Original Article

ผลการรักษาในระยะยาวของผู้ป่วยที่ได้รับการผ่าตัดใส่ลิ้นหัวใจเทียมชนิดทำด้วยโลหะ

สมชาย ไวกิตติพงษ์

Long-term Outcomes of Patients with Mechanical Valve Replacement.

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บทคัดย่อ:

วัตถุประสงค์: เพื่อรายงานการเกิดภาวะแทรกซ้อนในระยะยาวและการอยู่รอดของผู้ป่วยที่ได้รับการผ่าตัดใส่ลิ้นหัวใจเทียมชนิดทำด้วยโลหะ

วัสดุและวิธีการ: เป็นการศึกษาย้อนหลังจากประวัติการรักษาในเวชระเบียนของผู้ป่วย 260 ราย ที่ได้รับการผ่าตัดใส่ลิ้นหัวใจเทียม ระหว่างมกราคม พ.ศ. 2544 ถึง ธันวาคม พ.ศ. 2555 โอกาสการเกิดภาวะแทรกซ้อนและการอยู่รอดของผู้ป่วยได้รับการวิเคราะห์ด้วย Kaplan-Meier analysis ผู้ป่วยที่ไม่ได้มาตรวจติดตามจะถูกค้นหาว่ายังมีชีวิตอยู่หรือไม่จากฐานข้อมูลทะเบียนราษฎร์ กรมการปกครอง

ผลการศึกษา: ในระหว่างติดตามพบผู้ป่วย 63 ราย เกิดภาวะแทรกซ้อน ในจำนวนนี้ 40 ราย เสียชีวิต อัตราการรอดพ้นจากภาวะแทรกซ้อนของการมีลิ้นหัวใจเทียมชนิดทำด้วยโลหะที่ 5 ปี และ 10 ปี เท่ากับร้อยละ 75.4 และร้อยละ 69.2 ตามลำดับ และอัตราการรอดพ้นจากการเสียชีวิตที่เนื่องมาจากการมีลิ้นหัวใจเทียมชนิดทำด้วยโลหะที่ 5 ปี และ 10 ปี เท่ากับร้อยละ 85.8 และร้อยละ 80.5 ตามลำดับ

สรุป: ผลการรักษาในระยะยาวของผู้ป่วยที่ได้รับการผ่าตัดใส่ลิ้นหัวใจเทียมชนิดทำด้วยโลหะของการศึกษานี้ใกล้เคียงกับการศึกษาอื่น ข้อมูลที่ได้จากการศึกษานี้สามารถนำไปใช้อ้างอิงสำหรับการศึกษาต่อไปเกี่ยวกับการดูแลผู้ป่วยที่ผ่าตัดใส่ลิ้นหัวใจเทียมได้

คำสำคัญ: การผ่าตัดเปลี่ยนลิ้นหัวใจเทียมชนิดทำด้วยโลหะ, ผลของการรักษาในระยะยาว, ลิ้นหัวใจเทียมชนิดทำด้วยโลหะ

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Abstract:

Objective: To report the long-term outcomes of patients with mechanical valve replacement in terms of valve related complications and death.

Material and Method: The medical records of 260 patients who underwent mechanical valve replacement between January 2001 to December 2012 were retrospectively reviewed. Late valve related complications and death rates were calculated with Kaplan-Meier analysis. The status of the patients who were lost during follow up was retrieved from Registration Database of Department of Provincial Administration.

Results: During follow up time, 63 patients (26.9%) developed valve related complications. Of these, 40 patients died. The valve-specific complication-free survival rates at 5 and 10 years were 75.4% and 69.2% respectively. The valve-specific survival rates at 5 and 10 years were 85.8% and 80.5% respectively.

Conclusion: The long-term outcomes of patients with mechanical valve replacement in this study was comparable to other studies. The data from this study could be a reference for further study in the management of patients with prosthetic heart valve.

Keywords: long-term outcomes, mechanical valve, mechanical valve replacement

Introduction

The major problem of mechanical valve replacement is late valve related complications due to life long risks of thromboembolism or bleeding from anticoagulant drugs. The long term outcomes of patients with mechanical valve replacement therefore may be unsatisfactory. However, with our knowledge there was no report of the long-term outcomes of the patients with mechanical valve replacement in Thailand. The aim of this study was to report the local data of the long-term outcomes of patients with mechanical valve replacement.

Material and Method

All the medical records of consecutive patients who underwent mechanical valve replacement at Yala Hospital from January 2001 to December 2012 were retrospectively reviewed. The status of the patients who were lost during follow up was retrieved from Registration Database of Department of Provincial Administration.

The outcomes of the patients were defined as late valve related complications and death according to the guidelines for reporting mortality and morbidity after cardiac valve interventions.[1] Valve-related mortality is any death caused by structural valve deterioration, nonstructural dysfunction, valve thrombosis, embolism, bleeding event, or operated valve endocarditis, death related to reintervention on the operated valve; or sudden, unexplained death. A sudden, unexplained death is one in which the cause of death has not been determined by clinical investigation or autopsy findings and the relationship to the operated valve

is undefined. These deaths should be reported as a separate category, but also included in valve-related mortality.[1]

For this study, if the patient was lost during follow up and the records from the Registration Database of Department of Provincial Administration showed that the patient was dead, the cause of death would be defined as sudden unexplained death.

This study has been approved by the committee on ethical research of Yala Hospital. All statistical data were analyzed with program Statistical Package for the Social Science for Windows (SPSS) version 17.0. Categorical variables were expressed as frequencies and percentages. Continuous variables were expressed as means ± SE. Valve-related events, including late complications and death, were reported in a time-related manner with Kaplan-Meier analysis.

Results

From January 2001 to December 2012, there were 260 patients who underwent mechanical valve replacement from Yala Hospital. There were 10 hospital deaths. Sixteen patients were lost during follow up and their status could not be retrieved from Registration Database of Department of Provincial Administration. Thus, there were 234 patients (90%) remaining in the study. Follow up time ranged from 2 to 152 months, mean 83.9± 2.9 months.

There were 95 males and 139 females. Age ranged from 12 to 65 years, mean 36.4±0.8 years. The most common diagnosis was rheumatic valvular heart disease in 214 patients (91%). The operations performed were as follows: mitral valve replacement (MVR) 149, aortic valve replacement (AVR) 34, mitral with aortic valve replacement (DVR) 41, aortic valve replacement with mitral valve repair 9, and tricuspid valve replacement 1 (Table1).

Table 1 Patients characteristics

Characteristics	Number (%)
Number of patients	234
Mean age (years), mean±SE	36.4±0.8
Range (years)	12-65
Sex	
Male	95 (40.6)
Female	139 (59.4)
Diagnosis	
Rheumatic valvular heart disease	214 (91.0)
Infective endocarditis	8 (3.4)
Degenerative valve	6 (2.4)
Bicuspid aortic valve	4 (1.7)
NYHA functional classification	
I	1 (0.4)
II	87 (37.0)
III	138 (58.7)
IV	8 (3.4)
Rythym	
Atrial fibrillation	140 (59.6)
Previous operation	
Closed mitral valvulotomy	19 (8.1)
Mitral valve repair	6 (2.5)
Balloon mitral valvulotomy	5 (2.1)
Operation performed	
Mitral valve replacement	149 (63.6)
Aortic valve replacement	34 (14.5)
Mitral with aortic valve replacement	41 (17.5)
Mitral valve repair with aortic valve replacement	9 (3.8)
Tricuspid valve replacement	1 (0.4)

NYHA=New York Heart Association, SE=standard error

During follow up time, 63 patients (26.9%) developed valve related complications. Of these, 40 patients (17%) died. Valve related complications were as follows: sudden unexplained death 27, major bleeding 14, cerebral haemorrhage 9, cerebral emboli 7, valve thrombosis 5, and endocarditis 1. Valve related deaths were as follows: sudden unexplained death 27, cerebral haemorrhage 8, valve thrombosis 4, and endocarditis 1 (Table 2).

Table 2 Late valve related complications and deaths

Late complication	N	Died
Sudden unexplained death	27	27
Major bleeding (excluding cerebral haemorrhage)	14	0
Cerebral haemorrhage	9	8
Cerebral emboli	7	0
Prosthetic valve thrombosis	5	4
Prosthetic valve endocarditis	1	1
Total	**63**	**40**

Valve-specific complication-free survival rates at 5 and 10 years were 75.4% and 69.2% respectively (Figure 1). Valve-specific survival rates at 5 and 10 years were 85.8% and 80.5% respectively (Figure 2). For patients having DVR, valve-specific complication-free survival rates at 5 year and valve-specific survival rates at 5 year were 72.6% and 87.7%, respectively. For patients having MVR, valve-specific complication-free survival rates at 5 year and valve-specific survival rates at 5 year were 73.2% and 83.9%, respectively. For patients having AVR, valve-specific complication-free survival rates at 5 year and valve-specific survival rates at 5 year were 85.8% and 92%, respectively (Figure 3 and 4).

There was one reoperation. A forty-eight year old woman who underwent mitral valve replacement due to rheumatic valvular heart disease ten years after her original operation developed severe aortic regurgitation and tricuspid regurgitation. The aortic valve replacement with tricuspid annuloplasty was performed with uneventful recovery. Her prosthetic mitral valve was still in good function.

Discussion

Long-term outcomes of patients with mechanical valve replacement vary among reports depending on the patients population. Patient with higher risk factors for thromboembolism and those with risk factors for anticoagulation will have a higher incidence of valve related complications. Khan and colleagues[2] reportd freedom from all valve reported complications for patients having mechanical valve replacement. For patients having MVR, freedom from all valve related complications at 5 and 10 years were 76±2.4% and 65±3.1%, respectively. For patients having AVR, freedom from all valve related complications at 5 and 10 years were 80±1.8% and 65±2.8%, respectively. Svennevig and colleagues[3] reported twenty-five year experience with the mono-leaflet mechanical valve for 816 patients undergoing AVR. The survival rate at 5 and 10 years were 78.6% and 61.9%, respectively. The mean age of patients in this report was 54±13.6 years which was higher than our report. Toole and colleagues[4] reported twenty-five experience with the bi-leaflet mechanical valve for 945 patients. For patients having MVR, the survival rate at 5 and 10 years were 84±2% and 63±3%, respectively. For patients having AVR, the survival rate at 5 and 10 years were 81±2% and 59±2%, respectively.

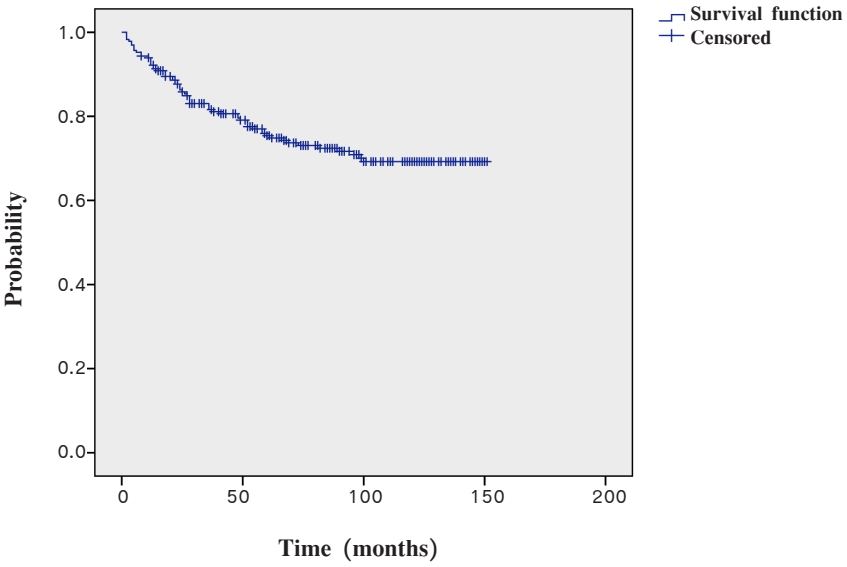


Figure 1 Freedom from all late valve related complications

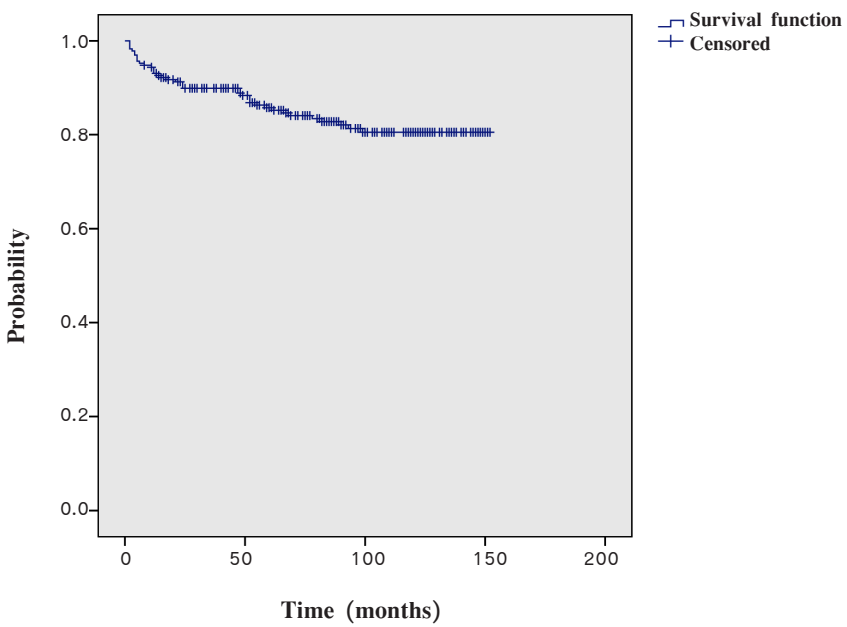
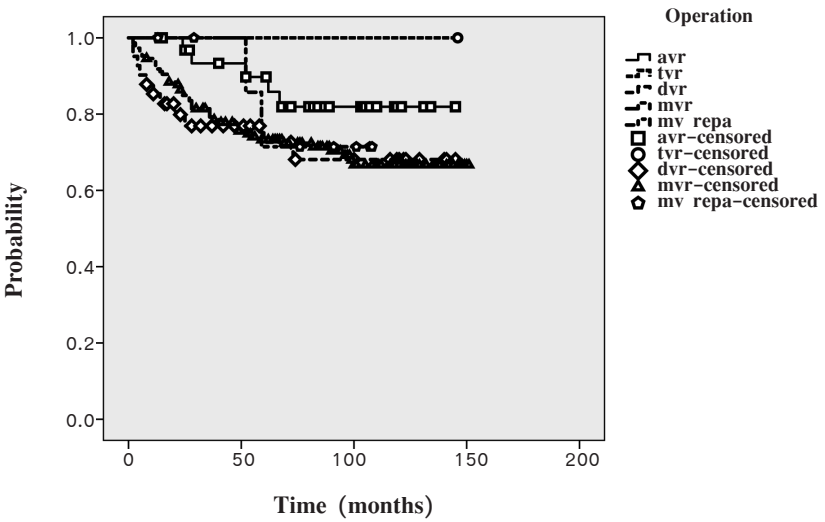
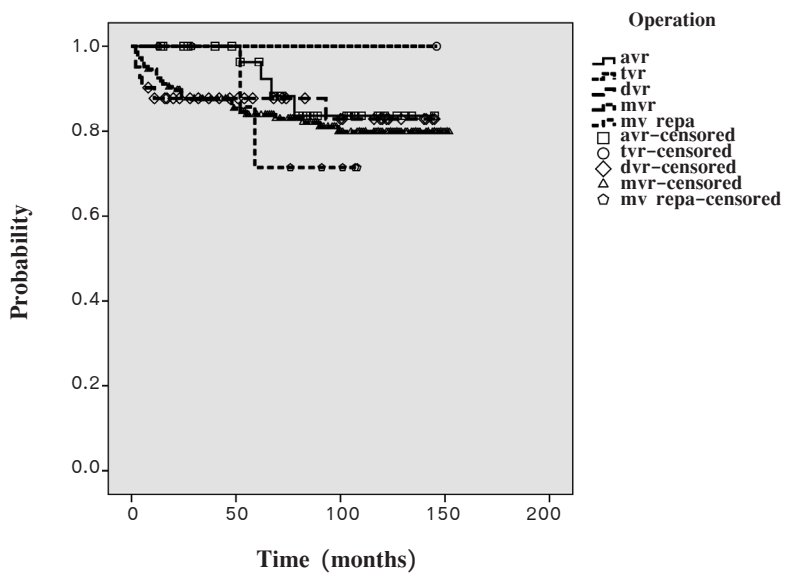


Figure 2 Freedom from all late valve related deaths



avr=aortic valve replacement, tvr=tricuspid valve replacement, dvr=mitral valve with aortic valve replacement, mvr=mitral valve replacement, mv repa=mitral valve repair with aortic valve replacement

Figure 3 Freedom from all late valve related complications according to the operation



avr=aortic valve replacement, tvr=tricuspid valve replacement, dvr=mitral valve with aortic valve replacement, mvr=mitral valve replacement, mv repa=mitral valve repair with aortic valve replacement

Figure 4 Freedom from all late valve related deaths according to the operations

The major drawbacks of mechanical valve is its life-long risks of thromboembolism and bleeding from anticoagulant drugs. Even though acceptable durability of mechanical valves have been reported by many studies,[2-4] these potential life-long risks still persist. Data from many reports showed that patients with a mechanical heart valve have a life expectancy lower than the national average, especially the young.[2,5] However, there are also other factors that could determine the long-term outcomes of patients with mechanical valve.[6,7] The patient-related factors are age and underlying diseases. Health care delivery could be another important factor, such as early diagnosis and proper treatment of complication of mechanical valve, specialized care with anticoagulant drug, and patient cooperation and compliance with long-term care.[7] These factors are multiple, complex, and interrelated. Improving the long term outcomes of patients with mechanical valve is therefore complicated. Possible ways to improve the long-term outcomes for patients with mechanical valve replacement might be to promote self monitoring anticoagulant therapy,[8] or choose bioprosthetic valve instead of mechanical valve.[9]

In this study, the valve-specific complication free rate and valve-specific survival rate were comparable to other studies (Table 3). However, could we improve the survival rate and complication free rate of patients with prosthetic valve replacement? Recently, the number of valve replacement in Thailand was around 2,500 cases each year[10] and there is still no ideal prosthetic heart valve. If we want to improve the long term outcomes, we should have the information of late valve related complications and deaths. The result of this study could be a reference for further study.

Limitation of the study

This study was retrospective and the most common complication was sudden unexplained death, which the cause of death could not be exactly determined. This could have the effect on the reliability of the study.

Table 3 Complication-free rate and survival rate following mechanical valve replacement

Author	Mitral valve relplacement		Aortic valve replacement	
	5 year complication-free rate (%)	5 year survival rate (%)	5 year complication-free rate (%)	5 year survival rate (%)
This study	73.2	83.9	85.8	92
Khan[2]	76.2	NA	80.1	NA
Svennevig[3]	NA	NA	NA	78.6
Toole[4]	NA	84.2	NA	81.2

NA=not

Conclusion

The long-term outcomes of patients with mechanical valve replacement in this study was comparable to other studies. The data from this study could be a reference for further study of the management of patients with prosthetic heart valve.

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