Less Invasive Aortic Valve Surgery

SCTS Brighton  19th March 2013

Andrew Chukwuemeka MD FRCS
Consultant Cardiothoracic Surgeon

Hammersmith Hospital
Imperial College Healthcare NHS Trust
Less Invasive Aortic Valve Surgery

- TAVI
- New valves
  - Sutureless, “rapid deployment”, AVR
- Incisions
  - Mini-sternotomy / mini-thoracotomy
- Mini-CPB
Changes in the makeup of workload over time (n=292,130)

- Isolated CABG
- CABG & valve
- CABG, valve & other
- CABG & other
- Isolated valve
- Valve & other
- Other

Financial year ending:
- 2001
- 2002
- 2003
- 2004
- 2005
- 2006
- 2007
- 2008
Rises in the numbers of elderly cardiac surgery patients (n=53,266)

- 76-80 years old
- 81-85 years old
- >85 years old

Number of patients

Financial year ending

All AV surgery: Average age; bars denote standard error (n=58,195)

AV alone

AV & CABG
Is this safe?
Valve surgery in selected octogenarians is associated with low morbidity and mortality. The outlook after surgery is very good, and surgery should not be denied to this group on the basis of age alone.

The Journal of Heart Valve Disease
2006;15:191-196
1 in 3 patients with severe symptomatic AS did not have surgery
Unmet need in severe AS

  - 60%

  - 32%

- Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. Heart 1999;82:143-148
  - 41%
Unmet need in severe AS

  - 60%

  - 32%

- Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. Heart 1999;82:143-148
  - 41%

TAVI is a much needed alternative to conventional AVR
Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis
First Human Case Description

Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; Francois Laborde, MD; Martin B. Leon, MD

Background—The design of transcatheter aortic valve implantation was performed because it may become an important area for treatment. To our knowledge, transcatheter aortic valve implantation has been performed in animals and other associated nonfluoroscopic maneuvers. We report a case in which transcatheter valve implantation was performed in a 74-year-old patient with severe calcific aortic stenosis.

Methods and Results—With the help of an antiplatelet agent, the patient was brought to the operating room with aortic valve stenosis and severe leg ischemia. A single balloon-expandable stent was placed in the aorta, and then the valve implantation was performed. The valve prosthesis was successfully implanted within the aortic valve. The patient was discharged 7 days later in a good condition.

Received September 5, 2002; revision received October 7, 2002; accepted October 15, 2002.

From the Department of Cardiology, University Hospital of Rouen, Rouen, France; the Centre d'Investigation et de Recherche Applied to Experimental and Clinical Medicine, Rouen, France. Correspondence to Dr Alain Cribier, University Hospital of Rouen, 102 Chemin des Planier, 76000 Rouen, France. E-mail: Alain.Cribier@chu-rouen.fr

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What is TAVI (R)?
Less Invasive Aortic Valve Surgery - TAVI

Access routes:
- Transfemoral
- Transapical
- Direct aortic
- Subclavian (axillary)
- Iliac
- +/- conduit

Depends on:
- patient anatomy
- team preference
- experience
The Clinical Development of Percutaneous Heart Valve Technology

A Position Statement of The Society of Thoracic Surgeons (STS), the American Association for Thoracic Surgery (AATS), and the Society for Cardiovascular Angiography and Interventions (SCAI)

Thomas A. Vassiliades, Jr, MD, Peter C. Block, MD, Lawrence H. Cohn, MD, David H. Adams, MD, Jeffrey S. Borer, MD, Ted Feldman, MD, David R. Holmes, MD, Warren K. Laskey, MD, Bruce W. Lytle, MD, Michael J. Mack, MD, and David O. Williams, MD

Preamble

This joint position statement represents the combined efforts of four professional societies (Society of Thoracic Surgeons [STS], American Association for Thoracic Surgery [AATS], American College of Cardiology [ACC], and Society for Cardiovascular Angiography and Interventions [SCAI]), two government agencies (the U.S. controversy, and formulate clinical guidelines for the continued development of PHVT.

Process

On April 22, 2004, the STS/AATS Committee/Workforce for the Assessment of New Technology (Appendix 1) organized a workshop on PHVT. Included were repre-
Multidisciplinary approach

Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)†

Authors/Task Force Members: William Wijns (Chairperson) (Belgium)*, Philippe Koller (Chairperson) (Belgium)*, Nicolas Danchin (France), Carlo Di Mario (UK), Volkmar Falk (Switzerland), Thierry Folliguet (France), Scot Garg (The Netherlands), Kurt Huber (Austria), Stefan James (Sweden), Juhan Knuuti (Finland), Jose Lopez-Sendon (Spain), Jean Marco (France), Lorenzo Menicanti (Italy), Miodrag Ostojic (Serbia), Massimo F. Piepoli (Italy), Charles Pirlet (Belgium), Jose L. Pomar (Spain), Nicolaus Reifart (Germany), Flavio L. Ribichini (Italy), Martin J. Schalij (The Netherlands), Paul Sergeant (Belgium), Patrick W. Serruys (The Netherlands), Sigmund Silber (Germany), Miguel Sousa Uva (Portugal), David Taggart (UK)

“Heart Team”
TAVI team

• Cardiac surgeons
• Interventional cardiologists
  • Imaging cardiologists
    • Radiologists
• Elderly care physicians
  • Anaesthetist
• Critical care physicians
  • Specialist nurses

• Physiotherapists
• Occupational therapists
  • Rehabilitation
  • Perfusionists
• Operating theatre team
  • Psychologists
TAVI – patient selection

Anatomically suitable, inoperable or very high-risk, severe symptomatic AS

- Elderly (but not exclusively)
- Co-morbidities
  - respiratory, renal, poor LV, hepatic ++++

- Contraindication to AVR
  - porcelain aorta, mediastinal radiation

- Risk score (STS >10%, EuroSCORE >20%)

- Frailty
Frail Patients Are at Increased Risk for Mortality and Prolonged Institutional Care After Cardiac Surgery. *Circulation* 2010;121:973-8

- Complex interaction between age and chronic illness
- Chronological age is not the same as biological age
- Subjective

- Parameters:
  - gait, 5m walk speed, grip strength, ADL, biological markers (albumin, bilirubin, lung function tests), +++
Frailty in TAVI

Patient A vs. Patient B

Same age and predicted risk
One passes the “eyeball test” – one does not

Photos courtesy of Michael J. Mack, MD
Medical City Dallas
85 year old female, EF 30%, renal dysfunction and pulmonary hypertension

High Risk Patient

Estimated operative mortality (%)

- Nashef et al. - EuroSCORE: 59.8%
- STS online calculator: 15.4%
- Nowicki et al. - NNE: 4.3%
- Jin et al. - PHS: 6.6%
- Rankin et al. - STS score: 7.2%
- Hannan et al. - NY State: 8.5%
- Kuduvalli et al. - Multicenter: 27.4%
Risk scoring in TAVI

AVR Mortality Estimated by EuroSCORE vs Observed

N = 1177 isolated AVR patients
01/01/2000–12/30/2006

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Risk scoring in TAVI

European Heart Journal Advance Access published March 15, 2011

ESC Working Group on Valvular Heart Disease Position Paper: assessing the risk of interventions in patients with valvular heart disease

Raphael Rosenhek¹, Bernard Iung², Pilar Tornos³, Manuel J. Antunes⁴, Bernard D. Prendergast⁵, Catherine M. Otto⁶, Arie Pieter Kappetein⁷, Janina Stepinska⁸, Jens J. Kaden⁹, Christoph K. Naber¹⁰, Esmeray Acartürk¹¹, and Christa Gohlke-Bärwolf¹²

¹Department of Cardiology, Medical University of Vienna, Vienna, Austria; ²Cardiology Department, Bichat Hospital and Paris 7 University, Paris, France; ³Cardiology Department, University Hospital Vall d’Hebron, Barcelona, Spain; ⁴Cardiothoracic Surgery, University of Coimbra, Coimbra, Portugal; ⁵Department of Cardiology, The John Radcliffe Hospital, Oxford, UK; ⁶Division of Cardiology, Department of Medicine, University of Washington, Seattle, WA, USA; ⁷Department of Cardio-Thoracic Surgery, Erasmus Medical Center, Rotterdam, The Netherlands; ⁸Institute of Cardiology, Warsaw, Poland; ⁹Medical Faculty Mannheim, University of Heidelberg, Heidelberg, Germany; ¹⁰International Heart Center Essen, Essen, Germany; ¹¹Department of Cardiology, Çukurova University, Adana, Turkey; and ¹²Herzzentrum Bad Krozingen, Bad Krozingen, Germany

Received 26 September 2010; revised 28 December 2010; accepted 1 February 2011
Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

ABSTRACT
A.Death from Any Cause (%)

Hazard ratio, 0.55 (95% CI, 0.40–0.74)
P < 0.001

No. at Risk
TAVI 179 138 122 67 26
Standard therapy 179 121 83 41 12

B. Death from Cardiovascular Cause (%)

Hazard ratio, 0.39 (95% CI, 0.27–0.56)
P < 0.001

No. at Risk
TAVI 179 138 122 67 26
Standard therapy 179 121 83 41 12

C. Death from Any Cause or Repeat Hospitalization (%)

Hazard ratio, 0.46 (95% CI, 0.35–0.59)
P < 0.001

No. at Risk
TAVI 179 117 102 56 22
Standard therapy 179 86 49 23 4

D. Death from Any Cause or Major Stroke (%)

Hazard ratio, 0.58 (95% CI, 0.43–0.78)
P < 0.001

No. at Risk
TAVI 179 132 118 66 25
Standard therapy 179 118 83 41 12
PARTNER B - NYHA

NYHA Class

P=0.68

P<0.001

P<0.001

P<0.001

Patients (%)

TAVI  Standard TAVI  Standard TAVI  Standard TAVI  Standard
Baseline 30 Days 6 Months 1 Year
Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators*

CONCLUSIONS
In high-risk patients with severe aortic stenosis, transcatheter and surgical procedures for aortic-valve replacement were associated with similar rates of survival at 1 year, although there were important differences in periprocedural risks. (Funded by Edwards Lifesciences; Clinical Trials.gov number, NCT00530894.)
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Transcatheter Replacement (N=348)</th>
<th>Surgical Replacement (N=351)</th>
<th>P Value</th>
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<td>From cardiac causes</td>
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PARTNER A: UPDATE - 2 year results

PARAVALVULAR LEAK

Percent of evaluable echos

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<th></th>
<th>TAVR 30 Day</th>
<th>AVR 226</th>
<th>TAVR 6 Month</th>
<th>AVR 172</th>
<th>TAVR 1 Year</th>
<th>AVR 155</th>
<th>TAVR 2 Year</th>
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<td>Mild</td>
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</tbody>
</table>

N = 277, N = 230, N = 216, N = 145
PARTNER A: UPDATE - 2 year results

HR [95% CI] = 2.01 [1.38, 2.92]
p (log rank) = 0.0002

Numbers at Risk

<table>
<thead>
<tr>
<th>None-Tr</th>
<th>167</th>
<th>149</th>
<th>140</th>
<th>126</th>
<th>87</th>
<th>41</th>
<th>16</th>
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</thead>
<tbody>
<tr>
<td>Mild-Mod-Sev</td>
<td>160</td>
<td>134</td>
<td>112</td>
<td>101</td>
<td>64</td>
<td>26</td>
<td>12</td>
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</table>
The future of TAVI?

- Improving patient selection ("picking the winners")
- Improving technology (access, paravalvular leak, stroke)
- Adhering to established principles (durability etc.)
New TAVR Designs...

- Direct Flow
- Sadra
- AorTx
- Jena Valve
- HLT
- ABPS PercValve
- EndoTech
- Ventor Embracer
Major Dwight Harken – US Army

- 133 consecutive survivors
- First series of successful “open heart” operations
Ten Commandments - Dwight Harken

• It must not propagate emboli
• It must be chemically inert and not damage blood elements
• It must offer no resistance to physiological flows
• It must close promptly
• It must remain closed during the appropriate phase of the cardiac cycle
• It must have lasting physical and geometric features
• It must be inserted in a physiological site
• It must not annoy the patient
• It must be capable of permanent fixation
• It must be technically practical to insert

“A device is safe when it is safer than the condition it corrects”
Effect of sutureless implantation of the Perceval S aortic valve bioprosthesis on intraoperative and early postoperative outcomes

Willem Flameng, MD, PhD, Marie-Christine Herregods, MD, PhD, Hadewicha Hermans, MD, Gerry Van der Mieren, MD, Monique Vercalsteren, RN, Gert Poortmans, MD, Jan Van Hemelrijk, MD, PhD, and Bart Meuris, MD, PhD

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, Sallugia, 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 paraavalvular 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 stent-mounted 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; 141:1-5)
PERCEVAL S – sutureless AVR

Dedicated tools facilitate visibility at the implant site and accurate valve positioning

As supplied

Collapsed

Ready to implant

Perceval S

Valve collapsing

Valve collapsed to a reduced diameter (not crimped)
Sutureless AVR - Potential benefits

- Ease of implantation resulting in a shorter cross-clamp and cardiopulmonary bypass time
  
  - High-risk – comorbidities, advanced age
  - Concomitant cardiac procedures

- Adhere to established surgical principles (unlike TAVI)
  
  - Annular decalcification (emboli, paravalvular leak)
  - Direct vision
IMPLANTATION

Ready to implant

Valve is collapsed to a reduced diameter

Valve deployment

2-Step Deployment & Balloon Dilatation

Implant

Valve is positioned in aorta
IMPLANTATION
# Sutureless AVR – HAMMERSMITH EXPERIENCE

<table>
<thead>
<tr>
<th>Total</th>
<th>Gender</th>
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<tbody>
<tr>
<td>n=17</td>
<td>Female: 6 (35%)</td>
</tr>
<tr>
<td></td>
<td>Male: 11 (65%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>Logistic Euroscore</th>
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<tbody>
<tr>
<td>Range: 76 – 90</td>
<td>Range: 9.76 – 49.75</td>
</tr>
<tr>
<td>Mean: 85.6 yrs +/- 5.9</td>
<td>Mean: 20.9 +/- 13.8</td>
</tr>
</tbody>
</table>
Sutureless AVR – HAMMERSMITH EXPERIENCE

- **Procedure**
  - AVR only – 12 (61%)
  - AVR + CABG – 5 (29%)

- **Valve Sizes**
  - S – 5
  - M – 8
  - L – 4

- **Bypass Time**
  - Range: 49 – 77min
  - Mean: **59.4min +/- 11.6**

- **Cross-clamp Time**
  - Range: 27 – 58min
  - Mean: **44.1min +/- 10.4**
Sutureless AVR –
Hammersmith Experience

- In-hospital mortality – Nil
- Late mortality - Nil
- Mean Gradient
  - Mean: 9.5 mmHg +/- 4.4
  - Range: 0 – 15 mmHg
- CICU stay
  - Mean: 1.6
  - Range: 1 – 2
- Hospital stay
  - Mean: 8
  - Range: 5 – 13
- Paravalvular leak – Nil
- Central regurgitation – Nil
- Valve migration – Nil
- Re-opening for bleeding – 1
- Stroke - Nil
- Renal failure -Nil
- Wound infection - Nil
Minimally-invasive aortic surgery
Minimally-invasive AVR

Ministernotomy versus conventional sternotomy for aortic valve replacement: A systematic review and meta-analysis.

Morgan L. Brown, MD, Stephen H. McKellar, MD, Thoralf M. Sundt, MD, and Hartzell V. Schaff, MD

Conclusion: Ministernotomy can be performed safely for aortic valve replacement, without increased risk of death or other major complication; however, few objective advantages have been shown. Surgeons must conduct well-designed, prospective studies of relevant, consistent clinical outcomes to determine the role of ministernotomy in cardiac surgery.

Brown et al. JTCVS March 2009
Minimal Access Aortic Valve Replacement: Is It Worth It?

Bari Murtuza, PhD, FRCS, John R. Pepper, FRCS, Rex DeL Stanbridge, FRCS, Catherine Jones, BSc, MBBS, Christopher Rao, MBBS, Ara Darzi, KBE, FRCS, and Thanos Athanasiou, PhD, FETCS

Departments of Cardiothoracic Surgery and Surgical Oncology and Technology, St. Mary’s Hospital, Faculty of Medicine, Imperial College, and Department of Cardiothoracic Surgery, Royal Brompton Hospital, Faculty of Medicine, Imperial College, London, England

Controversy surrounds the use of minimal access aortic valve replacement (AVR). This meta-analytical study quantified the effects of minimal access AVR on morbidity and mortality compared with conventional AVR and evaluated study heterogeneity and robustness of the findings using sensitivity analysis. Overall, meta-analysis suggested marginal benefits in perioperative mortality (4,667 patients; odds ratio, 0.72; 95% confidence interval, 0.51-1.00; p = 0.05), intensive care unit stay, total hospital stay, and ventilation time in the minimal access AVR group, although cross-clamp, cardiopulmonary bypass, and total operation times were longer. Study heterogeneity and apparent benefits in perioperative mortality were related to study quality, although results for intensive care unit and hospital stay were maintained according to the sensitivity analysis. This suggests that minimal access AVR can be offered on the basis of patient choice and cosmesis rather than evident clinical benefit.

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Marginal benefit wrt mortality, ICU stay. Longer CPB and XC time

Patient choice
Cosmesis
Cardiopulmonary bypass

- Cardioplegic arrest in diastole
- Bloodless operative field
- Detrimental effects of extracorporeal circulation
- Risks vs. benefits
Miniature Cardiopulmonary Bypass

1. Optimise venous drainage
2. Minimise microair
3. Minimise surface contact
4. Minimise blood damage
5. Minimise haemodilution
Optimise Venous Drainage

- Controlled Kinetic Venous Drainage
- Smaller cannula – 29 French
- Many draining holes
- Holes set into grooves
- Long cannula
- Improves Liver/ GIT drainage?
Minimise Microair

Active rather than Passive air removal

Minimise Surface Contact

Oxygenator is the largest non-physiological surface in CPB circuit

1.8m² Gas Exchange Surface Area

1.1m² Gas Exchange Surface Area
Minimise Blood Damage

Well Managed Suction/Vent Blood (↓ Air Mixing and -P)

Poorly Managed Suction/Vent Blood (↑ Air Mixing and -P)
Minimise Haemodilution

Patient Specific Volume Strategy

NOT

Volume Restrictive

Retrograde Autologous Prime

Antegrade Autologous Prime
Less Invasive Aortic Valve Surgery

- TAVI
- New valves
  - Sutureless, “rapid deployment”, AVR
- Incisions
  - Mini-sternotomy / mini-thoracotomy
- Mini-CPB
“In times of change, the learners inherit the Earth while the learned find themselves beautifully equipped to deal with a world that no longer exists.”

The Future of Cardiac Surgery: The Times, They Are a Changin’

Bruce Lytle, MD, and Michael Mack, MD

Cleveland Clinic Foundation, Cleveland, Ohio, Medical City Dallas Hospital, Dallas, Texas

The last 50 years have been halcyon days for cardiac surgeons. The technological innovations of cardiopulmonary bypass and heart valve prostheses led to the development of the specialty in the early 1960s. The subsequent development of coronary bypass surgery, an

ment of cardiovascular disease outside of our specialty has been dramatic and profound, particularly in regard to percutaneous technologies. The disruptive technology of percutaneous transluminal intervention (PCI) of coro

nary artery disease has progressed from the primitive and relatively ineffective use of balloon angioplasty in the late 1970s to the reproducible and largely safe interventions employing drug-eluting stents and platelet inhibitors that are available today for the treatment of a great
