

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

| 1. Device identification | n and general information | | | | | |
|---|--|--|--|--|--|--|
| Device trade name(s) | <u>NuMED Aortic PTV Family</u> Z-MED Z-MED II NuCLEUS NuCLEUS-X | | | | | |
| Model Number | NuMED Aortic PTV Family – Model 1150 Z-MED – Model 302.1 Z-MED II – Model 305.1 NuCLEUS – Model 230 NuCLEUS-X – Model 230X | | | | | |
| Manufacturer's name and address | NuMED, Inc. 2880 Main Street Hopkinton, NY 12965 USA | | | | | |
| Manufacturer's single registration number (SRN) | US-MF-000010948 | | | | | |
| Basic UDI-DI | 08877141150SQ | | | | | |
| Medical device nomenclature description / text | EMDN – C019014 – CARDIAC VALULOPLA | STY CATHETERS | | | | |
| Class of device | III | | | | | |
| Year when first | NuCLEUS – Aortic / Mitral (1998) | Z-MED – Pulmonary (1999) Z-MED – Aortic / Mitral (2013) | | | | |
| certificate (CE) was issued | NuCLEUS-X – Aortic / Mitral (2008) | Z-MED II – Pulmonary (1999) Z-MED II – Aortic / Mitral (2013) | | | | |
| Authorised Representative (AR) | G. van Wageningen B.V. Hallenweg 40, 5683 CT Best, The Netherlands | | | | | |
| AR SRN | NL-AR-000010437 | | | | | |
| Notified Body | SGS Belgium NV | | | | | |
| Notified Body ID number | 1639 | | | | | |



| 2. Intended use of the | device |
|---|--|
| Indications for use | Recommended for Percutaneous Transluminal Valvuloplasty (PTV) of aortic positions. The use of this catheter is particularly indicated in stenosis where difficulty in balloon positioning during inflation is experienced. |
| | In addition to the standard risks associated with insertion of a cardiovascular catheter, the below contraindications apply: |
| Contraindications and/or limitations | Contraindications for Aortic Balloon Valvuloplasty: Aortic Stenosis Moderate to Severe Aortic Valve Regurgitation The patient's medical condition could affect successful use of this catheter. |

| 3. Device description | | | | | | | | | |
|---|--|--|--|--|--|--|--|--|--|
| | The NuMED PTV Catheters are coaxial in construction. The inner and outer shafts are constructed of polyamide tubing. The x-line versions inner tubing is comprised of a multi-layer extrusion of polyamide that surrounds a braid of 304 LV Stainless Steel. All catheters feature a proximal end bifurcate with two distinct luminal passages. The inflation lumen terminates into a distally mounted balloon. This balloon is non-compliant. The balloon is designed to inflate to the diameter and length listed on the label at a specific pressure. Thus, it is recommended that the device be used in conjunction with a mechanism to monitor pressure, an inflation device with pressure gauge. | | | | | | | | |
| | The balloon size is \pm 10 % at Nominal Pressure (NP) or Rated Burst Pressure (RBP) and the Rated Burst Pressure (RBP) is not to be exceeded. | | | | | | | | |
| Description of the device | Catheters with NuCLEUS in the name feature a balloon with a waist. The balloon is designed with a wais formed into the middle of the balloon to allow accurate balloon placement and stability. Upon reaching a specified pressure, the waist will expand to the rated balloon diameter and dilate the valve to the rated diameter. | | | | | | | | |
| | The through lumen terminates at the tip of the catheter and will accept the passage of the appropri guidewire. All catheter sizes will have radiopaque platinum marker band(s), centered or under balloon shoulders to aid during placement. | | | | | | | | |
| | These devices are also designed to be used with an appropriately sized introducer and guidewire. | | | | | | | | |
| | The catheters are supplied sterile, by ethylene oxide gas, and are intended for single use only. The catheters are invasive and intended for transient use (continuous use of <60 minutes) on patients. | | | | | | | | |
| Reference to previous generation(s) or variants | N/A | | | | | | | | |
| Accessories which are intended to be used in combination with the device | There are no accessories that are intended to be used with this device. | | | | | | | | |
| Description of any other devices and products which are intended to be used in combination with the device | This device is designed to be used with a guidewire, introducer, and an inflation device with pressure gauge. | | | | | | | | |



| The clinical data, availability of guidelines from expert groups, established use of the device technology and the large numbers of devices sold demonstrate that there is high quality data of sufficient amounts to detect undesirable side-effects associated with the use of the PTV Catheters. |
|---|
| Known and foreseeable clinical risks have been considered for the PTV Catheters in accordance with risk management (RM) procedure AP-346 and through the RM files for PTV Pulmonary Catheters and mitigated as far as possible (AFAP). |
| Identified clinical residual risks/undesirable side-effects for the PTV Catheters are: Potential balloon separation following balloon rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces. |
| NOTE: There have been infrequent reports of larger diameter balloons bursting circumferentially, possibly due to the combination of tight focal strictures in large vessels. In <u>any</u> instance of a balloon rupture while in use, it is recommended that a sheath be placed over the ruptured balloon prior to withdrawal through the entry site. This can be accomplished by cutting off the proximal end of the catheter and slipping an appropriately sized sheath over the catheter into the entry site. For specific technique, refer to : tegtmeyer, Charles J., M.D. & Bezirdijan Diran R., M.D. "Removing the Stuck, Ruptured Angioplasty Balloon Catheter." Radiology, Volume 139, 231-232, April 1981. |
| Potential complications and related adverse effects associated with the valvuloplasty catheter use include, but are not limited to:-Perforation-Conduction System Injury-Thromboembolic Events-Cardiovascular Injury-Balloon Rupture-Arrythmia Development-Valvular Tearing or Trauma-Restenosis Development-Inflammation-Cardiac Tamponade-Death-Valvular Regurgitation-Access Site Complications |
| The following Warnings and Precautions have been identified and are called out in the Instruction for Use: Warnings CAUTION: Do not exceed the RBP. An inflation device with pressure gauge is recommended to monitor pressure. Pressure in excess of the RBP can cause balloon rupture and potential inability to withdraw the catheter through the introducer sheath. Catheter balloon inflation diameter must be carefully considered in selecting a particular size for any patient. The inflated balloon diameter should not be significantly greater than valvular diameter. The choice of the balloon size to be used for valve stenosis has been established by the VACA Registry to be approximately 0.9 to 1.0 times the valve annulus. It is important to perform an angiogram prior to valvuloplasty to measure the size of the valve in the lateral projection. Balloons longer than 4cm are not recommended for children ≤ 10 years old. Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. This catheter is not recommended for pressure measurement or fluid injection. Do not remove the guidewire from the catheter at any time during the procedure. This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially |
| |

| | NuMED Summary of Safety and Clinical Performance SSCP – Aortic PTV |
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| | The catheter should be used prior to the 'Use Before' date noted on the package label. The catheter is intended for valvuloplasty applications only, and is not intended for angioplasty. THE CATHETER IS NOT INTENDED FOR USE WITH STENTS. |
| | Precautions Dilatation procedure should be conducted under fluoroscopic guidance with appropriate x-ray equipment. Guidewires are delicate instruments. Care should be exercised while handling to help prevent the possibility of breakage. Careful attention must be paid to the maintenance of tight catheter connections and aspiration before proceeding to avoid air introduction into the system. Under no circumstances should any portion of the catheter system be advanced against resistance. The cause of the resistance should be identified with fluoroscopy and action taken to remedy the problem. If resistance is felt upon removal, then the balloon, guidewire, and the sheath should be removed together as a unit, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and sheath as a unit and withdrawing both together, using a gentle twisting motion combined with traction. Before removing the catheter from the sheath it is very important that the balloon is completely deflated. Proper functioning of the catheter depends upon its integrity. Care should be used when handling the catheter. |
| Other relevant aspects of safety, including a summary of any field safety corrective actions (FSCA including FSN) if applicable | There have been (2) FSCAs for devices in the Aortic PTV Family. Both FSCAs were from the NuMED Canada, Inc. manufacturing location and both were for labeling issues. Both of these FSCAs were in 2011. No adverse events were reported for either of the FSCAs. |
| 5. Summary of clinical | l evaluation and post-market clinical follow-up (PMCF) |

Summary of clinical data related to equivalent device:

NuMED has elected not to use the clinical data from an equivalent (clinical, technical, and biological characteristics) device(s). In the event there are devices considered equivalent, their data will be considered as similar devices.
Summary of clinical data from conducted investigations of the device :

1. Study name: Purpose: To establish t

Purpose: To establish the safety and effectiveness of the Tyshak and Z-MED models of the NuMED PTV Catheters, utilized for pulmonary valvuloplasty.

Clinical Study Methodology: Prospective study of 130 subjects (100 patients for the Tyshak model and 30 patients for the Z-MED model).

Reference to the clinical study plan (and amendment) n[•]: IDE # G890030

| Kejerence to the clinical study plan (and amenament) h : IDE | 7 0890030 |
|--|--|
| Investigation Sites: | |
| Dr Hugh Allen, Children's Hospital of Columbus | |
| Dr Ziyad Hijazi, New England Medical Center | |
| Dr Thomas Jones, Children's Hospital and Medical Center | |
| Dr Larry Latson, The Cleveland Clinic Foundation | |
| Dr Robert Morrow, Arkansas Children's Hospital | <i>Reference to Document n</i> [•] : <i>IDE # G890030</i> |
| Dr Michael Kuhn, Loma Linda University Children's Hospital | |
| Dr Donald Hagler, The Mayo Clinic Foundation | |
| Dr John Moore, Dupont Children's Hospital | |
| Dr Daphne Hsu, Columbia-Presbyterian Medical Center | |
| Dr Paul Seib Arkansas Children's Hospital | |

| | tion: Patients with >50mmHg gradient resting state or >35mmH ertrophy on ECG and/or echo. | g gradient resting state with right |
|--|---|---|
| Inclusion Crite | ria: | |
| | atient with a pulmonary valve gradient of >50mmHg, resting stat | e |
| | atient with a pulmonary valve gradient of >35mmHg, resting stat | |
| ECG a | nd/or echo | |
| Patien | s with isolated pulmonary valve stenosis | |
| • Patien interve | s with pulmonary valve stenosis with other minor congenital heat | art disease that does not require surgical |
| Exclusion Crit | eria: | |
| • Patien | s with pulmonary valve gradient of <35mmHg, with normal EC | G |
| • Other | significant cardiac abnormalities (such as tetralogy of Fallot, sup | ravalve pulmonary stenosis, or |
| | | |
| | ibular pulmonary stenosis) where dilatation may be achieved but | |
| the gra | ibular pulmonary stenosis) where dilatation may be achieved but dient and therefore be of no value to the patient | will not result in a significant change i |
| the gra • Patien | ibular pulmonary stenosis) where dilatation may be achieved but dient and therefore be of no value to the patient s with pulmonary valvar stenosis with major congenital heart de | will not result in a significant change i fects that require open heart surgery |
| the graPatienPatien | ibular pulmonary stenosis) where dilatation may be achieved but dient and therefore be of no value to the patient s with pulmonary valvar stenosis with major congenital heart de s enrolled in any other study for investigational devices or drugs | will not result in a significant change i fects that require open heart surgery |
| the gra • Patien | ibular pulmonary stenosis) where dilatation may be achieved but dient and therefore be of no value to the patient s with pulmonary valvar stenosis with major congenital heart de s enrolled in any other study for investigational devices or drugs | will not result in a significant change i fects that require open heart surgery |
| the graPatienPatien | ibular pulmonary stenosis) where dilatation may be achieved but dient and therefore be of no value to the patient s with pulmonary valvar stenosis with major congenital heart de s enrolled in any other study for investigational devices or drugs | will not result in a significant change i fects that require open heart surgery |
| the gra • Patien • Patien Clinical Study | ibular pulmonary stenosis) where dilatation may be achieved but dient and therefore be of no value to the patient as with pulmonary valvar stenosis with major congenital heart de as enrolled in any other study for investigational devices or drugs Results: | will not result in a significant change i fects that require open heart surgery should not be enrolled in this study. |
| the gra Patien Patien Clinical Study Purpose Procedural Success | ibular pulmonary stenosis) where dilatation may be achieved but dient and therefore be of no value to the patient as with pulmonary valvar stenosis with major congenital heart de as enrolled in any other study for investigational devices or drugs Results: Criteria Valvular pressure difference reduced by ≥ 50% or reduced to ≤ 30 mmHg. | will not result in a significant change i fects that require open heart surgery should not be enrolled in this study. Results 97% success rate (n=103); No deaths |
| the gra Patien Patien Clinical Study Purpose Procedural Success Devices Used: | ibular pulmonary stenosis) where dilatation may be achieved but dient and therefore be of no value to the patient as with pulmonary valvar stenosis with major congenital heart de senrolled in any other study for investigational devices or drugs Results: Criteria Valvular pressure difference reduced by \geq 50% or reduced to \leq 30 mmHg. Tyshak indicated for patients with non-dysplastic valves and Z-N | will not result in a significant change i fects that require open heart surgery should not be enrolled in this study. Results 97% success rate (n=103); No deaths |
| the gra Patien Patien Clinical Study Purpose Procedural Success Devices Used: and/or calcified | ibular pulmonary stenosis) where dilatation may be achieved but dient and therefore be of no value to the patient as with pulmonary valvar stenosis with major congenital heart de senrolled in any other study for investigational devices or drugs Results: Criteria Valvular pressure difference reduced by \geq 50% or reduced to \leq 30 mmHg. Tyshak indicated for patients with non-dysplastic valves and Z-N | will not result in a significant change i fects that require open heart surgery should not be enrolled in this study. |

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| Results/0 | Outco | ome | | | | | | | | | | | | | Clinical Applicatio | | |
|---------------------------------------|---|-----------------|-----------|---|--|--|----------|---------|----------|---------|--------------|---------------------|------|---------|---|--|--|
| State of t | State of the Art | | | | | | | | | | | | | | Applicatio | | |
| Medica | Appraisal Medical Alterna condition | | | | | atives Risk/benefit Side- effects Equivalence | | | | | | irrog | | | | | |
| | No 2 | Yes 1 | No 2 | | Yes 1 | No 2 | Yes 1 | No 2 | Yes 1 | No 2 | | dpoi es 1 | No | 0 2 | | | |
| Overall SOA Appraisal and Disposition | | | | | | | | | | | | | | | | | |
| SOA Grade (Range 12) | | 8 Di | | sition | | | | | | | | | | | | | |
| Safety & Performance Appraisal | | | | | | | | | | | | | | | | | |
| Level o Eviden | f S | Study Methoo | d/De | sign | Que | estion App | olied | | | | Oxfe 2011 | ord L | .OE | | | | |
| | | Prospec | | | To evaluate the results of such a1multidisciplinary PAVI program, focusing on patient and approach selection criteria, procedural results, and complications, as well as mid-term follow-up.1 | | | | | | | | 4 | 5 | Population Patients wissymptoma | | |
| Suitabi | litv | | Rel | levant Data Grad | | | | | | | | ding | | | severe aort stenosis | | |
| Device | • | | Z-N | MED (NuMED Canada, Inc.) D1 | | | | | | | | D2 | |)3 | Somuling | | |
| Applica | tion | | PA | VI | | | | | | | A1 | A2 | | 43 | Sampling: n=22 | | |
| Patient | | | San Me | npling an age | ents with symptomatic severe aortic stenosis upling: n=22 In age: 84 ± 7 years ± 10 M; 12 F | | | | | | | P2 | F | 23 | Mean age: years | | |
| Report | | | Hig | gh quality F | | | | | | | | R2 | e F | R3 | | | |
| Suitabi | Suitability Grade (Range 4-12) 5 | | | | | | | | | | | | | | | | |
| Data C | ontri | bution | | Rele | vant] | Data | | | | | | G | radi | ng | | | |
| Outcon | | ndpoir | nts | | | l success | | | | | | Y (| es | No 2 | | | |
| Follow- | - | | | 6 mo | | | | | | | | Y (1 Y (| | No 2 | | | |
| Statistic | cal ar | nalysis | | and c (rang perfo sum Diffe | Qualitative variables are expressed as percentages nd quantitative variables as mean \pm SD or median range). Comparisons of numerical variables were erformed using Student's t test or Wilcoxon's rank- um test depending on variable distribution. Differences were considered statistically significant | | | | | | | | | No 2 | | | |
| | l sign | ificanc | e | at p values <0.05. Procedural success was defined as the implantation of a functioning prosthetic valve within the aortic annulus at the end of the procedure without in- laboratory mortality. | | | | | | | | Y (| | No 2 | | | |



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|------------------|--|--|--------------------------------|---|--|-----------------|---------|----------------|--------|------|----------------|--------------------------|--|
| | Overall S& | P Annr | aisal Disn | osition | and Wei | ohtino | | | | | | | |
| | S&P Grade (Range 9- 25) | S&PLOE (5) +GradeSuitability (5) +(Range 9-Data Contribution | | | Disposition and Weighting (select) Accepted and 12 Accepted but Pivotal, 13-21 Excluded, 22-2 | | | | | | but n 3-21 | ot | |
| | Objective: H aortic valve : Method: Par to valve imp Relevant Re | implant tients ic lantatio | tation progra lentified for | am. | | | | - | | - | | | r |
| | Criteria | suits. | | Resu | te | | | | | | р | value | 7 |
| | Procedural | 6110000 | - | 91% | 115 | | | | | | | Value NA | |
| | Procedural mortality | | | | and 8.7% | 6 respe | ctively | / | | | | NA NA | - |
| | Mean aorti | c gradie | ent | Redu | ced from | 34±10 | mmH | g to $9\pm 3r$ | nmH | g | Р | < 0.001 | |
| | Mean aorti follow up | | | | ase from | | | | | | N | JA | |
| | Safety conce | ern: | | | | | | | | | | | |
| | Criteria | | | Result | t <mark>s</mark> ificant pr | | | | | | | P value | |
| | Adverse Ev | | | n=1 severe aortic regurgitation rectified with a second valve implantation, n=1 periprocedural cardiac tamponade treated with pericardiocentesis, n=1 myocardial apical tear and severe bleeding after left ventricular sheath removal requiring surgical repair of ventricular apex under femoral-femoral cardiopulmonary bypass. One patient died on day 29 due to pneumonia. Paravalvular aortic regurgitation was present in 13 patients (1+ in 9 patients, 2+ in 4 patients). | | | | | | | | | |
| | Conclusion: | | | | | | | | ed cat | hete | r whe | n used fo | or |
| | BAV of seve Device used | | - | orior to | aortic va | ive imp | nantat | ion. | | | | | |
| | State of the | | u | | | | | | | | | | Population: |
| | Appraisal | | | | | | | | | | | | Patients with |
| | Medical condition | | ternatives | | benefit | Side- effect | ts | Equiva | | e | Surro endpo | oints | severe aortic stenosis and |
| | Yes No | | | Yes | No | Yes | No | Yes | No | | Yes 1 | No 2 | |
| | 1 2 Overall SO ₄ | | 2 caisal and D | 1 Disposit | | 1 | 2 | | 2 | | | | obstructive pulmonary disease |
| ntias et 2016 | SOA Grad (Range 6-1 | | 8 | | Di | spositi | on (se | lect) | | | epted luded | , < 12 , 12 | Sampling : n= 131; patient: |
| | <u>Safety & Pe</u> Appraisal | | | | | | | | | | | | treated with balloon aortic |
| | Level of Evidence | | od/Design | - | tion App | | | | | 203 | 11 | LOE | valvuloplasty n=29 |
| | | | spective t study | To determine the outcomes in patients1with high-risk symptomatic AS withsever or very severe COPD referred formultispecialty evaluation by a high-risk | | | | | | | 2 3 | 3 4 5 | Mean age (BA) Group): 76.2 years |



| Suitability | | elevant Data | l | | Grad | | D.C |
|--|------------------------|---------------|---|-----------------|-----------------|--------------|----------|
| Device | | med II | D1 | D2 | D3 | | |
| Application Patient | | AV | evere aortic stenosis and sever | | A1 P1 | A2 P2 | A3 P3 |
| Patient | | | ctive pulmonary disease | re | FI | P2 | P3 |
| | | | 31; n=29 (BAV group) | | | | |
| | | | 3 ± 7.4 years (BAV group) | | | | |
| | | | (BAV group) | | | | |
| Report | | gh quality | | | R1 | R2 | R3 |
| Suitability (| Grade (Ra | nge 4-12) | | | 4 | | |
| Data Contri | ibution | Relevant I | Data | | | Grad | ding |
| Outcomes/H | | All-cause r | | | | Yes | No |
| | | | | | | 1 | 2 |
| Follow-up | | Median 3.0 | 0 ± 1.5 years | | | Yes | No |
| Stat 1 | | Carti | | | | 1 Var | 2 N |
| Statistical a | narysis | | s variables are expressed as me eviation, or median and interg | | or. | Yes 1 | No 2 |
| | | | stributions, and compared usir | | 51 | 1 | 1 |
| | | | est or ANOVA (for normally | | d | | 1 |
| | | | or the Wilcoxon test (for nonr | | | | |
| | | | variables). Categorical data a | | | | |
| | | | tage and compared using Fisl | | | | |
| | | | test. To assess outcomes, Coz alysis was performed to asses | | onal | | |
| | | independer | | | | | |
| | | for statistic | | | | | |
| | | | dence intervals were calculate | | | | |
| | | | Cumulative proportion of even | | | | |
| | | function ov | | | | | |
| <u></u> | • 6• | | do the survival analysis. | | | • • • | |
| Clinical sign | nificance | Cardiavasc | Yes 1 | N 2 | | | |
| Data Contr | ibution Gr | ade (Range | 4-8) | | | 4 | 4 |
| Data Contra | | , U | , | | | • | |
| | | | i and weighting | | | ad Dire | otal |
| Overall S&P | LOE (4) - | + | Disposition and | Accept | ed ar | | |
| Overall S&P | Suitabilit | y (4) + | Disposition and Weighting (select) | Accept 9-12 | ed an | | |
| Dverall S&P S&P Grade (Range 9- | Suitabilit Data Con | y (4) + | | 9-12 Accepte | ed bu | it not | |
| Overall S&P S&P Grade | Suitabilit | y (4) + | | 9-12 | ed bu , 13-2 | it not 21 | |

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|-------------|---|---------|----------------|--------------------------|---|---------|---------------------------|---------|----------|---------|--------------|----------------|------|---------|-------------------------------------|
| | Relevant Results: Criteria Results | | | | | | | | | | | D | . 1 | 1 | |
| | Criteria | | 1 | . 2 | | | 17 701 | . 1 5 1 | 00/ 5 | | | P v | alu | le | |
| | Cardiovas year follo | | leath at | t 3 | | | , 47.7% a respectiv | | 8% of p | atient | ts in | P<0 |).00 | 001 | |
| | Safety con | cern: | | | | | | | | | | | | | |
| | Criteria | | | | Resul | | | | | | | P v | alu | ıe | |
| | Adverse I | Events | | | Heart failure, respiratory failure, and COPD exacerbation leading to hospital readmissions within 30 days occurred in 43%, 42%, 9.6% and 14.8% of patients in groups 1-4, respectively. | | | | | | | | 0.0 | 16 | |
| | Conclusion | | | milon t | | | | | Cond | | | | | | |
| | COPD rega respiratory Device use | | | | | | | | | | | | | | |
| | State of th | | | | | | | | | | | | | | |
| | Appraisal Medical | | Alterna | atives | Risk/ | benefi | | | Equiv | valen | | irroga | | | |
| | condition | | 7 | NT. | N/ | IN. | effect | - | N/ | N. | | dpoin | 1 | | |
| | Yes N 1 2 | | Yes | No 2 | Yes 1 | No 2 | Yes 1 | No 2 | Yes | No 2 | Y Y | es 1 | ING | 0 2 | |
| | | | L | 2 | 1 | 2 | 1 | 2 | 1 | 4 | | | | | |
| | Overall SOA Appraisal and Disposition | | | | | | | | | | | | | | |
| | SOA Gra | | 8 | | - | | Dispositi | on (se | lect) | | Acce | Accepted, < 12 | | | |
| | (Range 6 | -12) | | | | | | | | | Exclu | ded, 1 | 2 | | |
| | | | | | | | | | | | | | | | |
| | Safety & Performance | | | | | | | | | | | | | | |
| | Appraisal | C. | • | | | | | | | | | | | | |
| | Level of Evidence | | ldy | Jacian | | Ques | stion App | lied | | | Oxfo 2011 | ord LOE | | | |
| | Evidence | | | Design ve stud | | Tore | nort initi | lavna | rionco | with | | | | | Donalotions |
| | | | | | ed control BAV using the V8 balloon compared to cylindrical balloons | | | | | | | 2 3 4 5 | | | Population: Patients with |
| | | | | neu eo | | | | | | | | | | | symptomatic |
| | group compared to cylindrical balloons | | | | | | | | | | | | | | severe AS. |
| Pedersen et | Suitabilit | у | Re | elevant | nt Data Gra | | | | | | rading | | | | |
| al. 2014 | Device | | Z-i | med an | | | | | | | D1 | D2 | | D3 | Sampling: |
| al. 2014 | Applicati | on | BA | | | | | | | | | A2 | | A3 | n=40; n=20 |
| | Patient | | | | | | atic sever | | | | P1 | P2 |] | P3 | using cylindrical |
| | | | | | ling: n=40; n=20 using cylindrical balloons | | | | | | | | | | balloons and $n=20$ using V8 |
| | | | | | =20 using V8 balloon | | | | | | | | | | n=20 using V8 balloon |
| | | | | | an age: 85.5 ± 6.8 years (for matched controls) = 14 M; 6 F (for matched controls) | | | | | | | | | | ballooli |
| | Report | | | gh quality | | | | | | R1 | R2 | 1 | R3 | | |
| | Suitabilit | v Grad | | | | | | | | | 4 | | | | |
| | | V | , | 0 | , | | | | | | | | | | |
| | Data Cor | tribut | ion | Rele | vant Da | ata | | | | | | Gr | adi | ing | |
| | Outcome | s/Endp | ooints | Aorti | ic Valve | e Area | and Aort | ic inst | ufficien | cy | | Ye | s | No | |
| | | | | | | | | | | | | 1 | | 2 | |
| | Follow-u | р | | 1 mo | nth | | | | | | | Ye | s | No | |
| | Stat - 4 | 1.08-2 | - - - - | D | | -+-+ | | 1. | 1 | | 100 | 1 Va | _ | 2 | |
| | Statistica | i analy | /SIS | | | | ics are dis iables; nu | | | | | | | No 2 | |
| | | | | | | | given for | | | | | 1 | | 4 | |
| | | | | | | | les were a | | | | | | | | |
| | | | | | | | r's exact | | | | | | | | |
| | | | | | | | udent's T- | | | | 0.05 | | | | |
| | | | | | | | | | | | | | | | |



| | | - | | ' – A0 | | 1 1 | | | | | - | |
|---|--|--|---|--|--|--|--|--|---|--|--------------------------------|------------------------|
| | | | | red signi | ificant. | | | | | | _ | _ |
| Clinical sig | gnifica | nce Char | nge in A | AVA | | | | | | Ye | | No |
| Data Cont | tributio | n Grade (l | 2ange / | L-8) | | | | | | 1 | 2 | <u>,</u> |
| Data Cont | innun | n Oraut (1 | ange - | F-0) | | | | | | | | |
| Overall S& | Р Аррг | aisal, Disp | osition | and We | ighting | | | | | | | |
| S&P | | (4) + | | Disposit | | | | Accep | ted ar | nd Piv | otal | 9- |
| Grade | | bility (4) + | | Weighti | ing (sel | ect) | | 12 | | | | |
| (Range 9- | | Contribut | ion | | | | | Accep | | | t | |
| 25) | (4) = | 12 | | | | | | Pivota Exclue | | | | |
| Objective: I balloon whe the aortic va persistently : compromise Method: Pa matched gro imaged were Change in ac studies. Relevant Ro Criteria | en used i ilve ana narrowe attients u oup white obtain ortic va esults: | for BAV. A tomy, havin ed waist to ndergoing l ch used cyli ed within o | n hour ng proxi permit c BAV wi indrical ne mon l aortic Resul Echoc | glass sha mal and enhanced ith a V8 balloons th pre-op insuffici | ped bal distal b l fixatio balloon f for BA perative ency we | loon w ulbous n bette were o V. Tra ly and ere obt | vas des s segme compar ansthor 72 hou ained f | igned to ents sep et openi red to a racic ec urs post from ec aseline | o betto parate ing wi prope hocar opera hocar to | er con d by a ithout ensity diogra trively. diogra | form annu aphic aphic | i to ilar : : |
| Aortic valv | | | V8 ba 0.30±0 No sig | lloon ove 0.23 cm ² gnificant | er cyline vs. 0.1 | 1rical 3 7±0.21 | group l cm ² | Mean | | | 0.06 | 3 |
| | | | either | group. | | | | | | 11/1 | - | |
| Safety conc | ern: | | Dogu | lta. | | | | | | D | volu | |
| Criteria Adverse Ev | vents | | pacer transf floor. | atient in naker for fer from o Procedu cylindri | transie cardiac ral mor | nt AV cathet tality (| block erizatio | at time on lab to | of the | / N. | <u>valu</u> A | ie |
| Conclusion | : The st | udv sugges | ts that la | arger AV | As may | be of | oup. stained | using t | he no | ovel ho | our g | lass |
| balloon in co authors did i | omparis not see | on to the st a greater in | andard cidence | cylindric of atriov | al ballo ventricu | ons in lar cor | patien iductio | ts with on disore | calcif der, n | fic AS. | . The | |
| permanent p | | er, change | | c insuffic | ciency of | r majo | or adve | rse ever | nt. | | | |
| Device used | | | ed II | | | | | | | | | |
| State of 41. | l: Z-Me | d and Z-Me | | | | | | | | | | |
| State of the Appraisal | l: Z-Me | | · · | | | | | | | | | |
| Appraisal | l: Z-Me Art | d and Z-Me | | /benefit | Side- | | Eani | valence | e Sr | urroge | ate | |
| Appraisal Medical | l: Z-Me Art | | | /benefit | Side- effect | S | Equi | valence | | urroga 1dpoin | | |
| Appraisal | I: Z-Me Art Al | d and Z-Me | | /benefit No | | s No | Equi Yes | valence | en | urroga ndpoin es 1 | | 2 |
| Appraisal Medical condition | l: Z-Me Art Al | d and Z-Me | Risk | | effect | | | | en | ndpoin | nts | 2 |
| Appraisal Medical condition Yes No 1 2 Overall SO | I: Z-Me Art Al D Ye A A D Ye A Apple | d and Z-Me Iternatives es No 2 raisal and I | Risk Yes 1 | No 2 | effect Yes 1 | No 2 | Yes 1 | No 2 | en Ye | ndpoin es 1 | nts No | |
| AppraisalMedicalconditionYesNo12Overall SOSOA Grad | I: Z-Me Art Art o Ye A o Ye A Appi A Appi A Appi A | d and Z-Me Iternatives es No 2 | Risk Yes 1 | No 2 | effect Yes | No 2 | Yes 1 | No 2 | en Ye Accej | ndpoin es 1 pted, • | <u>nts</u> No < 12 | |
| AppraisalMedicalconditionYesNo12 | I: Z-Me Art Art o Ye 1 A Appi de | d and Z-Me Iternatives es No 2 raisal and I | Risk Yes 1 | No 2 | effect Yes 1 | No 2 | Yes 1 | No 2 | en Ye Accej | ndpoin es 1 | <u>nts</u> No < 12 | |
| AppraisalMedicalconditionYesNo12Overall SOSOA Grad | I: Z-Me Art A D Ye 1 A Appi de 12) | d and Z-Me ternatives es No 2 raisal and I 9 ance | Risk Yes 1 Disposit | No 2 | effect Yes 1 | No 2 | Yes 1 | No 2 | en Yo Accej Exclu | ndpoin es 1 pted, • | nts No < 12 12 | |



| Evidence | Method/I | Design | | | 20 |)11 | | | | |
|--|----------------------------|--|---|--|---------|-------|----------|----------|--|--|
| | Retrospec | | To re | etrospectively analyze the | 1 | 2 | 3 | 4 5 | | |
| | review | | indic | ations and short-term outcomes of | of | | | | | |
| | | | | , not directly associated with | | | | | | |
| | | | | T, since that procedure was | | | | | | |
| | | | launo | ched in our institution. | | | | | | |
| Suitability | R | elevant | Data | | G | rad | ling | | | |
| Device | | umed Z- | | []-X | D | 1 | D2 D3 | | | |
| Applicatio | | AV | | | A | | A2 | A3 | | |
| Patient | | tients w | ith ad | vanced hemodynamically unstab | | | P2 | P3 | | |
| | | | | F) including cardiogenic shock | | | | | | |
| | | mpling | | | | | | | | |
| | | | | 11.4 years | | | | | | |
| | | x: 6 M; | | | | | | | | |
| Report | | gh qual | | | R | | R2 | R3 | | |
| Suitability | Grade (Ra | nge 4-1 | 12) | | 4 | | | | | |
| Data Cont | ribution | Relev | vant I | Data | | | Gra | ding | | |
| | /Endpoints | | | in maximal transaortic gradient | | | Yes | No | | |
| | 1.0000 | | | | | | 1 | 2 | | |
| Follow-up | | Medi | an = 2 | 0.5 ± 11.4 months | | | Yes 1 | No 2 | | |
| Statistical | analysis | Cont | inuous | variables were reported as mean | and | | Yes | No | | |
| | - | stand | ard de | viation. For nonparametric data, | the | | 1 | 2 | | |
| | | | | tric Mann-Whitney test was used | | | | | | |
| | | | | variables. Discrete variables wer | | | | 1 | | |
| | | | | counts or percentages. P values l | | n | | | | |
| Clinical et | mificance | | | considered statistically significant | | | Yes | No | | |
| Clinical sig | gimicance | 30% | reauci | ion in maximal transaortic gradie | ill | | res | 1NO 2 | | |
| Data Cont | ribution G | rade (R | ange | 4-8) | | | 4 | 1 | | |
| | D 4 | 1 D! | | and Weighting | | | | | | |
| S&P | LOE (4) | | siuon | and Weighting Disposition and A | ccepte | ne h | d Pir | ntel | | |
| Grade | Suitabili | | | - | 12 | u all | iu 1 1V | ordi | | |
| (Range 9- | Data Con | | | 0 0 0 | ccepted | l bu | t not | | | |
| 25) | (4) = 12 | | | | votal, | | | | | |
| | | | | | xcluded | | | | | |
| directly asso Method: Re Relevant Re | ciated with trospective | TAVI. | of pati | e the indications and short-term of the indications and short-term of the short shor | utcome | of] | - | | | |
| Criteria | | | Res | | | | | alue | | |
| In-hospital | | | | 5 (20%) | | | N/A | 1 | | |
| | tion in peak | | | ained in all patients who survived | l | | N/A | 1 | | |
| transaortic | 0 | | proc | cedure | | | 1.171 | | | |
| Safety conc | ern: | | р | | | | - | - | | |
| Criteria | | | Resu | | • | | P v | alue | | |
| Adverse Ev | vents | | In-hospital mortality was 20%. Other major complications included permanent pacemaker implantation (n=2), major vascular complications (n=4) (one patient required | | | | | NA | | |
| | | bailout vascular surgery), and cardiac | | | | | | | | |
| | | | | onade in one patient. There were | | | | | | |



| | | | | ~ | | $-\mathbf{A}$ | ortic I | | | | | | | | |
|--------|--|--|---|--|--|---|---|--|---|--|---------------------------------|---|---------------------------------------|--|--------------------------------------|
| | | | | | patien surgei | | required | conv | ersion to | cardia | ic | | | | |
| | Conclusion to the pro- | | | n results | 0 | | relative | y low | mortalit | y and r | mor | oidity | relat | ted | |
| | Device us | | | -X | | | | | | | | | | | |
| | State of t | he Ar | t | | | | | | | | | | | | |
| | Appraisa | | | | | | | | | | | | | | |
| | Medica | | Alter | natives | Risk/ | benefit | | | Equiva | alence | <u> </u> | | | | |
| | conditio | | | 1.5.7 | ** | 1.5.7 | effec | I | | . | _ | ndpoi | - | • | |
| | Yes 1 | No 2 | Yes 1 | No 2 | Yes 1 | No 2 | Yes 1 | No 2 | Yes 1 | No 2 | Y | es 1 | No | o 2 | |
| | Overall SOA Appraisal and Disposition | | | | | | | | | | | | | | |
| | SOA G | | 9 | | | Γ | Dispositi | on (se | lect) | | | epted, | | 2 | |
| | (Range | 6-12) | | | | | | | | ł | Excl | uded, | 12 | | |
| | <u>Safety &</u> Appraisa | | rmance | <u>e</u> | | | | | | | | | | | |
| | Level of | | Study | | Oues | tion Ap | pplied | | | | Ox | ford I | OE | | |
| | Evidenc | | | /Design | _ | | - | | | | 201 | 1 | | | |
| | | | Retrospe | ctive | | | he clini | | | | 1 | 2 3 | 4 | 5 | |
| | | re | eview | | | | | | P in high | | | | | | |
| | | | | | | | undergo lcific A | | ective BA | AV | | | | | |
| | | | | | 101 50 | | |). | | | | | | | Dopulations |
| | Suitabil | lity | ŀ | Relevant | Data | | | | | | Gr | ading | | | Populations: Patients with |
| | Device | | | Z-Med (N | | Inc) | D1 | | | | | | | D3 | severe AS |
| | Applica | tion | | BAV | | A1 | | | | | | | A3 | undergoing | |
| | Patient | | | atients v | | | undergo | ing B | AV | | P1 | P2 | 1 | P3 | BAV |
| et al. | | | | ampling | | | | | | | | | | | Same Para |
| | | | | /lean age Sex: 49 N | | | S | | | | | | | | Sampling: n=111 |
| | | | с I | юл. HJ IV | 1, UZ I' | | | | | | | | | R3 | |
| | Report | | F | | itv | | | | | | R1 | R | 2 1 | | M/F: 49/62 |
| | Report Suitabil | ity Gr | | ligh qua | | | | | | | R1 4 | R2 | 2 1 | 11.5 | |
| | - | ity Gr | | | | | | | | | | R | 2 1 | | Mean age: 82 |
| | - | | rade (R | High quai ange 4-1 Relev | 2) vant Da | | | | | | | | 2 1 radi | | Mean age: 82 years |
| | Suitabil | ontrib | rade (R oution | High quai ange 4-1 Relev s Comp | 2) vant Da | of hospi | | | procedu | | | G Y | radi es | ng No | Ũ |
| | Suitabil | ontrib | rade (R oution | High qual ange 4-1 Releves Comj myoc | 2) vant Da posite c | of hospi | on, cereb | rovas | cular acc | cident | 4 | G | radi es | ng | Ű |
| | Suitabil | ontrib | rade (R oution | High qual ange 4-1 Relev S Comp myoc (CVA | 2) vant Da posite c ardial i A), and | of hospi | on, cereb | rovas | | cident | 4 | G Y | radi es | ng No | Ű |
| | Suitabil Data Co Outcom | ontrib nes/En | rade (R oution | High qual ange 4-1 Relev s Comp myoc (CVA (CPR | 2) vant Da posite c ardial i A), and | of hospi | on, cereb | rovas | cular acc | cident | 4 | G Y 1 | radi es | ng No 2 | Ŭ |
| | Suitabil | ontrib nes/En | rade (R oution | High qual ange 4-1 Relev S Comp myoc (CVA | 2) vant Da posite c ardial i A), and | of hospi | on, cereb | rovas | cular acc | cident | 4 | G Y 1 | radi es es | ng No | Ũ |
| | Suitabil Data Co Outcom | ontribu nes/End | rade (R oution idpoints | Relevance Relevance S Comparison myood (CVA) (CPR) Not S | 2) vant Da posite o ardial i (A), and) btated | of hospi infarction need fo | on, ceret r cardio | provas pulmo | cular acc | vident uscitati | 4 | G Y 1 Y 1 | radi es es | ng No 2 No | Ũ |
| | Suitabil Data Co Outcom Follow- | ontribu nes/End | rade (R oution idpoints | Relevance Relevance Relevance Solution Comparison Myoor (CVAnce) (CPR) Not Solution Category analy | 2) vant Da posite c aardial i (A), and) stated gorical sis, or 1 | of hospi infarction need fo variable Fisher's | on, ceret r cardio es were o s exact to | compa est wh | red by cl | hi-squa | 4 ion are | G Y 1 Y 1 | radi es es es | ng No 2 No 2 | Ŭ |
| | Suitabil Data Co Outcom Follow- | ontribu nes/End | rade (R oution idpoints | High qual ange 4-1 Relevent S Comparison myood (CVA) (CPR) Not S Categent analy Control | 2) vant Da posite c aardial i (), and) tated gorical sis, or nuous | of hospi infarction need fo variable Fisher's variable | on, ceret r cardio es were o e exact to es were o | compa compa compa compa | red by cl en appro red by S | hi-squa priate. | 4 ion are 's t- | G Y 1 Y 1 Y | radi es es es | ng No 2 No 2 No | Ũ |
| | Suitabil Data Co Outcom Follow- | ontribu nes/End | rade (R oution idpoints | High qual ange 4-1 Relevent S Comparison myoc (CVA) (CPR) Not S Category analy Contract (contract) Contract (contract) test. S S | 2) vant Da posite c aardial i \), and) stated gorical sis, or 1 nuous Stratifie | of hospi infarctic need fo variable Fisher's variable ed analy | on, ceret r cardio es were o s exact to es were o rses were | compa est wh compa e perfo | red by cl en appro red by S ormed to | hi-squa priate. tudent ¹ | 4 ion are 's t- | G Y 1 Y 1 Y | radi es es es | ng No 2 No 2 No | Ũ |
| | Suitabil Data Co Outcom Follow- Statistic | ontrib nes/En up cal ana | rade (R ution dpoints alysis | High quai ange 4-1 Relevent S Comparison myoc (CVA) (CPR) Not S Category Contribution analy Contribution RP in RP | 2) vant Da posite c ardial i (), and) stated gorical sis, or l nuous Stratifie four p | of hospi infarction need fo variable Fisher's variable ed analy respecifi | on, ceret r cardio es were o e exact to es were o rses wer fied sub: | compa est wh compa e perfo sets of | red by cl en appro red by S ormed to patients | hi-squa priate. tudent ¹ | 4 ion are 's t- | G Y 1 Y 1 Y 1 | radi es es es | ng No 2 No 2 No 2 | Ũ |
| | Suitabil Data Co Outcom Follow- | ontrib nes/En up cal ana | rade (R ution dpoints alysis | High quai ange 4-1 Relevent S Comparison myoc (CVA) (CPR) Not S Category Contribution analy Contribution RP in RP | 2) vant Da posite c ardial i (), and) stated gorical sis, or l nuous Stratifie four p | of hospi infarction need fo variable Fisher's variable ed analy respecifi | on, ceret r cardio es were o s exact to es were o rses were | compa est wh compa e perfo sets of | red by cl en appro red by S ormed to patients | hi-squa priate. tudent ¹ | 4 ion are 's t- | G Y 1 Y 1 Y | es es es | ng No 2 No 2 No 2 | Ű |
| | Suitabil Data Co Outcom Follow- Statistic | ontrib nes/En up cal ana | rade (R ution dpoints alysis ficance | High quai ange 4-1 Relevent S Comparison myoc (CVA) (CPR) Not S Category Contribution analy Contribution RP in RP | 2) vant Da posite of ardial i (A), and (A), and (C) stated sis, or l nuous Stratifie four p parison | of hospi infarction need fo variable Fisher's variable ed analy respecifi betwee | on, ceret r cardio es were o es were o ses were o rses wer fied sub: | compa est wh compa e perfo sets of | red by cl en appro red by S ormed to patients | hi-squa priate. tudent ¹ | 4 ion are 's t- | G Y 1 Y 1 Y 1 Y Y | es es es | ng No 2 No 2 No 2 | Ũ |
| | Suitabil Data Co Outcom Follow- Statistic Clinical Data Co | ontrib nes/En up cal ana l signif | rade (R ution dpoints alysis ficance ution G | High qual ange 4-1 ange 4-1 Relevent Composition myocent (CVA (CPR Not S Categent analy Contribute test. S RP in Composition Grade (R | 2) vant Da posite c ardial i (A), and (C) sis, or 1 nuous Stratifie four p parison ange 4 | of hospi infarction need fo variable Fisher's variable ed analy respeciat betwee -8) | on, ceret r cardio es were o e exact to es were o reses were fied sub- n RP an | compa est wh compa e perfo sets of d no-H | red by cl en appro red by S ormed to patients | hi-squa priate. tudent ¹ | 4 ion are 's t- | G Y 1 Y 1 Y 1 Y 1 Y 1 | es es es | ng No 2 No 2 No 2 | Ũ |
| | Suitabil Data Co Outcom Follow- Statistic Clinical Data Co Overall S | ontrib nes/En up cal ana cal ana | rade (R ution dpoints alysis ficance ution G | High qual ange 4-1 ange 4-1 Relevent S Composition myood (CVA (CPR Not S Catege analy Contri test. S RP in Composition Grade (R al, Dispon | 2) vant Da posite c ardial i (A), and (C) stated stated stated stated four p parison ange 4 ssition | of hospi infarction need fo variable Fisher's variable ed analy respecifi betwee -8) and We | on, cerel r cardio es were o s exact to s were o ses were fied sub: n RP an eighting | compa est wh compa est sof d no-H | red by cl en appro red by S prmed to patients | ident uscitati hi-squa priate. tudent' evalua | 4 ion is t- ate | G Y 1 Y 1 Y 1 Y 1 4 | radi es es es es | ng No 2 No 2 No 2 No 2 | Ű |
| | Suitabil Data Co Outcom Follow- Statistic Clinical Data Co Overall S S&P | ontrib nes/En up cal ana cal ana signif | rade (R ution dpoints alysis ficance ution G appraiss LOE (4) | High qual ange 4-1 Relevent S Composition myock (CVA) (CPR) Not S Categent Contribution analy Contribution Composition Composition Grade (R All Disposition all Disposition Disposition | 2) vant Da posite c ardial i (A), and (C) stated stated stated stated four p parison ange 4 ssition | of hospi infarction need fo variable Fisher's variable ed analy respecifi betwee -8) and Wo Dispos | on, cerel r cardio es were o s exact to s were o reses were fied sub n RP an eighting ition an | compa est wh compa e perfo sets of d no-I | red by cl en appro red by S ormed to patients P | hi-squa priate. tudent ¹ evalua | 4 ion is t- ate | G Y 1 Y 1 Y 1 Y 1 4 | radi es es es es | ng No 2 No 2 No 2 No 2 | Ű |
| | Suitabil Data Co Outcom Follow- Statistic Clinical Data Co Overall S | up cal ana ontribu cal signif | rade (R ution dpoints alysis ficance ution G uppraiss LOE (4) Suitabili | High qual ange 4-1 Relevent S Composition myood (CVA (CPR Not S Categent Contribution Categent Contribution Categent Contribution test. S RP in Composition Composition Grade (R Restance) al, Disposition Disposition | 2) vant Da posite of ardial if (A), and (C) stated sis, or I nuous Stratifie four p parison ange 4 sition | of hospi infarction need fo variable Fisher's variable ed analy respecifi betwee -8) and Wo Dispos | on, cerel r cardio es were o s exact to s were o ses were fied sub: n RP an eighting | compa est wh compa e perfo sets of d no-I | red by cl en appro red by S ormed to patients RP | ident uscitati hi-squa priate. tudent' evalua | 4 ion are 's t- ate | G Y 1 Y 1 Y 1 Y 1 Y 1 4 and H | radi es es es es Pivot | ng No 2 No 2 No 2 No 2 | Ű |

| Excluded, 22-25 Objective: Evaluates the immediate results and in-hospital adverse events in patients with severe AS undergoing BAV with and without RP. Method: Patients who underwent BAV with RP (n=64) were compared to those who did not receive RP during BAV (n=47). Procedural outcomes, complications, and in-hospital adverse events were compared between both groups. Relevant Results: Criteria Results P value Aortic valve area 0.87 cm ² in the RP group and 1.02 cm ² in the no RP group. P=0.02 Procedural success There was a strong trend toward fewer successful valvuloplasties in the RP group compared to the no-RP group (67.2% vs. 82.9%) P=0.06 Safety concern: Intraprocedural complications - 1 death in RP group developed tamponade. Cardiopulmonary resuscitation n=10 in both groups. In-Hospital complications included: n=8 acute renal injury n=6 myocardial infarction and n=9 deaths (including the Intraprocedural death). In the RP group, there were 4 deaths; 2 due to progressive heart failure, 1 due to pulmonary | |
|--|---|
| severe AS undergoing BAV with and without RP. Method: Patients who underwent BAV with RP (n=64) were compared to those who did not receive RP during BAV (n=47). Procedural outcomes, complications, and in-hospital adverse events were compared between both groups. Relevant Results: Criteria Results P value Aortic valve area Mean increased from 0.64cm ² pre-procedure to 0.87 cm ² in the RP group and 1.02 cm ² in the no RP group. P=0.02 Procedural success There was a strong trend toward fewer successful valvuloplasties in the RP group compared to the no-RP group (67.2% vs. 82.9%) P=0.06 Safety concern: Criteria Results P value Intraprocedural complications - 1 death in RP group. 2 patients in the no-RP group developed tamponade. Cardiopulmonary resuscitation n=10 in both groups. In-Hospital complications included: n=8 acute renal injury n=6 myocardial infarction and n=9 deaths (including the Intraprocedural death). In the RP group, there were 4 deaths; 2 due to | |
| no RP group. There was a strong trend toward fewer successful valvuloplasties in the RP group compared to the no-RP group (67.2% vs. 82.9%) P=0.06 Safety concern: Criteria Results P value Intraprocedural complications - 1 death in RP group developed tamponade. Cardiopulmonary resuscitation n=10 in both groups. In-Hospital complications included: n=8 acute renal injury n=6 myocardial infarction and n=9 deaths (including the Intraprocedural death). In the RP group, there were 4 deaths; 2 due to | |
| Procedural successThere was a strong trend toward fewer successful valvuloplasties in the RP group compared to the no-RP group (67.2% vs. 82.9%)P=0.06Safety concern:ResultsP valueCriteriaResultsP valueIntraprocedural complications - 1 death in RP group. 2 patients in the no-RP group developed tamponade. Cardiopulmonary resuscitation n=10 in both groups. In-Hospital complications included: n=8 acute renal injury n=6 myocardial infarction and n=9 deaths (including the Intraprocedural death). In the RP group, there were 4 deaths; 2 due to | |
| CriteriaResultsP valueIntraprocedural complications - 1 death in RP group. 2 patients in the no-RP group developed tamponade. Cardiopulmonary resuscitation n=10 in both groups. In-Hospital complications included: n=8 acute renal injury n=6 myocardial infarction and n=9 deaths (including the Intraprocedural death). In the RP group, there were 4 deaths; 2 due to | |
| Intraprocedural complications - 1 death in RP group. 2 patients in the no-RP group developed tamponade. Cardiopulmonary resuscitation n=10 in both groups. In-Hospital complications included: n=8 acute renal injury n=6 myocardial infarction and n=9 deaths (including the Intraprocedural death). In the RP group, there were 4 deaths; 2 due to | |
| Adverse Eventsinfection and 1 from a pulseless electrical activity arrest just prior to discharge. In the no-RP group, there were 4 deaths; 2 due to septic shock not related to BAV and 2 due to progressive heart failure. The in-hospital mortality rate was similar in both groups. Access site complications included: n=5 pseudo aneurysm, n=9 severe bleeding, n=1 arterio- venous fistula and n=12 composite vascular complications.NA | |
| Conclusion: BAV using RP is feasible and safe. It offers greater balloon positioning and | |
| stability during inflation without affecting the incidence of in-hospital adverse events. However, the clinical benefit may be outweighed by a less increase in aortic valve area. Device used: Z-Med balloon | |
| Safety & Performance | Population: |
| AppraisalLevel ofStudyQuestion AppliedOxford LOEEvidenceMethod/Design2011 | Patients undergoing standard |
| Boland et al. 2014Prospective studyTo compare differences in procedure time, fluoroscopy time and dose-area product (DAP) between single-vessel percutaneous coronary intervention (standard PCI) and various SHIs12345 | percutaneous coronary intervention and structural heart interventions |
| Suitability Relevant Data Grading | |
| DeviceNuCLEUS (NuMED, Inc.)D1D2D3 | including BMV and BAV |
| ApplicationBAVA1A2A3PatientPatients undergoing standard percutaneous coronary intervention and structural heartP1P2P3 | including BMV |



| | | | P – Aortic PTV | | | |
|--|--|---|---|--|---|----------------|
| | | | ncluding BMV and BAV procedu | ures | | |
| | | | 85; n=57 for BAV 8 ± 6.6 years for BAV | | | |
| | | - | F for BAV | | | |
| Report | | quality | | R1 | R2 | R3 |
| Suitability Grade | | | | 4 | | |
| Data Contributio | n I | Relevant 1 | Data | | Gra | ding |
| Outcomes/Endpo | | Fluorosco | | | Yes | No |
| outcomes, Enapo | 1 | Procedure DAP | • | | 1 | 2 |
| Follow-up | | Not stated | | | Yes | No 2 |
| Statistical analysi | ie V | Walaamna | red proportions using the χ^2 test | and | 1 Yes | Z No |
| ounstrear analys | | means usin distributed tested usin comparing normal pro conform to | a two sample t-test for normal data. Normality of the variables g a normal probability plot and b a histogram of the sample data obability curve. For data that did a normal distribution, medians using the Wilcoxon Rank Sum to | ly was by with a not were | 1 | 2 |
| | | | ally distributed data. | | | |
| Clinical significat | i s | increased v significant | se times, fluoroscopy times and a with increasing PCI complexity. variability and spread in case times the second | There was ne, | Yes 1 | No 2 |
| Data Contributio | | | y time and DAP for both SHI an | d PCI. | 4 | |
| Grade Suita | E (3) + ability (a Contri = 11 | | Weighting (select) | Accepted a 9-12 Accepted bu Pivotal, 13- Excluded, 2 | it not 21 | otal |
| DAP) between sing tructural heart inter Method: The autho coronary interventic percutaneous translu | gle-vess ervention ors comp ons, 69 uminal e implan | sel percuta ns. pared data patent fora mitral valv | procedure time, fluoroscopy time neous coronary intervention (sta from 91 consecutive single-vess amen ovale closures, 25 atrial sep vuloplasties, 57 balloon aortic va CAVI), 21 left atrial appendage o | ndard PCI) sel percutan ptal defect c ilvuloplastic | and var eous losures es, 53 ti | rious s, 49 |
| Relevant Results: | es. | | | | | |
| Criteria | | R | sults | | P va | alue |
| Fluoroscopy and d product | dose-are | BN 87 BA Gy Me | AV - 14.3, 11.4-24.2 minutes; 37 .0 Gycm ² AV - 8.4, 5.2-13.2 minutes; 19.8, ycm ² edian dose –area product (DAP) in standard PCI for BMV and BA | 10.2-30.0 was less | NA | |
| greater than for core | onary a hould b | heart intengiograph | rventions, dose-area product was y with single-vessel percutaneou ng to patients and staff attending | s not signifi s coronary a | artery | al |

| NUMED | S | umma | • | afety | NuMF and (– Aor | Clini | cal Perfo TV | orman | ce | | | |
|--------------|-----------------------------------|--------------------|----------------------------|----------|------------------------|----------|-----------------|------------------------------|--------------|---------|--------|---------------------------|
| | Safety & Per | formanc | | JCI | 1101 | uc I | 1 1 | | | | | |
| | Appraisal | | _ | | | | | | | | | |
| | Level of Evidence | Study Mothor | J/Dogian | Ques | tion App | olied | | |)xfo 011 | rd LO |)E | |
| | Evidence | 3 Case | l/Design studies | N/A - | - Presenta | ation o | f findings to | | - | 3 | 4 5 | |
| | | | | | | | vent and | - | - | | | |
| | | | | diagn | ose cusp | perfor | ation at each | step | | | | |
| | Suitability | 1 | Relevant 1 | Data | | | | | Tra | ling | | |
| | Device | | Fyshak an | | LEUS | | | | D1 | D2 | D3 | |
| | Application | | BAV | 411401 | | | | | <u>41</u> | A2 | A3 | |
| | Patient | | | | | prior t | o transcathet | ter I | P1 | P2 | P3 | |
| | | | aortic valv | | antation | | | | | | | |
| | | | Sampling: Mean age: | | ars | | | | | | | |
| | | | Sex: 2 M; | | | | | | | | | |
| | Report | | High quali | | | | | | R1 | R2 | R3 | |
| | Suitability | Grade (R | Range 4-12 | 2) | | | | 4 | 1 | | | |
| | Data Contr | ibution | Releva | ant | Grad | ing | 1 | | | | | |
| | 2 0 0 | | Data | | 0144 | 8 | | | | | | |
| | Outcomes/I | Endpoint | | | Yes | No | | | | | | |
| | Follow-up | | perfor Not St | | 1 Yes | 2 No | - | | | | | |
| | ronow-up | | NOL SI | aleu | 1 | 2 | | | | | | Population: |
| | Statistical a | tical analysis N/A | | | Yes No | | | | | | | Patients undergoing |
| | | | | | 1 | 2 | - | | | | | BAV prior to |
| Ussia et al. | Clinical sig | nificance | Not st | ated | Yes | No 2 | | | | | | transcatheter |
| 2011 | Data Contr | ibution (| Grade (Ra | nge 4- | 6 | - | - | | | | | aortic valve implantation |
| | 8) | | | | | | | | | | | |
| | Overall S&P | Annraia | al Dicno | vition o | nd Woid | ahtina | | | | | | Sampling: |
| | | |) + | | | | | Accepted | d and | d Pivo | tal 9- | n=3 |
| | Grade | Suitabil | ity (4) + | V | Weightin | | | 12 | | | | |
| | (Range 9- | | ontributio | n | | | | Accepte | | | | |
| | 25) | (6) = 14 | | | | | | Pivotal , Excluded | | | | |
| | | | | | | | | | <i>4, 22</i> | . 23 | | |
| | Objective: P | | | | | | | | | | | |
| | prevent and d steps to corre | | | | | | | | te ap | propri | ate | |
| | Method: NA | - | biem bero | ie initi | anng me | next s | top in the pro | Jeeuure. | | | | |
| | Relevant Res | | | | | | | | | | | |
| | Cusp perforat | | | | | | | | | | | |
| | catheter was a manipulation | | | | | | | - | | • | | |
| | unusual beha | | | | | r | | | | | | |
| | Safety conce | | · | C | 0 | | | | | - | | |
| | The most con | | - | ot a cu | sp perfor | ration i | s acute sever | re regurgi | tatio | n, and | the | |
| | worst is an in Conclusion: | | | ortic cu | sp during | g attem | pts to cross | a stenotic | aort | ic orif | ice | |
| | should be sus | | | | | | | | | | | |
| | stage of the p | rocedure. | The use of | of TEE | and mult | ti-slice | computed to | omograph | y he | lps in | • | |
| | identification | | | | | | | | | | | |
| | early diagnos suspicion and | | | | | | | | | | | |
| | - aspieron unu | manoet | | K | | | ine proc | | | | J | <u> </u> |



| | | | CP = Aortic PT v | | | | |
|---|---|--|---|---|---------------------|--------------|----------------|
| diagnosis and r | remediatio | on. | | | | | |
| Device used: Z | | /shak | | | | | |
| Safety & Perfe | ormance | | | | | | |
| Appraisal | ~ ~ | | | | | | |
| Level of | Study | | Question Applied | | rd LO | E | |
| Evidence | | d/Design | | 2011 | 1 1 | | |
| | Prospe | ctive | To describe the use of BAV | ' to 1 2 | 3 | 4 5 | |
| | study | | select proper THV size | | | | |
| | | | | | | | |
| Suitability | R | elevant Da | nta | Grad | ling | | |
| Device | Z- | MED (Nu | MED, Inc.) | D1 | D2 | D3 | |
| Application | B | AV | | A1 | A2 | A3 | |
| Patient | Pa | tients und | ergoing implantation of THV fo | or P1 | P2 | P3 | |
| | ao | rtic stenos | is | | | | |
| | Sa | mpling: n= | =27 | | | | |
| | Μ | ean age: 8. | 3 years (range: 66-95) | | | | |
| | Se | x: 13 M; 1 | 4 F | | | | |
| Report | Hi | gh quality | | R1 | R2 | R3 | |
| Suitability G | | | | 4 | | | |
| · · · | ``` | <i>u</i> / | | · | | | |
| Data Contrib | bution | Relevan | nt Data | | Gra | ding | |
| Outcomes/En | | Annulus | | | Yes | No | |
| | | | nsufficiency | | 1 | 2 | Population: |
| Follow-up | | N/A | | | Yes | No | Patients |
| I onow up | | 1.0.11 | | | 1 | 2 | undergoing |
| Statistical an | alvsis | Compar | ison of aortic insufficiency and | annulus size | Yes | No | implantation o |
| Statistical an | u iy 515 | | rformed using a paired t test. Di | | 1 | 2 | THV for aortic |
| | | | nsidered statistically significant | | 1 | 2 | stenosis |
| | | | All values were expressed as n | | | | |
| Clinical signi | ificance | Not Stat | | | Yes | No | Sampling: |
| Chincal sign | mance | Not Stat | eu | | 1 | 2 | n=27 |
| Data Contrib | bution C | ada (Ran | ge (1-8) | | 5 | 2 | |
| Data Contin | | auc (Ran | gc +-0) | | 5 | | M/F: 13/14 |
| Overall S&P | Annraisa | Disnosit | ion and Weighting | | | | Mean age: 83 |
| | LOE (4) | | Disposition and | Accepted and | Divot | al 0 | years |
| | Suitabilit | | Weighting (select) | 12 | 11100 | lai)- | |
| | | tribution | (select) | Accepted bu | t not | | |
| | (5) = 13 | | | Pivotal, 13-2 | | | |
| | $(\mathbf{c}) = \mathbf{i}\mathbf{c}$ | | | Excluded, 22 | | | |
| size. | | | se of BAV to select proper trans | ing of aortic ann | ulus b | y | |
| BAV and trans than the annulu | eosophag 1s measur | | rdiogram (TEE). The minimal ' / was implanted. | | U | | |
| BAV and trans than the annulu Relevant Resu | eosophag 1s measur | ed by BAV | / was implanted. | | - | lue | |
| BAV and trans than the annulu | eosophag 1s measur | ed by BAV | / was implanted. Results | | P va | lue | |
| BAV and trans than the annulu Relevant Resu | eosophag 1s measur | ed by BAV | / was implanted. Results Measured by TEE was 21.3±1.6 | i mm and by | - | lue | |
| BAV and trans than the annulu Relevant Resu Criteria | eosophag 1s measur 1lts: | ed by BAV | / was implanted. Results Measured by TEE was 21.3±1.6 3AV was 22.6±1.8 mm. Annulu | 5 mm and by 15 | P va | | |
| BAV and trans than the annulu Relevant Resu | eosophag 1s measur 1lts: | ed by BAV | / was implanted. Results Measured by TEE was 21.3±1.6 BAV was 22.6±1.8 mm. Annulu neasurement by BAV was most | 5 mm and by 15 t helpful in | - | | |
| BAV and trans than the annulu Relevant Resu Criteria | eosophag 1s measur 1lts: | ed by BAV | / was implanted. Results Measured by TEE was 21.3±1.6 BAV was 22.6±1.8 mm. Annulu neasurement by BAV was most electing THV's in 7 patients (2 | 5 mm and by 15 t helpful in | P va | | |
| BAV and trans than the annulu Relevant Resu Criteria | eosophag us measur ilts: surement | ed by BAV | / was implanted. Results Measured by TEE was 21.3±1.6 BAV was 22.6±1.8 mm. Annulu neasurement by BAV was most | 5 mm and by 15 t helpful in | P va | | |
| BAV and trans than the annulu Relevant Resu Criteria Annulus meas Safety concern | eosophag us measur ilts: surement | ed by BAV | / was implanted. Results Measured by TEE was 21.3±1.6 BAV was 22.6±1.8 mm. Annulu neasurement by BAV was most electing THV's in 7 patients (2 nnulus considered borderline. | 5 mm and by 15 t helpful in | P va P<0. | .001 | |
| BAV and trans than the annulu Relevant Resu Criteria | eosophag us measur ilts: surement | ed by BAV | / was implanted. Results Measured by TEE was 21.3±1.6 BAV was 22.6±1.8 mm. Annulu neasurement by BAV was most electing THV's in 7 patients (2 nnulus considered borderline. esults | 5 mm and by 15 t helpful in 6%) with TEE | P va P<0. | | |
| BAV and trans than the annulu Relevant Resu Criteria Annulus meas Safety concern | eosophag us measur ilts: surement n: | ed by BAV F N E n s a 2 R N | / was implanted. Results Measured by TEE was 21.3±1.6 BAV was 22.6±1.8 mm. Annulu neasurement by BAV was most electing THV's in 7 patients (2 nnulus considered borderline. | 5 mm and by 15 t helpful in 6%) with TEE occlusion, | P va P<0. | .001 alue | |

| NuMED | S | ummar | · | | NuMED ty and Clinical Perf P – Aortic PTV | forma | ance | | | | |
|--------------------|---|--|---|-----------------------------------|--|--------------------------------------|---|--|-------------------|----|----------------------------------|
| | when selectir resulted in no improve the s oversizing (a coronary occ occurred usin Device used: | ng THV siz adverse e safety and e nnular disr lusion) or u ng this meth Z-Med ba | e. Implar vents. Th efficacy c uption, va under sizi nod. lloon | nting lese d of TH agall | e annulus is safe and is an im the minimal THV greater that lata suggest that the use of B IV implantation. No adverse y mediated hypotension seco THV embolization or PVL gr | an the H AV for consecondary t | BAV and THV se quences o annula | nulus a electio of TH ar stre | size n m IV | ay | |
| | Safety & Per | rformance | | | | | | | | | |
| | Appraisal Level of | Study | | Ou | estion Applied | | Oxfo | rd LC |)E | | |
| | Evidence | Method | /Design | 24 | estion applied | | 2011 | 14 20 | | | |
| | | Case rep | | per | A – Describes rare complicat cutaneous aortic valvuloplas loon rupture | | 1 2 | 3 | 4 | 5 | |
| | Suitability | D | elevant I | Data | | | Grad | dina | | | |
| | Device | | | | NuMED Canada) | | D1 | D2 | D | 3 | |
| | Application | | AV | , 11 (1 | | | A1 | A2 | A | | |
| | Patient | sy st Sa M | Patient undergoing palliative BAV for symptomatic heavily calcified severe aortic valve stenosisP1P2P3Sampling: n=1 Mean age: 86 years Sex: 1 FP3P4P4P4 | | | | | | 3 | | |
| | Report | | High quality R1 | | | | | | R | 3 | |
| | Suitability | | | | | | 4 | | | | Population: |
| | | | | | | | | 1 | | | Patient |
| | Data Contr Outcomes/ | | Releva | | | Grad | ling No | | | | undergoing palliative BAV |
| | Outcomes/1 | Enapoints | ts Balloon Rupture Yes 1 | | | | | | | | for symptomati |
| ozor et al. 014 | Follow-up | up Not S | | | Not Stated Yes 1 | | | | | | heavily calcifi severe aortic |
| | Statistical a | | N/A | | | Yes 1 | No 2 | | | | valve stenosis |
| | Clinical sig | nificance | Teh pa no seq | | made a full recovery will | Yes 1 | No 2 | | | | Sampling: 86 year old |
| | Data Contr | ibution G | | | | 5 | | | | | female |
| | | | | 0 | | | | | | | |
| | Overall S&P S&P Grade | <u>Appraisa</u> LOE (4) Suitabilit | + | sition | and Weighting Disposition and Weighting (select) | Acce | pted and | d Pivo | tal 9 | 9- | |
| | (Range 9- 25) | Data Con (5) = 13 | | n | | Pivot | pted bu t al, 13-2 ided, 22 | 21 | | | |
| | | subsequent | | | cation of percutaneous aortic pubble embolism and hemody | | | | n | | |
| | Criteria | | | Res | | | | P v | alu | e | |
| | Peak aortic | pressure gi | adient | impi | r use of second balloon dilat | | | NA | | | |
| | Mean pressure gradient After use of second balloon dilatation, improved to 29 mmHg | | | | | | | | | | |

| NUMED | S | umma | • | NuMED Sety and Clinical Performance CP – Aortic PTV | | |
|----------------------|------------------------------------|----------------------------|---|---|---------------|--------------|
| | Criteria | | | sults P value | | |
| | Adverse Ev | | Up bal rele nev ele her dys infu mid my sec per bal hea and mid em wit | on first balloon inflation, there was sudden loon rupture. This was associated with the ease of mass micro-bubbles into the left heart, w onset left bundle branch block on surface ctrocardiogram, and subsequent nodynamic collapse. There was severe LV sfunction with marked hypokinesis of the LV erior wall, septum and posterior walls, with cro-bubbles seen throughout these regions of rocardium. Once the patient was stabilised a cond dilatation with a new balloon was formed without complication. Cause of loon rupture has been thought to be caused by avy valve calcification tearing the balloon, d the hemodynamic collapse was as a result of cro-bubbles causing coronary air bolization and acute myocardial ischemia th subsequent severe LV dysfunction. | | |
| | preparation a Device used : | nd techni Nucleus | que balloon r -X | cautionary reminder that despite routine standard rupture during BAV can still occur. | | |
| | Safety & Perf | formance | 2 | | | |
| | Appraisal Level of Evidence | Study Method Retrosp | l/Design bective | Question AppliedOxfo2011Comparison of the acute efficacy and safety of1 | | 2 4 5 |
| | | cohort s | study | anterograde versus retrograde catheter approaches in the management of neonates with aortic stenosis | | |
| | Suitability | Relevan | nt Data | Grading | | |
| | Device | Sterling | (NuMED, In & Talon | ac.), Symmetry (Boston Scientific), D1 D2 D3 | | |
| Mozumdar | Application Patient | Samplir Mean ag | ng: n=42 [n= ge: 4 days (ra | A1A2A3days) with valvar aortic stenosisP1P2P313 (42%) Tyshak]ange 1-29 days)P3P3 | | |
| <i>et al.</i> (2018) | Report | Sex: 32 High qu | M; 10 F | R1 R2 R3 | | |
| (2018) | Report | ingn qu | lanty | Suitability Grade (Range 4-12) 4 | | |
| | | | D1 (D | | | 1. |
| | Data Contrib Outcomes/En | | Relevant D Procedural | time and change in gradient | Yes | ding No |
| | Follow-up | | Long-term | (not stated) | 1 Yes 1 | 2 No 2 |
| | Statistical an | | ± standard d with range total for cat approaches square, or F at a two-tai using STAT | escriptive statistics were used to summarize the data using mean deviation for normally distributed continuous variables, median for skewed continuous variables, and count with percentage of tegorical variables. Assessment of differences between the two was evaluated using either t test, Wilcoxon rank-sum, Chi- Fisher's exact test, as appropriate. Statistical significance was set led alpha less than 0.05. All statistical analyses were performed $\Gamma A v10$ (Stata Corp., College Station, TX). | Yes 1 | No 2 |
| | Clinical sign | ificance | Not stated | | Yes 1 | No 2 |



| Data Contribution Grade | (Range 4-8) |
|-------------------------|-------------|
|-------------------------|-------------|

| | | 000 | J – A | ior the | <u> </u> | Data (| Contribu | ution Gr | ade (R | ange 4. | -8) | 5 |
|---|---|---|--|---|--|--|---|---|---|--|---|--|
| | | | | | | Data | Control | | | unge 4 | 0) | 5 |
| Overall S& | P Apprais | sal, Disposition | 1 and W | eighting | g | | | | | | | |
| S&P Grade (Range 9- | LOE (4) (4) + Data Co |) + Suitability | | sition an | d Weight | ting | Accepte Accepte Pivotal | ed but 1 , 13-21 | not | 9-12 | | |
| 25) | (5) = 13 | | | | | | Exclude | ed, 22-2 | .5 | | | |
| Relevant S& Safety data | | s mplications du | | | | | 1 : | | | : | | |
| Safety data | gro of v ver occ app arte (18 | oup with suprav ventricular fibr ntricular fibrilla curred as the ca propriately defi ery thromboses 3%) in the anter charge. | ventricula illation. ation dur atheters v brillated s develop | ar tachy The pati- ring initi- were bein with respect in 19 | cardia, an ient in the al attemp ng pulled solution. 9 patients | nd one e anter ot to cro l from There s (61%) | in the ar ograde g oss the a the left v were no) in the r | nterogra group ex trial sep ventricle procedu etrograc | de gro sperien otum, a e. The ural m de grou | bup with aced an and the patient ortalitie up and 2 | n two episoo secon was es. Fei 2 patie | episode de of d episo moral ents |
| Performano data | ce The | e anterograde a d there was no o | | | | | equally | efficacio | ous in | gradier | ıt redu | iction, |
| Benefits/cla data | aims Borno no pos | Both anterograde and retrograde approaches to neonatal BAV have equal acute efficacy with no observed difference in post-intervention AI and MR. The anterograde approach, when possible, avoids the use of a larger catheter in the femoral artery, which may reduce the risk of arterial thrombosis. | | | | | | | | | | |
| Strengths | | one Stated | | | | | | | | | | |
| Weaknesse Potential b | ias pre mit fac | This study was limited by its retrospective design and small sample size. The sample size precluded the ability to adjust for cofounding factors. However, this potential limitation is mitigated by the lack of significant differences between the two treatment groups on baseline factors. Some data were not available, notably complete assessment of post-intervention mitral regurgitation. | | | | | | | | | | |
| State of the Appraisal Medical co | | Altomativas | Risk/be | mafit | Side-eff | - anto | Equiva | lance | Current | | u du ci | nto |
| | | Alternatives Yes 1 No 2 | Yes 1 | No 2 | | No 2 | Yes 1 | No 2 | Yes | ogate e | No 2 | |
| 1031 | 110 2 | 102 | 1051 | 110 2 | 1031 | 110 2 | 1031 | 110 2 | 105 | 1 | 110 2 | |
| Overall SO | A Apprais | sal and Disposi | ition | | | | | | | | | |
| SOA Grade | | 8 | | | Dispo | osition | (select) | | | | pted, | |
| (Range 6-1 | 2) | | | | | | | | | Exclu | ided, 1 | 12 |
| Relevant SC | A Pocult | re. | | | | | | | | | | |
| SOA data Comments | | In many cent aortic stenosi to surgical va show that BA may include None | is. Since alvotomy AV may | its intro y in redu confer a | duction induction induction in the second se | in 1984 severit isk of r | , BAV h y of valv e-interv | nas becc var aorti ention, l | ome an ic sten but bei | n effecti osis. Re | ive alte | ernativ studies |
| Safety & Pe | rformanc | <u>:e</u> | | | | | | | | | | |
| Appraisal | | | | | | | | | | | | |
| Level of Evidence | | y Method/Desig | | - | on Appli | | | | | 20 | xford)11 | |
| | | ospective review cal records | <i>v</i> of | | ermine th y after B n | | | | | 1 | 2 | 3 4 |
| 1 | | | | | | | | | | | | |
| Cultar 1:11 | | Dalayant Dat | | | | | | | | | C | dir - |
| Suitability Device | | Relevant Dat Tyshak | ta | | | | | | | D | | ading D2 [] |



| | —— | | | 1 | | | |
|--|--|--|---|---|--|---|---|
| Application | | BAV | | | A1 | A2 | A |
| Patient | | Patients with severe | e aortic stenosis | | P1 | P2 | P3 |
| | | Sampling: n=20 | | | | | |
| | | Mean age: 79 ± 12 y Sex: 11 M; 9 F | years | | | | |
| Papart | | High quality | | | R1 | R2 | R |
| Report | | nigii quality | Suitability Grade (| Range $(1-12)$ | NI | 4 | K. |
| | | | Suitability Grade (| $\operatorname{Kallge} + 12)$ | | | |
| Data Contribu | ution | Relevant Data | | | | Gra | din |
| Outcomes/En | | Transaortic gradien | its and AVAs | | | Yes | N |
| | 1 | C C | | | | 1 | 2 |
| Follow-up | | 7.3 ± 6.7 months | | | | Yes | N |
| | | | | | | 1 | 2 |
| Statistical ana | alysis | | ed as mean \pm standard deviation. Cate | | les | Yes | N |
| | | | ng Fisher's exact test. Continuous va | | n | 1 | 2 |
| | | | ired or unpaired Student's t-test, as ap | opropriate. SPS | 22 | | |
| Clinical signi | ficance | | e was used for statistical analyses was defined as a decrease in invasive | ly measured | | Yes | N |
| Chinear signi | manee | transaortic gradient | | Ty measured | | 1 | 2 |
| | | gruatent | Data Contribution | Grade (Range | 4-8) | - | 1 |
| | | | | 、 <u>o</u> - | , | • | |
| | | al, Disposition and V | | | | | |
| S&P Grade | LOE (| (4) + Suitability (4) | Disposition and Weighting | Accepted an | | | |
| (Range 9- | | | (select) | Accepted but | t not F | rvotal, | 13 |
| 25) | | Contribution (4) = | | 21 Englanded 22 | 0.05 | | |
| Relevant S&P | 12 P Results | | | Excluded, 22 | 2-23 | | |
| Safety data | | | tal death that occurred in an 88-year- | old natient on a | nost_n | rocedu | re |
| Survey dutu | | | been fed via a percutaneous gastrosto | | | | |
| | | | aspiration. There were no major vaso | | | | |
| | | | on fell from 11.4 ± 1.6 pre-procedure | | | | |
| | 0.0 | 022). One patient, wit | h a baseline hemoglobin concentration | on of 9.9 g/dL, | was s | emi- | |
| | | 2 | o units of red blood cells after BAV; | | | 0 | 5 |
| | | | ly the hemoglobin remained stable at | $11 4 \mathrm{g/dI}$ On | a nati | ent | |
| | 1.1 | | | | | | |
| | | | art block during the BAV necessitatin | g placement of | f a pei | rmanen | |
| | pao | cemaker at day 3. In o | one patient the balloon ruptured and | g placement of pon removal of | f a per of the | rmanen cathete | er, |
| | pac the | cemaker at day 3. In or balloon portion was | one patient the balloon ruptured and the sheared off. This was successfully re- | g placement of upon removal of moved with a | f a per of the snare | rmanen cathete device | er, an |
| | pao the no | cemaker at day 3. In o balloon portion was clinical sequelae. Th | one patient the balloon ruptured and the sheared off. This was successfully receive and severity of AR was not significant. | g placement of upon removal of moved with a ficantly different | f a per of the snare nt bef | rmanen cathete device ore and | er, an l |
| | pao the no afte | cemaker at day 3. In c_{e} balloon portion was clinical sequelae. Th er BAV (P = 0.72). C | one patient the balloon ruptured and sheared off. This was successfully re e mean severity of AR was not signif One patient had increase in AR severi | g placement of upon removal of emoved with a ficantly differe ty from 2+ to 2 | f a per of the snare nt bef 2-3+, t | rmanen cathete device ore and but had | er, an l |
| Performance | pao the no afte clin | cemaker at day 3. In c_{e} balloon portion was clinical sequelae. Th er BAV (P = 0.72). C nical sequelae from the | one patient the balloon ruptured and sheared off. This was successfully re e mean severity of AR was not signif One patient had increase in AR severi his. None of the patients developed se | g placement of upon removal of emoved with a ficantly differe ty from 2+ to 2 evere AR after | f a per of the snare nt bef 2-3+, t BAV | rmanen cathete device ore and but had | er, an l |
| Performance data | pao the no aft clin Th | cemaker at day 3. In cemaker at day 2. In cemaker at day 2. In cemaker at the sequelae. The sequelae from the mean gradient, mean gradient | one patient the balloon ruptured and sheared off. This was successfully re e mean severity of AR was not signif One patient had increase in AR severi | g placement of upon removal of emoved with a ficantly differe ty from 2+ to 2 evere AR after diography, dec | f a per of the snare nt bef 2-3+, t BAV crease | rmanen cathete device ore and but had d | er, and l no |
| | pao the no aft clin Th sig | cemaker at day 3. In cemaker at day 2. In cemaker at the sequelae. The er BAV (P = 0.72). Concern a sequelae from the mean gradient, mean gradient, mean gradiently (15 ± 9 and constantly (15 ± 9 and cons | one patient the balloon ruptured and a sheared off. This was successfully re e mean severity of AR was not signif One patient had increase in AR severi his. None of the patients developed se asured by catheterization and echocar | g placement of upon removal of emoved with a ficantly differently from 2+ to 2 evere AR after diography, dec 0.001), with a c | f a per of the snare nt bef 2-3+, t <u>BAV</u> crease corresp | rmanen cathete device ore and but had d ponding | er, an l no |
| | pad the no afte clin Th sig sig < 0 | cemaker at day 3. In c_{e} balloon portion was clinical sequelae. There BAV (P = 0.72). Conical sequelae from the mean gradient, mean gradient, mean gradient, mean gradient (15 ± 9 and gradificant increase in the theorem of the construction of the theorem of theorem of the theorem of theorem of theorem of the theorem | one patient the balloon ruptured and the sheared off. This was successfully respectively of AR was not signified on the patient had increase in AR severithes. None of the patients developed substant d 21 \pm 14 mm Hg, respectively; P < 0 the calculated AVA (0.26 \pm 0.17 and 0 the calculated AVA (0.26 \pm 0 the calculated AVA | g placement of upon removal of emoved with a ficantly different ty from $2+$ to 2 evere AR after diography, dec 0.001), with a c 0.23 \pm 0.14 cm | f a per of the snare nt bef 2-3+, t <u>BAV</u> crease corresp | rmanen cathete device ore and but had d ponding | er, an l no |
| data | pad the no aft clin Th sig sig < 0 Aft | cemaker at day 3. In c_{e} balloon portion was clinical sequelae. There BAV (P = 0.72). Conical sequelae from the mean gradient, mean gradient, mean gradient increase in the conficant increase in the conficant increase in the conficant sequence is t | one patient the balloon ruptured and the sheared off. This was successfully respectively of AR was not signified on patient had increase in AR severithis. None of the patients developed substantiation and echocard 21 \pm 14 mm Hg, respectively; P < 0 the calculated AVA (0.26 \pm 0.17 and 0 the calculated form 3.5 \pm 0.7 to 2.7 \pm 0 | g placement of pon removal of moved with a ficantly differe ty from 2+ to 2 evere AR after diography, dec 0.001), with a c 0.23 ± 0.14 cm 8 (P < 0.001). | f a per of the snare nt bef 2-3+, t <u>BAV</u> crease corresp ² , resp | rmanen cathete device ore and but had d ponding pective | er, and l no g ly; |
| data Benefits/clair | pac the no aft clin Th sig sig < 0 Aft ns Th | cemaker at day 3. In cemaker at day 2. In cemaker at day 2. Cemaker at the end of the end o | one patient the balloon ruptured and p sheared off. This was successfully re- e mean severity of AR was not signif one patient had increase in AR severi- his. None of the patients developed se- asured by catheterization and echocar d 21 ± 14 mm Hg, respectively; P < 0 he calculated AVA (0.26 ± 0.17 and 0 (A class fell from 3.5 ± 0.7 to 2.7 ± 0 valvuloplasty balloon for retrograde | ig placement of pon removal of emoved with a ficantly differently from 2+ to 2 evere AR after diography, dec 0.001), with a c 0.23 ± 0.14 cm $\frac{8}{100} (P < 0.001)$. BAV is technic | f a per of the snare nt bef 2-3+, t BAV crease corresp 2 , resp cally f | rmanen cathete device ore and but had d ponding poetive | er, an l no g ly; an |
| data | pac the no aft clin Th sig sig < 0 Aff ns Th ach | cemaker at day 3. In cemaker at day 5. In cemaker | one patient the balloon ruptured and p sheared off. This was successfully re- e mean severity of AR was not signif one patient had increase in AR severi- his. None of the patients developed se- asured by catheterization and echocar d 21 ± 14 mm Hg, respectively; P < 0 he calculated AVA (0.26 ± 0.17 and 0 A class fell from 3.5 ± 0.7 to 2.7 ± 0 valvuloplasty balloon for retrograde nodynamic and symptomatic results | ig placement of pon removal of proved with a ficantly different ty from 2+ to 2 evere AR after diography, dec 0.001), with a c 0.23 \pm 0.14 cm $\frac{.8}{.0000} (P < 0.001)$. BAV is technic with a low rate | f a per of the snare nt bef 2-3+, t BAV crease corresp ² , resp cally f of ac | rmanen cathete device ore and but had d ponding poective ceasible cess sit | er, an l nc ly; an e |
| data Benefits/clair | pac the no aft clin Th sig sig < 0 Af ms Th ach con | cemaker at day 3. In cemaker at the sequelae. The end of the | one patient the balloon ruptured and the sheared off. This was successfully respectively of AR was not signified one patient had increase in AR severithis. None of the patients developed substantiation and echocard d 21 ± 14 mm Hg, respectively; P < 0 the calculated AVA (0.26 ± 0.17 and 0) and valvuloplasty balloon for retrograde 2 modynamic and symptomatic results while the calculated be considered for patients and the calculated balloon for retrograde 2 modynamic and symptomatic results while the calculated be considered for patients and the calculated be calculated for patients and the calculated be calculated by the calculated by the calculated be calculated by the cal | in g placement of apon removal of semoved with a ficantly differently from 2+ to 2 evere AR after diography, dec 0.001), with a c 0.23 \pm 0.14 cm 8 (P < 0.001). BAV is technic with a low rate ents with severe | f a period of the snare nt bef 2-3+, t BAV crease corresp ² , resp cally f of acte e AS v | rmanen cathete device ore and but had d ponding pective cess sit who are | er, an l nc g ly; an e e nc |
| data Benefits/clair | pac the no aft clin Th sig sig < 0 Af ns Th ach con can | cemaker at day 3. In cemaker at the sequelae from the end of the mean gradient, mean gradient, mean gradient, mean gradient, mean gradient increase in the the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the sequelae from the day 3. In cemaker at the day 3. In cemaker a | one patient the balloon ruptured and a sheared off. This was successfully re- e mean severity of AR was not signif One patient had increase in AR severi- his. None of the patients developed se- asured by catheterization and echocar d 21 \pm 14 mm Hg, respectively; P < 0 he calculated AVA (0.26 \pm 0.17 and 0 (A class fell from 3.5 \pm 0.7 to 2.7 \pm 0 valvuloplasty balloon for retrograde 2 hodynamic and symptomatic results hnique should be considered for patie al surgical AVR, do not yet have access | in g placement of apon removal of semoved with a ficantly differently from 2+ to 2 evere AR after diography, dec 0.001), with a c 0.23 \pm 0.14 cm 8 (P < 0.001). BAV is technic with a low rate ents with severe | f a period of the snare nt bef 2-3+, t BAV crease corresp ² , resp cally f of acte e AS v | rmanen cathete device ore and but had d ponding pective cess sit who are | er, an l nc g ly; an e e nc |
| data Benefits/clair data | pac the no aft clin Th sig sig < 0 Aff ns Th ach con can pro | cemaker at day 3. In of e balloon portion was clinical sequelae. The er BAV (P = 0.72). Conical sequelae from the mean gradient, mean gradiently (15 ± 9 and gradient increase in the 0.001). The BAV, mean NYH we use of a compliant whieves acceptable here mplications. This tech andidates for traditional pocedure to reduce the | one patient the balloon ruptured and the sheared off. This was successfully respectively of AR was not signified one patient had increase in AR severithis. None of the patients developed substantiation and echocard d 21 ± 14 mm Hg, respectively; P < 0 the calculated AVA (0.26 ± 0.17 and 0) and valvuloplasty balloon for retrograde 2 modynamic and symptomatic results while the calculated be considered for patients and the calculated balloon for retrograde 2 modynamic and symptomatic results while the calculated be considered for patients and the calculated be calculated for patients and the calculated be calculated by the calculated by the calculated be calculated by the cal | in g placement of apon removal of semoved with a ficantly differently from 2+ to 2 evere AR after diography, dec 0.001), with a c 0.23 \pm 0.14 cm 8 (P < 0.001). BAV is technic with a low rate ents with severe | f a period of the snare nt bef 2-3+, t BAV crease corresp ² , resp cally f of acte e AS v | rmanen cathete device ore and but had d ponding pective cess sit who are | er, and no gly; an e |
| data Benefits/clair data Strengths | pac the no aft clin Th sig sig < 0 Aff ns Th ach con can pro | cemaker at day 3. In of e balloon portion was clinical sequelae. The er BAV (P = 0.72). Conical sequelae from the mean gradient, mean gradiently (15 ± 9 and gradient increase in the 0.001). The BAV, mean NYH we use of a compliant which is acceptable here mplications. This tech indidates for traditional pocedure to reduce the pone Stated | one patient the balloon ruptured and a sheared off. This was successfully re- e mean severity of AR was not signif One patient had increase in AR severi- his. None of the patients developed s- asured by catheterization and echocar d 21 \pm 14 mm Hg, respectively; P < C he calculated AVA (0.26 \pm 0.17 and C (A class fell from 3.5 \pm 0.7 to 2.7 \pm 0 valvuloplasty balloon for retrograde nodynamic and symptomatic results hnique should be considered for patie al surgical AVR, do not yet have accor risk of noncardiac surgery. | in g placement of apon removal of amoved with a ficantly differently from 2+ to 2 evere AR after diography, dec 0.001), with a c 0.23 \pm 0.14 cm $\frac{8}{2}$ (P < 0.001). BAV is technic with a low rate events with severe exists to TAVR of | f a performance of the snare of | rmanen cathete device ore and but had d ponding pective easible cess sit who are bridgin | er, an no gly; an e e e no |
| data Benefits/clair data Strengths Weaknesses/ | pac the no aft clin Th sig sig < 0 Aff ns Th ach con can pro No Th | cemaker at day 3. In of e balloon portion was clinical sequelae. The er BAV (P = 0.72). Conical sequelae from the mean gradient, mean gradiently (15 ± 9 and gradiently (15 ± 9 and gradient increase in the 0.001). The BAV, mean NYH we use of a compliant complications. This tech indidates for traditional poedure to reduce the point Stated are retrospective nature | one patient the balloon ruptured and a sheared off. This was successfully re- e mean severity of AR was not signif one patient had increase in AR severi- his. None of the patients developed s- sured by catheterization and echocar d 21 \pm 14 mm Hg, respectively; P < 0 he calculated AVA (0.26 \pm 0.17 and 0 (A class fell from 3.5 \pm 0.7 to 2.7 \pm 0 valvuloplasty balloon for retrograde nodynamic and symptomatic results hnique should be considered for patie al surgical AVR, do not yet have accor risk of noncardiac surgery. | g placement of pon removal of moved with a ficantly differe ty from 2+ to 2 evere AR after diography, dec 0.001), with a c 0.23 ± 0.14 cm $\frac{8}{P} < 0.001$). BAV is technic with a low rate ents with severe exists to TAVR of p mean that we | f a performance of the snare of | rmanen cathete device ore and but had d ponding pective easible cess sit who are bridgin | er, and no gly; and e no g |
| data Benefits/clair data Strengths | pac the no aftr clin Th sig sig < 0 Aff ns Th ach con car pro No s dir | cemaker at day 3. In of balloon portion was clinical sequelae. The er BAV (P = 0.72). Conical sequelae from the mean gradient, mean gradient, mean gradient increase in the 0.001). the BAV, mean NYH we use of a compliant complications. This technolicates for traditional pocedure to reduce the mention of the stated mention of the state of the stat | one patient the balloon ruptured and the sheared off. This was successfully respectively of AR was not signified by each off. This was successfully respectively of AR was not signified by each off. And the several has not several the patient had increase in AR several his. None of the patients developed seasured by catheterization and echocard d 21 ± 14 mm Hg, respectively; P < 0 the calculated AVA (0.26 ± 0.17 and 0 the calculated AVA (0.26 ± 0.17 to 2.7 ± 0 to valvuloplasty balloon for retrograde and surgical AVR, do not yet have account of the calculated AVA (0.26 ± 0.17 to 2.7 ± 0 to valvuloplasty balloon for retrograde and surgical AVR, do not yet have account of the calculated AVA (0.26 ± 0.17 to 2.7 ± 0 to valvuloplasty balloon for retrograde and surgical AVR, do not yet have account to the calculated as the lack of a control grout traditional BAV using compliant balloon to the calculated to the table of the calculated balloon to the calculated | g placement of pon removal of moved with a ficantly different ty from 2+ to 2 evere AR after diography, dec 0.001), with a c 0.023 \pm 0.14 cm $\frac{.8 (P < 0.001)}{.}$ BAV is technic with a low rate ents with severe exists to TAVR of p mean that we oons. Howeve | f a performance of the snare of | rmanen cathete device ore and but had d ponding poective feasible cess sit who are bridgin d make cohort | er, and no gly; and e no g |
| data Benefits/clair data Strengths Weaknesses/ | pac the no aftr clin Th sig sig < 0 Af ns Th ach con car pro No sig sig sig sig sig sig sig sig sig sig | cemaker at day 3. In of e balloon portion was clinical sequelae. The er BAV (P = 0.72). Conical sequelae from the mean gradient, mean gradient, mean gradient, mean gradient increase in the 0.001). the BAV, mean NYH we use of a compliant chieves acceptable here mplications. This technolicates for traditional potentiations. This technolicates for traditional potentiates for traditional potent | one patient the balloon ruptured and the sheared off. This was successfully respectively of AR was not signified one patient had increase in AR severithis. None of the patients developed substrated by catheterization and echocard d 21 \pm 14 mm Hg, respectively; P < 0 the calculated AVA (0.26 \pm 0.17 and 0 the calculated AVA (0.26 \pm 0.17 to 2.7 \pm 0 valvuloplasty balloon for retrograde 2 modynamic and symptomatic results while the should be considered for patienal surgical AVR, do not yet have account of a control grout traditional BAV using compliant ballon drisk profiles to other recent series. | g placement of pon removal of smoved with a ficantly different ty from 2+ to 2 evere AR after diography, dec 0.001), with a c 0.23 \pm 0.14 cm $\frac{.8}{.0000} (P < 0.001)$. BAV is technic with a low rate exists with severations to TAVR of p mean that we oons. Howeve Lack of routin | f a performance of the snare nt beff 2-3+, t BAV crease corresp 2, resp cally f of acte e AS v r as a e could r, our e late | rmanen cathete device ore and but had d ponding poective cess sit who are bridgin d make cohort | er, and no gly; and e no g |
| data Benefits/clair data Strengths Weaknesses/ | pac the no aft clin Th sig sig < 0 Af ns Th ach con can pro No S Th sig sig sig sig sig sig sig sig sig sig | cemaker at day 3. In of e balloon portion was clinical sequelae. The er BAV (P = 0.72). Conical sequelae from the er BAV (P = 0.72). Conical sequelae from the mean gradient, mean gradient, mean gradient, mean gradient, mean gradient increase in the bloch of a compliant of hieves acceptable here manifications. This tech indicates for traditional occure to reduce the point of the stated are retrospective nature for the stated of the states of the milar comorbidities are hocardiographic follo | one patient the balloon ruptured and a sheared off. This was successfully re- e mean severity of AR was not signif one patient had increase in AR severi- his. None of the patients developed se- asured by catheterization and echocar d 21 ± 14 mm Hg, respectively; P < 0 he calculated AVA (0.26 ± 0.17 and 0 (A class fell from 3.5 ± 0.7 to 2.7 ± 0) valvuloplasty balloon for retrograde nodynamic and symptomatic results hnique should be considered for patie al surgical AVR, do not yet have acce- risk of noncardiac surgery. | g placement of pon removal of smoved with a ficantly different ty from 2+ to 2 evere AR after diography, dec 0.001), with a c 0.23 \pm 0.14 cm $\frac{.8}{.0000} (P < 0.001)$. BAV is technic with a low rate exists with severations to TAVR of p mean that we oons. Howeve Lack of routin | f a period snare nt bef 2-3+, t BAV crease corresp 2, resp cally f of acte e AS v r as a e could r, our e late | rmanen cathete device ore and but had d ponding poective cess sit who are bridgin d make cohort | er, an l no gly; an e e no g |



| Safety & Perl | formance | 2 | | | | | |
|-----------------------------------|---|---|--|---|--|---|------------------|
| Appraisal Level of Evidence | Study | Method/Design | Question Applied | | Oxfor 2011 | rd LOE | E |
| | | pective review of l and procedural notes | To report experience with BAV indications, procedural success outcomes | | 1 2 | 3 | 4 : |
| Suitability | | Relevant Data | | | | Gradin | ~ |
| Device | | | ED, Inc.) or Cristal (Balt) | | D1 | D2 | D3 |
| Application | | BAV | (Dait) | | A1 | A2 | A3 |
| Patient | | Adult patients with se | - | =20 (36.4%) | P1 | P2 | P3 |
| Depart | | | | | D1 | D2 | R3 |
| Report | | High quality | Suitability Grade | (D_{a}) | R1 | R2 4 | K3 |
| | | | Suitability Grade | (Range 4-12) | | 4 | |
| Data Contrib | ution | Relevant Data | | | | Gra | ding |
| Outcomes/En | | Procedural success | | | | Yes 1 | N 2 |
| Follow-up | | 30 days | | | | Yes 1 | 2 N 2 |
| Statistical an | alysis | Results were reported variables; and counts After confirming nor | rmed using SPSS (V.22 SPSS, Chie d as mean (Standard deviation) for c (percentages) were reported for ca n-Gaussian distribution, paired sam echocardiographic and haemodyna V. | continuous ategorical varia ple Wilcoxon | ables. | Yes 1 | No 2 |
| Clinical sign | ificance | Procedural success w | vas defined by at least one balloon | inflation with a | a | Yes | No |
| | | | in the invasively measured gradient | | rtic | 1 | 2 |
| | | valve without occurre | ence of a major intraprocedural con | • | | | |
| | | | Data Contribution | n Grade (Rang | e 4-8) | | 4 |
| | | al, Disposition and W | | | | | |
| S&P Grade (Range 9- 25) | + | | Disposition and Weighting (select) | Accepted an Accepted bu 21 Excluded, 2 | it not F | | |
| Relevant S&I | | I | | , | | | |
| Safety data | Th arr two ma (10 uni tan | ree patients (5.5%) req est and complete AV d o cases (3.9%) with sud ijor vascular access site).9%) had minor vascu its) during the hospital nponade or developed | uired permanent pacemaker for con- lissociation). Periprocedural ventric ccessful resuscitation to discharge is e or access-related complications of lar complications of groin haemato admission. No patients had a strok new severe AR during 30-day follo g AR to the moderate-severe range. | cular arrhythm in one of these ccurred, howe ma with blooc e, myocardial ow-up. Two pa | ias occ patien ver, six l transf infarct | curred i its. No patien fusion (ion, | in its i≤2 |
| Performance data | BA cat | AV resulted in a signific theterization) by 16.5 n | cant reduction in the mean aortic gramHg (45%) from 36.5 ± 17.5 mm raphy) was also significantly reduction | radient (as means the to 20.0 ± 1 | 4.8 mi | nHg. N | /lean |



| | | | r = Aoruc | | | | | | | |
|------------|--------------------------------------|--|--|--|---|--|---|---|--|--|
| | | 46.9 ± 19.25 mm significantly imp | | | | | | | | |
| | Benefits/claims data | BAV can be perf | formed safely ar | d effectively in | a high-risk and | very elder | | | | |
| | Guita | role in palliation | | | | | | | | |
| | | uncertain or inap | • 1 | 0 | 1 | | | | | |
| | | | sed as a trial to determine who may derive most benefit from limited TAVI resources. | | | | | | | |
| | Strengths | | None Stated | | | | | | | |
| | Weaknesses/ | | is report arise fr | om the small na | tient numbers tr | eated in a | single centre. The | - | | |
| | Potential bias | data is observatio | | | | | | | | |
| | <u>State of the Art</u> Appraisal | | | | | | | | | |
| | Medical conditio | on Alternatives | Risk/benefit | Side-effects | Equivalence | Surrogat | te endpoints | | | |
| | Yes 1 No 2 | Yes 1 No 2 | Yes 1 No 2 | Yes 1 No 2 | Yes 1 No 2 | Yes 1 | No 2 | | | |
| | Overall SOA App | praisal and Disposi | ition | | | | | | | |
| | SOA Grade (Range 6-12) | 8 | | Disposition | (select) | | ccepted, < 12 cluded, 12 | | | |
| | Relevant SOA Re | esults | | | | | | | | |
| | | enthusiasm for morbidity wir refinements i vascular closs TAVI is curre are inoperabl reduced life e liver disease, either TAVI a large cohor used for palli In addition, E occasionally of severe AS (LVEF), or c | or BAV as an all th a lack of mor n BAV techniquure devices lead ently the preferre e or are at high expectancy due chronic obstruct or SAVR. These t of patients, off ation of sympto BAV may be use to facilitate non | ternative to SA tality benefit. T ac including sm ling to improved red treatment op surgical risk. He to comorbidities tive pulmonary e patients, toget en with disablin ms or to evalua ed as a bridge to -cardiac surgery heart failure, de | owever, patients s including malig disease (COPD) her with the frail ng symptomatic te a clinical resp definitive AVR | by early h of TAVI h of TAVI h r, use of ra- newed vig atients with with AS a gnancy, de and very AS, in who onse to rel (TAVI or patients w | high procedural as driven pid pacing and or for BAV. h severe AS who and significantly ementia, primary ppropriate for elderly, make up om BAV may be lieving their AS. • SAVR) or vith a combination | | | |
| | Comments | None | | | | | | | | |
| | Safety & Perforn | 19060 | | | | | | | | |
| | Appraisal | | | | | | | | | |
| Eugene et | | tudy Method/Design | n Question A | pplied | | | Oxford LOE 2011 | | | |
| al. (2018) | | bservational, | To assess th | e early and late | outcomes of res | cue | 1 2 3 4 5 | ; | | |
| | | etrospective study | | | or refractory pul | | | | | |
| | | T T T T T T T T T T T T T T T T T T T | | use of sever AS | | J | | | | |
| | Carital:11 | Del Del | | | | | Cure 1' | | | |
| | Suitability | Relevant Dat | | | | | Grading | | | |
| | Device | | NuMED, Inc.) o | r Cristal (Balt) | | | D1 D2 D3 | - | | |
| | Application | BAV | | | | | A1 A2 A3 | | | |



| Patient | | Patients with CS or | refractory pulmonary edema because | of severe | P1 | P2 | P3 |
|---|--|--|--|--|---|--|--|
| | | aortic stenosis | | | | | |
| | | Sampling: n=40 | | | | | |
| | | Mean age: 79 ± 9 y | vears | | | | |
| | | Sex: 22 M; 18 F | | | | | |
| Report | | High quality | | | R1 | R2 | R. |
| | | | Suitability Grade (I | Range 4-12) | | 4 | |
| Data Contribu | ition | Relevant Data | | | | Gra | din |
| Outcomes/En | | | nt, systolic pulmonary artery pressure, | AVA and L | VEF | Yes | N |
| | -F | 8 | , | | | 1 | 2 |
| Follow-up | | 11 months (range 5 | 5 to 39 months) | | | Yes | Ν |
| | | | | | | 1 | 2 |
| Statistical ana | alysis | | les are presented as mean \pm standard d | | | Yes | N |
| | | | en PBAV and TAVI or SAVR, and for | | | 1 | 2 |
| | | | are presented as median with 25^{th} to 75^{th} | | | | |
| | | | red using the t test when normally distributed. | | | | |
| | | | en non-normally distributed. Categori nd were compared between groups wit | | | | |
| | | | s in echocardiographic data were analy | | 151101 | | |
| | | | vn values at baseline and after PBAV v | | oxon | | |
| | | | urvival rates after PBAV were estimate | | 5A0H | | |
| | | | hod and cumulative survival rates were | | with | | |
| | | | A p-value <0.05 was considered to indi | | | | |
| | | Ũ | nce. All statistical calculations were pe | | | | |
| | | | oftware (SAS Institute Inc., Cary, NC) | | | | |
| Clinical signi | | | • | | | Yes | |
| Chinear signi | ficance | Not stated | | | | 165 | 1 |
| Chinear signi | ficance | Not stated | | | | 1 | 2 |
| | ficance | Not stated | Data Contribution | Grade (Rang | ge 4-8) | 1 | |
| | | | | Grade (Rang | ge 4-8) | 1 | 2 |
| Overall S&P 4 | Apprais | al, Disposition and V | Weighting | | | 1 | 2 5 |
| Overall S&P A S&P Grade | Apprais | | Weighting Disposition and Weighting | Accepted and | d Pivot | 1 al 9-12 | 2 5 2 |
| Overall S&P A S&P Grade (Range 9- | Apprais LOE + | cal, Disposition and (4) + Suitability (4) | Weighting Disposition and Weighting (select) | Accepted and Accepted but | d Pivot | 1 al 9-12 | 2 5 2 |
| Dverall S&P S&P Grade | Apprais LOE + | al, Disposition and V | Weighting Disposition and Weighting (select) | Accepted and Accepted bu 21 | d Pivot 1 t not I | 1 al 9-12 | 2 5 |
| Dverall S&P S&P Grade (Range 9- 25) | Apprais LOE + Data (13 | Sal, Disposition and V (4) + Suitability (4) Contribution (5) = | Weighting Disposition and Weighting (select) | Accepted and Accepted but | d Pivot 1 t not I | 1 al 9-12 | 2 5 2 |
| Dverall S&P S&P Grade (Range 9- 25) | Apprais LOE + Data 13 PResult | Sal, Disposition and V (4) + Suitability (4) Contribution (5) = S everal major complica | Weighting Disposition and Weighting (select) ations were observed during PBAV: 3 | Accepted and Accepted bu 21 Excluded, 22 resuscitated | d Pivot 1t not I 2-25 cardiac | al 9-12 Pivotal | 25 |
| Overall S&P A S&P Grade (Range 9- 25) Relevant S&P | Apprais LOE + Data 13 PResult | Sal, Disposition and V (4) + Suitability (4) Contribution (5) = S everal major complication systoles and 1 ventrice | Weighting Disposition and Weighting (select) ations were observed during PBAV: 3 ular fibrillation), 1 severe aortic regurg | Accepted and Accepted bu 21 Excluded, 22 resuscitated of gitation, and 2 | d Pivot 1t not I 2-25 cardiac | al 9-12 Pivotal | 25 |
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| | | l conditi | on Al | ternative | s Ri | sk/benet | fit | Side-e | ffects | Equival | ence | Surr | ogate ei | ndpoints |
| | Yes 1 | No 2 | Ye | es 1 No | 2 Ye | es 1 N | o 2 | Yes 1 | No 2 | Yes 1 | No 2 | Yes | 1 | No 2 |
| | Overall | SOA Ap | praisal | and Dis | positio | n | | | | | | | | |
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| | (Range | 6-12) | | | | | | | | | | | Exclu | ded, 12 |
| | Relevant | | | | | | | | | | <u> </u> | | | |
| | SOA da | | i j r i | 1986. Un ts indica PBAV w FAVI, Pl ndicated | nfavour tions. H as show BAV is | able mic lowever n to be conside | l-term , in pa lifesa red w | n outco atients ving in ith a re | mes rela with aon some c newed i | ated to ear tic stenos ircumstar | ly restends is and onces. Sinces. Sinces | enosis cardio nce th f the p | have ra genic s e devel rocedui | lain Cribier in apidly limited hock (CS), opment of re, and may be |
| | Comme | |] | None | | | | | | | | | | |
| | State of t Appraisa | | | | | | | | | | | | | |
| | Medica | 1 | Alter | natives | Risk/ | benefit | Side | | Equ | ivalence | | ogate | | |
| | Yes 1 | No 2 | Yes | No | Yes | No | effe Yes | 1 | Yes | No | endp | | No 2 | |
| | | | 1 | 2 | 1 | 2 | 1 | 2 | 1 | 2 | | | | |
| | Overall S | SOA Ap | praisal | and Dis | positio | n | | | | | | | | |
| | SOA G | | 10 Di | ispositio | n (selec | · · | | d, < 12 | | | | | | |
| | (Range | 6-1 2) | | | | Exc | cluded | 1, 12 | | | | | | |
| | Relevan Data fo SoA | | Results | 1 | | | | | | | | | | |
| | | | | | | | | | | ative to co to other ef | | | | n elderly and |
| | | | The cur | rent Am | erican (| College | of Car | diolog | y/Amer | ican Hear | t Assoc | iation | guidel | ines state that |
| Masaki et | Device concept | | | ay be co ass IIb, L | | | - | | /R or -1 | TAVR in p | patients | with | severe | symptomatic |
| al. 2020 | | | With th | e aging o | of the ge | eneral p | opulat | tion, th | | | | | | erly and frail |
| | | | | | | | | | | can provi espite the | | | al thera | peutic |
| | | | | | | | | | | | | | AS. The | resolution of |
| | | | AS, by | means of | f SAVR | or TAV | /R, le | ads to | an imme | ediate dro | p in lef | t vent | ricular | systolic |
| | Benefits | | pressur severity | | reduces | s the pre | ssure | gradiei | nt across | s the mitra | al valve | e and, | thus, in | nproves MR |
| | | | In this s | study, we | | | 0 | | | | | | | d 3 months |
| | | | | AV, inclı ant MR. | iding ar | n improv | emen | it in ca | diac sta | itus amon | g patiei | nts wit | th sever | re AS and |
| | before the than-mod Type of s Follow-u | e: Inves Based c e proced lerate M study: R up: 3 mo | tigate th in the da ure and R being etrospe- nths | e mid-te ata from at 1 and clinicall | 83 patie 3 mont | ents with hs after. | n seve | re AS t | reated u | ising BAV | V. Echo | ocardio | ography | AS. was performed , with more- |
| | Safety & | | | | | | | | | | | | | |



| Appraisal Level of | C4 | I | | | | | | | O-f | ord LO | T |
|---|--|---|---|---|--|---|--|---|---|--|---|
| Evidence | Stud Met | hod/Design | Q | estion Ap | pneu | | | | 2011 | | E |
| | Retr | ospective | То | assess mi | dterm outcomes | of BAV or | n mitra | ıl | 1 2 | 2 3 | 4 |
| | revie | ew | reg | gurgitation | in patients with | severe AS. | | | | | |
| ~ ~ ~ ~ ~ | | | _ | | | | | | - | | |
| Suitability | | Relevant l | Data | | | | | | | ding | 1 |
| Device | | Tyshak | | | | | | | D1 | D2 | Da |
| Application | | BAV | | | | | | | A1 | A2 | A |
| Patient | | Patients wi | | | | 1.1 57 1 | | • 、 | P1 | P2 | P3 |
| | | | | | many cases use | ed the Tysh | ak dev | /ice) | | | |
| | | Mean age: Sex: M:27 | | | | | | | | | |
| Report | | | | ak device v | vas one of many | devices us | ed Tł | ie. | R1 | R2 | R. |
| Кероге | | | | | nany patients w | | | | NI | 112 | 1. |
| | | Tyshak de | | | nuny putients w | ere treated | with t | ne | | | |
| Suitability G | rade (R | 2 | 100. | | | | | | 6 | | |
| salvasility c | | , , , , , , , , , , , , , , , , , , , | | | | | | | v | | |
| Data Contrib | oution | Relevant | t Data | | | | | | | Gra | ding |
| Outcomes/Ei | | | | l regurgita | tion following p | orocedure | | | | Yes | N |
| | • | | | 00 | 01 | | | | | 1 | 2 |
| Follow-up | | 3 months | 5 | | | | | | | Yes | N |
| | | | | | | | | | | 1 | 2 |
| Statistical an | alysis | | | | ify how many p | | | | | Yes | Ν |
| | | | | | alysis of outcom | nes specific | to th | is device | e | 1 | 2 |
| | | cannot be | | ined | | | | | | | |
| Clinical signi | | 4 .1 | . 1 1 | | C 1 | | | 1 . | .1 | * 7 | B .T |
| Chinear Sign | ificance | | | | ify how many p | | | | g the | Yes | |
| Chine Sign | ificance | Tyshak d | levice, cl | | ify how many particular technologies specific te | | | | g the | Yes 1 | N 2 |
| | | Tyshak d determin | levice, cl ed | | | | | | g the | 1 | |
| Data Contril | | Tyshak d determin | levice, cl ed | | | | | | g the | | No 2 |
| | oution G | Tyshak d determin Grade (Rang | levice, cl ed ge 4-8) | linical outo | comes specific to | | | | g the | 1 | |
| Data Contril Overall S&P 4 S&P Grade | oution G Apprais | Tyshak d determin Grade (Rang | levice, cl ed ge 4-8) on and V | Weighting | comes specific to | o this devic | e canr | epted an | nd Pive | 1 6 otal 9-1 | 2 12 |
| Data Contril Overall S&P 4 S&P Grade (Range 9- | Appraise | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi | levice, cl ed ge 4-8) on and V lity (6) | linical outc | comes specific to | o this devic | Acco | not be | nd Pive | 1 6 otal 9-1 | 2 12 |
| Data Contril Overall S&P 4 S&P Grade | Apprais LOE (+ Data (| Tyshak d determin Grade (Rang al, Dispositi | levice, cl ed ge 4-8) on and V lity (6) | Weighting | comes specific to | o this devic | Acco Acco 21 | epted an | nd Pivo ut not | 1 6 otal 9-1 | 2 12 |
| Data Contril Overall S&P 4 S&P Grade (Range 9- | Appraise | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi | levice, cl ed ge 4-8) on and V lity (6) | Weighting | comes specific to | o this devic | Acco Acco 21 | epted an | nd Pivo ut not | 1 6 otal 9-1 | 2 12 |
| Data Contril Overall S&P A S&P Grade (Range 9- 25) | Appraise LOE (+ Data (16 | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi | levice, cl ed ge 4-8) on and V lity (6) | Weighting | comes specific to | o this devic | Acco Acco 21 | epted an | nd Pivo ut not | 1 6 otal 9-1 | 2 12 |
| Data Contril Overall S&P 4 S&P Grade (Range 9- | Appraise LOE (+ Data (16 | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi | levice, cl ed ge 4-8) on and V lity (6) | Weighting | comes specific to | o this devic | Acco Acco 21 | epted an | nd Pivo ut not | 1 6 otal 9-1 | 2 12 |
| Data Contrit Overall S&P / S&P Grade (Range 9- 25) Relevant Resu Safety concern | Appraise LOE (+ Data (16 | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi | levice, cl ed ge 4-8) on and V lity (6) (6) = | Weighting Disposit (select) | comes specific to | o this devic | Acco Acco 21 | epted an | nd Pivo ut not | 1 6 otal 9-1 2 Pivot | 2 12 al, 13 |
| Data Contril Overall S&P A S&P Grade (Range 9- 25) Relevant Resu | Appraise LOE (+ Data (16 | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi | levice, cl ed on and V lity (6) (6) = Results | Weighting Disposit (select) | ion and Weigh | ting | Acco Acco 21 Excl | epted an epted bi | nd Pivo ut not 2-25 | 1 6 otal 9-1 : Pivot: | 2 12 al, 13 |
| Data Contril Overall S&P 4 S&P Grade (Range 9- 25) Relevant Resu Safety concern Criteria | Appraise LOE (+ Data (16 alts: n: | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi | levice, cl ed on and V lity (6) (6) = Results The mo | Weighting Disposit (select) | ion and Weigh | ting | Acco Acco 21 Excl | epted an epted bi luded, 2 | nd Pive ut not 2-25 | 1 otal 9-1 Pivota Bivota | 2 12 al, 13 |
| Data Contrit Overall S&P / S&P Grade (Range 9- 25) Relevant Resu Safety concern | Appraise LOE (+ Data (16 alts: n: | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi | levice, cl ed ge 4-8) on and V lity (6) (6) = Results The mo 22.8% | Weighting Disposit (select) | ion and Weigh | ting | Acco Acco 21 Excl | epted an epted bi luded, 2 | nd Pive ut not 2-25 | 1 otal 9-1 Pivota Bivota | 2 12 al, 13 |
| Data Contril Overall S&P 4 S&P Grade (Range 9- 25) Relevant Resu Safety concern Criteria Adverse Ever | Appraise LOE (+ Data (16 | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi Contribution | levice, cl ed ge 4-8) on and V lity (6) (6) = Results The mo 22.8% (78%). | Weighting Disposit (select) S ortality rate | ion and Weigh | ting | Acco Acco 21 Excl | epted an epted bi luded, 2 7 was as rdiac de | nd Pive ut not 2-25 | 1 otal 9-1 Pivota Pivota | 2 12 al, 13 |
| Data Contril Overall S&P A S&P Grade (Range 9- 25) Relevant Resu Safety concern Criteria Adverse Ever Conclusion: B | Appraise LOE (+ Data (16 alts: n: n: | Tyshak d determin Srade (Rang al, Dispositi (4) + Suitabi Contribution | levice, cl ed on and V lity (6) (6) = Results The mo 22.8% (78%). It therape | Weighting Disposit (select) S ortality rate in this stuce eutic strate | e even within 3 r by, but most of t gy for elderly pa | ting months afte hem were n | Acco Acco 21 Excl r BAV | epted an epted bu uded, 2 / was as rdiac de e AS wl | nd Pivo ut not 2-25 3 high eath ho are | 1 otal 9-1 Pivota Pivota Pivota | 2 12 al, 13 |
| Data Contril Overall S&P A S&P Grade (Range 9- 25) Relevant Resu Safety concern Criteria Adverse Ever Conclusion: B candidates for s | Appraise LOE (+ Data (16 hlts: n: AV prov surgical | Tyshak d determin Srade (Rang al, Dispositi (4) + Suitabi Contribution | levice, cl ed on and V lity (6) (6) = Results The mo 22.8% (78%). It therape | Weighting Disposit (select) S ortality rate in this stuce eutic strate | ion and Weigh | ting months afte hem were n | Acco Acco 21 Excl r BAV | epted an epted bu uded, 2 / was as rdiac de e AS wl | nd Pivo ut not 2-25 3 high eath ho are | 1 otal 9-1 Pivota Pivota Pivota | 2 12 al, 13 |
| Data Contril Overall S&P A S&P Grade (Range 9- 25) Relevant Resu Safety concern Criteria Adverse Ever Conclusion: B candidates for s Device used: T | Appraise LOE (+ Data (16 alts: n: AV prov surgical Cyshak | Tyshak d determin Srade (Rang al, Dispositi (4) + Suitabi Contribution | levice, cl ed on and V lity (6) (6) = Results The mo 22.8% (78%). It therape | Weighting Disposit (select) S ortality rate in this stuce eutic strate | ion and Weigh e even within 3 r ly, but most of t gy for elderly pa | ting months afte hem were n | Acco Acco 21 Excl r BAV | epted an epted bu uded, 2 / was as rdiac de e AS wl | nd Pivo ut not 2-25 3 high eath ho are | 1 otal 9-1 Pivota Pivota Pivota | 2 12 al, 13 |
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| Data Contril Overall S&P A S&P Grade (Range 9- 25) Relevant Resu Safety concern Criteria Adverse Ever Conclusion: B candidates for s Device used: T | Appraise LOE (+ Data (16 llts: n: AV prov surgical Cyshak rt | Tyshak d determin Srade (Rang al, Dispositi (4) + Suitabi Contribution | levice, cl ed on and V lity (6) (6) = Results The model of the mode | Weighting Disposit (select) S ortality rate in this stuce eutic strate | ion and Weigh e even within 3 r ly, but most of t gy for elderly pa | ting months afte hem were n | Acco Acco 21 Excl r BAV aon-ca sever ose with | epted an epted bu uded, 2 / was as rdiac de e AS wl | ad Pive ut not 2-25 s high eath ho are ficant | 1 otal 9-1 Pivot Pivot N N N MR. | 2 12 al, 13 7/alue |
| Data Contril Overall S&P 4 S&P Grade (Range 9- 25) Relevant Resu Safety concern Criteria Adverse Ever Conclusion: B candidates for : Device used: T State of the An Appraisal Medical cond | Appraise LOE (+ Data (16 dlts: n: AV prov surgical Cyshak ct | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi Contribution | levice, cl ed ge 4-8) on and V lity (6) (6) = Results The model 22.8% (78%). Il therape eter a orti s Risk | Weighting Disposit (select) S S S S S S S S S S S S S S S S S S S | e even within 3 r by but most of t gy for elderly pa blacement, espec | nonths afte hem were n atients with cially in the | Acco Acco 21 Excl r BAV aon-ca sever ose with | epted an epted bi uded, 2 / was as rdiac de e AS wl th signif | nd Pive ut not 2-25 s high eath ho are ficant | 1 otal 9-1 Pivot Pivot N N N MR. | 2 12 al, 13 7/alue |
| Data Contril Overall S&P 4 S&P Grade (Range 9- 25) Relevant Resu Safety concern Criteria Adverse Ever Conclusion: B candidates for : Device used: T State of the An Appraisal Medical cond | Appraise LOE (+ Data (16 dlts: n: AV prov surgical Cyshak ct | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi Contribution | levice, cl ed ge 4-8) on and V lity (6) (6) = Results The model 22.8% (78%). Il therape eter a orti s Risk | Weighting Disposit (select) s ortality rate in this stuc eutic strate c valve rep s/benefit | ion and Weigh ion and Weigh e even within 3 r ly, but most of t gy for elderly polacement, espec Side-effects | nonths afte hem were n atients with cially in the | Acco Acco 21 Excl r BAV oon-ca sever sever se with | epted an epted b uded, 2 / was as rdiac de e AS wl h signif | nd Pive ut not 2-25 s high eath ho are ficant | 1 otal 9-1 Pivota Pivota N as N not MR. | 2 12 al, 13 7/alue |
| Data Contril Overall S&P A S&P Grade (Range 9- 25) Relevant Resu Safety concern Criteria Adverse Ever Conclusion: B candidates for 3 Device used: T State of the An Appraisal Medical cond Yes 1 No Overall SOA A | Appraise LOE (+ Data (16 ilts: n: AV provements AV provements Surgical Cyshak Cyshak Cyshak Cyshak Cyshak Cyshak Cyshak Cyshak Cyshak Cyshak Cyshak | Tyshak d determin Frade (Rang al, Dispositi (4) + Suitabi Contribution vides a usefu or transcathe <u>Alternative</u> Yes 1 No al and Disp | levice, cl ed ge 4-8) on and V lity (6) (6) = Results The model 22.8% (78%). Il theraped eter aorti s Risk 2 Yes | Weighting Disposit (select) s ortality rate in this stuc eutic strate c valve rep s/benefit | ion and Weigh ion and Weigh e even within 3 r ly, but most of t gy for elderly pro- placement, espect Side-effects Yes 1 No 2 | nonths afte hem were n atients with cially in the Yes 1 N | Acco Acco 21 Excl r BAV oon-ca sever sever se with | epted an epted bu uded, 2 / was as rdiac de e AS wh th signif <u>Surrog</u> Yes 1 | ad Pive ut not 2-25 s high eath ho are ficant | 1 otal 9-1 Pivota Pivota No 2 | 2 12 al, 13 <i>value</i> NA |
| Data Contril Overall S&P A S&P Grade (Range 9- 25) Relevant Resu Safety concern Criteria Adverse Ever Conclusion: B candidates for : Device used: T State of the An Appraisal Medical conc Yes 1 | Appraiss LOE (+ Data (16 htts: nts AV provisurgical Tyshak Cyshak rt lition o 2 | Tyshak d determin Grade (Rang al, Dispositi (4) + Suitabi Contribution vides a usefu vides a usefu or transcathe Alternative Yes 1 No | levice, cl ed ge 4-8) on and V lity (6) (6) = Results The model 22.8% (78%). Il theraped eter aorti s Risk 2 Yes | Weighting Disposit (select) s ortality rate in this stuc eutic strate c valve rep s/benefit | ion and Weigh ion and Weigh e even within 3 r ly, but most of t gy for elderly polacement, espec Side-effects | nonths afte hem were n atients with cially in the Yes 1 N | Acco Acco 21 Excl r BAV oon-ca sever sever se with | epted an epted bi uded, 2 7 was as rdiac de e AS wi th signif Surrog Yes 1 | ad Pive ut not 2-25 s high eath ho are ficant | 1 6 0 tal 9-1 2 Pivota Fivota No 2 ed, < 12 | 2 12 al, 13 <i>value</i> NA |



| Relevant Data SoA | for | Results | | | | | | |
|--|--|--|--|--|--|-----------------------------|---|---|
| Alternatives | | Transcatheter aortic valve replacement (TAVR) has been successfully performed in inoperable, high-risk, intermediate-risk, and low-risk patients with low mortality and complication rates, | | | | | | |
| acilitated by pre Method: Based of hird-degree atric block (AVB) und provisional pacer bacemaker and a Safety & Perfor | edilatatic on the d oventric derwent maker (1 standar | on with the non ata from 142 p ular TAVR with th n = 121). The r | nocclus atients ne True remain | y of ACURATE neotranscatheter a sive TrueFlow balloon catheter s in a prospective registry. Patients eFlow balloon without rapid pacing hing 21 patients were predilated with the NuMED Z-MED). | at low risk for g and without i | r intraj | procedu | ral |
| Appraisal Level of | Study | , | Oue | estion Applied | | Oxf | ord LO | E |
| Evidence | Meth | od/Design | _ | | | 201 | <u> </u> | |
| | Prospe registr | | | assess midterm outcomes of BAV our gitation in patients with severe AS | | 1 | 2 3 | 4 |
| Suitability | | Relevant Data | 4 | | | Gr | ading | |
| Device | | Z-MED | • | | | D1 | D2 | D |
| Application | | Predilation bef | fore T | AVR | | A1 | A2 | A |
| Patient | Patients undergoing TAVRFSampling: n=121 (21 patients used either a TrueDilatation balloonrFNuMED Z-MED, unclear how many cases used the Z-MED device)Mean age: 82 yrs | | | | | P2 | P3 | |
| | | Sex: M:55, F:8 | | | | | | |
| Report | - | Low quality. Z "standard ballo many patients | 37 Z-MEE Don" c | D device was one of two devices us cohort (n=21). The study does not d treated with the Z-MED device. | | R1 | R2 | R |
| Report Suitability Gra | - | Low quality. Z "standard ballo many patients | 37 Z-MEE Don" c | whort (n=21). The study does not d | | R1 6 | R2 | R |
| - | ade (Ra | Low quality. Z "standard ballo many patients | 37 Z-MED bon" c were t | whort (n=21). The study does not d | | | R2 Grad | |
| Suitability Gra | ade (Ra | Low quality. Z "standard ballo many patients nge 4-12) | 37 Z-MED oon" c were t | whort (n=21). The study does not d | | | | ding |
| Suitability Gra Data Contribu | ade (Ra | Low quality. Z "standard ballo many patients nge 4-12) Relevant Da | 37 Z-MED oon" c were t | whort (n=21). The study does not d | | | Grae Yes | ding N 2 |
| Suitability Gra Data Contribu Outcomes/End | ade (Ra ation lpoints | Low quality. Z "standard balle many patients nge 4-12) Relevant Da Successful T 30 days As the article Z-MED devi cannot be de | 37 C-MEL bon" c were t ta ta AVR c does ice, sta termir | where the constant of the cons | re treated usin fic to this devi | g the ce | Grad Yes 1 Yes | ding N 2 N 2 |
| Suitability Gra Data Contribu Outcomes/End Follow-up | ade (Rat | Low quality. Z "standard balle many patients nge 4-12) Relevant Da Successful T 30 days As the article Z-MED devi cannot be de As the article | 37 2-MEL bon" c were t ta AVR a does ice, sta termin e does | where the constraints and the constraints are constraints and the constraints and the constraints are constraints are constraints and the constraints are cons | re treated usin fic to this devi- re treated usin | g the ce | Grad Yes 1 Yes 1 Yes | ding N 2 N 2 N 2 |
| Suitability Gra Data Contribu Outcomes/End Follow-up Statistical anal Clinical signifi Data Contribu | ade (Ra ation lpoints lysis cance | Low quality. Z "standard balle many patients nge 4-12) Relevant Da Successful T 30 days As the article Z-MED devi cannot be de As the article Z-MED devi determined "ade (Range 4 | AT AT AT AT AT AT AT AT AT AT | enot specify how many patients we atistical analysis of outcomes specific to this device inical outcomes specific to this dev | re treated usin fic to this devi- re treated usin | g the ce | Grad Yes 1 Yes 1 Yes 1 Yes | ling N 2 N 2 N 2 N |
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| Suitability Gra Data Contribu Outcomes/End Follow-up Statistical anal Clinical signifi Data Contribu Overall S&P Ap S&P Grade (Range 9- | ade (Ration lipoints lysis cance tion Gr ppraisal LOE (3 + | Low quality. Z "standard balle many patients nge 4-12) Relevant Da Successful T 30 days As the article Z-MED devi cannot be de As the article Z-MED devi determined "ade (Range 4 | AVR and W (6) | enot specify how many patients we atistical analysis of outcomes speci not specify how many patients we atistical analysis of outcomes speci- ned not specify how many patients we inical outcomes specific to this dev | re treated usin fic to this devi- re treated usin | g the ce g the nd Pivout no | Grad Yes 1 Yes 1 Yes 1 Yes 1 6 | ding N 2 N 2 N 2 N 2 2 2 |
| Suitability Gra Data Contribu Outcomes/End Follow-up Statistical anal Clinical signifi Data Contribu Overall S&P Ap S&P Grade (Range 9- 25) Relevant Result | ade (Ration lipoints lysis cance tition Gr opraisal LOE (3 + Data Co 15 s: | Low quality. Z "standard balle many patients nge 4-12) Relevant Da Successful T 30 days As the article Z-MED devi cannot be de As the article Z-MED devi determined rade (Range 4-) + Suitability | AVR and W (6) | enot specify how many patients we atistical analysis of outcomes specified not specify how many patients we atistical analysis of outcomes specified not specify how many patients we inical outcomes specific to this dev | re treated usin fic to this devi- re treated usin ice cannot be Accepted a Accepted b 21 | g the ce g the nd Pivout no | Grad Yes 1 Yes 1 Yes 1 Yes 1 6 | ding No 2 No 2 No 2 2 No 2 2 2 2 |
| Suitability Gra Data Contribu Outcomes/End Follow-up Statistical anal Clinical signifi Data Contribu Dverall S&P Ap S&P Grade (Range 9- 25) | ade (Ration lipoints lysis cance tition Gr opraisal LOE (3 + Data Co 15 s: | Low quality. Z "standard balle many patients nge 4-12) Relevant Da Successful T 30 days As the article Z-MED devi cannot be de As the article Z-MED devi determined rade (Range 4-) + Suitability | AT C-MED bon" c were t ta AVR e does ice, sta termir e does ice, cli -8) and W (6) = | enot specify how many patients we atistical analysis of outcomes specified not specify how many patients we atistical analysis of outcomes specified not specify how many patients we inical outcomes specific to this dev | re treated usin fic to this devi- re treated usin, ice cannot be Accepted a Accepted b 21 Excluded, 2 | g the ce g the nd Pivout no | Grad Yes 1 Yes 1 Yes 1 Yes 1 6 | No 2 No 2 No 2 No 2 |

| | ∃ Summ | • | | | nical Perfo PTV | rmance | | | | |
|---------------------|---|--|--|---|--|---|----------------------------------|---|---|---------------------------------------|
| | Adverse Events |] | Major or 1 | ife-threa 0 days o | tening bleeding r Mortality at 30 | blication at 30 da at 30 days, Any) days in "standa | , | differer TrueFlo cohort | ow bal | |
| | Conclusion: Among balloon catheter facil provisional pacemak Device used: Z-MEI State of the Art | litates implanta er. | | | | | | | | sive |
| | Appraisal | | | | | | | | | |
| | Medical condition | Alternative | s Risk/ | benefit | Side-effects | Equivalence | Surro | gate en | dpoin | ts |
| | Yes 1 No 2 | Yes 1 No | | | Yes 1 No 2 | Yes 1 No 2 | Yes 1 | | No 2 | |
| | Overall SOA Appra SOA Grade (Range 6-12) | aisal and Dispo 10 | osition | | Disposition | (select) | | ccepte | | 2 |
| | Relevant Data for SoA | Results | | | | | | | | |
| | Alternatives | | | | mplantation (TA | AVI) is increasin | gly appli | ied for | treatin | g |
| | Risks | rates of r Multiple disorders | epeated he reports sta . Howeve | ospitaliza ate that E | ation | tion duration, re | lopment | of cond | luction | 1 |
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| | Su | ımmaı | - | afety ar | MED nd Clinical Performance | 9 | | | |
|--|--|---|--|--|---|--|--|---|-------------------------------------|
| | 1 1 | | | | Aortic PTV | | | | 1 |
| | | | | ce of new I | PPMI | | | 1 | 2 |
| | Follow-up | | 30 days | | | | | Yes 1 | No 2 |
| | Statistical ana | alysis | The stu | dy compare | es small BAV (18mm) with standar | d BAV (<18m | m); | Yes 1 | 2 No 2 |
| | Clinical signif | ficance | | | MED devices used for predilation s l are relevant for the subject devices | | nical | Yes 1 | No 2 |
| | Data Contrib | ution Gr | | | <i>y</i> | | | 6 | |
| | Overall S&P A S&P Grade (Range 9- 25) | LOE (4 + | , Disposi) + Suital ontributio | oility (4) | Veighting Disposition and Weighting (select) | Accepted a Accepted b 21 Excluded, 2 | out not | | |
| | Relevant Resul Safety concern | | | | | | | | |
| | Criteria | | | Results | |] | P valu | e | |
| | Outcomes | | | Mean gra >18mm – PPMI: 18 | access – 91/94 (96.8%) dient post procedure: 18mm – 11.5 - 12.2mmHg 8mm – 3.5%, >18mm – 18.9% | 2 | Signifi | | ween |
| | PPMI: 18mm - 3.5%, >18mm - 18.9%differenceSevere or moderate AVR - 18mm - 5.3%, >18mm - 8.1% Conversion to surgery - 1/94 (1%) No reports of stroke or transient cerebral ischemic attack; 30-day mortality - 1/94 (1%)difference "small" an "standard" for PPMI | | | | | | " and ard" B/ | | |
| | | lf-expand | | egy is asso | ion in this single-center observation | | iplanta | tion aft | ter |
| A comprehens Catheters has a) Conf cond b) Unde curre c) The device | been carried out a ormity with rele itions of the inten esirable side-effec ent knowledge/the information mater ce. | and critica and docur vant gen ded use c ets and ac state of t rials, and | al evaluat nented in eral safe f the dev ceptabilit he art in the risk | ion of the p the CER. I ty and per ice has bee by of the be the medica reduction p | pertinent clinical data and pre-clinic Based on the results of this evaluati formance requirements set out in | on, it is conside MDR Annex I and are accep available medi account the int | ered th x I und table a ical alto tended | nat: der the accordinernative l purpos | e norm ng to t es. se of t |
| e) The purp f) The | claims foreseen i ose of the device. information mate | erials sup | plied and | the RM d | provided with the CER are adequa locumentation for the device unde the CER and with the current know | r evaluation ar | re con | sistent | |
| Overall, it is c to the patient acknowledged | concluded that the and are compatibl l state of the art; t | risks ass le with a l hat the in | ociated w nigh level tended cl | with the use l of protect inical perfo | of the PTV Catheters are acceptabl ion of health and safety, taking into prmances are achieved by the device when weighed against the benefits f | e when weighe account the ge e; and that know | ed agai enerall wn and | inst the y d forese | eeable |



Ongoing planned post-market clinical follow-up:

The PTV Catheters have been commercialized since 1998 in the EU. Since then, the device is likely to have been used in a variety of patients and populations. A PMCF study is not warranted at this time due to the fact that long-term safety and clinical performance has been established via device use and ample clinical experience. This experience would likely have identified any rare complications or problems that would become apparent only after widespread device use. Continued post-market surveillance activities will provide sufficient data to adequately address clinical risks, and detect emerging risks on the basis of evidence.

A PMCF study was conducted in the past on the Z-MED and Z-MED II, with the introduction of the mitral & aortic valvuloplasty indication, and did not identify any new risks.

Post-market surveillance data as part of the quality system is continually compiled as per an established quality system. Devicerelated adverse events and complaints are recorded with explicit purpose to identify and investigate any residual risks associated with the use of the device.

6. Possible diagnostic or therapeutic alternatives

The introduction of TAVR has revolutionized the management of patients with AS and is considered a viable option in high-risk and inoperable patients (2).

Surgical aortic valvotomy (SAV) is an alternative initial intervention to BAV for AS, where the choice of primary intervention is typically based on institutional preference.

7. Suggested profile and training for users

The intended users of PTV catheters are Cardiac Surgeons and/or Interventionalists.

8. Reference to any harmonised standards and CS applied

There are no Common Specifications for this type of device.

The following harmonised standards are followed for this device:

- EN ISO 11135:2014 Sterilization of health-care products Ethylene oxide Requirements for the development, validation and routine control of a sterilization process for medical devices.
- EN ISO 11737-1:2018/A1:2021 Sterilization of medical devices Microbiological methods Part 1: Determination of a population of microorganisms on products
- EN ISO 13485:2016/A11:2021 Medical devices Quality management systems Requirements for regulatory purposes
- EN ISO 15223-1:2021 Medical devices Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements

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| 10. Revisi | on History | | |
|----------------------------|--------------|------------------------|---|
| SSCP revision number | Date Issued | Change Description | Revision validated by Notified Body |
| 00 | 21 June 2022 | Initial implementation | ☐ Yes Validation Language: English ⊠ No |
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