Patient-Prosthesis Mismatch Has No Influence on In-Hospital Mortality after Aortic Valve Replacement

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Objective: *To analyze the relationship between prosthetic aortic valve orifice and body surface area (Effective Orifice Area Index, EOAI) and in-hospital mortality after aortic valve replacement.*
Material and Method: *A prospective study was conducted between October 2007 to September 2010, 536 patients underwent isolated aortic valve replacement (AVR) was recorded on preoperative, operative and postoperative data. Patient Prosthesis Mismatch (PPM) was classified by Effective Orifice Area Indexed (EOAI) by prosthetic valve area divided by body surface area as mild or no significance if the EOAI is greater than 0.85 cm^2/m^2, moderate if between 0.65 cm^2/m^2 and 0.85 cm^2/m^2, and severe if less than 0.65 cm^2/m^2. Statistical differences were analyzed by Chi-square and student t-test with p-value less than 0.05 considered significant.*
Results: *There were 304 men, mean age was 60.98 years, mean valve orifice area 1.69 cm^2, body surface area 1.60 m^2, cross clamp time 1.13 hrs., bypass time 1.67 hrs. Mechanical valves were used in 274 patients (51.2%) and Bioprosthesis were used in 181 patients (48.8%). PPM was found in 33.7%, 6.7% was severe PPM, 27% was moderate PPM and 66.3% has no significant PPM. Over all in-hospital mortality was 1.5%. There was no significant difference in hospital mortality between no PPM group, moderate PPM and severe PPM group (1.4% vs. 1.4% vs. 5.4%, p-value = 0.86).*
Conclusion: *In a large aortic valve surgery population, moderate and severe patient prosthesis mismatch occurred in 35.6% of patients but had no influence on in-hospital mortality.*

Keywords: *Patient-prosthesis mismatch, Effective orifice area indexed, Aortic valve surgery*

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Patient-prosthesis mismatch (PPM) is presented when the prosthesis used for aortic valve replacement is too small in relation to patient body size. According to the original definition published by Rahimtoola[1] in 1978, "mismatch can be considered to be present when the effective prosthetic valve area, after insertion into the patient, is less than that of a normal human valve". PPM is defined as an EOAI (Effective Orifice Area Indexed) to Effective Orifice Area divided by Body Surface Area[2-5]. Pibarot[6], more recently, has divided mismatch into 2 entities: severe mismatch defined by the presence of an effective orifice area indexed (EOAI) $\leq$ 0.65 cm^2/m^2 and moderate mismatch with EOAI values between 0.65 cm^2/m^2 and 0.85 cm^2/m^2. PPM occurs in 20-70% of aortic valve replacements[3] and generates higher transvalvular gradients[7,8]. PPM has also been associated with LV outflow obstruction and persistent LV hypertrophy[9,10], increased early and late mortality[3,9], decreased late survival[5,11] and high incidence of late adverse complications[4,12]. This subject is still a matter of controversy in the authors modern cardiac surgery. On one hand, several studies have demonstrated favorable results despite the occurrence of PPM after aortic valve replacement with the use of third generation prosthesis[13-15]. On the other hand, other studies have found this mismatch as a strong and independent predictor of short-term and late mortality among patients undergoing aorticvalve replacement and its impact was related both to itsdegree of severity and the status of left ventricularfunction[3,9]. So, the present study aimed to determine whether PPM is always tolerable in our current practice and the potential

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influence on aortic valve replacement outcomes in the presence of PPM.

Material and Method

From October, 2008 to September, 2010, a total of 536 patients who had undergone aortic valve replacement (AVR) were consecutively studied at Central Chest Institue of Thailand. The patients undergoing isolated AVR for aortic valve stenosis or mixed aortic valve disease were included. The following patients were excluded: those who underwent previous cardiac surgical procedures, multiple valve operation, valve endocarditis and concomitant coronary artery bypass grafting. Effective valve orifice area was obtained by reference table based on mean EOA values of the different prostheses, types and sizes (Table 1). Body surface area was calculated from the Mosteller formula[16]. The EOAI was calculated by dividing the EOA by the patient's body surface area. Moderate mismatch was assumed to be present if the anticipated EOAI was $\leq$ 0.85 cm^2/m^2 and > 0.65 cm^2/m^2. Severe mismatch was assumed to be present if the EOAI was $\leq$ 0.65 cm^2/m^2.

Statistical analysis

Categorical data were summarized using frequency and percentages while continuous data were summarized using mean $\pm$ standard deviations (SD). Chi-square tests were used to compare the outcomes. Statistical significance was determined as p-value less than 0.05.

Results

Preoperative and surgical characteristics of study patients

536 patients were enrolled in the present study. Mean age was 60.9 years and 56.7% were male. Mean LV function was 60.7% and 12.8% had poor LV function with ejection fraction less than 30%. Etiology of the disease mostly are stenotic lesion of 74.2% and was corrected with bioprosthesis of 48.8% which had mean orifice diameter of 22 mm and mean orifice area of 1.06 cm^2. Mean body surface area of the patient were 1.6 m^2. Calculated from the formula of Equation 1, the mean indexed EOA in the whole study was 1.8 $\pm$ 0.37 cm^2/m^2 (Table 2). The frequency distribution of EOAI is shown in Fig. 1. Severity of PPM was classified by EOAI which showed severe PPM of 6.7% and moderate PPM of 27%. There was no difference of sex, age, LV function, X-clamp time, CPB time between no PPM group, moderate PPM group and severe PPM group (Table 3).

Morbidity and in-hospital mortality

Univariate comparisons of postoperative morbidity in all groups of patients are presented in Table 4. There were no significant differences between groups with respect to most of the common post-operative complications, although low cardiac output incidence was significantly higher in patients with significant PPM (p-value = 0.02). In the present study, 9 patients died corresponding to an overall in-hospital mortality of 1.7% (9/536 patients). There was no difference on in-hospital mortality with respect to severity of PPM (Table 4).

Discussion

In patients with a small aortic root, it is difficult

$$BSA(m^2) = \sqrt{\frac{Wt(kg) \times Ht(cm)}{3600}}$$

Equation. 1 Mosteller formula to calculate body surface area

Table 1. Normal Reference Values of Effective Orifice Areas for the Prosthetic Valves

Type of Valve	No. 17	No. 19	No. 21	No. 23	No. 25	No. 27
St. Jude	1.0	1.3	1.6	1.8	2.4	2.7
On-X valve	-	1.5	1.8	2.3	2.7	-
Medtronic	-	-	1.74	2.26	3.07	3.64
Mira	-	-	2.27	2.83	3.45	4.14
Mira utra finesse	-	1.76	2.27	2.83	-	-
Sorin Fit Line	-	1.58	2.03	2.57	3.2	3.86
Sorin Slim line	1.58	2.03	2.57	3.2	3.86	4.73
Tissue CEPB	-	0.9	1.2	1.1	1.5	2.4
Tissue Perimount	-	1.24	1.45	1.63	-	-
Tissue Magna	-	1.58	1.9	2.07	2.33	-

to implant proper large valve prosthesis. Consequently, PPM is the immediate consequence of the aortic valve surgery. This sequele was addressed by Rahimtoola[1] as being present when the EOA of the prosthesis being implanted is less than that of the normal native aortic valve. Based on this definition, most patients undergoing aortic valve replacement would have at least mild PPM. The residual transvalvular pressure gradient (PG) is the most commonly used indicator to assess the residual obstruction of the prosthesis and is exponentially correlated with the EOAI.

In the present study, EOAI has been used to estimate PPM. Nowadays, the EOAI is the only parameter which demonstrated as being valid to demonstrate PPM[5]. Thus, the EOAI can be decreased within a wide range without significantly changing the

Table 2. Overall demographic data of the study population (n = 536)

Characteristics	Results
Age (mean, years)	60.98 ± 12.5
Sex (% Male)	56.7
LVEF (%)	60.7 (17)
LVEF < 30% (%)	12.8
X-clamp time (hrs) (mean ± SD)	1.13 ± 0.4
CPB time (hrs) (mean ± SD)	1.67 ± 0.8
Prosthesis type (%)	
Bioprosthesis	48.8
Mechanical	51.2
Pathology(%)	
Stenosis	74.2
Regurgitation	25.8
Orifice diameter (mm) (mean ± SD)	22 ± 2.4
Orifice area (cm^2) (mean ± SD)	1.06 ± 0.4
Indexed orifice area (cm^2/m^2) (mean ± SD)	1.8 ± 0.37
Body surface area (m^2) (mean ± SD)	1.6 ± 0.2

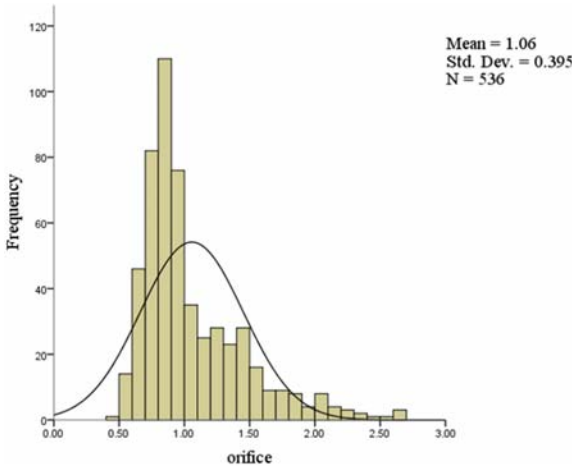

Fig. 1 Distribution of calculated indexed EOA (cm^2/m^2) in the whole cohort

Table 3. Characteristics and clinical outcomes of the patients undergoing aortic valve surgery according to severity of PPM

Patient Characteristics	NO PPM (n = 355)	Moderate PPM (n = 144)	Severe PPM (n = 37)	p-value
Age (mean, years)	60.4 ± 10.8	61.4 ± 9.4	64.8 ± 10.8	0.2
Sex (% Male)	54.7	60.4	56.8	0.3
LVEF (%)	68 ± 14	57 ± 12	59 ± 14	0.08
LVEF < 30% (%)	9.7	13.4	12.7	0.09
X-clamp time (hrs)	1.08 ± 0.4	1.15 ± 0.2	1.2 ± 0.7	0.5
CPB time (hrs)	1.4 ± 0.6	1.8 ± 0.7	1.9 ± 0.5	0.09
Prosthesis type (%)				
Bioprosthesis	45	44	75	0.9
Mechanical	55	56	25	
Pathology (%)				
Stenosis	68.4	72	74.4	0.08
Regurgitation	31.6	28	25.6	
Mean orifice area (cm^2)	1.4 ± 0.12	0.73 ± 0.14	0.59 ± 0.2	0.001*
Body surface area (m^2)	1.54 ± 0.8	1.64 ± 0.9	1.67 ± 0.4	0.22
Orifice diameter (mm)	21 ± 1.6	19 ± 1.4	18 ± 1.2	0.001*
Orifice area (cm^2)	1.3 ± 0.22	1.1 ± 0.11	1.0 ± 0.05	0.001*
Indexed orifice area (cm^2/m^2)	1.1 ± 0.11	0.7 ± 0.2	0.6 ± 0.02	0.01*

* Significant at p-value < 0.05, Data were presented as (mean ± SD) or as percentage

Table 4. Postoperative morbidity and mortality

Patient Characteristics	NO PPM (n = 355)	Moderate PPM (n = 144)	Severe PPM (n = 37)	p-value
Low cardiac output	18 (5.0)	8 (5.5)	4 (10.8)	0.02*
AV block	9 (2.2)	3 (2.1)	2 (5.4)	0.31
Postoperative stroke	6 (1.4)	2 (1.4)	2 (5.4)	0.22
Postoperative renal failure	14 (2.8)	8 (5.5)	4 (10.8)	0.08
Respiratory failure	9 (2.5)	5 (3.5)	3 (8.1)	0.09
Pneumonia	4 (1.1)	2 (1.4)	2 (5.4)	0.52
Reoperation for bleeding	9 (2.5)	4 (2.8)	3 (8.1)	0.09
Mortality (%)	5 (1.4)	2 (1.4)	2 (5.4)	0.86

*Significant at p-value < 0.05, Data were presented as percentage

PG until reaching a value of 0.85cm^2/m^2, when a steep increase in PG occurs. On the basis of this hemodynamic principle, itiswidely accepted that PPM (IEOA, $\leq$ 0.85 cm^2/m^2) should be avoided.

There are some debates of the insult of significant PPM. Hanayama[17] compared patients with and without PPM and demonstrated that patients with PPM had similar postoperative mean gradient, reduction in left ventricular hypertrophy, intermediate-term survival and freedom from symptoms. Their data suggested that even with the most conservative definition of PPM, there is no significant survival or hemodynamic difference between patients in the two groupswho have PPM and no PPM.

Pibarot P[2], who have championed the PPM theory, studied the impact of PPM on survival and found no difference between those with and without mismatch (7-year survival, 79% $\pm$ 3% and 75% $\pm$ 4%; p = 0.59, for non-mismatch and mismatchgroups, respectively). Rao[9] studied PPM in 2,504 patients undergoing aortic valve replacement. They demonstrated only valve-related mortality was higher in the PPM group at 10 years, but overall survival was no different. However valve-related mortality are totally unrelated to PPM (embolic stroke, valve failure, endocarditis, bleeding, reoperation and so forth). He GW[18], who assessed 30-year survival after aortic valve replacement in the small aortic root, concluded that body surface area (even in this high-risk group) influenced survival only in patients with concomitant coronary artery bypass grafting. Sawant[19] demonstrated that in patients with small aortic roots, body surface area and valve size were not determinants of long-term survival. Nevertheless, long-term sequele of PPM has no conclusion. Kohsaka[20] and Tasca[21] analyzed patients with pure aortic valve stenosis reporting a higher late-term mortality of patients with moderate mismatch.

Equally, Walther[22] was able to show that moderate mismatch was a predictor of adverse outcome after AVR. Florath[23] and Mohty[24] were able to show independently that severe PPM, but not moderate PPM, was an independent risk factor for late survival. Yap[25] confirmed that severe PPM was independently associated with higher early mortality. To prevent this event, Castro[26] routinely use aortic root enlargement as part of one strategy to avoid PPM defined as EOAI less than 0.85 cm^2/m^2 in patients with relatively small aortic roots who are undergoing AVR with 30-day mortality of 0.9%.

Although these procedures such as the Nicks procedure[27], the Manouguian technique[28] or the Konno procedure[29] have been frequently performed with good results, some authors have reported increased operative mortality[4]. It is clear that when performing these types of procedures, there is an increase in cross-clamptime[30]. This variable has been suggested to be associated with increased mortality following AVR, particularly in the elderly[31]. Contrary to other risk factors for short-term mortality, moderate-severe PPM can be largely prevented by implementing a simple three-step previously validated prospective strategy as follows[5] (1) Calculate patient's body surface area from patient's weight and height; (2) Multiply body surface area by 0.85, the result being the minimal EOA that the prosthesis tobe implanted should have in order to avoid moderate-severe PPM and (3) Verify if the reference EOA (see Table 1) for the model and size of prosthesis selected by the surgeon is equal or greater than the result of step 2; if not, there is a risk of moderate-severe PPM and the surgeon should either attempt to implant another type of

prosthesis with a larger EOA. The use of a stent less bioprosthesis has been proposed as an alternative to annulus enlargement when facing the possibility of PPM. This type of prosthesis has been said to have an excellent hemodynamic profile and resembles native aortic valve function when assessed by transthoracic echocardiography (TTE) postoperatively or alternatively perform an aortic rootenlargement to accommodate a larger valve of the same type[32].

In conclusion, the authors have found no influence of moderate-severe patient prosthesis mismatch on in-hospital mortality. Nevertheless, there is controversy in mid- and long- term effect of patient prosthesis mismatch, preventive implication might be routinely used with caution.

Potential conflicts of interest

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ผลของการเปลี่ยนลิ้นหัวใจเทียมที่มีขนาดเล็กเมื่อเทียบกับพื้นที่ผิวร่างกายต่ออัตราการเสียชีวิตหลังผ่าตัดเปลี่ยนลิ้นหัวใจเอออร์ติกในสถาบันโรคทรวงอก

ชัยวุฒิ ยศถาสุโรดม, เกรียงไกร นามไธสง, ปราโมทย์ ปรปักษ์ขาม, ชูศักดิ์ เกษมศานติ์, ทวีศักดิ์ โชติวัฒนพงษ์, ประดิษฐ์ชัย ชัยเสรี, สุวรรณี วงษ์ดิษฐ์, สุวรรณา ยโสธรินทร์

ภูมิหลัง: *การผ่าตัดเปลี่ยนลิ้นหัวใจเอออร์ติกด้วยลิ้นหัวใจเทียมที่มีขนาดเล็กเมื่อเทียบกับขนาดของร่างกายยังเป็นที่ถกเถียงว่าจะทำให้ผู้ป่วยยังมีความผิดปกติ เกิดภาวะแทรกซ้อนทั้งระยะสั้นและระยะยาว จนทำให้ต้องมีการผ่าตัดขยายฐานลิ้นหัวใจเพื่อให้ใส่ลิ้นหัวใจเทียมขนาดใหญ่ขึ้น ซึ่งเป็นการผ่าตัดที่มีความเสี่ยงสูง*

วัตถุประสงค์: *เพื่อศึกษาถึงผลการผ่าตัดเปลี่ยนลิ้นหัวใจเทียมที่ตำแหน่งเอออร์ติกที่มีขนาดพื้นที่รูเปิดของลิ้นหัวใจเทียมน้อยเมื่อเทียบกับพื้นที่ผิวร่างกายของ ผู้ป่วยโรคลิ้นหัวใจเอออร์ติกต่ออัตราการเสียชีวิตหลังการผ่าตัดในช่วงระยะแรกและภาวะแทรกซ้อนที่เกิดขึ้น*

วัสดุและวิธีการ: *เป็นการศึกษาไปข้างหน้าตั้งแต่ตุลาคม พ.ศ. 2550 ถึงกันยายน พ.ศ. 2553 ในผู้ป่วย 536 ราย ได้รับการผ่าตัดเปลี่ยนลิ้นหัวใจเอออร์ติกเทียม ได้รับการเก็บข้อมูลในเรื่องเกี่ยวกับข้อมูลพื้นฐานของผู้ป่วย ชนิดและขนาดของลิ้นหัวใจเทียม พื้นที่ผิวร่างกายและคำนวณหาอัตราส่วนระหว่างพื้นที่รูเปิดของลิ้นหัวใจเทียมกับพื้นที่ผิวร่างกายซึ่งแบ่งออกเป็น 1) ความรุนแรงมากเมื่ออัตราส่วนน้อยกว่า 0.65 ตารางเซนติเมตร/ตารางเมตร 2) ความรุนแรงปานกลาง เมื่ออัตราส่วนอยู่ระหว่าง 0.65-0.85 ตารางเซนติเมตร/ตารางเมตร และ3) ความรุนแรงน้อย เมื่ออัตราส่วนมากกว่า 0.85 ตารางเซนติเมตร/ตารางเมตร รวมทั้งภาวะแทรกซ้อนหลังผ่าตัดหรือการเสียชีวิต และเปรียบเทียบปัจจัยระหว่างความรุนแรงโดยใช้ Chi-square และ student t-test ที่ p-value น้อยกว่า 0.5*

ผลการศึกษา: *จากผู้ป่วยที่ได้รับการผ่าตัดมีเพศชาย 304 ราย (56.7%) อายุเฉลี่ย 60.98 ปี พื้นที่รูเปิดของลิ้นหัวใจเทียมเฉลี่ย 1.06 ตารางเซนติเมตรพื้นที่ผิวร่างกาย 1.6 ตารางเมตร ลิ้นหัวใจเทียมที่ใช้เป็นลิ้นหัวใจโลหะจำนวน 274 ราย (51.2%) และเป็นลิ้นหัวใจเนื้อเยื่อ จำนวน 181 ราย (48.8%) อัตราส่วนระหว่างพื้นที่รูเปิดของลิ้นหัวใจเทียมเทียบกับพื้นที่ผิวของร่างกายผู้ป่วยที่มีความรุนแรงมากพบได้ 6.7% ความรุนแรงปานกลาง 27% โดยไม่พบความแตกต่างของอัตราการเสียชีวิตหลังผ่าตัดในช่วงระยะแรก (1.4% vs. 1.5% vs. 1.7%, p-value = 0.86)*

สรุป: *จากข้อมูลผู้ป่วยที่ได้รับการผ่าตัดลิ้นเปลี่ยนหัวใจเทียมที่ตำแหน่งเอออร์ติกที่มีขนาดพื้นที่ผิวของรูเปิดเมื่อเทียบกับพื้นที่ผิวผู้ป่วยแตกต่างกันมาก โดยน้อยกว่า 0.65 ตารางเซนติเมตร/ตารางเมตร และอยู่ระหว่าง 0.65-0.85 ตารางเซนติเมตร/ตารางเมตร ไม่เพิ่มอัตราการเสียชีวิตหลังผ่าตัดและภาวะแทรกซ้อนหลังผ่าตัด*