Keynote Lecture Serious

The perfect prosthesis/patient match: pursuit of the Holy Grail

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In 1978, Rahimtoola published a successful series of surgical aortic valve replacements (SAVR) on patients with severe aortic stenosis (AS) with congestive heart failure (CHF). He described the perfect prosthesis-patient match as a "prosthetic valve with a functioning opening area that matches the patient's normal functioning valve." This manuscript revisits the forty-six-year journey in pursuit of that perfect match. We address the essential components for the perfect match, such as the usefulness of the current valve sizing techniques using the manufacturer's labeled valve size (MLVS) and sizer, the accuracy of an objective parameter to define the perfect match, and the need and safety to enlarge the patient's annulus and root to accommodate the proper size valve. A thorough literature search was performed using the University of Michigan Medical Library search engine. The population included patients who underwent SAVR. Three individual searches were conducted: (I) valve size and sizing techniques; (II) hemodynamic performance (HP) and prosthesis-patient mismatch (PPM); and (III) aortic root enlargement (ARE) procedures. Excluded were articles not in English, articles that involved animal research, duplicate articles, articles involving valve repair, allograft or autograft replacement, and articles specific to aortic sizing and congenital heart surgery. The emphasis was placed on randomized prospective trials, large registry trials with and without propensity matching, and meta-analysis articles. We discovered that the manufacturer-labeled valve size and sizing technique does not accurately represent the functional opening area of the valve. A pre-operative multidetector computed tomography (CT) scan is an accurate and reproducible method for measuring patient root and annulus dimensions and should be used for pre-operative valve sizing for SAVR. Matching the CT area derived aortic diameter with the true functional diameter of the opening of the prosthetic valve will yield the best prosthesis-patient match. ARE is safe and should be used to attain the best match.

Keywords: Prosthesis-patient match; area derived annular dimension (ADAD); functional internal diameter of prosthetic valve (FID of prosthetic valve); aortic annular enlargement (AAE)

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Introduction

In 1978, Shahbuden Rahimtoola published a series of 19 patients who underwent SAVR for aortic stenosis (AS), severely reduced left ventricular ejection fraction (LVEF), and congestive heart failure (CHF). These patients had improved survival, LVEF, New York Heart Association (NYHA)/CHF classification, and a marked reduction in their mean valve gradient (MVG) over similar medically treated patients. Rahimtoola recommended that AS patients with CHF should be offered SAVR (1). He also introduced the concept of valve prosthesis-patient mismatch (PPM), noting that "mismatch can be present when the post-operative prosthetic valve functioning opening is less than the patient's normal human valve opening" (2,3).

Dr. Rahimtoola's remarks initiated the journey to design and build more effective prosthetic valves whose true functioning opening will match the patient's opening area and produce a dynamic *in vivo* effective orifice area (EOA) that matches the normal valve function of the patient. This article is a literature review that describes the journey in

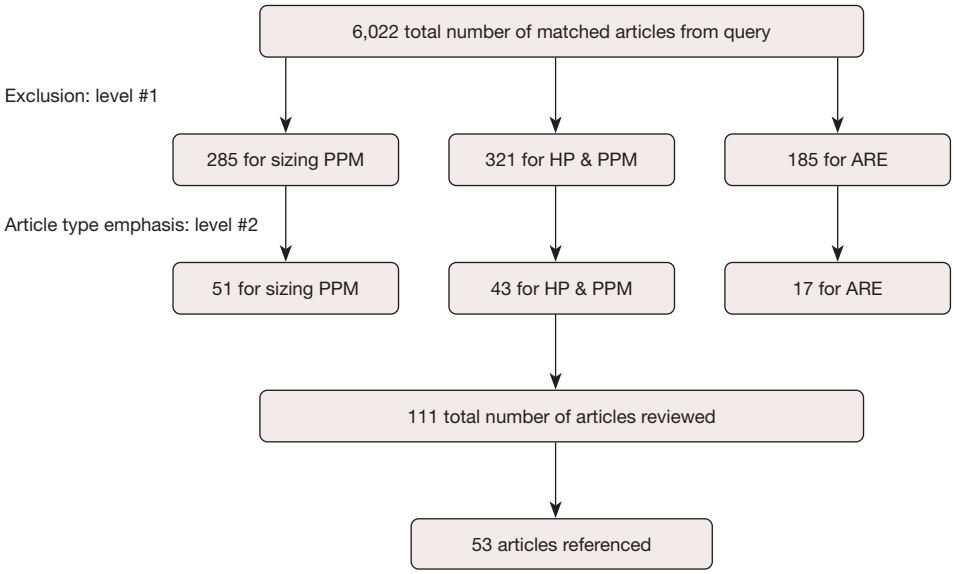

Figure 1 Depicts the schematic for the literature search and review. Three individual searches were conducted: (I) valve size and sizing techniques; (II) HP and PPM; and (III) ARE procedures. Level 1 exclusion included articles not in English, articles that involved animal research, duplicate articles, articles involving valve repair, allograft or autograft replacement and articles specific to aortic sizing and congenital heart surgery. Level 2 emphasis was placed on randomized prospective trials, large registry trials with and without propensity matching, and meta-analysis articles. HP, hemodynamic performance; PPM, prosthesis patient mismatch; ARE, aortic root enlargement.

pursuit of the Holy Grail, "The Perfect Match".

Three separate searches were performed: (I) valve size and sizing techniques; (II) hemodynamic performance (HP) and PPM; and (III) ARE. A total of 2,383 articles were identified for valve size and sizing, 2,708 articles for HP and PPM, and 931 for ARE. Excluded were articles not in English, those involving animal research, duplicates, valve repair, allograft or autograft replacement, as well as articles specific to aortic sizing and aneurysms, and congenital heart surgery. Emphasis was placed on randomized prospective trials, large registry trials with and without propensity matching, and meta-analysis articles, resulting in 51 sizing articles, 43 for PPM, and 17 for ARE, totaling 111 reviewed articles with 53 referenced (*Figure 1*).

Importance of SAVR sizing

George Christakis documented the inconsistency of the MLVS to the actual internal diameter (ID) and outer diameter (OD) of the valve by measuring *in vitro* the ID and OD of commercial aortic valves and comparing the measurements to MLVS. The MLVSs were 1 to 4 mm larger than the valve sizes measured by Christakis. He recommended standardized sizing nomenclature for all valves based on the ID and OD measurements (4). Bo Yang published a study in the *Journal of Thoracic and Cardiovascular Surgery* (*JTCVS*) in 2024 in which he measured the *in vivo* prosthetic valve opening size by placing incremental metric sizers into surgical aortic valves that were implanted and found the maximum sizer he could insert into the implanted valves was 5–7 mm smaller than the valve's MLVS (5). Yang demonstrated that a MLVS of 19- or 21-mm would allow only a 14-mm sizer; a MLVS of 23 mm would allow for a 16-mm sizer; a MLVS of 25 mm would allow for a 20-mm sizer; a MLVS of 27 mm would allow for a 22-mm sizer; and a 29-mm MLVS would allow for a 23-mm sizer. These sizing discrepancies would result in more than 50% reduction in the opening area for a MLVS 19-, 21- and 23-mm valve, and a 36% reduction for a MLVS of 25 mm valve when compared with the patient's opening area. Both studies demonstrated no correlation between the MLVS and sizer with the prosthetic valve functional opening size. In fact, using the MLVS and sizing tool, you could downsize the functional opening area of a patient with a computed tomography (CT) scan annulus diameter smaller than 25 mm anywhere from 35–55%.

The CoreValve clinical research group studied 726 SAVR and 923 transcatheter aortic valve replacement (TAVR)

patients from their randomized, prospective High-Risk TAVR and the Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trials to compare the MLVS, valve labeled ID, HP, and incidence of PPM for the different SAVR and TAVR valve types implanted into the same size multi-detector computerized tomography (MDCT) scan-measured annulus. The size, brand, and type of SAVR implanted were based upon surgeon discretion using the approved manufacturer's labeled valve sizer according to intension for use (IFU). Patients were sorted into three MDCT annular size groups: small (<23 mm), medium (23–26 mm), and large (>26 mm). Results showed the mean annular size was the same for all valve types and brands in each size group, thereby ensuring that all valves were implanted into the same size annulus. The results showed the MLVS, ID, HP, and PPM incidence varied significantly between each surgical valve type and brand implanted into the same-sized aortic annulus measured by CT scan, confirming inconsistencies between the MLVS and sizing tool of the various manufacturers, resulting in different size valves being implanted into the same aortic valve annulus (6). A subsequent commentary recommended the use of MDCT for pre-operative surgical sizing of the patient's annulus to match the most appropriate functional opening area of the type and brand of SAVR to implant in each specific patient (7).

MDCT also gives accurate measurements for the remaining anatomic components of the root, including the sinus widths and heights, coronary heights, and sino-tubular junction (STJ) size. Pollari states that surgical valves are currently placed in a supra-annular fashion. Therefore, root dimensions, rather than annular dimensions may define the choice of the SAVR size implanted because the valve's supporting structure outer dimensions vary between the different manufacturers, and the size of the root components varies dramatically between different patients with the same size annulus. Therefore, the limiting factor concerning the size of the SAVR implanted may not be the patient's annulus, but may be the size of the sinus or STJ (8). Therefore, the implanted valve should not be limited in size due to root anatomy, and a root enlargement should be performed to implant the "Best Annular Match". In Søndergaard's study of durability, almost 40% of SAVR were sizes 19 and 21 which suggests a high incidence of PPM secondary to sizing the SAVR with the manufacture's sizing tool rather than CT annular dimensions, which importantly, can lead to premature prosthesis degeneration (9).

In February 2018, the International Organization for Standardization (ISO) Task Force identified areas for sizing improvement and clarification: (I) reporting physical dimensions and characteristics of surgical valves; (II) determining and labeling of valve sizes; and (III) *in vivo* and *in vitro* testing and reporting of surgical valve HP and thrombogenicity (10).

TAVR sizing

Early TAVR experience used 2-dimensional (2D) transthoracic echocardiography (TTE) for sizing of the valve (11). However, the incidence of paravalvular leak (PVL) led to the use of MDCT for preoperative TAVR sizing (12,13). A meta-analysis by Tang, using six studies and 431 participants for MDT and 509 for TEE, showed that the use of MDCT in comparison with 2D TEE, is associated with significantly lower incidence of greater than moderate PVL after TAVR (14).

A meta-analysis comparing 3 dimensional (3D)-TEE and MDCT for TAVR aortic annular and root measurements was performed. A total of 889 patients from 10 studies were included in the meta-analysis. Pooled correlation coefficients between 3D-TEE and MDCT annulus area, perimeter, area derived-diameter, perimeter derived-diameter, maximum and minimum diameter measurements were strong: 0.89 [95% confidence interval (CI): 0.84–0.92], 0.88 (95% CI: 0.83–0.92), 0.87 (95% CI: 0.77–0.93), 0.87 (95% CI: 0.77–0.93), 0.79 (95% CI: 0.64–0.87), and 0.75 (95% CI: 0.61–0.84) (overall P<0.0001). The study implied that 3D-TEE, using novel software tools, is feasible to MDCT for annulus sizing in clinical practice (15). Currently, CT scan-derived root and annular dimensions are the standard of care in the United States (US) of America.

Importance of valve and annular size

The CoreValve research group studied the US Pivotal High-Risk Trial and SURTAVI patients to determine valve performance based on the patient's preoperative MDCT annular size. Patients were sorted into small (<23 mm), medium (23 to 26 mm), and large (>26 mm) groups. They evaluated the relationship of annular size to HP and the incidence of PPM in all patients at 3 months, 1 and 2 years. At all study times, MVGs were significantly lower for TAVR compared to SAVR in small and medium-size annuli (P<0.001). Annular size was significantly associated with MVG after SAVR, with smaller annuli having the highest

MVG (P<0.05 at all timepoints), but not in TAVR, which showed no significant difference in MVG due to annular size. PPM in SAVR was significantly associated with small annuli having the greatest incidence. No difference in PPM incidence by annular size was observed with TAVR. TAVR subjects had significantly less PPM than SAVR subjects in small and medium-sized annuli (P<0.001), with no difference in the incidence of PPM between TAVR and SAVR in large annuli (P=0.10). Annular size had a significant impact on HP and incidence of PPM in SAVR, a pattern not observed in TAVR. TAVR resulted in better HP and less PPM for annuli <26 mm (16). These significant performance differences between TAVR and SAVR can be explained by the significant downsizing of the prosthetic valve functional opening which occurs in SAVR using the manufacturer's sizing tool.

The Placement of Aortic Transcatheter Valves (PARTNER) research group also analyzed 270 SAVR and 304 TAVR patients from the PARTNER trial (Cohort A). Patients were placed into tertiles based on TTE diastolic annulus diameter into small annulus (SA, <18 mm), medium annulus (MA, ≥18 and <20 mm), and large annulus (LA, ≥20 mm) groups: SA TAVR patients had a lower incidence of severe PPM than SAVR (19.7% versus 37.5%; P=0.03). There were no differences in the rate of PPM between groups in the LA. The study supports SA SAVR leads to significantly compromised HP and a higher incidence of PPM (17).

The PARTNER research group also published data from their randomized control trial (RCT) comparing SAVR with TAVR, involving 2,134 valves with a functional internal diameter (FID) >19 mm to 130 valves with a FID ≤19 mm. Their data showed that a FID less than 19 mm may significantly increase 1-year mortality compared to a FID greater than 19 mm [hazard ratio (HR), 1.93; 95% CI: 1.03–3.61]. Small TAVR valve patients had significantly shorter lengths of stay than small SAVR (median 5 versus 9 days), significantly better postoperative MVG (13.4 versus 18.1 mmHg, P<0.006), and peak velocity (2.5 versus 2.9 m/s; P<0.003). They concluded that small valve size in SAVR patients has a significant negative impact on outcomes (18). González-Juanatey showed that small SAVR valves (FID <19 mm) have significantly less left ventricular mass regression (LVMR) when compared to larger valves (19). These findings were confirmed by an article published by Salna (20).

All the randomized prospective controlled (RPC) TAVR versus SAVR studies confirmed that a small-size annulus with a small implanted SAVR had a negative hemodynamic and clinical impact, not seen in TAVR (16-20). The reason the SAVR valves in the RPC trials showed such poor performance in the small and MA size is that the patient's prosthetic valve opening was being downsized by 4–6 mm according to Yang, using the inconsistent MLVS and sizer (5). This was verified by the CoreValve research group when they showed that different size types and brands of surgical valves were being implanted into the same-size patient annulus secondary to inconsistencies between the various manufacturers' valve sizing tools and nomenclature. The incidence of ARE in the RPC trials was approximately 4%. This translated to a 35% reduction in functioning opening area for medium-sized annulus and approximately 55% for SA SAVR patients (5). TAVR was able to minimize downsizing using CT scan-derived annular dimensions for sizing. The functional opening area of the surgical valve, not the MLVS, is the important measurement to match with the patient's annular opening area, and MDCT can provide the most accurate and reproducible area derived annular dimensions (ADADs) to allow for the "Best Prosthesis-Patient Match". The recommended way moving forward is to obtain a pre-operative CT scan ADAD for matching with the true functional opening area of the prosthetic valve (7). Whether you believe the functioning opening area of the valve is the manufacturer's measured ID (minus 0.5–1.0 mm for tissue) or 5–7 mm smaller than the MLVS, as shown by Yang, you need to match that opening with the CT-derived annular opening to maximize performance. If the anatomic parameters of the root on MDCT do not allow for implantation of the initially matched valve, then a root enlargement also should be performed.

Objective parameter to validate prosthesis patient match

Dumesnil validated the use of echocardiography Doppler flow to correlate the prosthetic valve *in vitro* area with the *in vivo* functional EOA using the patient's body surface area (BSA), demonstrating an excellent correlation between the standard and simplified continuity equations [r=0.98; standard error of estimate (SEE) ±0.07 cm^2; P<0.0095] and between *in vivo* and known *in vitro* prosthetic valve areas (r=0.86; SEE ±0.16 cm^2; P<0.0005). The peak gradient ranged from 10.8 to 75.0 mmHg (mean 35±16) and the mean gradient from 7.6 to 43.7 mmHg (mean 20.5±9.5). Correlations between prosthetic valve gradient and *in vivo* area were r=–0.53, SEE ±14 mmHg and r=–0.49, SEE

±8.63 mmHg for peak and mean gradient, respectively. These relations were further improved by indexing the valve area (i.e., EOA) to the BSA. The best correlations were obtained between indexed effective orifice area (iEOA) and a quadratic function of the gradient (r=–0.72; SEE ±11.72 mmHg and r=–0.70; SEE ±7.28 mmHg) for peak and mean gradient, respectively. This study initiated the concept of matching the prosthetic valve EOA with the BSA of the patient to establish an iEOA (21).

Pibarot determined the impact of iEOA on clinical and hemodynamic status when he published data from a group of SAVR patients evaluated by TTE at 6.2±4.4 years after implantation. Manufacturer-derived *in vitro* EOAs were available in 61 patients, allowing for the classification of patients with (0.85 cm^2/m^2 or less) or without (greater than 0.85 cm^2/m^2) PPM, based on iEOA. Follow-up clinical and hemodynamic parameters that were evaluated included NYHA class distribution, MVG, prosthetic valve area, and cardiac index. PPM was present in 32 of 61 patients (52%). Although the NYHA class of the patients was similar in both groups, HP was worse in patients with PPM as indicated by a higher MVG (22±9 versus 15±8 mmHg, P=0.002) and a lower cardiac index (3.0±0.7 versus 3.4±0.7 L/min/m^2, P=0.04). The occurrence of syncope, acute pulmonary edema, and angina pectoris was significantly higher in patients with mismatch (50% versus 21%, P=0.017). Pibarot concluded that PPM is associated with worse HP and higher prevalence of adverse clinical events (22). Pibarot, in an article review of PPM, published a three-step process and provided all the calculations and charts for a surgeon to use pre-operatively to avoid PPM when performing a SAVR (23).

The PARTNER Trial cohort A RCT patients were analyzed for PPM, LVMR and mortality among the SAVR-RCT (n=270), TAVR-RCT (n=304), and TAVR-non-randomized registry (NRCA) (n=1,637) cohorts, showing 60% PPM (severe: 28.1%) in the SAVR-RCT versus 46.4% (severe: 19.7%) in the TAVR-RCT (P<0.001) and 43.8% (severe: 13.6%) in the TAVR-NRCA. In the aortic annulus diameter smaller than 20 mm, severe PPM developed in 33.7% of SAVR cases versus 19.0% of TAVR cases (P=0.002). PPM was an independent predictor of less LVMR at 1 year in the SAVR-RCT (P=0.017) and TAVR-NRCA (P=0.012), but not in the TAVR-RCT (P=0.35). Severe PPM was an independent predictor of 2-year mortality in SAVR-RCT (HR, 1.78; P=0.041) but not in the TAVR-RCT cohort (HR, 0.58; P=0.11). In the TAVR-NRCA, severe PPM independently predicted mortality only in the subset of patients with no post-procedural PVL (HR, 1.88; P=0.02). They concluded that PPM was more frequent and severe in SAVR than TAVR, causing decreased survival and LVMR (24).

The CoreValve high-risk trial research group reported on the impact of PPM at 1 year in 389 TAVR and 353 SAVR patients. They defined PPM using the Valve Academic Research Consortium (VARC)-2 criteria. Severe PPM was significantly higher in SAVR than TAVR (25.7% versus 6.2%; P<0.0001). Indexed left ventricular mass regression at 1 year was 6.8% for TAVR and 15.1% for SAVR with severe PPM (P<0.0001). In all patients (TAVR and SAVR) both all-cause mortality and acute kidney injury were significantly greater with severe PPM (20.6% versus 12.0%; P=0.0145) and (19.2% versus 8.5%; P=0.0008) (25).

The SURTAVI trial group reported the incidence and risks associated with PPM in an additional article. The MDCT ADAD was divided by the BSA to produce an indexed annulus size (iAS). Patients were categorized into small (9–12 mm/m^2), medium (>12–14 mm/m^2), and large (>14–18 mm/m^2) iAS groups. One-year HP, PPM, and clinical outcomes were compared between TAVR and SAVR within these size groups. TAVR patients received a larger prosthesis with increasing iAS (P<0.001), while there was no difference in prosthesis size in SAVR (P=0.74). In all size groups, TAVR had significantly larger iEOAs with lower MVGs and rates of PPM versus SAVR (P<0.001). Indexed annulus size was an independent predictor of PPM after TAVR and SAVR. Clinical outcomes at one year were comparable between TAVR and SAVR across all groups. They concluded that MLVS small SAVR valves are being implanted into all annulus sizes, causing impaired HP and increased incidence of PPM; thus, more attention should be directed to the prevention of PPM in SAVR (26).

A meta-analysis of 58 studies, including 40,381 patients (39,568 SAVR and 813 TAVR), was analyzed to determine the impact of PPM on perioperative mortality and overall mortality. Perioperative and overall mortality rates were found to be increased in patients with PPM (odds ratio, 1.54; 95% CI: 1.25–1.91 and HR, 1.26; 95% CI: 1.16–1.36), respectively. The impact of PPM on mortality was higher in those studies in which the mean age of the patients was less than 70 years, encompassing AVR studies with or without associated coronary artery bypass grafting. Severe PPM was associated with increased perioperative and overall mortality, whereas moderate PPM was associated only with perioperative mortality but not with overall mortality. Predictors of PPM were older age, female sex, hypertension, diabetes, renal failure, larger BSA, larger BMI, and the

utilization of a bioprosthesis. The study group concluded that PPM proportionally increases perioperative and overall mortality according to its severity (27).

Another meta-analysis that included 34 studies comprising 27,186 patients, 1,141 patient-years, and defined PPM using VARC-2 criteria concluded that the severity of PPM increased the incidence of all-cause mortality (moderate PPM; HR =1.19; 95% CI: 1.07–1.33 and severe PPM; HR =1.84; 95% CI: 1.38–2.45), as well as cardiac-related death (moderate PPM; HR =1.32; 95% CI: 1.02–1.71 and severe PPM; HR =6.46; 95% CI: 2.79–14.97). The analysis recommended that efforts to avoid PPM be emphasized and widely adopted to improve long-term survival after SAVR (28).

Kolkailh assessed clinical outcomes and the incremental risk of PPM in 451 younger (age ≤65 years) females undergoing SAVR, using small prostheses (SP; ≤21 mm; n=256) and large prostheses (LP; ≥23 mm; n=195) prostheses. PPM was defined using VARC-2 criteria. Operative mortality was 2.4% in the SP group and 0.5% in the LP groups (P=0.146). Unadjusted 10-year survival was 82% (95% CI: 77–87%), and was similar in both groups (P=0.210). However, when grouped by standard PPM thresholds, severe PPM was associated with significantly decreased survival (P=0.007). A significant survival decrease was detected in the LP group with iEOA ≤0.75 cm^2/m^2 (P<0.001) and in SP patients, iEOA ≤0.65 cm^2/m^2 (P=0.075). After adjusting for potential confounders, the Cox proportional hazard model identified an iEOA of ≤0.65 cm^2/m^2 in the SP group (HR, 1.85; P=0.066) and ≤0.75 cm^2/m^2 in the LP group (HR, 2.3; P≤0.003) as predictors of decreased long-term survival (29).

Using the objective data parameter of iEOA and the PPM boundaries proposed by Dumesnil and Pibarot (21-23), and verified by VARC-2 the RCTs, the propensity-matched registry trials, and the major meta-analyses studies concluded that SAVR valves sized using the manufacturer's sizer in comparison to TAVR valves sized using MDCT have a significantly higher incidence of PPM in patients with low and moderate-sized annuluses, and there is a significant association of PPM with death, poor HP, and other negative clinical outcomes (24-29). This data supports both the concept of downsizing using the MLVS and sizer, with a reduction between 35–55% for moderate and small-size patient annuli (5) and the need to match the CT scan ADAD with the true functional opening of the prosthetic valve (7). This concept of mismatch due to sizing issues for SAVR explains the poor outcomes in female patients (29), who on average have smaller annuli and are being downsized by 55% for true valve opening area (5).

Aortic root enlargement (ARE) safety and reproducibility

ARE was rarely used in the SAVR arms of the TAVR versus SAVR RCTs (30-35), resulting in a high incidence of small valves being implanted to be associated with a higher incidence of PPM and poorer clinical outcomes for SAVR (16-25). There are no randomized prospective trials to determine the necessity, safety, and effectiveness of the ARE. Currently, only meta-analysis, propensity-matched registry studies (both single and multi-center), and expert opinions are available. There are three main techniques for ARE: the Nicks (36), the Manougian (36), and the Y-incision (Yang) procedures (37-39). The Y-incision technique was first published in 2021. Therefore, the data in the meta-analysis and propensity-matched papers only used data from the Nicks and the Manougian procedures.

In a meta-analysis of 10 articles, 13,174 patients (2,819 SAVR with ARE and 10,355 SAVR without ARE) were evaluated to determine the impact of ARE on the perioperative outcomes. The total rate of ARE was 21.4%, varying in the studies from 5.7% to 26.3%. The overall odds ratio (OR) for perioperative mortality showed a statistically significant higher risk in the aortic valve replacement (AVR) with ARE group (OR, 1.506; 95% CI: 1.209–1.875; P<0.001), but not when adjusted for isolated AVR with ARE without any concomitant procedures (OR, 1.625; 95% CI: 0.968–2.726; P=0.066; among six studies). The AVR with ARE group showed an overall lower risk of significant PPM among nine studies (OR, 0.472; 95% CI: 0.295–0.756; P=0.002), and a higher overall difference in mean EOA among 10 studies (random-effect model, 0.06 cm^2/m^2; 95% CI: 0.029–0.103; P<0.001) (40).

A random-effects meta-analysis including nine studies (2,570 AVR and 5,991 AVR + ARE patients) was performed to compare early and late clinical outcomes. There was no difference in early mortality [relative risk (RR), 1.21; 95% CI: 0.94–1.54; P=0.13]. Furthermore, there were no differences in the risk of permanent pacemaker implantation (RR, 1.02; 95% CI: 0.83–1.25; P=0.86), reoperation for bleeding (RR, 1.05; 95% CI: 0.84–1.32; P=0.64), or stroke (RR, 0.93; 95% CI: 0.68–1.27; P=0.65). The risk of moderate and severe PPM was lower for AVR with ARE (moderate, HR, 0.65; 95% CI: 0.51–0.83; P<0.01), and (severe, HR, 0.36; 95% CI: 0.16–0.82; P=0.01) respectively. There was no difference in

late mortality (incidence rate ratio, 1.05; 95% CI: 0.87–1.27; P=0.59) at a mean 7.8-year follow-up in five studies. It was concluded that surgical ARE is a safe adjunct to AVR in selected patients that does not increase early or late adverse events and results in less PPM (41). This strategy allows for a larger valve size at the time of implantation, an important consideration for potential future TAVR valve-in-valve procedures (41).

A multicenter propensity score-matched cohort analysis was undertaken to determine early and late mortality and safety outcomes of SAVR versus SAVR with ARE. Baseline characteristics for 16,656 patients from 11 institutions were compared using 1:1 propensity score matching to account for differences in baseline characteristics. Propensity score matching yielded 809 pairs for AVR versus AVR with ARE. There was no difference in 30-day mortality between AVR with ARE versus AVR (2.0% versus 2.1%; P=1.00). Rates of re-exploration for bleeding, permanent pacemaker implantation, and blood transfusions were similar. Late mortality over 8 years was similar between AVR with ARE and AVR (P=0.45). In a sensitivity analysis, results were similar in 525 pairs comparing AVR with ARE with coronary artery bypass grafting to AVR with coronary artery bypass grafting, except that reoperation for bleeding was higher with AVR + ARE with coronary artery bypass grafting (7.2% *vs* 3.2%; P=0.006). They concluded AVR with ARE can be safely performed to increase the size of implanted prosthesis without compromising early mortality (42).

The limitation of the Nicks and the Manougian enlargement procedures is they can upsize the valve only 1–2 sizes. The Yang Y technique increases the valve size by 2–5 sizes (38). The valve sits as a crown on the head of the left ventricular outflow tract (43). The advantage of the Y technique is the procedure does not enter the left atrium nor cut across the mitral fibrosa into or through the mitral annulus or anterior mitral leaflet, and the surgeon can still upsize 3–5 sizes to allow for the maximum increase in size to allow for a larger TAVR valve for a future transcatheter aortic valve-in-surgical aortic valve (TAV-in-SAV) procedure (44).

Yang reported clinical outcomes in 50 consecutive Y-incision ARE patients. The median age was 65 [59–71] years, with 70% being female, 26% had a previous cardiac surgery history, and 66% had isolated SAVR. The preoperative MVG was 40 [30–47] mmHg, and the native aortic annular size was 21 [19–23] mm. After ARE, the median prosthesis size was 27 [25–29] with 54% of the patients having a size 29 or the largest sized valve. The median increment of annulus enlargement was 3 valve sizes. Eighty-eight percent of patients received no blood transfusion. There was 1 stroke and no operative mortality, renal failure requiring permanent dialysis, mediastinitis, or reoperation for bleeding. Three-month postoperative computed tomography aortogram showed the aortic root was enlarged from 27 [24–30] to 40 [36–41] mm without aortic pseudoaneurysm. The postoperative mean gradient was 7 [5–8] mmHg and valve area was 1.9 [1.7–2.3] cm^2 at 3 to 12 months. Mitral and tricuspid valve functions were significantly improved. Survival was 100% at 18 months (5). A more recent report by the Bo Yang group showed data on 119 consecutive patients undergoing the Y-incision enlargement. The only differences in the outcomes from the first 50 consecutive patients reported were the median size prosthetic valve after enlargement, which had increased from 27 to 29 mm, and 63% of patients had a size 29 mm valve with a MVG of 6 mmHg and a EOA of 2.2 cm^2 for the entire cohort. There was one death (0.8%). The median incremental of enlargement was 3 valve sizes (45).

Fukuhara presented data at the 2023 Western Thoracic Surgical Association meeting on the implications of preoperative MDCT for SAVR in 1,503 consecutive procedures. The rates of ARE and preoperative SAVR CT angiography (CTA) increased over time from 5.4% and 4.7% in 2014 to 50.0% and 59.6% in 2022, respectively. He studied 373 patients with native valve AS and a pre-operative MDCT. The median age was 68.0 years, 37.0% were female, and 36.2% had a bicuspid valve. SAVR implantation techniques comprised of no ARE (n=239; 64.1%), conventional root enlargement (Nicks & Manougian) (n=72; 19.3%), and Y-incision root enlargement procedure (n=62; 16.6%), with corresponding median implanted valve sizes of 25.0 mm [interquartile range (IQR), 25.0–27.0 mm], 23.0 mm (IQR, 23.0–25.0 mm), and 27.0 mm (IQR, 25.0–29.0 mm) (P<0.001) and a corresponding PPM rate of 35.5%, 43.1% and 6.5%, respectively (P<0.001). Examining the SAVR MDCT ADAD with the implanted MLVS size revealed that the implanted SAVR size was almost always smaller in patients with no ARE or conventional root enlargement but significantly larger with Y-incision root enlargement. Based on the CTA parameters, a theoretically suitable TAVR valve for each patient was determined using both a self-expandable and a balloon-expandable device. Of these, 57 patients (15.3%) were deemed anatomically unsuitable with the self-expandable device, and 54 patients (14.5%) for the balloon-expandable device. Among patients with suitable TAVR anatomy, significant PPM was seen in

8.3% with the theoretical self-expandable device and 41.6% with the theoretical balloon-expandable device. In the subgroup analysis of SAVR to theoretical TAVR, Y-incision root enlargement was the only option that demonstrated a lower PPM rate compared to the theoretical self-expandable TAVR (3.2% versus 20.0%; P=0.008). Fukuhara concluded that the implanted SAVR size was much smaller than the preoperative MDCT ADAD. Utilizing preoperative MDCT, the risk of clinically relevant PPM and the necessity of aggressive root enlargement can be predicted, which may have a long-term favorable implication for lifetime management in younger patients. Additionally, when performed by experienced hands, SAVR using the novel Y-incision root enlargement technique even outperforms self-expandable TAVRs regarding PPM occurrence, while also optimizing the aortic root anatomy for future valve-in-valve TAVR (46).

The CoreValve research group recently presented at the Cardiovascular Research Technologies (CRT) 2023 on the 5-year incidence of bioprosthetic valve degeneration in patients randomized to SAVR or TAVR in the CoreValve United States High-Risk Pivotal and SURTAVI trials (47). The goal of the trial was to evaluate the incidence, outcomes, and predictors of long-term valve performance through assessing the 5-year bioprosthetic valve dysfunction (BVD). The four components of valve performance, as defined by the VARC-3 and European Association of Percutaneous Cardiovascular Intervention (EAPCI) consensus documents, were evaluated to determine BVD (48,49). The results indicated less BVD at 5 years in TAVR compared to SAVR (7.8% versus 14.2%; P<0.001). The difference was due to a 2-fold lower reduction in structural valve deterioration (SVD) and a 3-fold reduction in the PPM rate in TAVR patients. The difference was more profound in patients with annuli less than 23 mm (8.6% in TAVR versus 19.7% in SAVR; P<0.001). BVD imparted a 1.5-fold increased risk for all-cause mortality (P=0.004), cardiovascular mortality (P<0.001), and hospitalization for CHF (P=0.001) at 5 years. The lack of ARE in these studies, coupled with smaller surgical valves being implanted, caused a higher rate of SVD and an association with mortality (47).

Summation

The importance of the need for the "Perfect Prosthesis/Patient Match" proposed by Dr. Shahbuden Rahimtoola (3) 46 years ago has been validated by the inferior hemodynamic and clinical outcomes of SAVR compared to TAVR patients in RCTs (30-35). These poor outcomes were secondary to small surgical valves being implanted into patients (predominantly 21 & 23 mm), using the MLVS and sizer. Only 4% of patients in those trials received an enlargement. The inconsistent parameters of the manufacturer's valves were not meant to be misleading to surgeons; rather, they reflected the engineered sizes of the various components of the constructed prosthetic conduits and were not intended to convey the functional opening area of the valve.

Dumesnil defined the objective parameter (iEOA) to help identify the "Perfect Match" (21). Using iEOA as the parameter to evaluate Prosthesis-Patient match, studies by Pibarot (22,23), the PARTNER Research Group, the CoreValve Research Group, and additional individual propensity-matched trials and meta-analysis studies have demonstrated that SAVR performs significantly worse than TAVR in small and medium-sized annuli with a significantly higher incidence of severe PPM, resulting in higher mortality and worse hemodynamic and clinical outcomes (16-20,24-29,47).

The reason the SAVR valves performed worse was because the patients were unintentionally being downsized using the MLVS and sizer. Manufacturer's sizers and labeled valve size are not directly correlated to the annular size; rather, they represent measurements of the bulk of the supporting structure and do not reflect the true opening area of the valve. The CoreValve Research Group demonstrated using MDCT ADAD that different sized surgical bioprosthetic valves were being implanted into the same size patient annulus depending on the type and brand of valve (6). Christakis (4) actually measured the valves and found no correlation between the MLVS and the functional opening of the prosthetic valve. Yang demonstrated that the actual functioning opening area of the implanted prosthetic valve was 5–7 mm smaller than the MLVS. The table developed by Yang showed the percentage of downsizing (35–55%) that occurred in implanted valves between the MLVS and the actual opening size of the valve (5). Smaller patient annuli led to a greater percentage of downsizing, resulting in worse clinical and hemodynamic outcomes in SAVR patients. This phenomenon explains the poorer outcomes in female patients undergoing SAVR, as they have smaller annuli and are more at risk for PPM and adverse outcomes. The CoreValve Research group also showed the significant difference in the BVD in the RCTs favoring TAVR, which should have a long-term negative impact on the durability and mortality of the SAVR group (47).

It has been proposed to use a preoperative MDCT scan

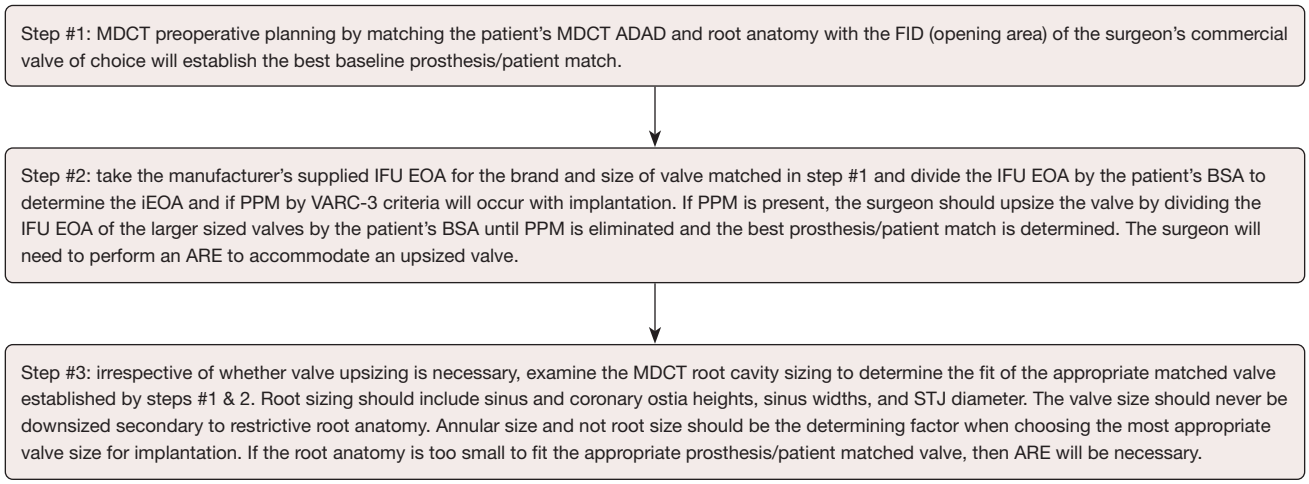

Figure 2 Depicts the suggested three-step process surgeons can perform for pre-operative planning to ensure the best prosthesis/patient match using the VARC-3 guidelines for PPM. MDCT, multi-detector computerized tomography; ADAD, area derived annular dimension; FID, functional internal diameter; IFU, intention for use; EOA, effective orifice area; BSA, body surface area; iEOA, indexed effective orifice area; PPM, prosthesis-patient mismatch; ARE, aortic root enlargement; STJ, sino-tubular junction.

as the method for sizing the patient's annulus for SAVR (6,7). This approach would allow the surgeon to match the functional opening of the prosthetic valve of choice with the CT scan ADAD. It also provides the surgeon with root measurements and allows for pre-operative determination if an ARE is needed (47).

The large meta-analysis and propensity-matched studies comparing AVR versus AVR with ARE showed no differences in short term outcomes between the groups. These studies confirm that ARE does not contribute to the mortality and morbidity of the procedure. However, the studies did show the hemodynamic benefits of ARE, resulting in significantly higher EOAs and lower incidences of PPM. Importantly, these studies did not compare patients with matched aortic annulus size. Instead, most studies compared patients with large annuli who did not need ARE to patients with small annuli who needed ARE. Despite that disadvantage, the studies showed no difference in perioperative outcomes. Without ARE, those patients in the AVR with ARE group would have had higher rates of PPM and worse long-term mortality.

Whether you are convinced with Yang's measurements of the functional opening portion of the prosthetic valve or you are more comfortable with the IFU ID minus 0.5–1.0 mm for tissue as your functional opening of the prosthesis, you will need to match the functional opening of the prosthetic valve with the CT-derived annular opening of the patient for the "Best Match". According to the Yang Table of Measured Functional Internal Diameters, if the CT scan-derived annular ID is ≤20 mm, implant a valve with MLVS of 25 mm; if the CT ID is 21–23 mm, implant a valve with MLVS 27 or 29 mm depending on the patient's size; if the CT ID is >23 mm, implant a valve with a MLVS of 29 mm. This technique will upsize the MLVS by 3 sizes. If you believe the functional area of the valve is IFU ID minus 0.5–1.0 mm, then calculate your opening and match it to the patient's annular opening based on the preoperative CT scan derived ADAD. Then, take the IFU EOA of the valve of your choice and divide it by the patient's BSA to determine the patient's iEOA and determine if PPM is present. If present, then upsize until the calculation shows no PPM (*Figure 2*). Another useful way of determining the valve size for implantation is to directly measure the aortic annulus using the manufacturer's sizing tool and upsize by 3 valve sizes since the effective orifice diameter of the MLVS is 3–6 mm (3 valve sizes) smaller than the labeled valve size, and the functional opening of the upsized valve is equal to the native aortic annular size. In larger annuli (i.e., ≥29 mm), you will be restricted by the availability of valve sizes.

Do not oversize your SAVR valve greater than the matching of the SAVR opening area with the CT scan-derived annular dimensions, especially in patients with low-positioned coronary arteries, as you do not want to compromise coronary access for future percutaneous coronary interventions (PCIs). To effectively compete with TAVR for HP, the incidence of PPM, BVD, and clinical

outcomes in patients with small and medium-sized annuli (<26 mm), surgeons must become comfortable with the Y enlargement procedure. Implanting a larger SAVR valve will also allow for a larger TAVR for a future TAV-in-SAV procedure, which will result in a better outcome for the procedure (44,50,51).

We have traveled many miles on our journey in pursuit of the Holy Grail in aortic valve surgery. We now realize the "Perfect Match" is more attainable by sizing the patient's annulus using pre-operative CT scan ADAD, matching the ADAD of the patient with the true functional opening of the prosthetic valve, and determining the necessity of ARE to ensure implantation of a valve size that will avoid PPM.

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Footnote

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