;82)
Marfan syndrom	2 (9%)
Tricuspid aortic valve	23 (100%)

n: number of patients; AAD: acute type A aortic dissection; AI: aortic insufficiency.

2.3. Surgical technique

The inner and outer layers of the arch wall were dried carefully and glued with a two-component glue (Colle Chiurgicale; Crdial, Saint-Etienne, France).

The distal repair was completed in a standard fashion using a collagen-coated woven polyester graft (Intergard, Maquet, Rasstatt, Germany or Vacutek, Inchinnan, Scotland, UK) with Prolene 4-0 sutures (Ethicon Ltd., Norderstedt, Germany) and reinforced with Teflon felts. Our routine approach was to reimplant the arch vessels "en bloc". Finally the prosthetic graft was clamped just proximally to the innominate artery after de-airing and arterial flow was returned to full body perfusion. Proximal repair followed during rewarming:

The operative technique has been described in former publications [8]. Until 2004, we performed the standard David technique (Fig. 1a) [9]. Later we modified the procedure, initially by creating a pseudosinus (Fig. 1b) to reduce leaflet stress [8]. For this we took a graft size with a diameter twice the leaflet height. In patients with a normal, non-dilated annulus, the size of graft was calculated by the annular diameter, adding about 2 mm for aortic wall thickness and an additional 5 mm in order to create the pseudosinus with three stitches at the base of the prosthesis [8]. We could show that valve opening velocity could be reduced in patients who received the pseudosinus procedure in comparison to the standard David procedure [10]. Later we performed the neosinus technique (Fig. 1c) [11,12] with three additional stitches at the prosthesis at the height of the commissures to optimize the aortic cusp dynamics and create a more physiological shape of the prosthesis. To avoid distortion of the right coronary cusp, the deepest or central stitch at the right sinus was placed in a supra-annular position [13]. The function of the aortic valve was assessed intraoperatively with transesophageal echocardiography. Patients received transthoracic echocardiograms before discharge. They did not receive oral anticoagulants postoperatively except when indicated by additional disease.

2.4. Clinical follow up data and echocardiography

The patients were contacted by phonecall or letter at follow-up. They were invited to our outpatient unit for transthoracic

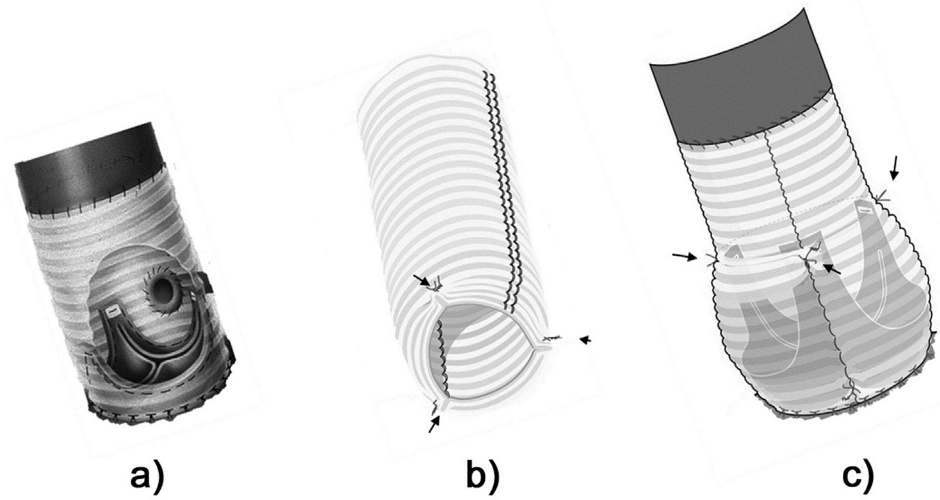

Fig. 1. David technique with modifications. a) Standard David technique, b) Pseudosinus technique: Arrows show three stitches at the base of the prosthesis, c) Neosinus technique: Three additional stitches (arrows) at the top of each commissure increase a bulge of the sinuses and creates a more physiologic shape of the prosthesis.

echocardiography examination and clinical status assessment at the same time.

Transthoracic echocardiography was performed at follow-up to assess valve function with a Vivid 7 echocardiography system (General electrics, Buckinghamshire, GB). The severity of valvular regurgitation was measured using a modification of the method of Perry and colleagues, in which the ratio of the width of the jet of regurgitation to the diameter of the left ventricular outflow tract just below the level of the valve annulus is determined. Valvular gradients were determined by Doppler echocardiography. Mean clinical follow up was 7.7 ± 3 years with cumulative 178 patient-years and was 100% complete.

The study was approved by our institutional ethics committee.

2.5. *Statistical analysis*

Means and standard deviation were calculated when appropriate. Median and range were also added for continuous variables. Results were considered to be significant at *p* value of less then 0.05. Long-term survival and freedom from reoperation and moderate AI were calculated according to the Kaplan–Meier method.

3. Theory

The David Procedure can even be performed in the emergency setting with encouraging results.

4. Results

4.1. *Operative and perioperative outcome*

The in-hospital and thirty-day mortality were zero. There was only one (4%) perioperative neurologic event in our series that was documented as a focal stroke with transient motor deficit. Table 2 illustrates the perioperative results and surgical procedures. Echocardiographic results before discharge showed unremarkable valve function in all patients: Seven patients had AI grade 1 and 16 patients AI grade 0.

4.2. *Follow up*

There were 4 late deaths (17%). One patient suffered from gastrointestinal bleeding, one patient died of rupture of the abdominal aorta, and in two cases the cause of death was unknown. Fig. 2 shows the Kaplan–Meier survival curve. Long-term survival was 88% at 10 years. The linearized late mortality event rate was 2.2%/pt-yr. One patient had a late neurologic event (0.6%/pt-yr) with a focal stroke. We observed two bleeding events as mentioned above (1.1%/pt-yr). The linearized reoperation rate was 1.7%/pt-yr. Three patients had to be reoperated at the aortic valve during follow up: in two cases leaflet perforation was observed, and one patient had to undergo aortic valve replacement because of endocarditis with severe AI. Each of them received a mechanical prosthesis. The 10-year freedom from reoperation was 81% (Fig. 3). In the three reoperated patients, postoperative echocardiography after David procedure showed no AI. They had no leaflet plication at time of repair. One underwent standard David technique, one the pseudosinus modification and the third one the neosinus modification at time of repair. The follow up and echocardiography data are presented in Tables 3 and 4. The freedom from AI$\geq$2° or reoperation at 10 years was 71% (Fig. 4). Clinical follow up revealed that the majority of the patients (74%) were in New York Heart Association functional class (NYHA) I. Only 5 patients (26%) were in NYHA class II at late follow up.

Table 2
Perioperative results and surgical procedures.

Surgical procedures n (%)	
Neosinus/pseudosinus/standard	9(39%)/6(26%)/8(35%)
Isolated ascending aortic replacement	3 (13%)
Hemiarch replacement	16 (70%)
Total arch replacement	4 (17%)
aortic prosthesis diameter (mm)	28.8 ± 3, median 28 (26;32)
Coronary artery bypass grafting	1 (4%)
Cardiopulmonary bypass time (min)	211 ± 50, median 208 (123;294)
Cross clamp time (min)	150 ± 36, median 148 (62;214)
Perioperative data n (%)	
Intensive care unit stay (days)	2 ± 1.5, median 1 (0.5;4)
Ventilation time (hours)	24 ± 18, median 18 (5;60)
Rethoracotomy because of bleeding	7 (30%)
Permanent neurologic deficit	0
Temporary neurologic deficit	1 (4%)
In-hospital mortality	0
30-day mortality	0

n: Number of patients; min: minutes.

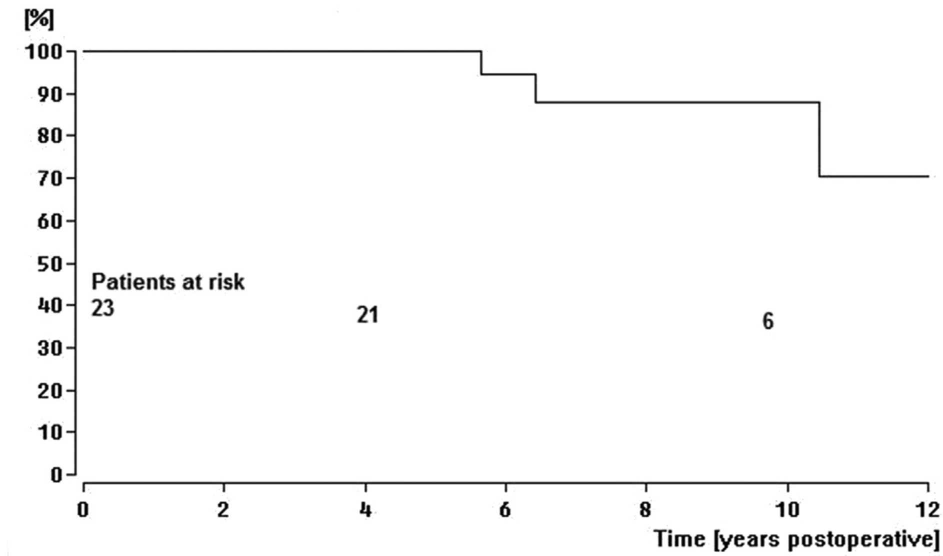

Fig. 2. Kaplan–Meier curve for survival.

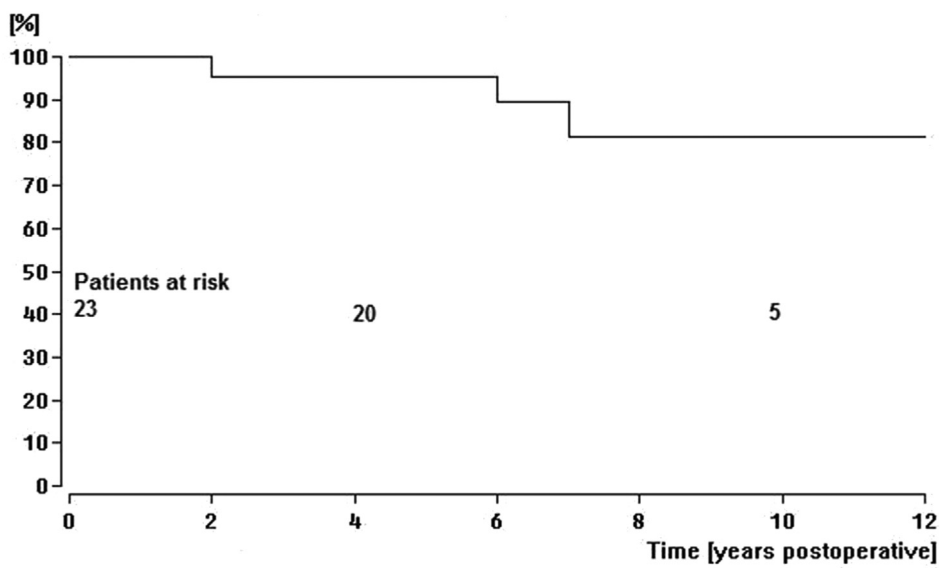

Fig. 3. Kaplan–Meier curve for freedom from reoperation.

Table 3
Follow up data.

Event [n (%/pt-yr)]	
Late mortality	4 (2.2)
Endocarditis	1 (0.6)
Stroke	1 (0.6)
All cases of bleeding	2 (1.1)
Reoperation at aortic valve	3 (1.7)
Reoperation at aorta	0
Echocardiographic data at late follow up	
AI≥2°	2 (1.1)
EF (%)	57 ± 12, median 60 (45;70)
Δpmean aortic valve (mmHg)	6 ± 5, median 3.3 (1;11)

n: Number of patients; AI: aortic insufficiency; EF: ejection fraction; p: pressure.

5. Discussion

Treatment of AAD with concomitant significant AI or root dilatation in emergency cases still represents a superb surgical challenge. With an experienced team the David procedure is a technically feasible option for this disease. The advantages of aortic valve-preserving procedures like the David technique seem obvious, because there is no need for anticoaglation in contrast to the Bentall procedure with mechanical conduits. The in-hospital mortality of the current series with a limited number of patients is zero which is below the reported mortality rates (2.9–28%) for Bentall procedure and for patients undergoing aortic arch replacement for AAD in general [14,15]. The 10-year survival rate of 88% in our series is comparable to that of other reports on elective aortic valve sparing root reimplantation procedures, ranging from 83 to 92% [16,17]. We observed one case of transient neurologic event (focal stroke) perioperatively (4%). This is still in the lower range in comparison to reported stroke rates (12–37%) in cases of AAD patients undergoing aortic surgery [18,19]. The linearized rate of stroke and death of 2.8%/pt-yr (5 in 178 patient-years) in our series is well comparable to that reported by Etz and colleagues

Table 4
Echocardiography data.

Preoperative	(n = 23)
AI ≤ 1°	3 (13%)
AI ≥ 2°	20 (87%)
Ejection fraction (%)	50 ± 14, median 54 (40; 60)
LVEDD (cm)	6.6 ± 0.6, median 6.5 (5.9; 7.2)
pmean ao valve (mmHg)	9 ± 4, median 6.5 (4; 17)
Postoperative (before discharge from hospital)	(n = 23)
AI ≤ 1°	23 (100%)
AI ≥ 2°	0
Ejection fraction (%)	50 ± 12, median 50 (40; 65)
LVEDD (cm)	5.4 ± 1.1, median 5.3 (4.2; 7)
pmean ao valve (mmHg)	9 ± 7, median 7 (4; 26)
Latest follow up	(n = 19)
AI ≤ 1°	17 (89%)
[a]AI = 2°	2 (11%)
Ejection fraction (%)	57 ± 12, median 60 (45; 70)
LVEDD (cm)	5.4 ± 0.7, median 5.6 (4.9; 6.5)
pmean ao valve (mmHg)	6 ± 5, median 3.3 (1; 11)

AI: Aortic insufficiency; LVEDD: Left Ventricular Enddiastolic Diameter (cm); Pmean Ao: mean pressure across the aortic valve (mmHg).
[a] AI>2° was not observed.

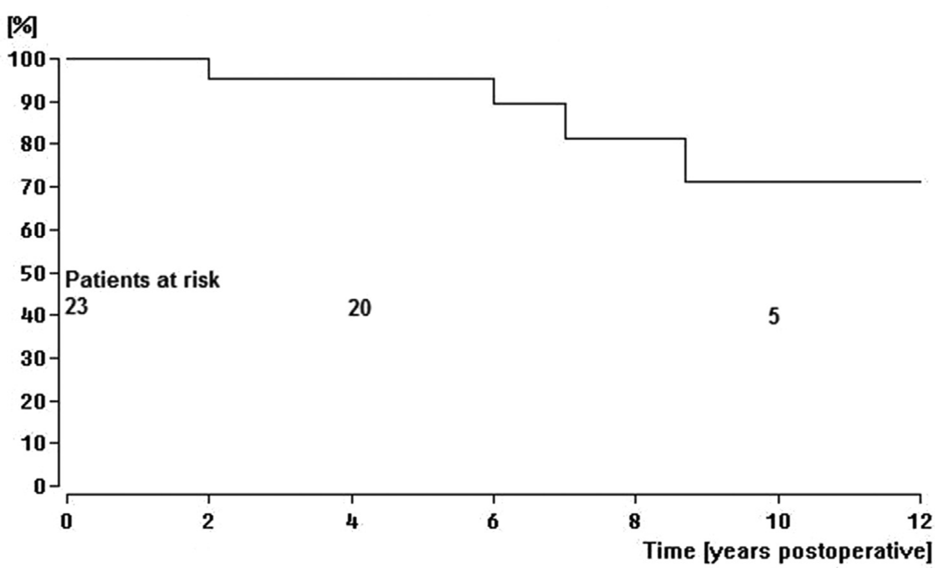

Fig. 4. Kaplan–Meier curve for freedom from reoperation and AI≥2°.

after the Bentall procedure (5.6%/pt-yr; 33 in 585 patient-years) [20]. There were two cases of bleeding events (1.1%/pt-yr) during follow up: one case of gastrointestinal bleeding and another case of rupture of the abdominal aorta. Both patients were not on any anticoagulants. Bleeding complications of patients with mechanical conduits were reported to be around 1.8%/pt-yr [21]. Three of our patients (1.7%/pt-yr) required aortic valve reoperation during follow up. Leshnower and colleagues report in their excellent work about no reoperation at the aortic valve in a series of 43 patients with type A aortic dissection (at 40 month follow up) who underwent David V procedure [22]. That is comparable to our series: In the first 48 month follow up we also did not have any reoperations at the aortic valve. The 10-year freedom from reoperation after valve-preserving aortic root repair varies between 80 and 92% in literature [16] that is similar to our data (81% at 10 years; Fig. 3). When we analyze valve function at time of repair all three reoperated patients had outstanding aortic valve function (AI grade 0°). The reason for recurrent AI grade 3° were endocarditis (n = 1) and leaflet perforation (n = 2). None of the three patients received leaflet plication at time of repair. Maybe this could have a negative impact on the recurrent AI as leaflet plication has been reported to have a positive influence on freedom from late AI [16]. Our data show a 10-year freedom from reoperation or AI≥2° of 71% which can be considered encouraging.

6. Conclusions

In summary, the David procedure is a feasible option to treat selected patients with AI even in the presence of AAD. Our data show low valve-related complications with stable aortic valve function at long-term follow up.

Ethical approval

Yes.

Sources of funding

None.

Author contribution

Nadejda Monsefi: study design, data collection, data analysis, writing.

Aleksandra Miskovic: data collection, data analysis.

Anton Moritz: study design, supervising.

Andreas Zierer: study design, supervising, correction of the manuscript.

Conflict of interest

None.

Guarantor

Prof. Anton Moritz.

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ORIGINAL ARTICLE

Aortic valve reimplantation for aortic root aneurysms: trainer and trainee differences on long-term results

Nadejda Monsefi · Patrick Primbs · Aleksandra Miskovic · Sandra Folkmann · Anton Moritz

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Abstract
Purpose The advantages of aortic valve-preserving surgery are still hampered by a higher rate of reoperations compared to root replacement with valved conduits. This study evaluates whether valve deterioration rate is related to the method or depends on stringent adherence to technical concepts, which might be lost once trainees perform this complex surgery on their own.
Methods From 1991 to 2011, the David procedure was performed in 209 consecutive patients. Mean age was 57±14 years. The patients were operated either by the senior author or trainees under his supervision (group 1, $n=130$) or by surgeons on their own after training by the senior author (group 2, $n=79$). Clinical and echocardiography data were evaluated pre- and postoperatively and at follow-up (mean 6.0 ±4 years).
Results In-hospital mortality was 1.5 % in group 1 and 5 % in group 2 ($p=0.29$), and late mortality was 12 % ($n=12$ in group 1 and $n=14$ in group 2, $p=0.11$), three were cardiac related. Nine patients (4.3 %) had to be reoperated; three for endocarditis in group 1, six for structural valve deterioration in group 2 ($p=0.14$). The 9-year freedom from reoperation or aortic valve insufficiency (AI) ≥2° was 93 % in group 1 and 78 % in group 2 ($p<0.01$). As groups showed differences in preoperative variables, results were compared also in a propensity matched subgroup. Despite no difference in perioperative results, long-term valve competence remained inferior in group 2.
Conclusions With stringent adherence to technical concepts, structural valve deterioration may virtually be considerably reduced in aortic valve reimplantation. Once performing this operation on their own, trainees—after training by the senior—achieved results as independent surgeons well comparable to published series. As long-term performance seems to depend more on judgment of the geometry achieved intraoperatively than on technical steps, a means of measurement of effective coaptation height with a caliper might facilitate evaluation of perfect repair.

Keywords Aortic valve repair · Aortic aneurysm · Surgical training

N. Monsefi (✉) · P. Primbs · A. Miskovic · A. Moritz
Department of Thoracic- and Cardiovascular Surgery, Goethe University Hospital, 60590 Frankfurt a.M., Germany
e-mail: nadi037@aol.com

S. Folkmann
Department of Cardiovascular Surgery, Hietzing Hospital, Wolkersbergenstr.1, 1130 Vienna, Austria

Introduction

There is still a controversial debate about the best treatment for patients with an aneurysm of the ascending aorta and concomitant aortic valve insufficiency. Reconstructive techniques [1–3] are compared to the "gold standard" of composite graft replacement [4].

After attending the first course on innovative cardiac surgery organized by Tirone David in Toronto in 1991, the senior author started a program on reimplantation of aortic valves and modified the surgical technique [5, 6]. As the major drawback of reimplantation is the reoperation rate, it is the interest of this paper to find out whether the surgical technique of reimplantation on its own is prone to long-term failure or this is a problem of surgical training, experience, or skill.

Most studies evaluating whether technical results are inferior in training cases compare supervised procedures to such performed by experienced surgeons [7, 8]. We could not find a surgical series evaluating technical success once trainees perform complex procedures on their own. However, at this stage, surgeons might tend to "simplify" the procedure.

For this, results achieved by supervised trainees and the senior author are compared to results achieved by surgeons performing procedures on their own after training.

Patients and methods

From 1991 to 2011, 209 consecutive patients with ascending aortic aneurysm and aortic valve insufficiency (AI) underwent replacement of the ascending aorta and reimplantation of the aortic valve in our department. Mean age was 57±14 years, range [18–87 years]. Tables 1 and 2 contain patient characteristics.

Patients were operated either by the senior author or trainees under his supervision (group 1) or by surgeons on their own trained by the senior author at our institution (group 2).

All cases operated by the trainees were performed in the same institution in Frankfurt.

Adequate function of the aortic valve was ascertained intraoperatively with transesophageal echocardiography. Transthoracic echocardiograms were obtained before discharge from the hospital and at follow-up. The severity of aortic regurgitation was measured using a modification of the method of Perry and colleagues [9]. Most patients were seen at regular intervals in our outpatient department. For the purpose of this study, the latest echocardiographic and clinical data were evaluated systematically. Patients who were not seen personally were contacted by letter or phone. Results of echocardiographies and clinical data were also retrieved from referring cardiologists. Patients who underwent the reimplantation procedure did not receive oral anticoagulants except indicated by additional disease like coronary artery disease treated with aspirin. Patients with additional mitral valve repair received phenprocoumon for 6 weeks and those with persistent atrial fibrillation lifelong phenprocoumon.

Ten patients were lost to follow-up (95 % complete). Mean follow-up was 6.0±4 years with 1,184 cumulative patient years. Median follow-up was 5 years (4.9 for group 1 and 5 years for group 2 patients, p=0.5). The study was approved by our institutional ethics committee.

Operative procedure

The decision to preserve the native AV was made intraoperatively after root and leaflet inspection. The base of the aortic root was then dissected circumferentially for adequate exposure. After excision of the coronary buttons, the sinuses of Valsalva were excised, leaving approximately 5 to 7 mm of aortic wall adjacent to the insertion line of the leaflets. In acute dissection, the layers of the wall were reconstructed at this point with gelatine-resorcin-formol surgical glue (Colle chirurgicale, Cardial, St Etienne, France) and additional sutures. The graft is slightly beveled to account for the septal muscle extension at the commissure between the right and left coronary base. Transmural mattress sutures are placed just below the leaflet insertion to the aortic wall. These sutures are then passed through the graft and are tied. This standard David technique was performed in 34 % of group 1 and 49 % of group 2 patients (p=0.04). In order to avoid distortion of the right coronary cusp, the deepest or "central" stitch at the right sinus was placed supra-annularly as the prostheses cannot be brought down below the annulus due to the septal muscle shelf [10]. This was performed later in the series of 25 patients (all from group 1). The supra-annular stitch was only performed in group I starting in 2006 and was recommend to the trainees. We found it first used in group 2 in 2013. The valve is reimplanted. Sinus wall remnants are fixed to the prostheses with 4/0 continuous sutures. Coronaries were reimplanted as buttons. To prevent the leaflets from touching the prostheses and to compensate for the frequently observed secondary elongation of the leaflet edges, a "pseudosinus" was created later in the series [5]. This technique was performed in 16 % of group 1 and 28 % of group 2 patients (p=0.06). Lately, neosinuses were shaped by plicating the base and the sinotubular junction of the graft with three 4–0 braided polyester sutures creating a bulge of the sinuses that was developed by the senior author [6]. This technique was performed in 50 % of group 1 and 23 % of group 2 patients (p=0.001). Since we could prove that leaflet dynamic of the aortic valve improved more with the neosinus than the standard or pseudosinus technique initially in 2011, trainees did more standard David procedure till 2011. Leaflet correction was performed after reimplantation with the valve in the new geometric position to ensure sufficient coaptation with belly-shaped leaflets and to avoid prolapse or sagging. In the case of bicuspid aortic valves, the David procedure was modified mainly by augmenting the fused leaflet with a patch [11]. The average diameter of chosen graft prosthesis was 30±2 mm in group 1 and 29.6±3 mm in group 2 patients (p>0.05).

Statistical analysis

All statistical analyses were performed with the BIAS 9.05 software (Frankfurt, Germany). Categorical variables are expressed as frequencies. Continuous variables are expressed as mean ± standard deviation and were compared with age- and sex-matched German population. The chi-square test was used to compare qualitative data. Analyses between patient groups were performed using the Mann–Whitney U test. Long-term survival, freedom from reoperation, and freedom from moderate or severe AI were calculated according to the Kaplan–Meier method and compared by logrank test between patient groups. To compensate for differences in preoperative patient characteristics, a propensity matching was performed

Table 1 Patient characteristics

	All (n=209)	Group 1 (n=130)	Group 2 (n=79)	p value
Age (years)	57±14	56±14	59±13	0.59
Male	148 (71 %)	91 (70 %)	57 (72 %)	0.74
Hypertension	96 (46 %)	58 (45 %)	38 (48 %)	0.73
Diameter: ascending aorta (cm)	5.8±1	5.4±1.5	5.8±1	0.54
Type A dissection	25 (12 %)	11 (8 %)	14 (18 %)	0.07
Aortic valve morphology:				
Bicuspid/tricuspid (n)	20/189	18/112	2/77	0.01
AI ≥3°	126 (60 %)	73 (56 %)	48 (61 %)	0.6

All all patients, *group 1* patients operated either by the senior author or under his direct supervision, *group 2* patients operated by surgeons on their own trained by the senior author, *AI* aortic valve insufficiency

with R software (R Foundation for Statistical Computing, Vienna, Austria) and package Matching by J.S. Sekhon. This was done with the following parameters: age, sex, type A dissection, preoperative grade of AI, diameter of the aorta, concomitant surgical procedure like coronary artery bypass grafting (CABG), or mitral valve repair (MVR).

Results

Perioperative

There were no relevant differences in cardiopulmonary bypass time (CPB), myocardial ischemic time, intensive care unit stay, or ventilation time between the groups; however, there were significant differences in operative techniques: In group 1, more bicuspid valves were treated (14 % vs 2.5 %). In contrast, more patients with type A dissection were operated in group 2 (18 % vs 8 %). Tables 3 and 4 show the perioperative data.

More operations with the neosinus technique (50 % vs 23 %), more supraannular stitches, and slightly more leaflet plications were performed in group 1. There were one temporary and three permanent neurological deficits (two critical illness polyneuropathies and one focal event) in group 1. We observed no perioperative neurological deficit in group 2.

In-hospital mortality was 1.5 % in group 1, one patient died of multi organ failure (MOF) and one due to pneumonia. There were four in-hospital deaths (5 %) in group 2: two died of MOF, one due to heart failure, and one after rupture of the spleen.

In-hospital and 30-day mortality for all patients with acute aortic dissection type A (AADA) was zero percent.

Follow-up

We documented 26 late deaths. Twelve in group 1; one died of rupture of the descending aorta, one of gastrointestinal bleeding, and another one of lung cancer. One patient suffered from respiratory failure and one from sepsis. In seven patients, the cause of death was unknown.

There were 14 late deaths in group 2, three for cardiovascular events like sudden cardiac death, myocardial infarction, and cardiac decompensation owing to exsiccosis. One patient died of gastrointestinal bleeding, another one had a rupture of the abdominal aorta. One patient committed suicide, one

Table 2 Patient characteristics of propensity matched groups

	Group 1 (n=68)	Group 2 (n=68)	p value
Age (years)	61±12	61±13	0.4
Male	51 (75 %)	48 (71 %)	0.7
Diameter of ascending aorta (cm)	5.8±1	6.0±1	0.12
Type A dissection	7 (10 %)	8 (12 %)	0.8
Aortic valve morphology:			
Bicuspid/tricuspid (n)	8/60	2/66	0.05
AI ≥3°	44 (65 %)	47 (69 %)	0.7

All all patients, *group 1* patients operated either by the senior author or under his direct supervision, *group 2* patients operated by surgeons on their own trained by the senior author, *AI* aortic valve insufficiency

Table 3 Perioperative results and surgical procedures

	All	Group 1 (*n*=130)	Group 2 (*n*=79)	*p* value
Surgical procedures (*n*)				
Neosinus/pseudosinus/standard (*n*)	83/43/83	65/21/44	18/22/39	0.001/0.06/0.04
Isolated ascending aorta replacement	140 (67 %)	88 (68 %)	52 (66 %)	0.9
Hemiarch replacement	53 (25 %)	31 (24 %)	22 (28 %)	0.6
Total arch replacement	6 (3 %)	4 (3 %)	2 (2.5)	0.85
Elephant trunk	10 (5 %)	7 (5 %)	3 (3.8 %)	0.85
Partial/full sternotomy	28/181	25/105	3/76	0.03
Concomitant procedures (*n*)	56	30	26	
Coronary artery bypass grafting	36 (17 %)	18 (14 %)	18 (22 %)	0.14
Atrial septal defect closure	5 (2 %)	2 (1.5 %)	3 (3.8 %)	0.56
Mitral valve repair	10 (5 %)	5 (3.8 %)	5 (6 %)	0.6
Tricuspid valve repair	5 (2.4 %)	5 (3.8 %)	0	0.19
Leaflet plication of the aortic valve	67 (32 %)	46 (35 %)	21 (26 %)	0.24
Supra-annular stitch (aortic valve)	25 (12 %)	25 (19 %)	0	<0.01
Perioperative data				
CBP time (min)	200±45	199±44	202±45	0.5
Myocardial ischemic time (min)	147±32	146±33	148±32	0.52
Intensive care unit stay (days)	2.7±5.4	2.5±5.4	3.2±5.6	0.55
Temporary neurological deficit	1 (0.5 %)	1 (0.8 %)	0	0.80
Permanent neurological deficit	3 (1.4 %)	3 (2 %)	0	0.40
In-hospital mortality	6 (2.9 %)	2 (1.5 %)	4 (5 %)	0.29

All all patients, *group 1* patients operated either by the senior author or under his direct supervision, *group 2* patients operated by surgeons on their own trained by the senior author, *CPB* cardiopulmonary bypass

Table 4 Perioperative results and surgical procedures of propensity matched groups

	Group 1 (*n*=68)	Group 2 (*n*=68)	*p* value
Surgical procedures (*n*)			
Neosinus/Pseudosinus/Standard (*n*)	37/15/16	18/18/32	0.001/0.7/0.01
Isolated ascending aorta replacement	38 (56 %)	49 (72 %)	0.07
Hemiarch replacement	19 (28 %)	15 (22 %)	0.6
Complete arch replacement	4 (6 %)	2 (3 %)	0.7
Elephant trunk	7 (10 %)	2 (3 %)	0.2
Concomitant procedures (*n*)	37	36	
Coronary artery bypass grafting	13 (35 %)	13 (36 %)	0.9
Atrial septal defect closure	0	1 (3 %)	0.9
Mitral valve repair	0	4 (11 %)	0.1
Tricuspid valve repair	0	0	
Leaflet plication of the aortic valve	24 (65 %)	18 (50 %)	0.1
Perioperative data			
CBP time (min)	202±51	202±45	0.5
Myocardial ischemic time (min)	143±36	150±32	0.2
Intensive care unit stay (days)	3±6	3.3±6	0.42
Temporary neurological deficit	1 (1 %)	0	0.3
Permanent neurological deficit	1 (1 %)	0	0.3
In-hospital mortality	2 (3 %)	3 (4 %)	0.9

All all patients, *group 1* patients operated either by the senior author or under his direct supervision, *group 2* patients operated by surgeons on their own trained by the senior author, *CPB* cardiopulmonary bypass patient suffered from sepsis, and another one from intracerebral bleeding. We documented one death due to stroke in group 2. In five patients, the cause of death remained unknown.

The Kaplan–Meier estimates for survival compared to an age- and sex-matched German population are shown in Fig. 1a for both groups. There is no significant difference between patients of group 1 and the normal population ($p=0.07$); however, there is a significant survival difference between patients of group 2 and the normal population ($p<0.01$) as well as between groups 1 and 2 ($p=0.02$).

However, cause of death was valve related only in a minority of group 2 patients. The survival difference between groups 1 and 2 was difficult to explain. In order to rule out an impact of preoperative differences in the patient groups, we reanalyzed survival after propensity matching. After correcting for age, sex, type A dissection, preoperative grade of AI, diameter of the aorta, and concomitant surgical procedure (CABG or MVR), there was no difference in long-term survival between groups (Fig. 1b, $p=0.3$).

Four patients of group 2 had late neurologic events: three with focal transitory neurologic events and one fatal cerebral bleeding, which was mentioned above. We observed only one late focal neurological deficit in group 1, this difference was not significant ($p=0.13$).

The linearized neurologic event rate for all patients was 0.42 %/pt-y.

Only one case of anticoagulation-related hemorrhage was observed as described above in one patient with gastrointestinal bleeding in group 2.

Three cases of endocarditis with severe aortic insufficiency (AI) were observed in group 1 (vs. none in group 2, $p=0.45$). Two of them had bicuspid aortic valves. All three patients underwent reoperation. Structural valve deterioration with severe aortic insufficiency (AI) was the cause of reoperation in five patients of group 2 (three with leaflet prolapse, one with leaflet perforation, and one with torsion of the right coronary leaflet), one other patient (group 2) had to be reoperated for combined aortic valve disease. In patients who later underwent reoperation, perioperative echocardiography showed no significant AI (seven with AI grade 0, two with AI grade 1). Five of the nine reoperated patients had no leaflet plication at repair. In all nine reoperated patients, the aortic valve had to be replaced with a biological ($n=1$) or mechanical ($n=8$) prosthesis.

At latest follow-up, 137 patients were in New York Heart Association functional class I, 27 patients (16 vs. 11) were in class II, and 3 patients (1 vs 2) in class III.

The Kaplan–Meier curves for freedom from reoperation and relevant AI (≥2°) are illustrated in Fig. 2a, b. Both curves show significant differences between groups 1 and 2 with $p<0.01$ (Fig. 2a). This difference remained significant after propensity matching (Fig. 2b, $p=0.02$).

Table 5 illustrates the echocardiographic data of the propensity matched groups. At latest follow-up, 100 % of patients in group 1 vs 87 % of patients in group 2 had no significant AI ($p=0.03$).

Discussion

Composite graft replacement is associated with a risk of thromboembolic events and anticoagulation-related hemorrhage [12]. Over the last 20 years, innovative valve-sparing techniques have become popular in selected patients [2, 3].

Reimplantation of the aortic valve is a complex operation due to the fact that the aortic valve and the aortic root act as a geometric and functional unit, and secondary changes of the aortic valve like elongation of the closing edges have to be compensated for at reimplantation.

Reimplantation is a reliable technique; freedom from moderate AI is described to be 94 % at 10 years [3]. Several modifications of the original David operation have been described to create a bulge at the sinus level in order to avoid leaflet abrasion at the conduit wall and reduce leaflet stress during opening and closing [5, 13].

At our institution, we developed the neosinus technique to more closely resemble the natural aortic root [6] and found improved cusp dynamics [14].

In the present study, patients were operated according to standardized, however, developing protocols. Supervised procedures (group 1) were compared to procedures done after training without supervision (group 2). There were differences in the patient characteristics and operative details such as less acute type A dissections in group 1. However, this did not lead to significant differences in the perioperative results including CBP time, ischemic time, or intensive care unit stay (Table 3). The in-hospital mortality of group 1 is not significantly different from group 2. The total in-hospital mortality of 2.9 % is comparable to other reports [15].

There was a significant survival difference between patients of group 2 and a control population ($p<0.01$) which was difficult to explain. Survival of group 1 did not differ significantly from a normal population ($p=0.07$). At 9 years, survival was significantly better in group 1 than in group 2.

However, the 9-year survival rate of both groups is comparable to that of other reports ranging between 83 and 92 % [15, 16]. As the two groups differed in relevant preoperative variables, we performed propensity matching. After this, the difference in long-term survival between the two groups was no longer significant ($p=0.3$).

Valve-related complications after reimplantation are lower compared to conduit root replacement [17]: The linearized rate of stroke and death for both groups (2.6 %/pt-y-31 in 1,184 pt-y) was lower than that reported by Etz after the

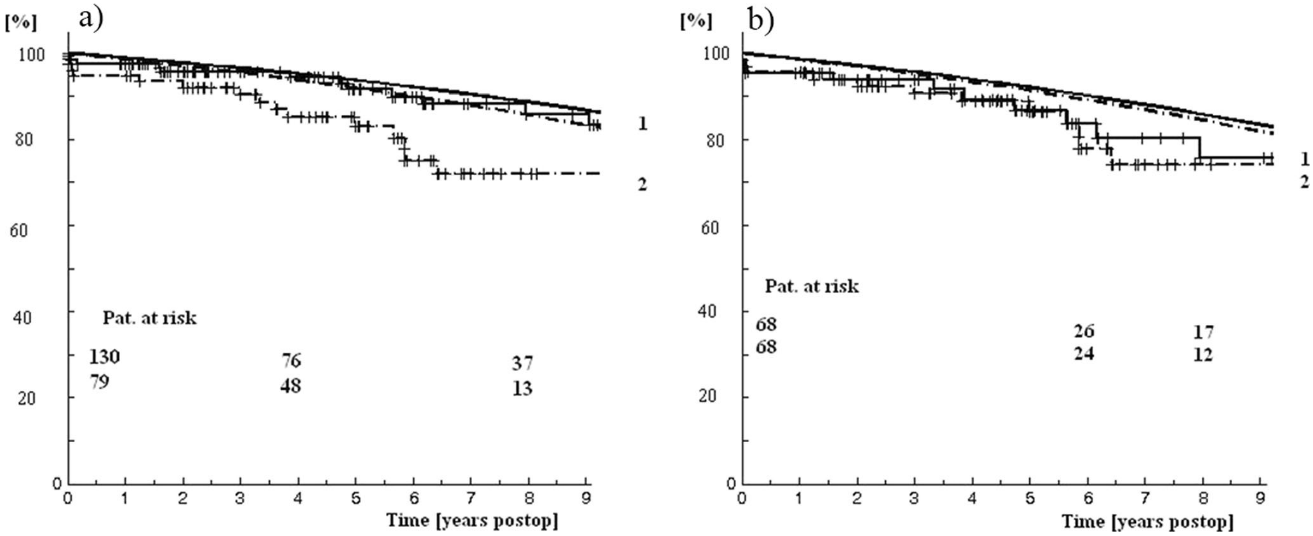

Fig. 1 Kaplan-Meier curve for survival compared with age- and sex-matched German population (*continuous* and *dotted curve*). (**a**) Not propensity matched survival; Logrank test between group 1 (*1*) and normal population, $p=0.07$; Logrank test between group 2 (*2*) and normal population, $p<0.01$; Logrank test between groups 1 and 2, $p=0.02$. (**b**) Propensity matched survival; Logrank test between group 1 (*1*) and normal population, $p=0.02$; Logrank test between group 2 (*2*) and normal population, $p=0.004$; Logrank test between groups 1 and 2, $p=0.3$

Bentall procedure (5.6 %/pt-y-33 in 585 pt-y) [18]. Bleeding complications in patients receiving mechanical conduits are reported at 1.8 %/ pt-y (10 in 571 pt-y) by Hagl [17]; in our study, the rate of bleeding events during follow-up was 0.08 %/pt-y in both groups together (1 in 1,184 pt-y).

Endocarditis is reported to occur in about 1.4 % after the Bentall procedure [17], that is, lower compared to our group 1 (2.3 %) but higher than in group 2 (0 %); linearized rate of endocarditis of (0.34 %/pt-y) is reported for the Bentall procedure [17] which is higher than observed in our patients (0.25 %/pt-y).

The 9-year freedom from reoperation was different between the two groups (95 % vs. 88 %, $p=0.04$). Group 1 patients had a better combined freedom from reoperation and AI ≥2° after 9 years compared to group 2 (93 % vs. 78 %, $p<0.01$). At latest follow-up, nine patients (two vs seven) had AI ≥2° ($p=0.01$); this difference remained significant after propensity matching (0 vs 6, $p=0.03$).

Only three patients of group 1 had to be reoperated, all for endocarditis. In contrast, all six patients who had to be reoperated for structural valve deterioration belonged to group 2. In five of the nine reoperated patients, leaflet plication had not been performed. In our series, cusp plication was more frequently performed in group 1 and had rather a positive influence on freedom from AI as it also has been described by Kunihara et al. [15]. We could not observe a negative impact of cusp repair on long-term valve function like others [19]. According to our protocol, secondary changes of leaflet geometry following aortic root dilatation should be corrected to avoid sagging and, by this, reduce closing stress.

As the difference in long-term performance remained after propensity matching, an impact of preoperative differences could be ruled out.

Analysis of the perioperative echocardiographies of reoperated patients showed no significant AI (seven with AI

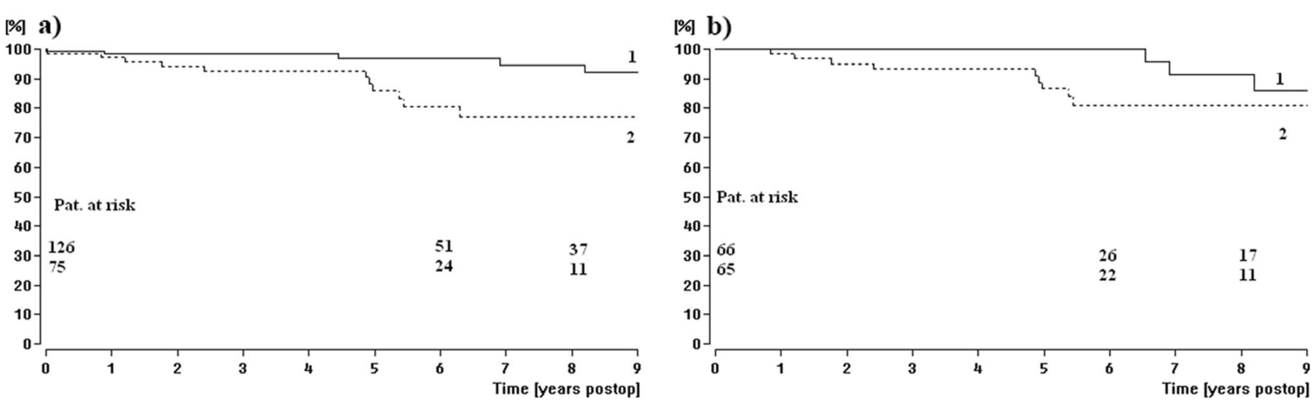

Fig. 2 Kaplan-Meier curves of rate for freedom from reoperation and aortic valve insufficiency (AI) ≥2°. (**a**) Not propensity matched; Logrank test between group 1 (*1*) and group 2 (*2*), $p<0.01$. **b**) Propensity matched Logrank test between group 1 (*1*) and group 2 (2), $p=0.02$

Table 5 Echocardiography data of propensity matched groups

Postoperative (before discharge from hospital)	Group 1 (*n*=66)	Group 2 (*n*=65)	*p* value
AI <2°	66 (97 %)	62 (95 %)	0.2
[a]AI ≥2°	0	3 (5 %)	0.2
Ejection fraction (%)	54±10	49±11	0.05
Pmax Ao valve (mmHg)	14±5	15±9	0.3
Latest follow-up	Group 1 (n=52)	Group 2 (n=47)	*p* value
AI <2°	52 (100 %)	41 (87 %)	0.03
*AI ≥2°	0	6 (13 %)	0.03
Ejection fraction (%)	59±11	56±15	0.14
Pmax Ao valve (mmHg)	8±4	13±8	0.01

All all patients, *group 1* patients operated either by the senior author or under his direct supervision, *group 2* patients operated by surgeons on their own trained by the senior author, *AI* aortic insufficiency, *Pmax Ao*: maximal pressure across the aortic valve

[a] AI ≥3° was not observed

grade 0, two with AI grade 1). We were not able to discern suboptimal functional or geometric results in the nine patients who needed late reoperation. However, one patient received too small prostheses (22 mm); in one patient, the graft had slipped above the base of the noncoronary sinus at reoperation. Incompletely corrected leaflet prolapse is difficult to determine at echocardiography. Resolution is not good enough to identify the position of both matching closing edges. So the higher rate of leaflet repair in group 1 may have an impact.

Reoperation for the Bentall procedure is 2.8 % [17], thus higher compared to group 1 (2 %) but lower than in group 2 (8 %). A linearized reoperation rate of 0.7 %/pt-y [17] is reported for Bentall procedures that compares to our cohort (0.76 %/pt-y for groups 1 and 2 together).

Quality of surgical procedures performed by trainees has been the topic of several papers. Usually no difference is found whether procedures are performed under supervision or by an experienced surgeon [7, 8]. We were unable to find reports dealing with quality differences between supervised procedures and such performed by relatively unexperienced surgeons in heart surgery. Especially as being the case here performing the first cases of a technically complex procedure on their own.

Our series shows that technical knowhow can be transferred from the experienced surgeon to his students to an extent that they are able to perform aortic valve reimplantation with results comparable to published series. The 9-year freedom from reoperation ranges between 81 and 98 % [15] in the literature and compares well to the trainee group (88 % in group 2). Kallenbach and colleagues described an 80 % 9-year freedom from reoperation after the David operation [16]. A 5-year freedom from reoperation rate of 95.9 % is described by the Leipzig group [20] which again compares to the 5-year freedom rate of 95 % for group 2.

As the objective differences in technical steps, applied only marginally, achieved significance and postoperative echocardiograms did not predict later valve deterioration, the reason for better performance in group I cannot fully be explained. Especially the need for and the extent of leaflet plication is dependent on subjective judgment. Effective height can be measured with a caliper as described by Schäfers [21]. Including this step of confirmation of adequate coaptation could be a means to improve long-term results also for less experienced surgeons.

Conclusion

Our data show a low valve-related complication rate after aortic valve reimplantation irrespective of the experience of the surgeon. Neurologic and bleeding complications are scarce. Reoperation rate and the frequency of late aortic incompetence for the trainee group, once working as independent surgeons, compares well to the published literature, but is higher than reported rated after conduit implantation. Long-term stability can be improved with experience and stringency to published technical details, achieving equal or even lower reoperation rates as described for conduits. However, the differences between achieved and achievable long-term stability raises the question whether or not this complex surgical repair should be confined to the most experienced surgeons or even to centers with experience and track of technical results. Besides further improving training, the means to objectively measure achieved valve geometry and effective height with calipers might further reduce subtle misjudgment by less experienced surgeons. As a technique, aortic valve reimplantation allows repair with a very low rate of structural and non-structural valve deterioration up to 20 years.

Study limitations

The performance of the supra-annular stitch which was only performed in group 1 could be an additive factor to the superior results.

Conflicts of interest disclosure There is no conflict of interest to be disclosed.

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Erklärung

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