

The Rapid Deployment (Sutureless) AVR only for selected patients



7th
AP VALVES 2018

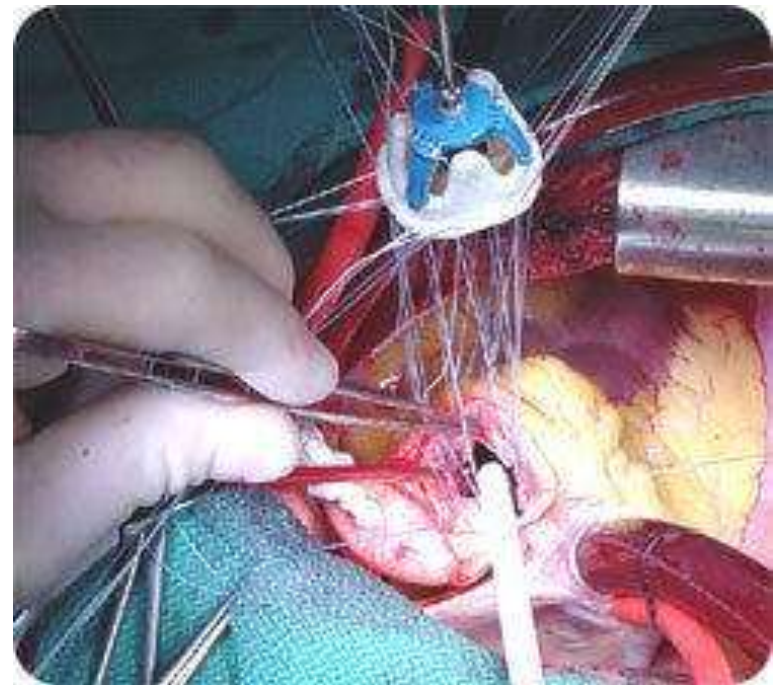


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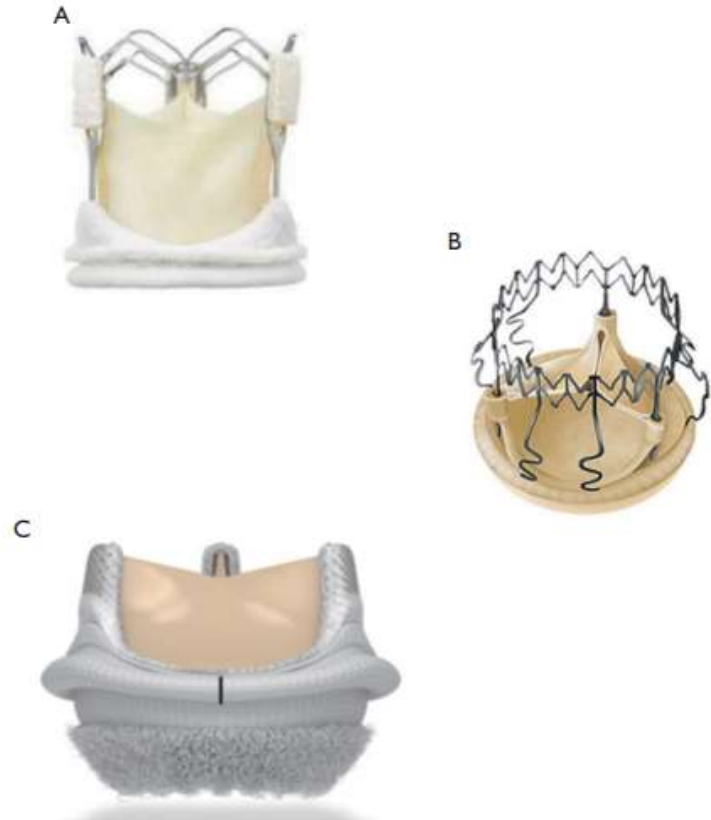
Conventional AVR

- **Full Sternotomy**
- **CPB/ACC**
- **Aortotomy**
- **Resection of native aortic valve**
- **Aortic valve suture :10~15 ea**
- **Aortotomy closure**
- **ACC off / CPB weaning**
- **Sternotomy closure**



Sutureless AVR

- **Sternotomy/thoracotomy**
- **CPB/ACC**
- **Aortotomy**
- **Resection of native aortic valve**
- **Aortic valve suture : 0~3ea**
- **Aortotomy closure**
- **ACC off / CPB weaning**
- **Sternotomy closure**



Sutureless Aortic Valve Replacement International Registry (SU-AVR-IR): design and rationale from the International Valvular Surgery Study Group (IVSSG)



Table 1 List of participating centers and sites

| Country | Center |
|-------------|--|
| France | Montreal Heart Institute, University of Montreal, Montreal, QC |
| Germany | University Medical Center (Ulm), Ulm |
| Germany | Freeman Hospital, Newcastle upon Tyne |
| Germany | Paracelsus Medical University, Nuremberg |
| Germany | University of Leipzig, Leipzig |
| Germany | Hannover Medical School, Hannover |
| Germany | University Hospital Cologne, Cologne |
| Germany | Dresden University Hospital, Dresden |
| Germany | European Medical School Odenburg Groningen, Odenburg |
| Germany | University of Bologna, Bologna |
| Germany | Passerelle Heart Hospital, Paris |
| Germany | Terraviva Hospital, Zurigo |
| Germany | Ulm Institute, Ulm |
| Germany | Saku Hospital, SVM Care & Research, Plymouth |
| Germany | Pellegrini Hospital, Pavia |
| Canada | Montreal Heart Institute, Montreal |
| Canada | Tribuna Health Center, Mississauga |
| Canada | Sauvêtre Regional Health Center, Canada |
| Canada | New Brunswick Heart Centre, Saint John |
| France | Université de Saint-Etienne, Saint-Etienne |
| France | Hopital de la Timone, Marseille |
| France | Centre Hospitalier Universitaire de Nancy, Nancy |
| Belgium | Gaizulberg University Hospital, Zurich |
| Austria | Medical University Vienna, Vienna |
| Switzerland | University Hospital Geneva, Geneva |
| Australia | Cooperative Research (CORE) Group, Göteborg |



Conventional surgery, sutureless valves, and transapical aortic valve replacement: What is the best option for patients with aortic valve stenosis? A multicenter, propensity-matched analysis

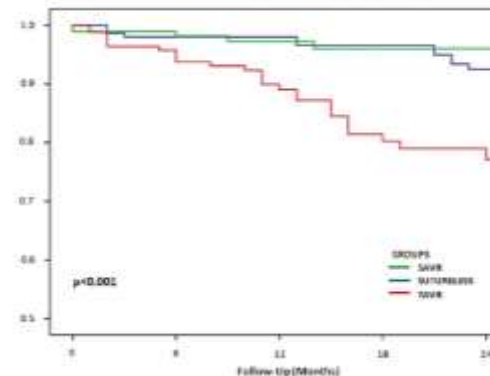
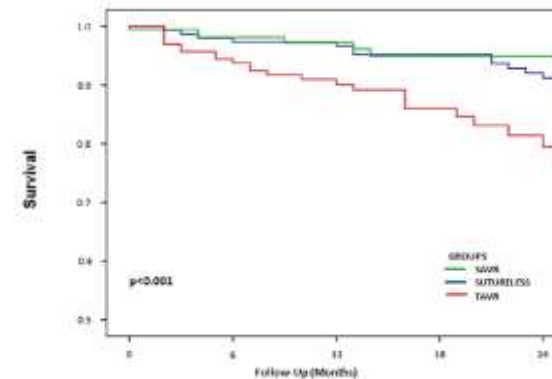
TABLE 5. Postoperative outcomes after TA-TAVR, SU-AVR, and SAVR; analysis included 286 patients with caliper matching 1:1

| Outcome | TA-TAVR (n = 143) | SU-AVR (n = 31) | SAVR (n = 112) | P value | |
|-------------------------------------|-------------------|-----------------|----------------|-------------------|-----------------|
| | | | | TA-TAVR vs SU-AVR | TA-TAVR vs SAVR |
| Death (n) | 10 (7) | 0 | 1 (1.8) | 0.21 | .026* |
| Stroke (n) | 4 (2.8) | 0 | 0 | 1 | .13* |
| PPM (n) | 7 (4.9) | 1 (3.2) | 1 (0.9) | 1 | .082* |
| RRT (n) | 7 (4.9) | 1 (3.2) | 0 | 1 | .019* |
| AMI (n) | 5 (3.5) | 0 | 1 (0.9) | 0.59 | .23* |
| Postoperative AR ($\geq 1+ / 3+$) | 41 (28.7) | 6 (19.4) | 2 (1.8) | 0.37 | <.001* |
| Mean gradient (mm Hg) | 10.7 \pm 4.4 | 11.1 \pm 3.3 | 16.5 \pm 5.8 | 0.69* | <.001† |

A comparison of conventional surgery, transcatheter aortic valve replacement, and sutureless valves in “real-world” patients with aortic stenosis and intermediate- to high-risk profile

TABLE 3. Operative data and performance of hemodynamic prostheses

| Variables | SAVR | Sutureless | TAVR | p value |
|--|------------------|------------------|------------------|---------|
| | n = 204 n (%) | n = 204 n (%) | n = 204 n (%) | |
| Preoperative echocardiography assessment | | | | |
| Peak gradient (mm Hg) | 84 ± 21 | 80 ± 27 | 77 ± 20 | .084 |
| Mean gradient (mm Hg) | 51 ± 15.2 | 49 ± 18 | 48 ± 14 | .122 |
| Valvular area (cm ²) | 0.77 ± 0.21 | 0.66 ± 0.2 | 0.7 ± 0.2 | .017 |
| CPB time (min) | 79.4 ± 12.4 | 50 ± 11.5 | | <.001 |
| Aortic crossclamp time (min) | 61.2 ± 11.7 | 32.8 ± 12.6 | | <.001 |
| MV >48 h | 7 (3.4) | 4 (1.9) | 3 (1.5) | .066 |
| ICU stay (d) | 2.2 ± 3.4 | 1.6 ± 2.3 | 3.2 ± 2 | .011 |
| Prostheses diameters (mm) | 22.4 ± 2.0 | 23.3 ± 2.7 | 25.8 ± 1.5 | <.001 |
| Hemodynamic parameters at discharge | | | | |
| Postoperative peak gradient (mm Hg) | 22.75 ± 11.7 | 19.52 ± 12.45 | 14.34 ± 7.5 | .015 |
| Postoperative mean gradient (mm Hg) | 11.4 ± 6 | 10.8 ± 6.8 | 7.6 ± 4.2 | .077 |
| AR greater than grade 2 | 1 (0.5) | 4 (1.9) | 18 (8.8) | .028 |



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TABLE 4. Postoperative complications

| Variables | <u>SAVR (G3)</u> | <u>Sutureless (G2)</u> | <u>TAVR (G3)</u> | <i>P</i> value | <i>P</i> value G1 vs G2 | <i>P</i> value G1 vs G3 | <i>P</i> value G2 vs G3 |
|---|------------------|------------------------|------------------|----------------|----------------------------|----------------------------|----------------------------|
| | n = 204 n (%) | n = 204 n (%) | n = 204 n (%) | | | | |
| Bleeding requiring revision | 6 (2.9) | 10 (4.9) | 4 (1.9) | .526 | .447 | .271 | .314 |
| Anemia requiring at least 2 units of RBCs | 116 (57) | 73 (35.7) | 67 (32.8) | <.001 | <.001 | <.001 | .683 |
| Acute renal failure | 30 (14.7%) | 11 (5.3) | 24 (11.7) | .007 | .003 | .462 | .039 |
| CVVH | 7 (3.4) | 3 (1.5) | 12 (5.8) | .063 | .547 | .255 | .019 |
| Stroke | 6 (2.9) | 4 (2) | 7 (3.4) | .661 | .617 | .733 | .587 |
| Peripheral vascular complications | 0 (0) | 0 (0) | 20 (9.8) | <.001 | 1 | <.001 | <.001 |
| PM implantation | 8 (3.9) | 20 (9.8) | 30 (14.7) | <.001 | .021 | <.001 | .228 |
| 30-d mortality | 7 (3.4) | 12 (5.8) | 20 (9.8) | .005 | .341 | .015 | .341 |

SAVR, Surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement; RBC, red blood cell; CVVH, continuous venovenous hemofiltration; PM, pacemaker.

Sutureless versus Conventional Aortic Valve Replacement:

Tex Heart Inst J 2018;45(1):11-6

Outcomes in 70 High-Risk Patients Undergoing Concomitant Cardiac Procedures

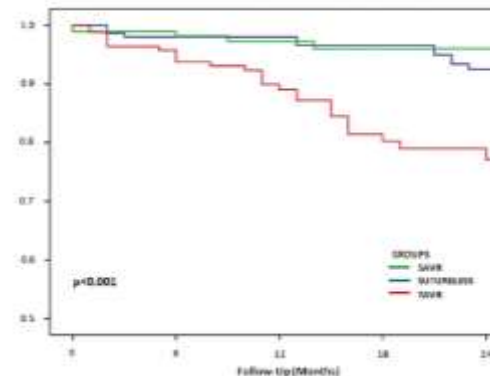
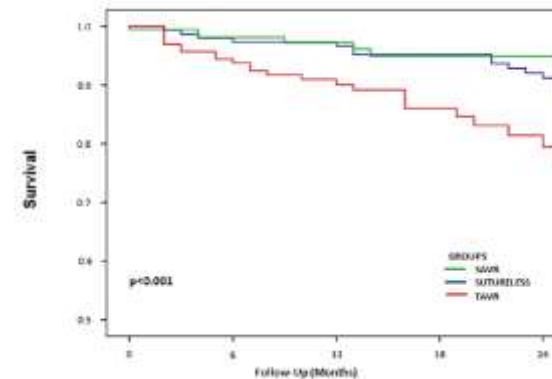
TABLE II. Comparison of Operative and Postoperative Results

| Variable | Group 1 (Sutureless AVR) (n=38) | Group 2 (Conventional AVR) (n=32) | P Value |
|--------------------------------|------------------------------------|--------------------------------------|---------|
| Operative time (min) | 253 ± 76 | 350 ± 85 | 0.001 |
| Cross-clamp time (min) | 78 ± 28 | 122 ± 38 | 0.001 |
| CPB time (min) | 119 ± 42 | 166 ± 50 | 0.001 |
| Ventilator dependence (hr) | 9.4 ± 3.5 | 11.6 ± 7.8 | 0.134 |
| Intensive care unit stay (d) | 4.2 ± 3.7 | 4.9 ± 4.8 | 0.462 |
| Drainage (mL) | 396 ± 153 | 1,010 ± 1,208 | 0.009 |
| Re-exploration for bleeding | 2 (5.3) | 2 (6.3) | 0.999 |
| Red blood cell transfusion (U) | 2.2 ± 1.8 | 3.4 ± 3 | 0.037 |
| FFP transfusion (U) | 2.2 ± 1.9 | 2.9 ± 3.4 | 0.262 |
| 30-day hospital death | 2 (5.3) | 5 (15.6) | 0.234 |
| Hospital stay (d) | 9.3 ± 5.1 | 13.6 ± 6.6 | 0.004 |

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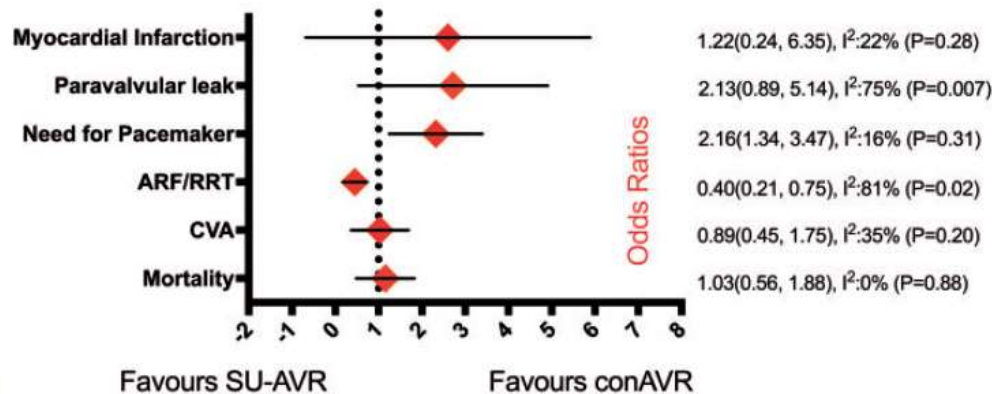
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Meta-analysis of sutureless technology versus standard aortic valve replacement and transcatheter aortic valve replacement

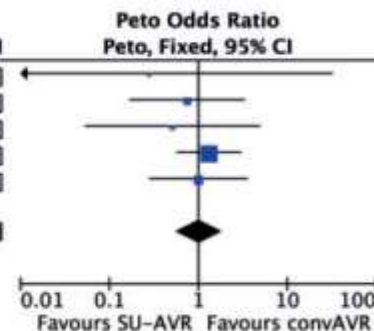
Saqib H. Qureshi^{a,*}, Anas Boulemden^a, Adam Szafranek^a and Hunaid Vohra^b



DISCUSSION

This meta-analysis attempted to evaluate evidence with the aim to appraise clinicians on the quality and direction of available evidence. The key findings are that SU-AVR is associated with 30% reduction in relative risk for PVL and 30-day mortality compared with TAVR. The effect of SU-AVR on 30-day mortality versus conAVR requires further evidence. There is also 'firm evidence' to implicate sutureless technology associated with the increased risk of PPM compared with conAVR.

| Study or Subgroup | SU-AVR | | convAVR | | Weight | Peto Odds Ratio | |
|--|--------|------------|---------|------------|---------------|---------------------|---------------------|
| | Events | Total | Events | Total | | Peto, Fixed, 95% CI | Peto, Fixed, 95% CI |
| D'Onofrio 2013 | 0 | 31 | 1 | 112 | 1.6% | 0.28 | [0.00, 32.45] |
| Dalen M 2015 | 3 | 171 | 4 | 171 | 16.5% | 0.75 | [0.17, 3.33] |
| Gilmanov D 2014 | 1 | 133 | 2 | 133 | 7.1% | 0.51 | [0.05, 4.95] |
| Muneretto C 2015 | 13 | 204 | 10 | 204 | 52.1% | 1.32 | [0.57, 3.05] |
| Pollari 2014 | 5 | 82 | 5 | 82 | 22.6% | 1.00 | [0.28, 3.58] |
| Total (95% CI) | | 621 | | 702 | 100.0% | 1.03 | [0.56, 1.88] |
| Total events | 22 | | 22 | | | | |
| Heterogeneity: Chi ² = 1.16, df = 4 (P = 0.88); I ² = 0% | | | | | | | |
| Test for overall effect: Z = 0.09 (P = 0.93) | | | | | | | |



30 day mortality

Meta-analysis of sutureless technology versus standard aortic valve replacement and transcatheter aortic valve replacement

Saqib H. Qureshi^{a,*}, Anas Boulemden^a, Adam Szafranek^a and Hunaid Vohra^b

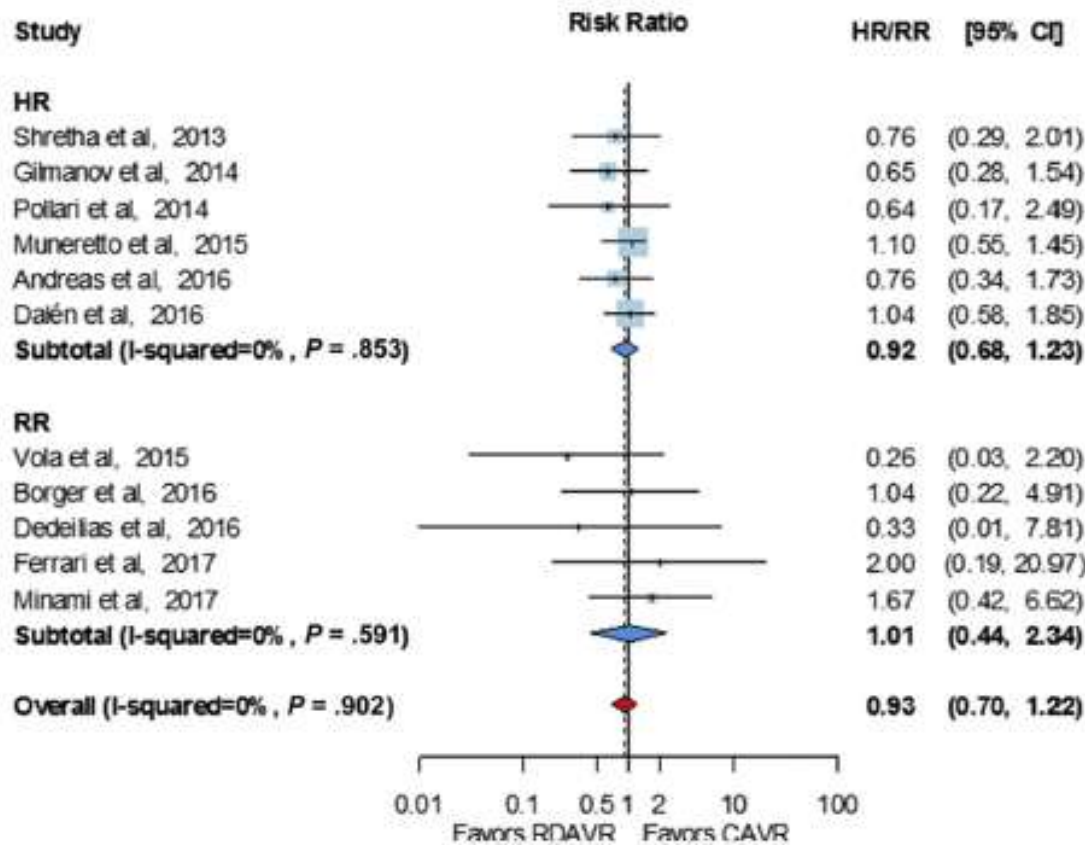
Implications for clinical practice

Recent expert consensus supports the use of sutureless technology in patients with isolated or concomitant procedures where controlling CPB comorbidity is imperative and in calcified root, porcelain aorta as well as prior implantation of aortic homograft [29]. Acknowledging the limitations of current evidence, this meta-analysis advocates selected patients with worse annular characteristics and higher inherent risk for PVL to be offered SU-AVR and not TAVR. Neither superiority nor inferiority can be firmly established against conAVR. **It is our recommendation that the safety and efficacy of sutureless and rapid-deployment technology should be further tested in large-scale randomized trials controlling annular characteristics beyond other variables against both TAVR and conAVR.**

Rapid deployment or sutureless versus conventional bioprosthetic aortic valve replacement: A meta-analysis

Suk Ho Sohn, MD,^a Myoung-jin Jang, PhD,^b Ho Young Hwang, MD, PhD,^a and Kyung Hwan Kim, MD, PhD^a

Early death

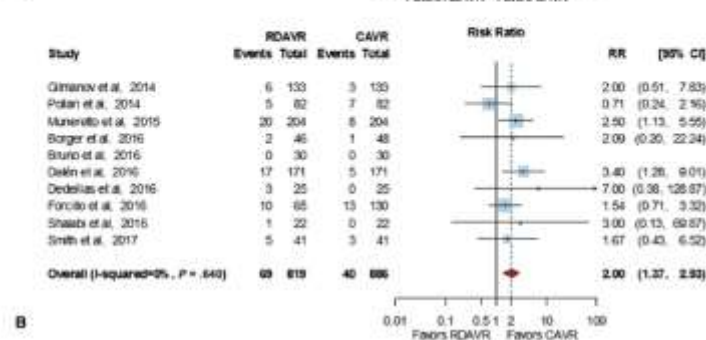
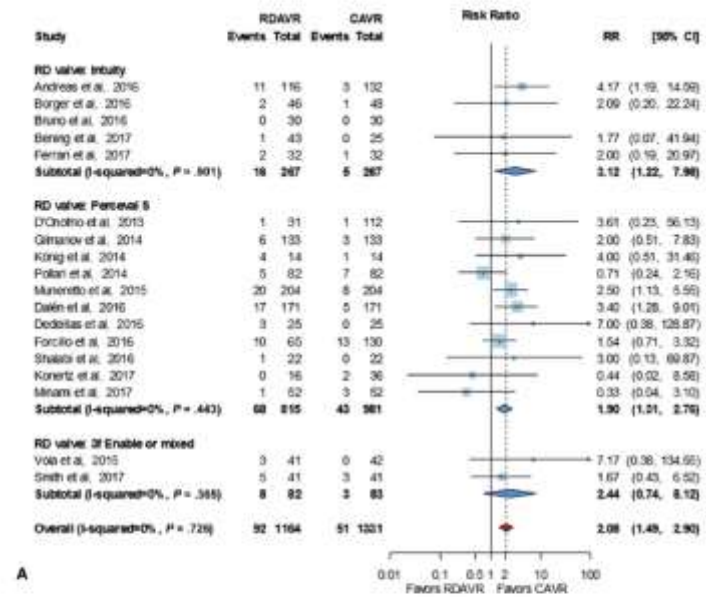
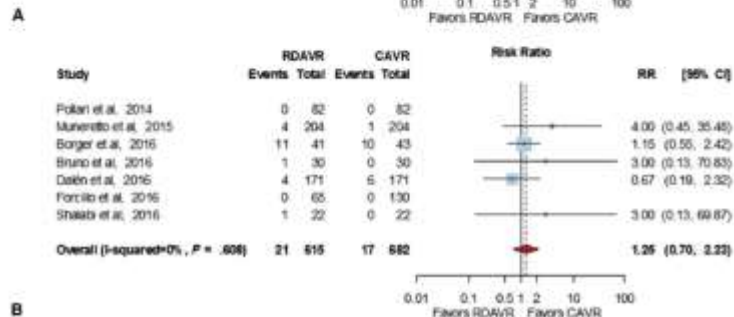
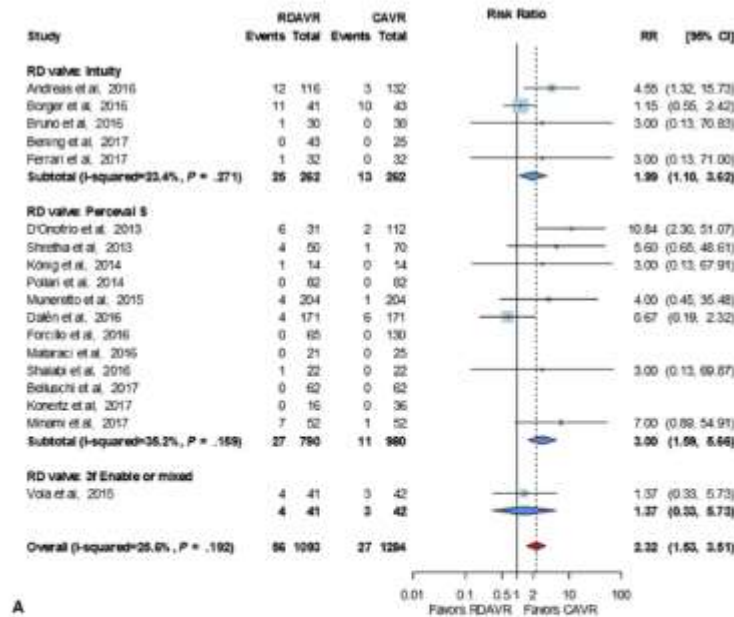


Rapid deployment or sutureless versus conventional bioprosthetic aortic valve replacement: A meta-analysis

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PVL

PPM



Rapid deployment or sutureless versus conventional bioprosthetic aortic valve replacement: A meta-analysis

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CONCLUSIONS

Aortic valve replacement with RD valves is associated with significantly shorter ACC and CPB times than conventional AVR, although these differences did not translate into improved postoperative complications and mortality early after surgery and during the follow-up. Care might be needed when implanting RD valves because they are associated with a higher incidence of PPM insertion, regardless of the RD valve type.

Cost in Korea

| Valve | Price | Pt's pay(%) | Pt's pay |
|--------------------|-----------------------|-------------|----------------------|
| Sutureless valve | ₩11,000,000 (\$9,792) | 50 | ₩5,500,000 (\$4,896) |
| Conventional valve | ₩2,802,660 (\$2,500) | 5 | ₩140,133 (\$125) |

Conclusion

- We can not justify the use of Sutureless valve instead of classical valve
 - ◆ There are no definite advantages - sutureless valve can only save operation time just less than 30min.
 - ◆ There are two definite disadvantages - paravalvular leakage and permanent pacemaker insertion
 - ◆ The patient and the government have to spend a lot of money (patient – 50times, government - 4times)



감사합니다 !!

Thank you !!