CLINICAL RESULTS
AND PUBLICATIONS RESUME
CLINICAL RESULTS OF THREE PROSPECTIVE MULTICENTRIC STUDIES

Pooled analysis of 3 prospective multicentric studies

- 765 patients
- 5 years follow-up
- 3 consecutive trials in 26 Centers in 8 European Countries
- Surgical access: median and mini- sternotomy
- Age: ≥ 65 years
- Mean Euro score: 11.04%
- Available sizes: S, M, L, (XL*)

26 Investigational Sites in Europe

- Austria (2 centers)
- Belgium (2 centers)
- France (4 centers)
- Germany (12 centers)
- Netherlands (3 centers)
- Poland (1 center)
- Switzerland (1 center)
- UK (1 center)

*SORIN GROUP CLINICAL REPORT PERCEVAL CLINICAL EXPERIENCE: POOLED ANALYSIS OF PILOT (V10601), PIVOTAL (V10801) AND CAVALIER (TPS001) TRIALS - CLNR-00011 A.

*XL size included in clinical trial although not reported in the results of the present pooled analysis.
INCLUSION CRITERIA AND PATIENTS

DEMOGRAPHIC DATA

Major Inclusion Criteria
- Adult patients (≥75 yrs; ≥65 yrs from 2010)
- Stenosis or steno-insufficiency
- Aortic annulus in the range 19 - 25 mm

Major Exclusion Criteria
- Pure aortic regurgitation
- Congenital bicuspid aortic valve
- Subjects with aortic root enlargement

Demographic Data

<table>
<thead>
<tr>
<th>Implant period</th>
<th>April 2007 - September 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age</td>
<td>78.9 ± 5.4</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>68.1%</td>
</tr>
<tr>
<td>EuroScore (Mean)</td>
<td>11.04%</td>
</tr>
<tr>
<td>STS score (Mean)</td>
<td>8.59%</td>
</tr>
</tbody>
</table>

Age distribution

<table>
<thead>
<tr>
<th>&lt;70</th>
<th>70-74</th>
<th>75-79</th>
<th>80-84</th>
<th>≥85</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.8%</td>
<td>16.2%</td>
<td>35.3%</td>
<td>29.4%</td>
<td>13.3%</td>
</tr>
</tbody>
</table>

More than 40% of pts older than 80 years
SURGICAL APPROACH AND PROCEDURE

AV pathology

- Stenosis: 69%
- Steno-insufficiency: 31%

Surgical approach

- Median Sternotomy: 75%
- Mini Sternotomy: 25%

Concomitant procedures

- CABG: 75%
- Myectomy: 10%
- Other: 15%
- Concomitant: 67%
- Isolated: 33%
HEMODYNAMICS

Pressure Gradients

EOA and EOAI
CLINICAL OUTCOMES

- No thrombosis
- No post-operative migrations
- No structural valve deterioration
- Early cardiac mortality 1.9% (late 1.4%)
- Survival @ 5 years 74.7%
- Early AV Block III leading to PM implantation 6% (late 1.4%)
- Early major stroke 1.6% (late 0.8%)
- Early major paravalvular leak 1.4% (late 1%)

SURGICAL TIMING

<table>
<thead>
<tr>
<th></th>
<th>Median Sternotomy</th>
<th>Mini Sternotomy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Isolated AVR</td>
<td>Complex AVR</td>
</tr>
<tr>
<td></td>
<td>Mean±SD</td>
<td>Mean±SD</td>
</tr>
<tr>
<td>X-clamp (min)</td>
<td>30.7±10.7</td>
<td>51.1±23.2</td>
</tr>
<tr>
<td>Pump time (min)</td>
<td>50.3±18.7</td>
<td>79.4±32.8</td>
</tr>
</tbody>
</table>
PERCEVAL PUBLICATIONS

2014
Minh et al. - Expanding the Indication for Sutureless Aortic Valve Replacement to Patients with Mitral Disease. The Journal of Thoracic and Cardiovascular Surgery - Manuscript accepted Articles in Press
Ouazzani et al. - Première étude comparative entre les trois prothèses valvulaires aortiques sutureless disponibles. Journal de Chirurgie Thoracique et Cardio-Vasculaire 2014;18(2) 89-95
Pollari F. et al. - Doppia sostituzione mitro-aortica in paziente ad alto rischio: the sutureless way. - G Ital Cardiol 2014;15(2)
Santarpino G. et al. - Aortenklappenersatz mit nahtfreien Herzklappenprothesen - aktueller Stand und Stellenwert in der Zukunft. Aktuelle Kardiologie - 2014; 3(2): 105-112
Tavlasoglou M et al. - Should sutureless aortic valve replacement be preferred only for decreasing aortic crossclamp time? The Journal of Thoracic and Cardiovascular Surgery- Volume 147, Issue 5, Pages 1726–1727 Letter to the editor

2013
Carrel T. et al - Recent developments for surgical aortic valve replacement: The concept of sutureless valve technology. Open Journal of Cardiology; 4:1
Doppia sostituzione mitro-aortica in paziente ad alto rischio: the sutureless way. - G Ital Cardiol 2014;15(2)
Raja S. - Sutureless Aortic Valve Replacement Using Perceval S Valve - Recent Patents on Cardiovascular Drug Discovery; Vol. 8, No. 2.


2012


2011


Santarpino G. et al. - Perceval Sutureless aortic valve prosthesis easy fast and safe. Innovations; Vol. 6, No. 6.


2010


2009


2008

Sutureless Perceval Aortic Valve in Comparison with the Stented Carpentier-Edwards Perimount Aortic Valve

Karl Christian König, Thorsten Wahlers, Maximilian Scherner, Jens Wippermann

Klinik für Herz- und Thoraxchirurgie, Herzcentrum, Universitätsklinik Köln, Cologne, Germany

Background and aim of the study: The Sorin Perceval S (SP) sutureless bioprosthesis was developed as an advancement of conventional biological aortic valve replacement (AVR) with stented bioprostheses, and perhaps also as an alternative to the transcatheter aortic valve implantation (TAVI) procedure, especially for high-risk patients. Herein are described the authors’ early results with SP valve replacement, compared to AVR with Carpentier-Edwards Perimount (EP) stented valves.

Methods: Between September 2012 and February 2013, a total of 14 patients was enrolled in a single-center SP study group, and their data were analyzed in a prospective manner. For comparison, 14 patients who received an EP valve replacement during the same period were matched with the SP group, in a retrospective manner. Hemodynamic parameters and clinical outcome were monitored until discharge of the patients in order to analyze the early results of the two groups.

Results: The cardiopulmonary bypass (CPB) and aortic cross-clamp (ACC) times needed for AVR with SP valves were significantly shorter than with EP valves. The mean CPB time for SP valve replacement without concomitant procedures was 58.4 ± 11.0 min, compared to 71.8 ± 11.3 min in the EP group (p = 0.015), while the mean ACC times were 37.3 ± 6.8 and 49.1 ± 11.2 min, respectively (p = 0.006). Permanent pacemaker implantation was required in four patients after SP valve replacement, but in only one patient after EP valve replacement (p = 0.326). The mean transprosthetic peak and mean gradients were 24.8 ± 5.2 mmHg and 13.3 ± 3.3 mmHg, respectively, in the SP group, and 19.0 ± 6.5 mmHg and 10.4 ± 3.0 mmHg, respectively, in the EP group (p = 0.024 and p = 0.007). The mean valve size was 23.8 ± 1.3 mm and 23.3 ± 1.5 mm in the SP and EP groups, respectively. The fall in platelet count after SP valve replacement was 180.4 ± 79.4 x 10^9/µl on the first postoperative day (POD), and 114.1 ± 51.2 x 10^9/µl with a minimum of 42 x 10^9/µl and a maximum of 230 x 10^9/µl at the nadir on POD 2.6 ± 4.0. The mean minimum values at the nadir corresponded to 40% of the initial preoperative value.

Conclusion: The sutureless SP bioprosthesis seems to represent a good alternative to conventional stented bioprostheses, especially in older patients with a high-risk profile, and particularly if concomitant surgical procedures are planned.

The Journal of Heart Valve Disease 2014;23:253-258
An Alternative for Surgical Management of Calcific Aortic Valve Stenosis: Sutureless Valve Implants

Hector I. Micheleva, M.D.,* Robert E. Michler, M.D.,† Maurice Enríquez-Sarano, M.D.,* Hartzell V. Schaff, M.D.,† and Rakesh M. Suri, M.D., D.Phil.‡

*Division of Cardiovascular Diseases, Mayo Clinic, Rochester, Minnesota; †Department of Cardiovascular & Thoracic Surgery, Montefiore Medical Center/Albert Einstein College of Medicine, New York, New York; and ‡Division of Cardiovascular Surgery, Mayo Clinic, Rochester, Minnesota

Abstract: Patients who are candidates for surgical valve replacement (AVR) may benefit from diminished length of cardiopulmonary bypass time. Sutureless valve technology for AVR may facilitate the performance of the operation through smaller incisions, and more expeditiously due to the ability to anchor traditional bovine pericardial prostheses without the need for sutures. We report the first successful US implants of the Sorin PERCEVAL valve as part of the FDA IDE trial. doi: 10.1111/jocs.12333 (J Card Surg 2014;XX:1-4)

ARTICLE IN PRESS

Minimally invasive aortic valve replacement with Perceval S sutureless valve: Early outcomes and one-year survival from two European centers

Antonio Miceli, MD, PhD,‡§ Giuseppe Santarpino, MD,¶ Steffen Pfeiffer, MD,† Michele Murzi, MD,¶ Daniyar Gilmanov, MD,¶ Giovanni Concistré, MD,‖ Eugenio Quaini, MD,¶ Marco Solinas, MD,¶ Theodor Fischlein, MD,§ and Mattia Glairer, MD‡

Objective: The aim of our study was to evaluate the early outcomes and 1-year survival of patients undergoing minimally invasive aortic valve replacement with the Perceval S sutureless valve for severe aortic stenosis.

Methods: From March 2010 to March 2013, 281 high-risk patients underwent minimally invasive aortic valve replacement with the Perceval S sutureless valve through either right anterior minithoracotomy (n = 164) or upper ministernotomy (n = 117) at 2 cardiac centers.

Results: The overall in-hospital mortality was 0.7% (2 patients). The overall median cardiopulmonary bypass and crossclamp time was 81 minutes (interquartile range, 68-98) and 48 minutes (interquartile range, 37-60), respectively. Postoperative stroke occurred in 5 patients (1.8%). The incidence of paravalvular leak greater than 1 of 4 and atroventricular block requiring pacemaker implantation was 1.8% (5 patients) and 4.2% (12 patients), respectively. No migration occurred, and the mean postoperative gradient was 13 ± 4 mm Hg. At a median follow-up of 8 months (interquartile range, 4-14), the overall survival was 90%.

Conclusions: Minimally invasive aortic valve replacement with the Perceval S sutureless valve in high-risk patients is a safe and reproducible procedure associated with excellent hemodynamic results, postoperative outcomes, and 1-year survival. (J Thorac Cardiovasc Surg 2014; ■:1-6)
Expanding the Indication for Sutureless Aortic Valve Replacement to Patients with Mitral Disease

Tam Hoang Minh MD,‡ Amine Mazine MD,‡ Ismail Bouhout MD,‡
Ismail El-Hamamsy MD, PhD,§ Michel Carrier MD, MBA,§ Denis Bouchard MD, PhD,§
Philippe Demers MD, MSc,§

Introduction

Sutureless aortic valve replacement (AVR) is an emerging alternative to standard AVR in elderly high-risk surgical patients. Potential advantages include shorter aortic cross-clamp times and easier access for minimally invasive surgery. Several case series have shown good early clinical and hemodynamic outcomes with the use of sutureless prostheses. However, despite promising initial clinical results, indications for sutureless AVR are still being refined. Patients undergoing multiple valve surgery present a higher operative risk, partly as a result of prolonged periods of cardiopulmonary bypass and myocardial ischemia. These patients could theoretically benefit from the reduction in cross-clamp times associated with sutureless AVR. However, presence of a previously implanted mitral prosthesis or need for concomitant mitral valve (MV) surgery are generally viewed as contraindications to sutureless AVR, due to a potential risk of interference between the two valves at the level of the aorto-mitral continuity.

We assessed the hypothesis that sutureless AVR could be safely performed in patients requiring concomitant MV surgery. We review our experience with sutureless AVR in this setting and describe the technical considerations.

METHODS

Between June 2011 and May 2013, 120 patients with severe aortic stenosis underwent sutureless AVR using the Perceval S prosthesis (Sorin, Saluggia, Italy). Of these, 10 had concomitant mitral valve disease.

The Perceval S sutureless valve is a new generation aortic bioprosthesis is composed of bovine pericardium mounted within a super-elastic alloy frame. The device can be collapsed through a dedicated device and deployed using a specific delivery system.
Première étude comparative entre les trois prothèses valvulaires aortiques sutureless disponibles

Marouane Ouazzani, Jean-Marc Frapier, Philippe Rouvière, Pascal Battistella, Thomas Gandet, Bernard Albat, Roland Demaria*

RÉSUMÉ
Mots clés: valve aortique, prothèses valvulaires, chirurgie mini-invasive.
Objectif : L'objectif de cette revue de la littérature est de réaliser une étude comparative des trois prothèses à déploiement rapide dites « sutureless » disponibles.
Méthodes : une recherche sur Medline Pubmed a été réalisée. Nous avons comparé les caractéristiques et les différentes techniques de mise en place ainsi que les résultats cliniques des premières études sur ces trois valves.
Résultats : la mortalité hospitalière est légèrement plus importante avec l'Enable alors que la mortalité tardive est similaire. Le temps de clampage aortique est moins important pour la Percovale. Les gradients postopératoires sont moins importants avec l'Intuity et l'Enable alors que les gradients à un an semblent meilleurs avec l'Intuity et la Percovale. On constate plus de fuites périprothétiques avec la Percovale, plus de pacemakers avec l'Enable, mais moins d'accidents thromboemboliques. Enfin, moins d'endocardites sont rapportées avec l'Intuity.

ABSTRACT
Aim: The aim of this literature review was to compare the three available “sutureless” valvular prostheses.
Methods: A search on Medline Pubmed was conducted. We compared the characteristics and various implementation techniques as well as the clinical results of the latest studies on these three valves.
Results: Hospital mortality is slightly higher with the Enable and late mortality is similar for the three valves. Time of "aortic clamping" is less important for the Percovale. Post-operative gradients are less with the Intuity and the Enable and favor the Intuity and the Percovale at one year. There are more peri-prosthetic leaks with the Percovale and a greater requirement for pacemakers with the Enable but fewer thromboembolic events. Finally, less endocarditis is reported with the Intuity.
Conclusion: "Sutureless" valves are a new surgical alternative for aortic valve replacement. They are less traumatic to the aortic annulus. They allow easier access for minimally invasive surgery. Each valve has its strengths and weaknesses. The choice of valve is based on the habits and beliefs of the surgeons, along with financial considerations.
Sutureless aortic valve replacement: a systematic review and meta-analysis

Kevin Phan¹, Yi-Chin Tsai², Nithya Niranjan¹, Marco Di Eusanio³,⁴, Tristan D. Yan¹,⁴

¹The Collaborative Research (CORE) Group, Macquarie University, Sydney, Australia; ²Department of Cardiothoracic Surgery, The Prince Charles Hospital, Chermside, Australia; ³Cardiovascular Surgery Department, Sani Orsola-Malpighi Hospital, Bologna University, Bologna, Italy; ⁴Department of Cardiothoracic Surgery, Royal Prince Alfred Hospital, University of Sydney, Sydney, Australia

Correspondence to: Tristan D. Yan, PhD, MS, MD, FRACS, Professor of Cardiovascular and Thoracic Surgery, Macquarie University Hospital, Sydney, Australia; The Collaborative Research (CORE) Group, Macquarie University, 2 Technology Place, Sydney, Australia. Email: tristan.yan@anu.edu.au.

Background: Sutureless aortic valve replacement (SU-AVR) has emerged as an innovative alternative for treatment of aortic stenosis. By avoiding the placement of sutures, this approach aims to reduce cross-clamp and cardiopulmonary bypass (CPB) duration and thereby improve surgical outcomes and facilitate a minimally invasive approach suitable for higher-risk patients. The present systematic review and meta-analysis aims to assess the safety and efficacy of SU-AVR approach in the current literature.

Methods: Electronic searches were performed using six databases from their inception to January 2014. Relevant studies utilizing sutureless valves for aortic valve implantation were identified. Data were extracted and analyzed according to predefined clinical endpoints.

Results: Twelve studies were identified for inclusion of qualitative and quantitative analyses, all of which were observational reports. The minimally invasive approach was used in 90.4% of included patients. While 22.3% underwent concomitant coronary bypass surgery. Pooled cross-clamp and CPB duration for isolated AVR was 56.7 and 46.3 minutes, respectively. Pooled 30-day and 1-year mortality rates were 2.1% and 4.9%, respectively, while the incidences of strokes (1.5%), valve degenerations (0.6%) and paravalvular leaks (1.5%) were acceptable.

Conclusions: The evaluation of current observational evidence suggests that sutureless aortic valve implantation is a safe procedure associated with shorter cross-clamp and CPB duration, and comparable complication rates to the conventional approach in the short-term.

Keywords: Sutureless aortic valve replacement (AVR); meta-analysis; minimally invasive

Submitted Mar 20, 2014; Accepted for publication Apr 27, 2014.

doi: 10.1097/JTC.00000000000000601

View this article at: http://dx.doi.org/10.1097/JTC.00000000000000601

Better Short-Term Outcome by Using Sutureless Valves: A Propensity-Matched Score Analysis

Francesco Pollari, MD,¹ Giuseppe Santarpino, MD, Angelo Maria Dell’Aquila, MD, Laszlo Gazdag, MD, Husam Alnahas, MD, Ferdinand Vogt, MD, Steffen Pfeiffer, MD, and Theodor Fischlein, MD

Department of Cardiac Surgery, Klinikum Nürnberg, Paracelsus Medizinische Privatuniversität, Nuremberg and Department of Cardiac Surgery, Universitätsklinikum Mainz, Mainz, Germany

Background. Sutureless aortic valve prostheses have the potential of shortening ischemic time. However, whether shorter operative times may also result in improved patient outcomes and have an effect on hospital costs remains to be established.

Methods. From March 2010 to April 2013, 566 patients underwent aortic valve replacement with bioprostheses; of these, 166 received a sutureless valve, and 400 received a stented valve. Redo and associated procedures were included. A propensity-score analysis was used to create two groups (sutureless and stented) with 82 matched pairs with comparable preoperative characteristics. Hospital outcome, follow-up, and health care resource consumption were compared.

Results. There were 3 hospital deaths in the stented group and 2 in the sutureless group (p = 0.65). Aortic cross-clamp, cardiopulmonary bypass, and operation times were significantly shorter in the sutureless group (p < 0.001). Patients in the sutureless group required blood transfusion less frequently (1.2 ± 1.3 vs 2.5 ± 3.7 units, p = 0.005), with a similar need for reexploration for bleeding (2 vs 3, p = 0.221). The sutureless group had a shorter intensive care unit stay (2.0 ± 1.2 vs 2.8 ± 1.3 days, p < 0.001), hospital stay (10.9 ± 2.7 vs 12.4 ± 4.4 days, p = 0.001) and intubation time (9.5 ± 4.6 vs 16.6 ± 6.4 hours, p < 0.001), and a lower incidence of postoperative atrial fibrillation (p = 0.015), pleura effusions (p = 0.024), and respiratory insufficiency (p = 0.016). Pacemaker implantation and occurrence of neurologic events were similar between groups (p > 0.05). A lower rate of postoperative complications resulted in reduced resource consumption in the sutureless group for diagnostics ($2,153 vs $1,387), operating room ($5,879 vs $5,527), and hospital stay ($59,873 vs $61,584), with a total cost saving of approximately 25% ($17,905 vs $43,498).

Conclusions. A shorter procedural time in the sutureless group is associated with better outcomes in hospitalization and reduced hospital costs.

Early and intermediate outcome with the sutureless Perceval S aortic valve bioprosthesis: Results of a multicenter study

Antonio S. Rubino, MD,1 Giuseppe Santarpino, MD,2 Herbert De Praetere, MD,2 Keieicho Kasama, MD,3 Magnus Dalén, MD,4 Ulrik Sartipy, MD,4 Jarro Lahtinen, MD,5 Joimi Heikkinen, MD,5 Wanda Deoste, MD,6 Francesco Pollari, MD,7 Peter Svennud, MD, PhD,7 Bart Meuris, MD, PhD,7 Theodor Fischlein, MD,8 Carmelo Mignosa, MD, FECTS,9 and Fausto Biancardi, MD, PhD9

Objective: The aim of this study was to evaluate the outcome of aortic valve replacement with the sutureless Perceval S aortic valve bioprosthesis ( Sorin Biomedica Cardio Srl, Saluggia, Italy).

Methods: This is a retrospective analysis of 314 patients (mean age, 77.9 ± 5.0 years, mean European System for Cardiac Operative Risk Evaluation II, 9.0% ± 7.6%) who underwent aortic valve replacement with the Perceval S valve with (94 patients) or without (220 patients) concomitant coronary artery bypass surgery at 5 European centers.

Results: The Perceval S valve was successfully implanted in all but 1 patient (99.7%). The mean aortic crossclamping time was 41 ± 20 minutes (isolated procedure, 39 ± 15 minutes; concomitant coronary surgery, 52 ± 26 minutes). Severe paravalvular leak occurred in 2 patients (0.6%). In-hospital mortality was 3.2% (1.4% after isolated procedure and 7.4% after concomitant coronary surgery). In-hospital mortality was 2.8% and 4.0% among patients with a European System for Cardiac Operative Risk Evaluation II less than 10% and 10% or greater, respectively (P = .358). Octogenarians had slightly higher in-hospital mortality (5.2% vs 2.0%, P = .125) after isolated procedure; 2.7% vs 0.7%, P = .223; after concomitant coronary surgery: 9.5% vs 5.8%, P = .491) compared with younger patients. Full sternotomy did not increase the in-hospital mortality risk compared with miniminustomotomy or minithoracotomy access (1.3% vs 1.4%, when adjusted for baseline covariates: P = .921; odds ratio, 0.886; 95% confidence interval, 0.064–12.346). One-year survival was 90.5%. Freedom from valve-related mortality, stroke, endocarditis, and reoperation was 99.0%, 98.1%, 99.2%, and 98.3%, respectively.

Conclusions: The sutureless Perceval S valve is associated with excellent early survival in high-risk patients, particularly among those undergoing an isolated procedure. Further studies are needed to prove the durability of this bioprosthesis. (J Thorac Cardiovasc Surg 2014;147:1-7)
Sutureless replacement versus transcatheter valve implantation in aortic valve stenosis: A propensity-matched analysis of 2 strategies in high-risk patients

Giuseppe Santarpino, MD, a, 1 Steffen Pfeiffer, MD, a Jürgen Jessl, MD, a Angelo Maria Dell’Aquila, MD, c Francesco Potlari, MD, a Matthias Paussinger, MD, a and Theodor Fischlein, MD a

Objective: This propensity-matched study compared clinical and echocardiographic outcomes between patients undergoing transcatheter aortic valve implantation (TAVI) and sutureless aortic valve replacement.

Methods: From January 2010 to March 2012, 122 patients (age 79.4 ± 5.3 years, logistic euroSCORE 12% ± 8.4%) underwent minimally invasive sutureless aortic valve replacement, and 122 (age 84.6 ± 6.2 years, logistic euroSCORE 20.9% ± 2.5%) underwent TAVI. After propensity matching, 37 matched pairs were available for analysis.

Results: Preoperative characteristics and risk scores of matched groups were comparable. In-hospital mortalities were 0% in the sutureless group and 8.1% (n = 3) in the TAVI group (P = .24). Permanent pacemaker implantation was required in 4 patients in the sutureless group and 1 patient in the TAVI group (10.8% vs 2.7%; P = .18). A neurologic event was recorded in 2 patients of each group. Predictive echocardiographic data showed higher paravalvular leak rate in the TAVI group (13.5% vs 0%; P = .027). At mean follow-up of 18.9 ± 10.1 months, overall cumulative survival was 91.9% and significantly differed between groups (sutureless 97.3% vs TAVI 86.5%; P = .015). In the TAVI group, a significant difference in mortality was observed between patients with (n = 20) and without (n = 17) paravalvular leak (25% vs 0%; P = .036).

Conclusions: Combining the advantage of standard diseased valve removal with shorter procedural times, minimally invasive sutureless aortic valve replacement may be the first-line treatment for high-risk patients considered in the “gray zone” between TAVI and conventional surgery. (J Thorac Cardiovasc Surg 2013;145:1-7)
Aortenklappenersatz mit nahtfreien Herzklappenprothesen – aktueller Stand und Stellenwert in der Zukunft

Use of Sutureless Valves for Aortic Valve Replacement in Clinical Practice: State of the Art

Giuseppe Santarpino, Theodor Flischlein
Klinikum Nürnberg, Klinik für Herzkatheter- und Herz-ClinoR Zentrum, Nürnberg

Was ist wichtig?


- Schlussfolgerung: Die gegenwärtige Datenlage zeigt, dass die nahtfreie Bioprothese eine wirksame und funktionsfähige Alternative für die chirurgische Therapie der symptomatischen Aortenklappenstenose darstellt, gerade bei einem älter werdenden, multimorbiden Patientengut.
Aortic Valve Replacement and Concomitant Procedures With the Perceval Valve: Results of European Trials

Malaksh Shrestha, MBBS, PhD, Thierry A. Folliguet, MD, Steffen Pfoffer, MD, PhD, Bart Meuris, MD, PhD, Thierry Carrel, MD, Matthias Bechtel, MD, Willem J. Flameng, MD, Theodora Fischlein, MD, PhD, Francois Laborde, MD, and Axel Haverich, MD, PhD

Cardiovascular, Transplantation, and Vascular Surgery, Hannover Medical School, Germany; Cardio Medicosurgical Department, Institute Mutualiste Montsouris, Paris, France; Klinikum Nurnberg, Heart Center of Cardiac Surgery, Nuremberg, Germany; Cardiac Surgery, UZ Gasthuisberg, Leuven, Belgium; Inselspital, Bern, Switzerland; Ruhr University of Bochum, Department of Cardiothoracic Surgery, Bochum, Germany

Background. The Perceval (Sorin Group, Milan, Italy) is a self-anchoring sutureless aortic valve prosthesis. We report the short- to midterm results of combined aortic valve replacement (AVR) with concomitant procedures in elderly patients undergoing operation as part of 3 consecutive prospective multicenter European studies.

Methods. From April 2007 to February 2013, 243 patients (mean age, 79.7 ± 8.1 years; female patients, 61%; median EuroSCORE, 9%) underwent AVR with concomitant procedures. The concomitant procedures were coronary artery bypass grafting (CABG) (182 cases), septal myectomy (21 cases), CARG + other procedures (18 cases), and 22 other procedures. Primary and secondary end points included implant feasibility and safety (for mortality and morbidity) and efficacy (New York Heart Association [NYHA] class improvement and hemodynamic results) of the prosthesis at the different follow-up periods. Data were expressed as mean ± standard deviation. Kaplan-Meier analysis was performed for survival analysis.

Results. Mean aortic cross-clamp and extracorporeal circulation (ECC) times were 50.7 ± 22.8 minutes and 78.9 ± 32.3 minutes, respectively. Thirty-day mortality was 3.7%. Mean postoperative gradient and effective orifice area were 10.1 ± 4.7 mm Hg and 1.5 ± 0.4 cm² and 8.9 ± 5.6 mm Hg and 1.6 ± 0.4 cm², respectively, at 1 year. There were early explantations, 4 of which resulted from paravalvular leaks. One additional valve explantation resulted from aortic root bleeding; probably caused by excessively extensive decalcification. In the late period, there was 1 mild paravalvular leak and no intravalvular insufficiency. No migration, dislodgement, or degeneration of the valve occurred during follow-up. Median follow-up was 444 days.

Conclusions. These trials confirm the safety and efficacy of the Perceval sutureless aortic valve, especially in elderly patients requiring AVR + concomitant procedures. In this patient group, sutureless valves may be advantageous compared to transcatheter valve implantations as concomitant procedures other than percutaneous coronary artery angioplasty are not always possible in the latter.

(Ann Thorac Surg 2015;—–) © 2014 by The Society of Thoracic Surgeons
Recent developments for surgical aortic valve replacement: The concept of sutureless valve technology

Thierry Carrel, Lars Engblom, Mario Stalder
Open Journal of Cardiology, 2013, 4-1

ABSTRACT

Aortic stenosis has become the most frequent type of valvular heart disease in Europe and North America and presents in the large majority of patients as calcified aortic stenosis in adults of advanced age. Surgical aortic valve replacement has been recognized to be the definitive therapy which improves considerably survival for severe aortic stenosis since more than 40 years. In the most recent period, operative mortality of isolated aortic valve replacement for aortic stenosis varies between 1–3% in low-risk patients younger than 70 years and between 4% and 8% in selected older adults. Long-term survival following aortic valve replacement is close to that observed in a control population of similar age. Numerous observational studies have consistently demonstrated that corrective surgery in symptomatic patients is invariably followed by a subjective improvement in quality of life and a substantial increase in survival rates.

More recently, transcatheter aortic valve implantation (TAVI) has been demonstrated to be feasible in patients with high surgical risk using either a retrograde transfemoral or transsubclavian approach or an antegrade, transapical access. Reported 30-day mortality ranges between 5% and 15% and is acceptable when compared to the risk predicted by the logistic EuroSCORE (varying between 20% and 35%) and the STS Score, although the EuroScore has been shown to markedly overestimate the effective operative risk. One major concern remains the high rate of paravalvular regurgitation which is observed in up to 85% of the patients and which requires further follow-up and critical evaluation. In addition, long-term durability of these valves with a focus on the effects of crimping remains to be addressed, although 3-5 year results are promising.

Sutureless biological valves were designed to simplify and significantly accelerate the surgical replacement of a diseased valve and allow complete excision of the calcified native valve. Until now, there are 3 different sutureless prostheses that have been approved. The Edwards Sapien valve from Medtronic received CE market approval in 2010, the Perceval S from Sorin during Q1 of 2011 and the intuition sutureless prosthesis from Edwards in 2012. All these devices aim to facilitate valve surgery and therefore have the potential to decrease the invasiveness and to shorten the conventional procedure without compromise in terms of excision of the diseased valve. This review summarizes the history and the current knowledge of sutureless valve technology.
Two Alternative Sutureless Strategies for Aortic Valve Replacement
A Two-Center Experience

Giovanni Concistrè, MD, Giuseppe Santarpino, MD, Steffen Pfeffer, MD, Pierandrea Farnetti, MD, Antonio Miceli, MD, Francesca Chiaromonti, MD, Marco Solinas, MD, Mattia Glauber, MD, and Teodor Fischlein, MD

Objective: Important comorbid conditions in patients referred for aortic valve replacement (AVR) require less invasive strategies. We describe our initial experience with the Perceval S (Sorin Group, Saluggia, Italy) and 3F Enable (Moldtech, Minneapolis, MN USA) sutureless aortic bioprostheses.

Methods: We compared perioperative data, postoperative clinical outcomes, and echocardiographic results from patients receiving a Perceval S (P group: n = 93) or a 3F Enable (E group: n = 32) prosthesis in two cardiac surgery departments (Nurnberg, Germany, and Massa, Italy).

Results: Baseline patient characteristics were similar in both groups, except for mean ± SD body surface area (P group = 2.01 ± 2.9 m², E group = 1.83 ± 3.8 m², P < 0.001). Sixty-five patients (67%) in the P group and 59 patients (59.5%) in the E group (P = 0.22) underwent minimally invasive AVR with either minimization of right anterior minithoracotomy approach. Concomitant procedures were performed in 37 patients (38%) in the P group and 9 patients (28%) in the E group (P = 0.56). In-hospital mortality was 2%. The mean ± SD prosthesis diameter was 23.8 ± 1.4 mm (P group) compared with 22.1 ± 2 mm (E group) (P < 0.001). In isolated AVR, aortic cross-clamp time was 36 ± 12.7 minutes in the P group and 66 ± 18 minutes in the E group (P < 0.001). At a mean ± SD follow-up of 8.3 ± 4.5 months, survival was 97% (one death in the P group). In five patients (P group: 1, E group: 4), a moderate paravalvular leak was present (P = 0.013). The mean ± SD transvalvular gradient was 9.1 ± 3.3 mm Hg with the Perceval S and 11.2 ± 5.2 mm Hg with the 3F Enable (P = 0.017).

Accepted for publication July 11, 2013.

From the *Department of Cardiovascular Surgery - Klinikum Nürnberg; Nurnberg, Germany, and †Department of Cardiovascular Surgery, Ospedale del Cerrà “G. Pauiniucci,” Fondazione Monastico-CNR, Massa, Italy.

Giovanni Concistrè and Giuseppe Santarpino contributed equally to this study and should be considered co-first authors.

Presented at the Annual Scientific Meeting of the International Society for Minimally Invasive Cardiothoracic Surgery, May 30–June 2, 2012, Los Angeles, CA, USA.

Disclosure: The authors declare no conflicts of interest.

Address correspondence and reprint requests to Giovanni Concistrè, MD, Department of Cardiovascular Surgery - Klinikum Nürnberg, Klinikum Str., Braustetterstr. 201, 90421 Nürnberg, Germany. E-mail: giovanni.concistre@sh-klinikum.de.

Copyright © 2013 by the International Society for Minimally Invasive Cardiothoracic Surgery.

ISSN: 1556-9945/13/04004-0253

Innovations • Volume 8, Number 4, July/August 2013

Conclusions: Aortic valve replacement with sutureless aortic bioprosthesis is feasible, also with a minimally invasive approach. The Perceval S showed lower operative times and moderate paravalvular leaks and lower mean transvalvular gradients than the 3F Enable, related to the larger diameter of the Perceval S implanted. Both prostheses showed an excellent hemodynamic performance. This new technology needs long-term follow-up.

Key Words: Sutureless aortic valve, Aortic valve replacement, Minimally invasive surgery.

(Innovations 2013;8:253–257)

Pre-implantation collapse in the Sorin Perceval S Sutureless prosthesis does not affect pericardial graft structure

Mila Della Barbera, Cristina Basso, Marialuise Valente, Gaetano Thiene

Department of Cardiological, Thoracic and Vascular Sciences, University of Padua, Italy

Purpose: Sutureless valves have been conceived to perform aortic valve replacement by simplifying the procedure and shortening the cross-clamping time as to limit myocardial damage due to cardiac arrest. At difference from transcatheter aortic valve implantation (TAVI), sutureless procedure is associated to native cusps retraction, and to reduced valve collapse time before implantation. The Sorin Perceval S provides short collapse time, with limited involvement of the pericardial cusps, and does not undergo, after deployment, to prosthesis cup ballooning except only to anchoring stent level.

Methods: Eleven Sorin Perceval S Sutureless prostheses underwent to different collapse times (four 15 and 60 min each and three 180 min) followed by deployment and balloononing. Two unimplanted pericardial sheets and four uncollapsed valves served as control. Gross, histological staining, including Periunlar red, scanning electron microscopy (SEM) and morphometry were carried out to study collagen fibers waverness periodicity.

Results: Gross examination revealed optimal pericardial cup coaptation. No tears, perforations or folding were observed. Prosthetic frame showed a preserved shape. Histology and SEM exhibited neither breaks nor differences in collagen periodicity (16.5±2.89 μm in 15 min, 17.61±3.11 μm in 60 min, 16.45±2.13 μm in 180 min collapsed valves) when compared to controls (17.67±2.50 μm in uncollapsed pericardium, 16.51±2.65 μm in uncollapsed valves) (p = NS).

Conclusions: At difference with TAVI, pre-implantation collapse, deployment and balloononing do not affect the structural integrity of the collagen network of the pericardial tissue in Sorin Perceval S Sutureless prosthesis.

http://dx.doi.org/10.1016/j.innov.2013.01.052

Augusto D’Onofrio, MD, Giulio Rizzoli, MD, Antonio Messina, MD, PhD, Ottavio Alfieri, MD, Roberto Lorusso, MD, PhD, Stefano Salizzi, MD, Mattia Glauber, MD, Roberto Di Bartolomeo, MD, Laura Besola, MD, Mauro Rinaldi, MD, Giovanni Troisi, MD, and Gino Gerosa, MD

Objective: Although surgical aortic valve replacement (SAVR) is the treatment of choice for patients with aortic valve stenosis, transcatheter aortic valve replacement (TAVR) and sutureless aortic valve replacement (SU-AVR) have shown good results. The aim of our multicenter, propensity-matched study was to compare the clinical and hemodynamic outcomes of surgical SAVR, transapical TAVR (TA-TAVR), and SU-AVR.

Methods: We analyzed data from 566 TA-TAVR, 349 SAVR, and 38 SU-AVR patients treated from January 2009 to March 2012. We used a propensity-matching strategy to compare on-pump (SAVR, SU-AVR) and off-pump (TA-TAVR) surgical techniques. The outcomes were analyzed using multivariate weighted logistic regression or multivariable logistic analysis.

Results: In the matched cohorts, the 30-day overall mortality was significantly lower after SAVR than TA-TAVR (7% vs 13.5%, P = 0.02), with no differences in mortality between SU-AVR and TA-TAVR. Multivariate analysis showed SU-AVR to have a protective effect, although not statistically significant, against aortic regurgitation, pacemaker implantation, and renal replacement therapy compared with TA-TAVR. Compared with TA-TAVR, SAVR demonstrated significant protection against aortic regurgitation (odds ratio, 0.04; P < 0.01) and a trend toward protection against death, pacemaker implantation, and myocardial infarction. The mean transaortic gradient was 10.3 ± 4.8 mm Hg, 11 ± 3.4 mm Hg, and 16.5 ± 5.8 mm Hg in the TA-TAVR, SU-AVR, and SAVR patients, respectively.

Conclusions: SAVR was associated with lower 30-day mortality than TA-TAVR. SAVR was also associated with a lower risk of postoperative aortic regurgitation compared with TA-TAVR. We did not find other significant differences in outcomes among matched patients treated with SAVR, SU-AVR, and TA-TAVR. (J Thorac Cardiovasc Surg 2013;146:1065-71)

Sutureless Implantation of the Perceval S Aortic Valve Prosthesis Through Right Anterior Minithoracotomy

Daniyar Gilmanov, MD, Antonio Miceli, MD, Stefano Bevilacqua, MD, Pierandrea Farneti, MD, Marco Solinas, MD, Matteo Ferrarini, MD, and Mattia Glauber, MD

Department of Adult Cardiac Surgery, G. Pasquinozzi Heart Hospital, Gabriele Monasterio Foundation, Massa, Italy

Background. Many new, less invasive strategies are proposed for aortic valve operation in elderly patients. Rapid deployment sutureless aortic valve prosthesis has been recently introduced. We analyzed our experience with a sutureless valve implanted through a minimally invasive approach.

Methods. A retrospective observational study with prospectively registered data was conducted on 137 patients undergoing aortic valve replacement through a right anterior minithoracotomy. Between April 2011 and January 2013, 137 consecutive patients underwent aortic valve replacement with a recently introduced, rapid deployment, sutureless pericardial valve in minithoracotomy access (47 men; mean age, 76.6 ± 7.1 years). There were 35 obese patients with a body mass index of more than 30 kg/m². Mean logistic EuroSCORE was 10.0; 74 (54%) patients were in New York Heart Association functional class III and IV. In all, 19 (13.9%), 45 (32.8%), and 73 (53.3%) patients received 21-, 23-, and 25-mm valve prostheses, respectively.

Results. The mean aortic cross-clamp and cardiopulmonary bypass times were 59.3 ± 19 min and 92.3 ± 27 min, respectively. No operative mortality occurred. Median stay in the intensive care unit was 1 day, with assisted ventilation necessary for a median of 6 hours. Three cases of postoperative ischemic stroke were observed (1 patient with a previous history of an ischemic cerebral event). Median hospital length of stay was 6 days.

Conclusions. A sutureless valve for minimally invasive aortic valve replacement is a feasible, effective, and safe tool. Ultimately amplifying indications for less invasive aortic valve replacement in a high surgical risk subset of patients, it can become a valid alternative for transcatheter aortic valve implantation.

(Ann Thorac Surg 2013;___:___)

© 2013 by The Society of Thoracic Surgeons
Sutureless aortic valve replacement: an alternative to transcatheter aortic valve implantation?

Roberto Lorusso a,b, Sandro Gelsomina a,b, and Attilio Renzi a,b

Purpose of review
The sutureless aortic bioprosthesis has been recently introduced in clinical practice for aortic valve replacement (SUA- AVR) and appears to provide enhanced implantability and favourable haemodynamics, particularly advisable in minimally invasive surgery, in difficult anatomical situations or elderly patients. Implants of sutureless bioprosthesis are increasingly performed, and the first meaningful findings have been released and are herein analysed.

Recent findings
A two-centre experience in 208 patients has shown safety, ease of implantation, excellent haemodynamic performance and limited aortic cross-clamp (ACC) and cardiopulmonary (cardio-pulmonary bypass, CPB) times, also in the case of associated coronary artery bypass grafting. Another multicentre experience with a third sutureless, albeit stented, valve implanted in 146 patients has been also presented with early favourable results. The sutureless aortic valve has been reported to be competitive also in relation to the transcatheter aortic valve implantation (TAVI) procedure in high-risk patients, as demonstrated by a propensity score based comparative analysis in a multicentre study, with reduced paravalvular leak rate but with increased atrial fibrillation occurrence in SUA- AVR cases. Other single-centre series have been published with satisfactory results in terms of excellent haemodynamic performances or of enhanced implantability in high-risk patients or during minimally invasive procedures.

Summary
Sutureless aortic valve replacement has been shown to be well tolerated, to provide excellent haemodynamic performance and to be particularly suitable in minimally invasive procedures or in patients with extensive calcified aortic root or with the need of short ACC and CPB times for marked comorbidities. Further evaluations are, however, still necessary to conclusively show the actual advantages of SUA- AVR, also as an alternative to TAVI procedures in operable high-risk patients.

Keywords
aortic valve replacement, bioprosthesis, sutureless

Sutureless aortic bioprostheses – initial experience with Sorin Perceval S prosthesis

Sutureless aortic bioprostheses are a new generation of bioprostheses constructed for treatment of aortic stenosis. Their construction is focused on safety and on procedure and haemodynamic parameters. They are compatible with minimally invasive surgery. In our paper we present a first experience with prosthesis Perceval S, Sorin.

Key words: aortic stenosis, sutureless bioprostheses.

Aleš Molnářek a, b, Jitka Kanáčová a, Vejtlích Kurfírster a, Martin Rezler a

aKardioklinické oddělení, Nemocnice České Budějovice
bKEM Praha

Zdravotní sociální fakulta, Jihočeská univerzita České Budějovice
Sutureless Aortic Valve Replacement Using Perceval S Valve

Shahzad G. Raja

Department of Cardiac Surgery, Harefield Hospital, London, United Kingdom

Received: May 5, 2013; Revised: May 21, 2013; Accepted: May 22, 2013

Abstract: Surgical aortic valve replacement is the treatment of choice in patients with severe symptomatic aortic valve stenosis because it provides excellent early and long-term clinical outcomes in terms of hemodynamics, valve durability, and freedom from valve-related complications. In recent years, the number of high-risk patients being referred for surgical aortic valve replacement has increased. A considerable proportion of these patients are deemed operable despite the high risk. In order to modify the risk predominantly associated with duration of cardiopulmonary bypass and cross clamp time, sutureless aortic valve technology has been developed. Sutureless aortic bioprosthetic valves, introduced in clinical practice in 2009, contrast to the conventional surgical technique for implantation (interrupted or continuous sutures, after thorough annular decalcification) are not hand sewn. This technological modification reduces the implantation time with potential translation into improved outcomes for high-risk patients undergoing surgical aortic valve replacement. Currently, three sutureless bioprostheses are available and amongst these the largest published experience is available for the patented and CE marked truly sutureless PERCEVAL S valve (Sorin Group, Saluggia, Italy). This article provides an overview of the published literature for Perceval S valve with an attempt to better define the role of sutureless aortic valve replacement in the treatment of critical aortic valve stenosis.

Journal of Cardiovascular Medicine:
POST AUTHOR CORRECTIONS, 11 September 2013
doi: 10.2459/JCM.0b013e328360936a
Original article: PDF Only

Minimally invasive aortic valve replacement with Perceval valves: first clinical experience

Santarpino, Giuseppe; Pfeiffer, Steffen; Sırch, Joachim; Vogl, Ferdinand; Concistrè, Giovanni; Fischlein, Theodor

Abstract

Aim: Although minimally invasive aortic valve replacement (MIAVR) has been shown to cause less morbidity than conventional surgery, it has not yet received broad application. The purpose of this study was to evaluate sutureless implantation using the Perceval S aortic valve bioprosthesis (Sorin Group, Saluggia, Italy) via ministernotomy.

Methods: Seventy-two patients (43 women, 29 men; mean age 77.4 +/- 5.3 years) with isolated aortic valve stenosis (mean gradient of 52 +/- 14 mmHg) underwent aortic valve implantation with the sutureless Perceval S bioprosthesis, following cardiopulmonary bypass (CPB), aortic cross-clamping (ACC), cardiopлегic arrest, and removal of the calcified native valve. The mean logistic EuroSCORE was 9.7 +/- 6.2%.

Results: The prosthetic valve was successfully deployed in all patients. Thirty-day mortality was 1.4% (n = 1). Mean CPB, ACC, and implantation times were 68 +/- 38, 40 +/- 13, and 8.9 +/- 4 min, respectively. Perioperative echocardiography revealed significant paravalvular leakage in one patient. Postoperative mean gradient was 11.6 +/- 5.1 mmHg. At a mean follow-up of 13 +/- 6.7 months, no significant paravalvular leakage or valvular regurgitation was observed, and no migration or dislodgement of the prosthesis occurred.

Conclusion: This study shows that sutureless implantation of the Perceval S aortic valve bioprosthesis provides a simple and reproducible alternative for MIAVR. As the valve does not need to be sutured, it may also result in reduced ACC and CPB times. This self-anchoring valve may also allow the application of MIAVR to a broader spectrum of patients. This new technology needs a long-term follow-up.

(C) 2013 Italian Federation of Cardiology. All rights reserved.
Left ventricular mass regression after sutureless implantation of the Perceval S aortic valve bioprosthesis: preliminary results

Giuseppe Santarpino*, Steffen Pfeiffer, Francesco Pollari, Giovanni Concistrè, Ferdinand Vogt and Theodor Fischlein

Department of Cardiac Surgery, Klinikum Nürnberg, Nuremberg, Germany

* Corresponding author. Department of Cardiac Surgery, Klinikum Nürnberg, Klinikum Süd, Berndauerstraße 201, 90471 Nürnberg, Germany. Tel: +49-911-3985441; fax: +49-911-3985448; e-mail: g.santarpino@klinikum-n.de (G. Santarpino).

Received 6 April 2013; received in revised form 10 July 2013; accepted 15 July 2013

Abstract

OBJECTIVES: Left ventricular (LV) hypertrophy in aortic stenosis (AS) is considered a compensatory response helping maintain systolic function, but constitutes a risk factor for cardiac morbidity and mortality. The aim of this study was to assess the degree of LV mass regression after sutureless implantation of the Perceval S aortic valve bioprosthesis (Coren Group, Saluggia, Italy).

METHODS: Between March 2010 and July 2012, 78 patients with symptomatic AS underwent isolated aortic valve replacement (AVR) with the Perceval bioprosthesis. Mean age was 77.1 ± 5.3 years, 46 patients were female (59%) and mean logistic EuroSCORE was 11 ± 7.5%. Echocardiography was performed preoperatively, at discharge, and at follow-up (mean 13.5 ± 7.3 months). LV mass was calculated using the Devereux formula and indexed to body surface area.

RESULTS: There was 1 in-hospital non-cardiac death and 3 late deaths. LV mass index decreased from 148.4 ± 46 g/m² at baseline to 119.7 ± 38.5 g/m² at follow-up (P = 0.002). No significant changes were observed in LV hypertrophy and/or relative wall thickness >0.42 as well as in LV ejection fraction. Mean aortic gradient decreased from 49.5 ± 15.8 mm Hg at baseline to 11.6 ± 5.1 mm Hg at discharge and 8.3 ± 4.4 mm Hg at follow-up (P < 0.001), resulting in significant clinical improvement. No moderate or severe paravalvular leakage was observed at discharge and at follow-up.

CONCLUSIONS: In AS patients, isolated AVR with the Perceval sutureless bioprosthesis is associated with significant LV mass regression at 1-year follow-up. However, longer-term follow-up is necessary to confirm these findings.

Keywords: Aortic valve replacement • Echocardiography • Heart valve bioprosthesis • Left ventricle • Right ventricle
Advanced Age Per Se Should not be an Exclusion Criterion for Minimally Invasive Aortic Valve Replacement

Giuseppe Santarpino, Steffen Pfeifer, Ferdinand Vogt, Martin Hinzmann, Giovanni Concistré, Theodor Fischlein

Department of Cardiac Surgery, Klinikum Nürnberg, Nuremberg, Germany

Background and aim of the study: The introduction of transcatheter aortic valve implantation (TAVI), coupled with the increasing number of elderly patients requiring cardiac surgery, has given rise to an intense debate on the most appropriate treatment strategy for this high-risk population. The study aim was to compare clinical outcomes in older versus younger patients undergoing minimally invasive aortic valve replacement (AVR).

Methods: Between March 2010 and July 2012, 66 patients undergoing minimally invasive isolated AVR with the sutureless Percival S bioprosthesis (Sorin Group, Saluggia, Italy) were allocated to two groups according to age ≥80 years (group A, n = 23) or <80 years (group B, n = 43). In-hospital and follow-up data were collected for all patients, including an evaluation of the patients’ quality of life, using the SF-36 questionnaire.

Results: Mean age and logistic EuroSCORE were statistically different between groups (p < 0.001 and p = 0.002, respectively). The length of intensive care unit stay was similar in groups A and B (1.5 ± 0.8 and 2.5 ± 1.4 days, respectively; p = 0.61). In-hospital mortality occurred in only one patient of group A (1.5%). Postoperative transient cerebral ischemic events occurred with similar frequency in both groups (two in group A and four in group B; p = 0.39). One patient in group A and two patients in group B required pacemaker implantation (1.5 versus 5%; p = 0.60). The mean follow-up was 13.9 ± 7.4 months, during which time three patients died (two in group A, one in group B). All enrolled patients answered the SF-36 questionnaire, and there were no significant differences between groups in all eight domains of the test.

Conclusion: Within the setting of minimally invasive isolated AVR, the study results showed that the clinical outcomes and quality of life in patients aged ≥80 years were comparable to those of younger patients. Therefore, advanced age per se does not preclude successful AVR through a minimally invasive approach.

The Journal of Heart Valve Disease 2013;22:455-459

The Perceval S Aortic Valve Has the Potential of Shortening Surgical Time: Does It Also Result in Improved Outcome?

Giuseppe Santarpino, MD, Steffen Pfeifer, MD, Giovanni Concistré, MD, Irena Grossmann, MD, Martin Hinzmann, MD, and Theodor Fischlein, MD

Departments of Cardiac Surgery and Anaesthesiology, Klinikum Nürnberg, Nuremberg, Germany

Background. Sutureless aortic valve prostheses have the potential of shortening surgical time. However, whether shorter operative times may also result in improved patient outcomes remains to be established.

Methods. One hundred patients underwent minimally invasive isolated aortic valve replacement. Of these, 50 patients received a Perceval (Sorin Group, Saluggia, Italy) bioprosthesis (group P) and 50 patients received a non-Perceval valve (group NP).

Results. The group P patients were older (77.5 ± 5.3 versus 71.7 ± 10 years, p = 0.001) and at higher risk (logistic European System for Cardiac Operative Risk Evaluation [EuroSCORE] 9.9 ± 6.5 versus 4.3 ± 1, p = 0.001) than group NP patients. One implant failure occurred in group P (p = 0.5), and conversion to full sternotomy was necessary in 1 patient from each group. Aortic cross-clamp and cardiopulmonary bypass times were 39.4% and 34% shorter in group P (both p < 0.001). Within 30 days, a total of 5 patients died (2 in group P and 3 in group NP, p = 0.5). No significant differences were observed between groups in postoperative arrhythmias and need for pacemaker implantation (p = 0.3 and p = 0.5, respectively). Despite the higher surgical risk, group P patients less frequently required blood transfusion (1.1 ± 1.1 units versus 2.3 ± 2.8 units, p = 0.007), and had a shorter intensive care unit stay (1.9 ± 0.7 versus 2.8 ± 1.9 days, p = 0.002) and a shorter intubation time (6.2 ± 3.6 hours versus 15 ± 13.8 hours, p = 0.013). Group NP patients had a mean prosthesis size significantly smaller than for group P (23 ± 2 mm versus 23.9 ± 1.1 mm, p = 0.01). The Perceval valve provided comparable hemodynamic performance to that of non-Perceval valves (mean gradient 8.4 ± 6 mm Hg versus 10 ± 4.9 mm Hg, p = 0.24).

Conclusions. Sutureless implantation of the Perceval valve is associated with shorter cross-clamp and cardiopulmonary bypass times, resulting in improved clinical outcome. In addition, it compares favorably with conventional valves in terms of mortality and outcome variables.

REDO Aortic Valve Replacement: The Sutureless Approach

Giuseppe Santarpino, Steffen Pfeiffer, Giovanni Concistrè, Theodor Fischlein

Department of Cardiac Surgery, Klinikum Nürnberg, Nürnberg, Germany

Background and aim of the study: The study aim was to report the results of a single-center cohort of patients who underwent aortic valve replacement (AVR) with a sutureless prosthesis in case of cardiac reoperation (REDO).

Methods: Between March 2010 and December 2011, a total of 83 patients underwent AVR with the Perceval™ S sutureless aortic bioprosthesis (Sorin Biomedica Cardio Srl, Saluggia, Italy) at the authors’ institution. Thirteen of these patients (six males, seven females; mean age 75.2 ± 5.6 years) had previously undergone cardiac surgery and represented the study population. Preoperative, periprocedural, and echocardiographic parameters, as well as clinical outcomes, were analyzed for all patients.

Results: The primary procedure was AVR, using a bioprosthesis in six patients (46%) and coronary artery bypass grafting in seven (54%). The logistic EuroSCORE was 19.4 ± 10.7%. Surgery was always performed via a full sternotomy; the mean implanted valve size was 23.6 ± 1.3 mm (the previous valve size was 23.2 ± 3.2 mm; p = 0.66). The mean cross-clamp time was 44 ± 16 min, and the mean intensive care unit stay was 3.3 ± 2.3 days. No intraoperative or in-hospital deaths occurred, and all patients were alive at a mean follow up of 8.5 months. Two postoperative events included transient ischemic attack in one patient, and the need for pacemaker implantation in one patient. On echocardiographic evaluation, no patient showed signs of paraprosthetic leak. The mean transvalvular gradient was 10.3 ± 1.5 mmHg.

Conclusion: Use of the Perceval S sutureless AVR offers a fast and safe procedure, even in high-risk REDO surgery, providing a good hemodynamic performance with excellent clinical recovery, demonstrated at a follow up of six months. Although the sample size was limited, the results were encouraging and support the use of sutureless valves in the frame of REDO surgery for aortic valve disease.

The Journal of Heart Valve Disease 2013;22:615-620
Aortic valve replacement in geriatric patients with small aortic roots: are sutureless valves the future?

Malaksh Shrestha*, Ilona Maeding, Klaus Höffler, Nurbol Koigeldiyev, Georg Marsch, Thierry Siemeni, Felix Fleischner and Axel Haverich

Division of Cardio-Thoracic, Transplantation and Vascular Surgery, Hannover Medical School, Hannover, Germany

* Corresponding author. Division of Cardio-Thoracic, Transplantation and Vascular Surgery, Hannover Medical School, Carl-Neuberg-Str. 1, 30625 Hannover, Germany. Tel: +49-511-5326338, fax: +49-511-5328215, e-mail: shrestha.malaksh.lab@mh-hannover.de (M. Shrestha).

Received 4 January 2013, received in revised form 29 April 2013, accepted 2 May 2013

Abstract

OBJECTIVE: Aortic valve replacement (AVR) in geriatric patients (>75 years) with small aortic roots is a challenge. Patient-prosthesis mismatch and the long cross-clamp time necessary for stainless valves or root enlargement are matters of concern. We compared the results of AVR with sutureless valves (Sorin Perceval), against those with conventional biological valves.

METHODS: Between April 2007 and December 2012, 120 isolated AVRs were performed in patients with a small annulus (<22 mm) at our centre. In 2G patients (68 females, age 77.4 ± 5.5 years), conventional valves (C group) and in 50 patients (47 females, age 79.8 ± 4.5 years), sutureless valves (P group) were implanted. The logistic EuroSCORE of the C group was 16.7 ± 10.4 and that of the P group 20.4 ± 10.7, (P = 0.054). Minimal-access surgery was performed in 4.3% (378) patients in the C group and 72% (36/50) patients in the P group.

RESULTS: The cardiopulmonary bypass (CPB) and cross-clamp times of the C group were 75.3 ± 23 and 50.3 ± 14 min vs 58.7 ± 20.9 and 30.3 ± 9 min in the P group, (P < 0.001). In the C group, two annulus enlargements were performed. Thirty-day mortality was 4.3% (n = 3) in the C group and 4% (n = 3) in the P group, (n.s.). At follow-up (up to 5 years), mortalities were 17.4% (n = 12) in the C group and 14% (n = 7) in the P group, (n.s.).

CONCLUSIONS: This study highlights the advantages of sutureless valves for geriatric patients with small aortic roots reflected by shorter cross-clamp and CPB times, even though most of these patients were operated on via a minimally invasive access. Moreover, due to the absence of a sewing ring, these valves are also almost needless, with greater effective orifice area (EOA) for any given size. This may potentially result in better haemodynamics even without the root enlargement. This is of advantage, as several studies have shown that aortic root enlargement can significantly increase the risks of AVR. Moreover, as seen in this series, these valves may also enable a broader application of minimally invasive AVR.

Keywords: Small aortic root - Elderly patients - Aortic valve stenosis - Sutureless aortic valve

Minimally Invasive Aortic Valve Replacement with Self-Anchoring Perceval Valve

Malaksh Shrestha, Rebecca Timm, Klaus Höffler, Nurbol Koigeldiyev, Nawid Khaladj, Christian Hagl, Axel Haverich, Samir Sarikouch

Division of Cardio-Thoracic, Transplantation and Vascular Surgery, Hannover Medical School, Hannover, Germany

Background and aim of the study: Although minimally invasive aortic valve replacement (AVR) has been proposed to cause less morbidity in patients, it still has not seen broad application. The study aim was to evaluate the implantation of the self-anchoring aortic valve (Perceval S; Sorin) via a mini-sternotomy.

Methods: As a part of a multicenter, European, prospective, non-randomized, clinical trial, 35 patients (30 females, five males; mean age 80 ± 4 years) with isolated aortic valve stenosis (mean gradient 48 ± 21 mm Hg) were operated on at the authors’ center. Perceval S self-anchoring valves were implanted following a mini-sternotomy, extracorporeal circulation (ECC), aortic cross-clamping, cardioplectic arrest and removal of the calcified native valve. The mean EuroSCORE and STS score were 12 ± 9% and 4 ± 2%, respectively.

Results: There were no failures of deployment, and nor was there any intra-procedure or 30-day mortality. The mean ECC-time was 70 ± 24 min, and cross-clamp time 34 ± 10 min. The valve implantation time was 9 ± 5 min. Perioperative echocardiography revealed no significant aortic insufficiency or paravalvular leakage. The postoperative mean gradient was 16 ± 6 mmHg. At follow up, there was no paravalvular leakage or significant valvular insufficiency. No migration or dislodgement of the prosthesis occurred.

Conclusion: This trial highlights the advantages of the Perceval S self-anchoring valve which, technically is a more reproducible alternative for minimally invasive AVR. As the valve does not need to be sutured, the limited exposure is not a disadvantage even in patients with calcified or small aortic roots. This also potentially reduces the cross-clamp and ECC-times. This valve may enable a broader application of minimally invasive AVR.

Recambio valvular aórtico mediante prótesis sin sutura en pacientes con estenosis aórtica grave y alto riesgo quirúrgico: revisión sistemática

Leonor Varela-Lema*, Ramón De La Fuente Cid y María Luisa López García

Asistencia de Análisis de Tecnologías Sanitarias de Galicia (avesta), Consejería de Sanidad, Sede Unión de Centros, A Coruña, España

INFORMACIÓN DEL ARTÍCULO

Fecha del artículo:
Recibido el 23 de marzo de 2012
Aceptado el 17 de mayo de 2012
On-line el 2012

PALABRAS CLAVES:
Estenosis aórtica
Prótesis valvular
Revisión sistemática

RESUMEN

El recambio valvular aórtico mediante prótesis sin sutura se plantea como un tratamiento alternativo para pacientes con estenosis aórtica grave y alto riesgo quirúrgico. Este trabajo presenta los resultados de una revisión sistemática destinada a evaluar la efectividad y seguridad de este procedimiento. Se identificaron 6 estudios prospectivos, sin grupo de comparación. Cuatro evaluaron el modelo ATS 3 Liteable® y dos el Perceval S. Los resultados muestran buenos resultados hemodinámicos y clínicos para ambas prótesis. El porcentaje de éxito de implantación de las válvulas ATS 3 Liteable® registrado fue superior al 85% y el tiempo medio de bypass cardiopulmonar (BCP) varió entre 58 y 85 minutos. La implantación de las Perceval S fue exitosa en todos los pacientes y el tiempo medio de BCP inferior a 30 minutos. Dado que no se tienen resultados a largo plazo, se desconoce la durabilidad de las prótesis y las complicaciones tardías.

© 2012 Elsevier España, S.L. Todos los derechos reservados.

Sutureless aortic valve replacement for high surgical risk patients with aortic stenosis: systematic review

ABSTRACT

Sutureless aortic valve replacement is perceived to be an alternative treatment for high surgical risk patients with severe aortic stenosis. This work presents the results of a systematic review undertaken to assess the effectiveness and safety of this procedure. Eight low quality case series were identified. Six focused on prosthesis ATS 3 Liteable® and 2 on Perceval S. Results show good hemodynamic and clinical results for both prostheses. Implantation of ATS 3 Liteable® valves was successful in more than 85% of the patients and the mean cardiopulmonary bypass (BCP) time ranged from 58 to 85 minutes. For Perceval S, implantation was successful in all patients and the mean BCP time was less than 30 minutes. Since there are no long-term follow-up studies, the durability of the prosthesis and the appearance of late complications is uncertain.

© 2012 Elsevier España, S.L. All rights reserved.
Sutureless aortic valve replacement as an alternative treatment for patients belonging to the “gray zone” between transcatheter aortic valve implantation and conventional surgery: A propensity-matched, multicenter analysis

Augusto D’Onofrio, MD, Antonio Messina, MD, Roberto Lorusso, MD, Ottavio R. Alfieri, MD, Melissa Fusari, MD, Paolo Rubino, MD, Mauro Rinaldi, MD, Roberto Di Bartolomeo, MD, Mattia Glauber, MD, Giovanni Troise, MD, and Gino Gerosa, MD

Objective: The aim of this propensity-matched, multicenter study was to compare early clinical and echocardiographic outcomes of patients undergoing transcatheter aortic valve implantation (TA-TAVI) versus patients undergoing sutureless aortic valve replacement (SU-AVR) for severe symptomatic aortic valve stenosis.

Methods: We reviewed 468 TA-TAVIs performed in 20 centers from April 2008 to May 2011, and 51 SU-AVRs performed in 3 centers from March to September 2011. Based on a propensity score analysis, 2 groups with 38 matched pairs were created. Variables used in the propensity analysis were age, sex, body surface area, New York Heart Association class, logistic EuroSCORE, peripheral vascular disease, chronic obstructive pulmonary disease, aortic valve area, mitral regurgitation, and left ventricular ejection fraction.

Results: Preoperative characteristics of the 2 groups were comparable. Hospital mortality was 5.3% and 0% in the TA-TAVI and SU-AVR groups, respectively (P = .49). We did not observe stroke or acute myocardial infarction in the 2 groups. Permanent pacemaker implantation was needed in 2 patients of each group (5.3%, P = 1.0). Dialysis was required in 2 patients (5.3%) in the SU-AVR group and in 1 patient (2.7%) in the TA-TAVI group (P = 1.0). Predischarge echocardiographic data showed that the incidence of paravalvular leak (at least mild) was greater in the TA-TAVI group (44.7% vs 15.8%, P = .001), but there were no differences in terms of mean transprosthetic gradient (10.3 ± 5 mm Hg vs 11 ± 3.7 mm Hg, P = .59).

Conclusions: This preliminary experience showed that, in patients at high risk for conventional surgery, SU-AVR is as safe and effective as TA-TAVI and that it is associated with a lower rate of postprocedural paravalvular leak. (J Thorac Cardiovasc Surg 2012;144:1010-8)

Sutureless Perceval Aortic Valve Replacement: Results of Two European Centers

Thierry A Folliguet, MD, François Laborde, MD, Konstantinos Zannis, MD, Gabriel Ghorayeb, MD, Axel Haverich, MD, and Malakh Shrestha, MD
Institut Mutualiste Montrouge, Paris, France; Medizinische Hochschule Hannover, Hannover, Germany

Background. The Perceval S bioprosthesis (Sorin Biomedica Cardio Srl, Sallugia, Italy) is a self-expanding valve designed to preserve aortic sinuses and sinotubular junction. We report the midterm results of a prospective, multicenter clinical study evaluating the safety and efficacy of this stented bioprosthesis in patients undergoing aortic valve replacement with or without concomitant procedures.

Methods. From January 2007 to September 2011, a total of 208 high-risk patients (mean European system for cardiac operative risk evaluation: 8.7 ± 5.3 years) received a Perceval bioprosthesis in 2 European centers. Median follow-up was 10 ± 20 months and 100% complete, and the total accumulated follow-up was 156 patient-years. Ten patients have reached a 4-year follow-up. Valve function was assessed in all patients.

Results. Valve implantation resulted in significant improvement of patients’ symptoms. Mean preoperative and postoperative gradients were 48.6 ± 18.6 mm Hg and 10.4 ± 4.3 mm Hg, respectively, and preoperative and postoperative mean effective orifice areas were 0.7 ± 0.2 and 1.4 ± 0.4 cm². Survival at 12 months was 87.1%, success of implantation was 99%, and freedom from reoperation was 96%. In hospital mortality was 2.4%. During follow-up, 9 patients (4%) required reoperation for paravalvular regurgitation; 7 early and 2 late reoperations. Mean cross-clamp time (CCT) and extracorporeal circulation time (ECT) were, respectively, 33 ± 14 minutes and 54 ± 24 minutes, including 45 patients who underwent surgery through ministernotomy. Concomitant coronary bypass was done in 48 patients with mean CCT 43 ± 13 and ECT 68 ± 25 minutes.

Conclusions. Perceval sutureless is a safe bioprosthesis that can easily be implanted, including by a minimally invasive technique. It provides excellent hemodynamic with significant clinical improvement. Overall, these data confirm the safety and utility of the Perceval bioprosthesis aortic valve replacement for high-risk patients. (Ann Thorac Surg 2012;93:1483–8) © 2012 by The Society of Thoracic Surgeons
Aortic valve replacement with a new sutureless aortic valve Perceval S prosthesis: 12 months of Polish experience

Implantacja nowego typu bezszwowej aortalnej zastawki biologicznej Perceval S – dwunastomiesięczne doświadczenie polskie

Tomasz Nikleński, Krzysztof Filipiak, Roman Przybylski, Michał Zembala, Tomasz Kukulski, Mariam Zembala

Department of Cardiac Surgery and Transplantation, Medical University of Silesia, Silesian Center For Heart Diseases in Zabrze, Poland

Kardiochirurgia i Torakochirurgia Polska 2012; 2: 165–169

Abstract

Introduction: The increasing number of high-risk patients with narrow aortic root undergoing major cardiac surgery has led to the need for alternative treatment options and the development of new techniques for valve replacement. These patients have frequently multiple comorbidities that impose an increased risk of perioperative complications. Recent data from a multicenter registry have demonstrated a big success rate of transcatheter aortic valve implantation (TAVI) procedures. However, because of many adverse events it is necessary to introduce another device assigned for this group of patients. Implantation of a sutureless valve seems to be the right choice, especially those implanted from a minimally invasive approach.

Aim of the study: The aim of the study was to analyze the implantation procedure, hemodynamic and clinical parameters of the new sutureless Perceval S valves and compare them to other prostheses implanted in a narrow aortic root.

Material and methods: 14 Perceval S sutureless bioprosthetic valves were successfully implanted: eight valves size 23, four size 25, and two size 21. There were 3 early explantations by the surgeon’s decision because of valve malposition and unacceptable paravalvular leak. In those patients other bioprosthesis were implanted. Eight implantations were made by mini-thoracotomy. All patients are alive. In the postoperative period most of the patients changed their NYHA class from III or IV to I (72%) or II, with evident improvement of exercise capacity. The mean diameter of the native aortic annulus measured in TEE before the operation was 21.9 mm and the mean size of the implanted Perceval S valves was 23.9.

Results: The mean transvalvular gradient changed significantly from 54.5 mmHg before the operation to 13 mm Hg in follow-up. The ejection fraction (EF) was the same before and in

Streszczenie

Wstęp: Zgodnie z danymi Euro Heart Survey, ok. 30% chorych kwalifikowanych do leczenia istotnej stenozy aortalnej nadal nie jest leczona z uwagi na zaawansowany wiek, towarzyszące obciążenia lub bardzo wąskie, natywnie ujęcie aortalne. Przede wszystkim w ostatnich latach stało się leczenie przeszklone oraz dobre wyniki implantacji zastawek bezszwowych. Niestety, część chorych nie spełnia kryteriów leczenia metodą TAVI lub ma istotne obciążenia wykluczające ich z klasyfikowanego krążenia pozaustrackowego. Wprowadzenie zastawki o bardzo krótkim czasie implantacji, dającej optymalne parametry przepływu u chorych z wąskim pierścieniem, pozwala mieć nadzieję na uzupełnienie brakującej opcji leczenia powyższych chorych.

Cel pracy: Celem badania była ocena skuteczności implantacji oraz parametrów hemodynamicznych i klinicznych nowego typu biologicznej zastawki bezszwowej oraz porównanie z innymi zastawkami implantowalnymi w wąskie ujęcie aortalne.

Materiał i metody: W ramach wieloosrodkowego badania Cavalier w Śląskim Centrum Chorób Serca w Zabrzu skutecznie wszczepiono 14 zastawek Perceval S. U 3 innych chorych z uwagi na suboptymalny efekt implantacji potwierdzony przeciwciek okołostawkowym w środowiskowym badaniu TEE wymieniono zastawkę Perceval na klasyfikowaną zastawkę biologiczną. Średni wiek leczonych chorych wynosił 71,7 roku.

 Wyniki: Średni gradient przedoperacyjny wynosił 54,5 mmHg, zaś średnica natywnego pierścienia oceniona w badaniu TEE wyniosła 21,9 mm. Pomimo to implantowane 8 zastawek o średnicy 23 mm, 4 o średnicy 25 mm oraz 2 protetyki 21 mm. Średni czas implantacji zastawek wynosił 8,9 min, co znacząco skróciło długość zabiegu operacyjnego, a tym samym czas krążenia pozaustrackowego, który wyniósł średnio 39,2 min. Implantowane zastawki spowodowały istotny spadek maksymal-
Perceval Sutureless valves in isolated and concomitant AVR procedures: an economic model shows overall decrease of costs for isolated or combined operations

Lorenzo Pradelli ¹, Orietta Zaniolo ²
¹ AdRes, Health Economics & Outcomes Research, Turin

ABSTRACT

Background: aortic valve replacement (AVR) is the most common heart valve operation, accounts for a majority of all valve surgery performed in the elderly. The Perceval S (P) is a new aortic valve which is implanted without suturing, which causes a significant reduction in cross-clamping times (CCTs), and makes valve implantation easier and faster thanks to its collapsed profile. These features potentially allow the pool of operable patients to be expanded, even with minimally invasive surgery in isolated AVRs.

Aim: to predict costs and outcomes of AVR procedures associated with this new valve in 4 European countries (Italy, France, Germany, and UK), as compared to traditional (T) valve implants, from the cost perspective of the hospital.

Method: a probabilistic, patient-level simulation model was fully coded in WinBugs, permitting a seamless integration of parameter estimation and outcomes prediction, which was entirely based on the associated CCTs and on the surgical technique (mini-invasive [MIS] vs. full sternotomy [FS]), through published correlations. Unit cost were retrieved from official and literature sources for all countries. Besides the incorporated probabilistic sensitivity analysis, a series of deterministic sensitivity analyses was performed.

Results: the model predicts the use of the Perceval S valve to be associated with less complications and with savings (valve cost excluded), mainly related to a reduction in surgery costs and ICU/hospital bed days. These savings range from € 3,600 (Italy) to € 3,900 (UK) for MIS in isolated AVRs and from about € 6,000 (Italy) to € 6,700 (UK) for MIS in isolated AVRs, and for MIS in concomitant. Extensive sensitivity analyses confirm the robustness of such findings.

Conclusions: the results of the present analysis indicate that the hospital acquisition cost difference between the new sutureless Perceval S valve and traditional valves is offset by important savings in other cost items.

Keywords
Aortic valve replacement; Economic model; Perceval S
Aortic Cross-Clamp Time, New Prostheses, and Outcome in Aortic Valve Replacement

Marco Ranucci, Alessandro Frigiola, Lorenzo Menicanti, Serenella Castelvecchio, Carlo de Vincentis, Valeria Pistuddi, for the Surgical and Clinical Outcome Research (SCORE) Group

Departments of Cardiothoracic and Vascular Anesthesia and Intensive Care and Cardiac Surgery, IRCCS Policlinico San Donato, Milan, Italy

Background and aim of the study: A number of sutureless bioprosthetic aortic valves have been recently introduced in clinical practice, their main advantage being a reduction in the aortic cross-clamp time (AXCT). The study aim was to investigate if AXCT was a determinant of cardiovascular morbidity in patients undergoing surgical aortic valve replacement (AVR) to treat aortic valve stenosis, and to identify any subset of patients who might benefit from a reduction in AXCT.

Methods: A retrospective analysis was conducted of 579 consecutive patients with aortic valve stenosis who underwent surgical AVR. The AXCT was analyzed as an independent predictor of severe cardiovascular morbidity, defined as the presence of a low cardiac output, stroke, acute kidney injury, or operative mortality. Subgroups of patients who benefited more from a reduction in AXCT were investigated.

Results: The AXCT was an independent predictor of severe cardiovascular morbidity, with an increased risk of 1.4% per 1 min increase. Patients with a left ventricular ejection fraction ≤40%, and also diabetic patients, showed the most relevant clinical benefits induced by a reduction in AXCT.

Conclusion: In selected patient populations at high risk of systolic dysfunction, the use of sutureless aortic valve bioprostheses may be considered. However, the routine use of such bioprostheses should be pondered within a cost-benefit analysis.

The Journal of Heart Valve Disease 2012;21:


Perceval S aortic valve implantation in mini-invasive surgery: the simple sutureless solution

Giuseppe Santarpino, Steffen Pfeiffer, Giovanni Concistrè and Theodor Fischlein

Department of Cardiac Surgery, Klinikum Nürnberg, Nuremberg, Germany

*Corresponding author, Department of Cardiac Surgery, Klinikum Nürnberg, Klinikum Süd, Breslauer Straße 261, 90471 Nürnberg, Germany. Tel: +49-911-398-5441; fax: +49-911-398-5443; e-mail: giovanni.secret@gmail.com (G. Santarpino).

Received 17 December 2011; received in revised form 28 February 2012; accepted 13 March 2012

Abstract

The Perceval S bioprosthesis (21 and 23 mm) was approved for clinical use in December 2010 and is now routinely used. This bioprosthesis is suggested for the treatment of patients undergoing minimally-invasive surgery for reasons of safety and reduction in implantation time. Here we describe the use of the Perceval bioprosthesis in patients undergoing minimally invasive cardiac surgery.

Keywords: Aortic valve replacement • Heart valve bioprosthesis • Minimally-invasive surgery • Surgery/incisions/exposure/techniques • Outcomes
Sutureless Aortic Valve Replacement: First-Year Single-Center Experience

Giuseppe Santarpino, MD,* Steffen Pfeiffer, MD,* Joachim Schmidt, MD, Giovanni Concistrè, MD, and Theodor Fischlein, MD

Departments of Cardiac Surgery and Cardiology, Klinikum Nürnberg, Nuremberg, Germany

Background. Sutureless aortic bioprostheses bear the potential of easy implantation, reduced ischemic time, and surgical trauma in aortic valve replacement. We herein show our clinical and echocardiographic results after a 1-year experience with a new sutureless bioprosthesis.

Methods. The Percival S (Sorin Biomedica Cardio Srl, Saluggia, Italy) is a pericardial aortic prosthesis assembled in the manufacturing line. It is implanted intra-annularly, without the need of suture. As part of a premarketing multicenter study (Cavaller Trial), since March 2010, 63 patients were screened for implantation in our center.

Results. The patients received a size S (41), M (38), or L (41) prosthesis, either as isolated (57) or combined procedures (26). Fifty-one patients (63.5%) received a "J" sternotomy. Mean logistic Eurosystem for cardiac operative risk evaluation was 10. ± 7.5%, mean aortic cross-clamp time was 43.8 ± 20.8 minutes (36 ± 12.7 minutes for isolated procedures). Mean implantation time was 8 ± 3.8 minutes (range 4 to 28 minutes). In-hospital mortality was 2.4% (1 patient for multiorgan failure and 1 for liver insufficiency); mean hospital stay was 11.5 ± 4.4 days (range 2 to 28 days). We recorded 5 pacemaker implantations (6%). At follow-up, we had 2 deaths (1 patient for congestive heart failure and 1 for gastrointestinal bleeding). At 1 year, mean New York Heart Association functional class was 1.0 ± 0.6. Mean transprosthetic gradients were 13.4 ± 2.6, 12.6 ± 2.3, and 10.8 ± 1.3 mm Hg postoperatively, at 6 months, and at 1 year, respectively.

Conclusions. The Percival S shows satisfactory clinical and hemodynamic results. Due to its simple implantation technique, it represents an alternative especially for minimally invasive surgery. Operative trauma can be minimized by short aortic cross-clamp time.


What are the current results of sutureless valves in high-risk aortic valve disease patients?

Amir H. Sepehrpour*, Leanne Harling* and Thanos Athanasiou*

* Department of Cardiothoracic Surgery, Wythenshawe Hospital, Manchester, UK
* Department of Cardiothoracic Surgery, Imperial College Healthcare, London, UK
* Corresponding author. Department of Cardiothoracic Surgery, Wythenshawe Hospital, Southmoor Road, Manchester M23 9LT, UK. Tel: +44-783-4697517; e-mail: amir.sepehrpour@imperial.ac.uk (AHS).Sepehrpour).

Received 14 September 2011; received in revised form 20 December 2011; accepted 9 January 2012

Abstract

A best evidence topic was written according to a structured protocol. The question addressed was whether sutureless aortic valves have a clinical and haemodynamic benefit in high-risk patients with aortic valve disease. A total of 207 papers were found using the reported searches of which, six represented the best evidence to answer the clinical question. The authors, date, journal, study type, population, main outcome measures and results are tabulated. The studies found analysed the outcomes of sutureless aortic valve implantation in high-risk patients undergoing aortic valve replacement. Reported measures included mortality; post-operative complications namely stroke; renal failure, endocarditis and bleeding; valve deployment, cardiopulmonary bypass [CPB] and aortic cross-clamp [ACC] times; echocardiographic assessment of paravalvular leaks [PVLs] and valve haemodynamics; and symptomatic functional class. Hospital mortality ranged between 3.1 and 12.5% and long-term mortality ranged between 3.1 and 10%. Incidence of PVL was found to be between 0.0 and 11.1%. Stroke was observed in 0.7%, renal failure in 3.1%, prosthetic valve endocarditis in 21–31% and major bleeding in 3.1%. The valve deployment time was 9–21 min, CPB time 35–111 min and ACC time 17–70 min. Short-term mean and peak valve gradients were in the ranges of 10–11 and 18–22 mm Hg, respectively, reducing to 8–9 and 16–19 mm Hg, respectively, at follow-up. Owing to the lack of comparative studies analysing the outcomes of sutureless and conventional aortic valves, we compared these results with the recently published PARTNER Trial (Transcatheter vs Surgical Aortic Valve Replacement in High-Risk Patients); and it can be shown that the outcomes of sutureless aortic valves compare favourably with conventional valves in terms of mortality, neurological deficit, renal failure and post-operative bleeding. However, there is increased incidence of endocarditis and PVLs, together with raised mean valve gradients, perhaps owing to the mechanical properties and deployment techniques of sutureless aortic valves.

Keywords: Sutureless valve • Aortic valve • Aortic valve replacement
New sutureless aortic valve prosthesis: another tool in less invasive aortic valve replacement

Konstantinos Zannis, Thierry Folliguet, and François Laborde

Purpose of review
Sutureless aortic valve prosthesis is a new and promising tool for treatment of aortic valve stenosis. It could increase applicability of surgical aortic valve replacement in the elderly with severe comorbidities.

Recent findings
Three devices are currently available. The 3T Enable (ATS, Minneapolis, USA) and the Perceval S (Sorin, Saluggia, Italy) have a CE mark, whereas the Intuity (Edwards Lifesciences, Irvine, California) is still under investigation. We present the above valves, focusing on the Perceval S, which was used in our institution. Indications, contraindications, technical considerations and patient selection are described. The potential advantages of sutureless valve technology over conventional aortic and percutaneous valves are discussed. We emphasize new perspectives offered by sutureless valves in the aortic replacement field.

Summary
This new technology may offer improved results. Cost-effectiveness and fine-tuning of patient selection are two aspects that future investigation should address.

Keywords
aortic valve, minimally invasive AVR, sutureless

Effect of sutureless implantation of the Perceval S aortic valve bioprosthesis on intraoperative and early postoperative outcomes

Willem Flameng, MD, PhD,1 Marie-Christine Herregods, MD, PhD,2 Hadewich Hermans, MD,3 Gerry Van der Mieren, MD,4 Monique Vercalsteren, RN,4 Gert Poortmans, MD,4 Jan Van Hemelrijck, MD, PhD,4 and Bart Meuris, MD, PhD4

Objective: Prolonged aortic crossclamping can increase mortality and morbidity after aortic valve replacement in elderly and high-risk patients. Sutureless implantation of the prosthesis has the potential to shorten aortic crossclamp time.

Methods: The Perceval S valve (Sorin Biomedica Cardio Srl, Saluggia, Italy), a sutureless implantable aortic bioprosthesis, was used in 32 patients (median age, 78 years; median logistic euroSCORE, 9.99) requiring aortic valve replacement with or without concomitant coronary artery bypass grafting. Hemodynamic parameters and clinical outcome were obtained at discharge, at 6 months, and up to 1 year postoperatively.

Results: Aortic crossclamp time needed for aortic valve replacement was 18 ± 6 minutes. Hemodynamics at discharge showed good function of all Perceval S valves with low transvalvular pressure gradients (mean, 12 ± 5 mm Hg and peak, 23 ± 9 mm Hg) and low incidence of paravalvular or valvular leakage. Operative mortality was 0%. Follow-up at 1 year showed 3 non-valve-related deaths. Survivors showed good clinical outcome and stable hemodynamic function of the valve prosthesis, except for 1 patient in whom endocarditis developed. Despite a moderate decrease in platelet counts persisting up to 12 months, freedom of bleeding and thromboembolic events was 100%.

Conclusions: It is possible to implant a well-functioning sutureless aortic valve in the aortic position in less than 20 minutes of aortic crossclamping. This is associated with excellent early clinical and hemodynamic outcome in high-risk patients. Moderate changes in hematologic parameters persisted but were not related to clinical events. (J Thorac Cardiovasc Surg 2011;142:1453-7)
Perceval Sutureless Aortic Valve Prosthesis

Easy, Fast, and Safe

Giuseppe Santarpino, MD, Steffen Pfeiffer, MD, Giovanni Concistré, MD, and Theodor Fischlein, MD

Objective: There is an increase of old patients needing aortic valve surgery. Especially in this age group, a lot of new less-invasive strategies are proposed. Our goal was to study whether a sutureless aortic valve, which is implanted surgically after removal of the native valve, could be an alternative for a subgroup of patients.

Methods: The Swit Cardiovascular System is a biologic pericardial aortic valve assembled as a metal super-elastic alloy stent and implanted in the aortic root without the need of suturing. As part of a premarketing multicenter study (Swit Cardiovascular System), 54 patients were screened for Perceval S implantation. All patients underwent cardiopulmonary bypass and cardioplegic approach (partial upper sternotomy).

Results: Seventeen patients were excluded due to standardized criteria. Twenty patients received a 21-mm valve (2 patients), 23-mm valve (6 patients), or 25-mm valve (12 patients). X-ray time was 20.6 ± 7.6 minutes, and implantation time was 8.6 ± 3 minutes. Intra- and postoperative echocardiography showed no paravalvular leakage, low gradients (max 16.5 ± 5 mm, mean 9.8 ± 4.2), and two conduction disturbances (one patient with 1/4+, one patient with 2/4+). All patients were discharged without major in-hospital complications (intensive care unit stay 1.4 ± 0.5 days, hospital stay 7 ± 0.7 days).

Conclusions: The sutureless Perceval S aortic valve is hemodynamically excellent and a safe prosthesis in selected patients. Due to a simple and fast implantation technique, this valve could guarantee a shorter operation time in combination with a minimally invasive approach.

Key Words: Biologic valve, Aortic, Sutureless prostheses, Minimally invasive surgery.

Accepted for publication December 12, 2011.

From the Department of Cardiovascular Surgery, Klinikum Nürnberg, Nürnberg, Germany.

Presented at the Annual Scientific Meeting of the International Society for Minimally Invasive Cardiothoracic Surgery, June 8–11, 2011, Washington, DC, USA.

Disclosure: The authors declare no conflict of interest.

Address correspondence and reprint requests to Giuseppe Santarpino, MD, Cardiovascular Surgery Unit, Klinikum Nürnberg, Klinikum Str., 90471 Nürnberg, Germany. E-mail: g.santarpino@t-online.de.

Copyright © 2012 by the International Society for Minimally Invasive Cardiothoracic Surgery.

ISSN: 1556-9845/11/0606-0378

Transapical Implantation of a Novel Self-Expanding Sutureless Aortic Valve Prosthesis

Mario Stalder,1 Rakesh M. Suris,2 Eva S. Krahenbuehl,3 Gerrit Hellige,3 Peter Wenaweser,3 Claudia Zobrist,4 Harzell V. Schaff,2 Thierry P. Carrel2

Departments of 1Cardiovascular Surgery, 2Cardiology, and 4Anesthesiology, University Hospital, Bern, Switzerland, 3Mayo Clinic, Rochester, MN, USA

Background and aim of the study: To date, transapical aortic valve implantation has required a balloon-expandable stented valve prosthesis. More recently, a novel self-expanding sutureless stented bovine pericardial prosthesis has been developed which allows rapid aortic valve replacement via an open transapical approach in humans. The aim of this animal study was to develop a reliable protocol to facilitate the transapical implantation of this self-expanding valve in a porcine model.

Methods: Off-pump transapical aortic valve implantation was performed through a left mini-thoracotomy using a bovine pericardial valve mounted on a self-expandable nitinol stent of size 21 mm and 23 mm in 11 pigs (average weight 60 kg). The crimped valve was introduced through the left ventricular apex using a flexible and steerable delivery sheath, using a three-step technique. Biplane fluoroscopy and transesophageal echocardiography were simultaneously used for guidance. Successful adjustment of alignment along three axes prior to deployment of the valve was accomplished in each animal. Deployments were performed during a period of rapid pacing.

Results: All valves were successfully deployed and functioned normally following transapical removal of the delivery system. Paravalvular leak was documented in one case (9.1%) due to prosthetic misalignment. There was no evidence of valve migration. Correct anatomic seating was confirmed during post-procedure necropsy.

Conclusion: Successful transapical implantation of a novel self-expandable bovine pericardial valve was accomplished in 11 animals, without cardiopulmonary bypass. A flexible, steerable delivery system with a three-step release mechanism allowed precise positioning of the valve with a low rate of paravalvular leakage, and excellent device stability.

The Journal of Heart Valve Disease 2010;19:182–188
Robot-Assisted Aortic Valve Replacement Using a Novel Sutureless Bovine Pericardial Prosthesis

Proof of Concept as an Alternative to Percutaneous Implantation

Rakesh M. Suri, MD, DPhil, Harold M. Burkhart, MD, and Hartzell V. Schaff, MD

Objective: Percutaneous aortic valve implantation within native valve calcium has progressed to clinical use despite the absence of data proving equivalence to complete surgical excision and prosthetic valve replacement. A novel self-expanding sutureless bovine pericardial prosthesis (Sorin Percival) derived from a proven stented valve has been successfully used in humans recently through an open transaortic approach. We sought to develop a minimally invasive technique for native aortic valve excision and sutureless prosthetic aortic valve replacement using robot assistance.

Methods: The da Vinci S-110 system was used to open and suspend the pericardium anterior to the phrenic nerve in cadavers. A transaortic cross-clamp was placed across the midascending aorta, following which a transverse aortotomy was made. The native aortic valve cusps were excised, and aortic calcium was removed with robotic instruments. After placement of three guide sutures, the Percival self-expanding pericardial prosthesis mounted on a flexible delivery system was inserted through a working port and lowered into the aortic annulus.

Results: Successful implantation of all valves was possible using a 3-cm right second intercostal space working port, along with two additional 1-cm instrument ports. A standard transverse aortotomy was sufficient for examination/bridegment of the native aortic valve cusps, sizing of the annulus, and deployment of the nitinol-stented, bovine pericardial prosthesis. Delivery, seating, and stability of the device were easily confirmed above and below the aortic valve annulus using the robotic camera.

Conclusions: Complete excision of diseased native aortic valve cusps with robot assistance facilitates accurate and reproducible aortic valve replacement using a novel self-expanding sutureless version of a proven bovine pericardial prosthesis. This approach is comparable to the current surgical gold standard and is ready for clinical use as an alternative to percutaneous aortic valve implantation.

Key Words: Sutureless, Self-expanding, Aortic valve, Minimally invasive, percutaneous.

(Ann Thorac Surg 2010;5:419-423)

Future of cardiac surgery: minimally invasive techniques in sutureless valve resection

Thierry Folliguet1, Akain Djiele & François Laborde

Author for correspondence, Department of Cardiovascular Surgery, L'Institut Mutualiste Montrouzier, 40 Boulevard Jourdan, Paris 75014, France • Tel.: +33 15 661 6510 • Fax: +33 15 661 6503
1 thierry.folliguet@immm.fr

Aortic valve replacement with mechanical or biological heart valves is the treatment of choice for aortic valve stenosis when it is symptomatic or with severe aortic stenosis (≥0.6 cm²/m²) or with left ventricular dysfunction. In an effort to improve the outcomes of patients with stented biological valves, sutureless valves were introduced to clinical practices in the early 1990s. These valves were designed to be less obstructive, and thus result in a lower transvalvular gradient. Technically the implantations of these valves are more demanding resulting in longer cross clamp and bypass times. However, important comorbid conditions in elderly patients referred for aortic valve replacement require alternative treatment options with possible reductions of the extracorporeal bypass time and reliable hemodynamic features. In order to comply with these requirements, percutaneous valves and sutureless surgical valves have been developed. The percutaneous technique has the advantage of being performed without circulatory bypass but leaving the aortic calcifications in place, thereby resulting in a higher degree of paravalvular insufficiency, atriointricular block and strokes. The surgical approach has the advantage of removing all calcifications and the valves can be implanted optimally, resulting in minimal paravalvular leak with a low incidence of atriointricular block and strokes; however it requires cardiopulmonary bypass. In addition, it can be performed with a low mortality (<3% in isolated aortic replacement, even in older patients). This article reviews the various techniques and strength and limitations of these sutureless valves implanted in the aortic position.
Sutureless Perceval S Aortic Valve Replacement: A Multicenter, Prospective Pilot Trial

Malakh Shrestha\textsuperscript{1}, Thierry Folliguet\textsuperscript{2}, Bart Meuris\textsuperscript{3}, Alain Dibie\textsuperscript{4}, Christoph Bara\textsuperscript{1}, Marie-Christine Herregods\textsuperscript{3}, Nawid Khaladj\textsuperscript{1}, Christian Hagl\textsuperscript{5}, Willem Flameng\textsuperscript{3}, Francois Laborde\textsuperscript{4}, Axel Haerich\textsuperscript{1}

\textsuperscript{1}Division of Cardiac, Thoracic, Transplantation and Vascular Surgery, Hannover Medical School, Hannover, Germany, \textsuperscript{2}Cardiac Medico-Surgical Department, Institute Mutualiste Montrouzier, Paris, France, \textsuperscript{3}Cardiac Surgery, U.Z. Gasthuisberg, Leuven, Belgium

Background and aim of the study: A European, multicenter, prospective, non-randomized, clinical pilot trial was designed to evaluate the feasibility of the Perceval S sutureless aortic valve prosthesis. A clinical and echocardiographic follow up was performed at the time of hospital discharge and subsequently after one, three, six, and 12 months.

Methods: The valve was implanted following sternotomy, extracorporeal circulation (ECC), aortic cross-clamping, cardioplegic arrest, and removal of the native valve. Implantation suturing was not required. Optimal annular sealing was obtained with brief low-pressure balloon dilation. If coronary bypass was indicated, a distal anastomosis was performed first. Between April 2007 and February 2008, 30 patients (mean age 81 ± 4 years) underwent aortic valve replacement. The prevalence of pure aortic stenosis was 76.7\%, and that of mixed lesion 23.3\%. The mean logistic EuroSCORE was 13.18\%, and the NYHA class was III and IV in 93.3\% and 6.7\% of patients, respectively. The implanted valve size was 21 and 23 mm in 37\% and 63\% of patients, respectively, and 14 (46.7\%) underwent coronary artery bypass grafting (11 internal mammary artery, nine vein grafts).

Results: The mean aortic cross-clamp and ECC times were 34 ± 15 min and 59 ± 21 min, respectively. There was one in-hospital death (3.3\%), and three deaths occurred within 12 months of follow up (one death was valve-related, and two deaths were independent of the valve implantation). A total of 28 patients was assessed at one month post-implantation, and 23 after 12 months. No migration or dislodgement of the valve had occurred, but there were two mild paravalvular leakages and two mild intravalvular insufficiencies.

Conclusion: The preliminary results of the trial confirmed the safety and efficacy of the Perceval S sutureless aortic valve. In this high-risk subset of patients, shortening the aortic cross-clamp and ECC times may help to reduce mortality and morbidity.

The Journal of Heart Valve Disease 2009;18:698-702
A Staged Approach towards Interventional Aortic Valve Implantation with a Sutureless Valve: Initial Human Implants

M. Shrestha, N. Khalaji, C. Bara, K. Hoeffer, C. Hagl, A. Haverich
Department of Cardiac, Thoracic, Transplantation and Vascular Surgery, Hannover Medical School, Hannover, Germany

Abstract

Objective: Percutaneous implantable aortic valves may become an alternative to conventional approaches. The purpose of this study was to assess a new sutureless aortic valve (Percival Sorin). As a first step, an open approach using cardiopulmonary bypass (CPB) was chosen to evaluate the feasibility of implantation.

Methods: Between April and September 2007, 16 high-risk patients (13 females, aged 81 [76–88]) were operated on via a median sternotomy, using CPB and cardioplegia (Euro-Score 17 [8–71]). All patients had significant aortic valve disease and seven of these patients had concomitant coronary artery disease. This pilot project was initiated with prior approval of the Institutional Review Board. All patients gave informed consent.

Results: One patient died during hospital stay for unknown reasons. Autopsy revealed no valve-related pathologies. CPB time was 60 min (41–130), cross-clamping time was 36 (22–79) min. Intraoperative as well as postoperative echocardiography revealed neither aortic insufficiency nor paravalvular leakage in any of the patients.

Conclusions: The new approach as described here is a technically simple alternative to conventional aortic valve replacement in high-risk patients and offers the potential of less invasive approaches. It appears especially useful in patients with severe calcification of the aortic root. CPB and cross-clamping times were markedly reduced compared with patients who underwent conventional operations.