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CURRENT TOPICS REVIEW ARTICLE

Current status of cardiovascular surgery in Japan: analysis of data from Japan Cardiovascular Surgery Database in 2015, 2016. 3—Valvular heart surgery

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Abstract

Objectives Data related to valvular heart surgeries from the Japan Cardiovascular Surgery Database in 2015 and 2016 were analyzed to demonstrate the associated mortality and morbidity rates and choice of surgical procedures.

Methods We used the Japan Cardiovascular Surgery Database to extract data related to cardiac valve replacement procedures performed in 2015 and 2016. The cases were further evaluated depending upon the type of procedure and prosthesis used at each site. The percentage of bio-prosthesis usage was calculated for each valve position and age group. The rates of operative mortality and morbidity were calculated for each valve position and type of procedure.

Results Overall, 26,054 aortic valve replacements were performed in 2015 and 2016, showing a slightly larger number than the last report (2013–2014). A total of 3305 transcatheter aortic valve replacements, 5652 mitral valve replacements and 12,024 mitral valve repair procedures were performed. The percentage of bio-prosthesis usage in aortic valve replacement was 96.5, 92.7, and 63.5% for patients in their 80s, 70s, and 60s, respectively, demonstrating an increase in usage since 2013–2014. Mechanical valves were preferred in patients on chronic hemodialysis. The mortality rates of aortic valve replacement, mitral valve replacement, mitral valve repair, and tricuspid valve replacement procedures were 4.1, 7.1, 2.2, and 10.5%, respectively.

Conclusion We evaluated recent trends in valvular heart surgery in Japan with respect to the type of procedure and prosthesis preferred and the postoperative outcomes. We found that bio-prosthesis usage was becoming more common.

Keywords Prosthetic valve selection · Mechanical valve · Bio-prosthesis · Hemodialysis · Surgery

Introduction

The aim of this paper was to summarize data related to valvular heart surgery in Japan in 2015 and 2016 derived from the Japan Cardiovascular Surgery Database (JCVSD). In this biennial report of valvular heart surgery from JCVSD, we attempted to provide additional information such as procedural and prosthesis choice and results for each age group succeeding the policies of the previous report [1]. We also report trends from the years 2013 and 2014. The rates of operative morbidity are also reported. We obtained data related to patients undergoing hemodialysis separately because they often present different percentages for prosthesis selection.

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Methods

From January 2013 to December 2014, valve surgery data were extracted from the JCVSD according to items derived from the data manager manual of JCVSD [2]. Data extraction from the JCVSD was complex for valve surgery [1]. We used the same inclusion criteria as the previous report [1]. In the aortic position (A-group), cases of valvuloplasty were excluded because the number was small. In the mitral position (M-group), cases with concomitant aortic valve replacement (AVR) and/or tricuspid valve replacement (TVR) were excluded. Extracted conditions are outlined below:

A-group: (⌈aortic valve⌋ + ⌈replacement⌋)
− (⌈mitral valve⌋ + ⌈replacement⌋
and/or ⌈tricuspid valve⌋ + ⌈replacement⌋).
M-group: ⌈mitral valve⌋ − (⌈aortic valve⌋ + ⌈replacement⌋)
and/or (⌈tricuspid valve⌋ + ⌈replacement⌋).
T-group: ⌈tricuspid valve⌋.

In the A-group, isolated AVR and AVR + mitral valve plasty cases were mainly included. In the M-group, isolated mitral valve surgery and mitral valve surgery + tricuspid valvuloplasty cases were mainly included. Regarding the T-group, all cases in which procedures were performed on the tricuspid valve were included. Because we focused on the choice of procedure and prosthesis, we did not exclude cases with concomitant coronary artery surgery and aortic surgery, which usually do not affect choice of valve prosthesis.

Numbers were expressed separately for mechanical valves and bio-prostheses. We classified transcatheter aortic valve replacement (TAVR) separately in this report for the first time because the number of TAVR significantly increased from the previous report, which included only 583 cases in the years 2013 and 2014. In the A-group, ⌈New Product⌋ was assigned to the bio-prosthesis group and ⌈Other⌋ was excluded from both groups. In contrast, in the M- and T-groups, ⌈New Product⌋, ⌈Other⌋, and ⌈None⌋ were included in the valvuloplasty group. The number and results of mitral valve plasty (MV Plasty) procedures were described separately from mitral valve replacement (MVR) in this report. Tricuspid valve procedures were divided in TVR and tricuspid valve plasty (TV Plasty), which included tricuspid valve annuloplasty. We described data related to hemodialysis patients separately because they often have different percentages of prosthesis selection.

The rates of operative mortality, stroke, renal failure, deep sternal infection, bleeding, pneumonia, and re-admission within 30 days were described. The operative mortality was defined as all deaths occurring during hospitalization in which the operation was performed or all deaths occurring before the end of postoperative day 30. Stroke was defined as neurological deficit that did not resolve within 72 h and occurring during the hospitalization in which the operation was performed and was caused by brain damage. Post-operative renal failure was defined as acute renal failure or worsening renal function resulting in one or both of the following: (1) an increase in serum creatinine level 2.0-fold greater than baseline or serum creatinine level ≥ 2 mg/dL and (2) new requirement for dialysis postoperatively. Deep sternal infection was defined as infection involving deep soft tissues at the incision site (muscle layers, the sternum, the mediastinum) and patient presented at least one of the following: deep incision or drainage by a surgeon, culture with positive findings, or requirement for administration of antibiotics. Bleeding was defined as bleeding requiring re-exploration. Pneumonia was defined as a condition fulfilling one or both of the following: (1) clinical signs of pneumonia with positive culture results of sputum or chest fluid and/or (2) chest X-ray images revealing positive findings of pneumonia. Re-admission was defined as re-admission to hospital within 30 days of discharge from hospitalization for this surgery.

The trends of operative mortality were compared for the years 2013–2014.

Categorical variables were assessed by Chi square test or Fischer's exact test and 95% confidence intervals (CI) were reported for some of the results, such as operative mortality and operative morbidity.

Results

Number of valvular heart procedures performed

In the years 2015 and 2016, a total of 5535 surgical AVR with mechanical valves, 20,519 surgical AVR with bio-prostheses, and 3305 TAVR procedures were performed in Japan (Table 1). The number of AVR with mechanical valves was slightly smaller than 5855 in years 2013 and 2014, while the number of AVR with bio-prostheses was slightly larger than 19,507 in the years 2013 and 2014. The number of TAVR in the JCVSD in the years 2015 and 2016 was 3305. In the previous report, we did not count TAVR separately, which was only 583 cases in years 2013 and 2014. The percentage of enrollment in the JCVSD may be relatively low for TAVR. We speculate that the percentage of enrollment was approximately 70% judged from sales data. The total number of surgical AVR procedures was 25,362, which was slightly larger than the 26,054 procedures in 2013 and 2014. The number of TAVR procedures in hemodialysis patients was very small; however, the number of AVR procedures with bio-prostheses for hemodialysis patients was 1966 in 2015 and 2016, which was larger than 1539 procedures in 2013

Table 1 The number and mortality rate of the patients who underwent AVR at each age group

Age	2013–2014			2015–2016				
	Mech AVR	Bio AVR	Total AVR mortality *N* (%)	Mech AVR	Bio AVR	Total AVR mortality *N* (%)	TAVR	TAVR mortality *N* (%)
< 20	36	38	3 (4.1)	19	27	4 (8.7)	2	0 (0)
20	113	29	2 (1.4)	94	19	4 (3.5)	0	
30	325	70	13 (3.3)	262	66	16 (4.9)	1	0 (0)
40	685	119	26 (3.2)	739	125	26 (3.0)	0	
50	1331	337	64 (3.8)	1354	366	57 (3.3)	3	0 (0)
60	2069	3149	178 (3.4)	2038	3538	171 (3.1)	32	1 (3.1)
70	998	9587	472 (4.5)	805	10,198	452 (4.1)	420	8 (1.9)
80	293	5944	328 (5.3)	220	5992	321 (5.2)	2357	40 (1.7)
90	5	234	11 (4.6)	4	188	8 (4.2)	489	7 (1.4)
	5855	19,507	1097 (4.3)	5535	20,519	1059 (4.1)	3305	56 (1.7)

Mech mechanical valve, *Bio* biological valve, *AVR* aortic valve replacement, *TAVR* transcatheter aortic valve replacement, *N* number

Table 2 The number and mortality rate of the chronic hemodialysis patients who underwent AVR at each age group

Age	2013–2014			2015–2016				
	Mech AVR	Bio AVR	AVR mortality *N* (%)	Mech AVR	Bio AVR	AVR mortality *N* (%)	TAVR	TAVR mortality *N* (%)
< 20	3	2	0 (0.0)	0	1	0 (0.0)	0	
20	3	0	0 (0.0)	2	0	0 (0.0)	0	
30	8	0	0 (0.0)	4	0	1 (25.0)	0	
40	25	8	0 (0.0)	20	5	1 (4.0)	0	
50	145	27	13 (7.6)	150	36	14 (7.5)	1	0 (0.0)
60	368	345	63 (8.8)	412	434	61 (7.2)	2	0 (0.0)
70	252	821	146 (13.6)	239	1062	151 (11.2)	13	0 (0.0)
80	26	333	52 (14.5)	40	422	74 (16.0)	22	0 (0.0)
90	0	3	2 (66.7)	1	6	0 (0.0)	1	0 (0.0)
	830	1539	276 (11.7)	868	1966	302 (10.7)	39	0 (0.0)

Mech mechanical valve, *Bio* biological valve, *AVR* aortic valve replacement, *TAVR* transcatheter aortic valve replacement, *N* number

and 2014. The number of AVR with mechanical valves in hemodialysis patients was 830 in 2015 and 2016, which was slightly smaller than 868 in 2013 and 2014 (Table 2). The number of AVR procedures for hemodialysis patients was larger compared to 2013 and 2014 in individuals in their 60s, 70s, and 80s, especially for cases with bio-prostheses (Table 2).

Regarding mitral valve surgery, the number of MVR with mechanical valves was 2009 in 2015 and 2016, and the number of MVR with bio-prostheses was 3643 (Table 3).

The number of TVR procedures with mechanical valves was 23, which were fewer than the 41 procedures in 2013 and 2014, while the number of bio-prostheses was 282, which was 318 in 2013 and 2014. The number of TV Pasty was 12,342, compared to 11,469 in 2013 and 2014 (Table 4).

Choice of valve prosthesis

The percentage of bio-prostheses at each age group in the years 2015–2016 and years 2013–2014 are shown in Fig. 1. The percentage of bio-prostheses used was 63.5% in patients in 60s, which was 60.3% in the years 2013–2014, and was 92.3% in patients in 70s, which was 90.6% in the years 2013–2014. For patients in 80s, the percentage of bio-prostheses used was 96.5%, which was 95.3% in years 2013–2014. The difference was statistically significant in these age groups ($p < 0.05$). The percentage of bio-prostheses in patients in their 50s was 21.3%.

The percentage of bio-prostheses at each age group in hemodialysis patients in the years 2015–2016 and years 2013–2014 is shown in Fig. 2. The percentage of bio-prostheses was 51.3% in patients in 60s, previously 48.4% in years 2013–2014, and was 81.6% in patients in

Table 3 The number and mortality rate of the chronic hemodialysis patients who underwent MVR at each age group

Age	2013–2014					2015–2016				
	Mech MVR *N*	Bio MVR *N*	Total MVR mortality *N* (%)	MV plasty *N*	MV plasty mortality *N* (%)	Mech MVR *N*	Bio MVR *N*	Total MVR mortality *N* (%)	Plasty *N*	MV plasty mortality *N* (%)
< 20	16	11	1 (3.7)	66	0 (0.0)	10	7	1 (5.9)	34	1 (2.9)
20	27	14	1 (2.4)	160	1 (0.6)	33	14	1 (2.1)	143	1 (0.7)
30	82	25	2 (1.9)	367	1 (0.3)	69	30	10 (10.1)	362	4 (1.1)
40	224	44	21 (7.8)	993	14 (1.4)	190	35	3 (1.3)	1029	6 (0.6)
50	522	111	35 (5.5)	1994	27 (1.4)	437	97	18 (3.4)	1978	15 (0.8)
60	1052	687	85 (4.9)	3637	89 (2.4)	883	616	85 (5.7)	3753	69 (1.8)
70	460	1925	173 (7.3)	3688	127 (3.4)	343	1980	188 (8.1)	3557	99 (2.8)
80	54	756	80 (9.9)	1106	70 (6.3)	44	842	95 (10.7)	1151	62 (5.4)
90	1	15	2 (12.5)	19	0 (0.0)		22	1 (4.5)	17	2 (11.8)
	2438	3588	400 (6.6)	12,030	329 (2.7)	2009	3643	402 (7.1)	12,024	259 (2.2)

Mech mechanical valve, *Bio* biological valve, *MVR* mitral valve replacement, *Plasty* mitral valvuloplasty, *N* number

Table 4 The number and mortality rate of the patients who underwent TV surgery at each age group

Age	2013–2014					2015–2016				
	Mech TVR *N*	Bio TVR *N*	TVR mortality *N* (%)	TV plasty *N*	Plasty mortality *N* (%)	Mech TVR *N*	Bio TVR *N*	TVR mortality *N* (%)	TV plasty *N*	TV plasty mortality *N* (%)
< 20	1	0	0 (0.0)	42	1 (2.4)	0	2	0 (0)	26	2 (7.7)
20	2	5	2 (28.6)	59	1 (1.7)	1	5	0 (0)	51	2 (6.7)
30	5	8	0 (0.0)	150	1 (0.7)	1	9	1 (10.0)	143	5 (3.5)
40	7	12	2 (10.5)	418	20 (4.8)	4	14	0 (0)	453	13 (2.9)
50	4	28	4 (12.5)	1041	32 (3.1)	8	21	1 (3.4)	1081	30 (2.8)
60	15	81	18 (18.8)	3116	128 (4.1)	6	67	9 (12.3)	3256	120 (3.7)
70	6	137	14 (9.8)	4831	222 (4.6)	3	122	12 (9.6)	5183	293 (5.7)
80	1	47	8 (16.7)	1782	143 (8.0)	0	41	9 (9)	2112	151 (7.1)
90	0	0	0 (0.0)	30	1 (3.3)	0	1	0 (0)	37	6 (16.2)
	41	318	48 (13.4)	11,469	549 (4.8)	23	282	32 (10.5)	12,342	486 (4.0)

Mech mechanical valve, *Bio* biological valve, *TVR* tricuspid valve replacement, *Plasty* tricuspid valvuloplasty, *N* number

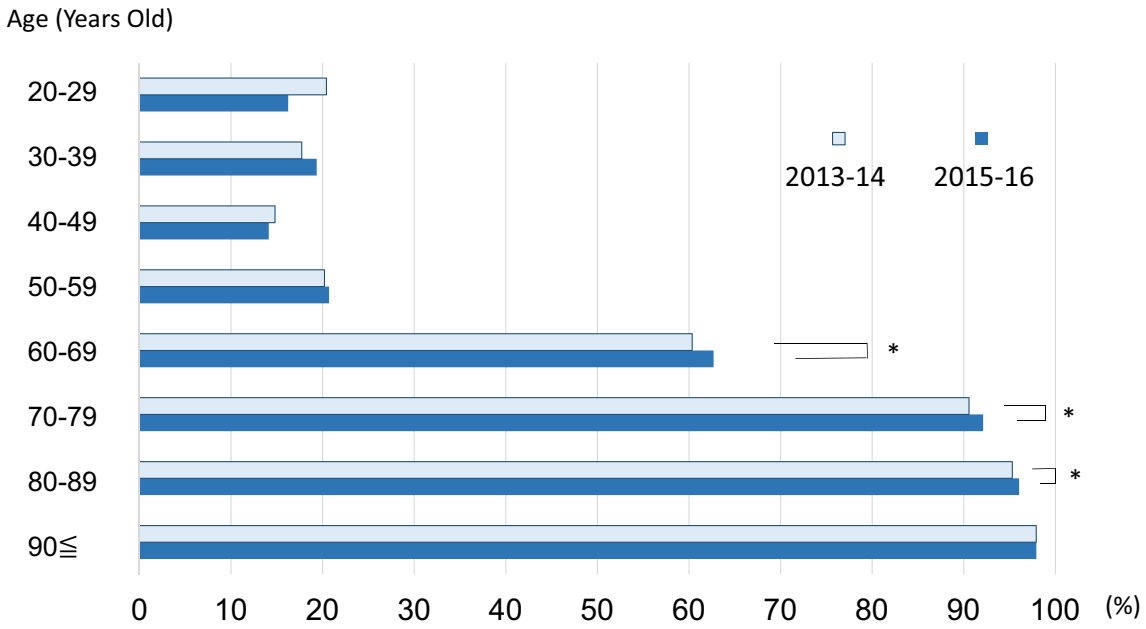

Fig. 1 Percentages of bio-prosthesis in aortic valve replacement in each age group. *$p < 0.05$

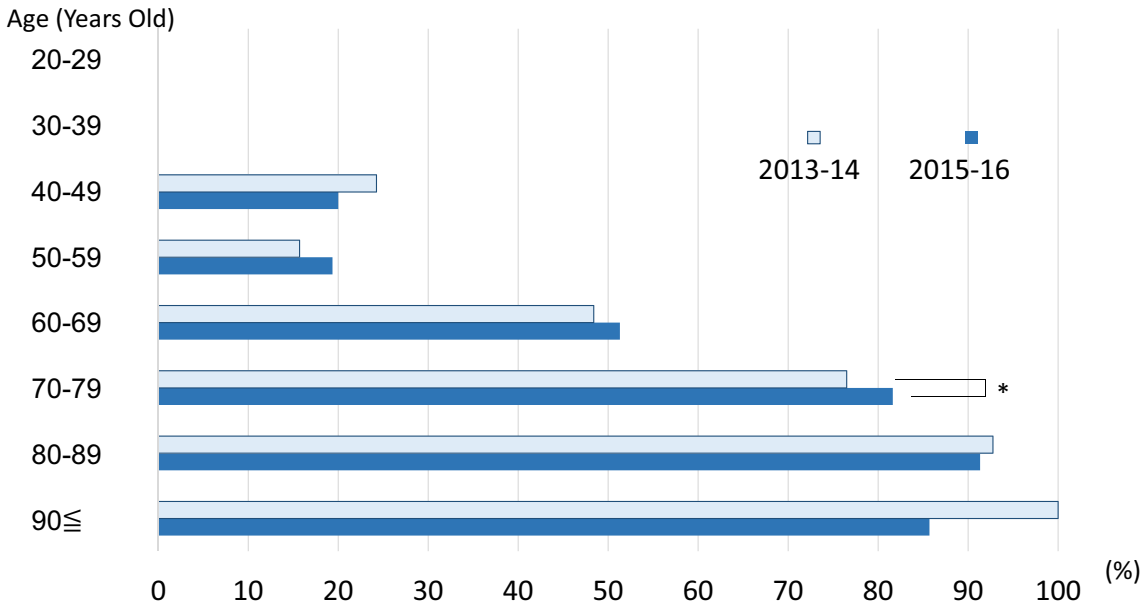

Fig. 2 Percentages of bio-prosthesis in aortic valve replacement in chronic hemodialysis patients in each age group, *$p < 0.05$

70s, previously 76.5% in the years 2013–2014. Similarly, for patients in 80s, the percentage was 91.3%, which was 92.8% in years 2013–2014. The difference between the present and previous study period was statistically significant for patients in the 70s age groups ($p < 0.05$). The percentage of bio-prostheses in hemodialysis tended to be lower than in the previous report [1].

The percentage of bio-prostheses used in MVR procedures at each age group is shown in Fig. 3. There was a statistically significant increase in the percentage of bio-prostheses used from 80.7% in 2013–2014 to 85.2% in 2015–2016 in patients in their 70s.

We did not report the results of MVR for hemodialysis patients and TVR as the numbers were too small for adequate analysis.

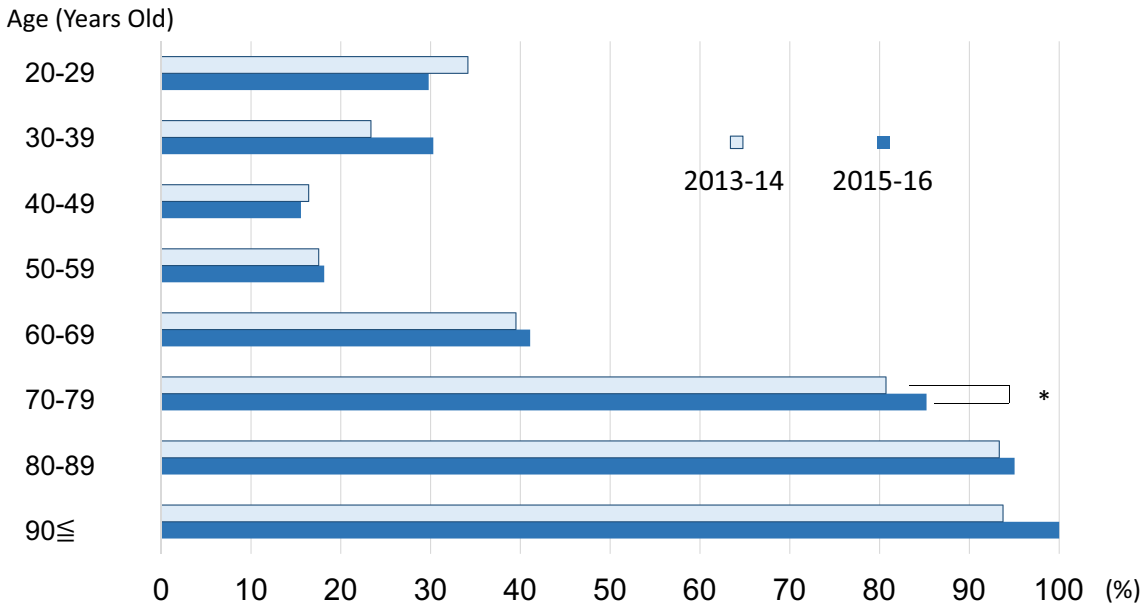

Fig. 3 Percentages of bio-prosthesis in mitral valve replacement in each age group, $*p < 0.05$

Table 5 Operative mortality and morbidity of valve surgery in Japan in 2015–2016

	AVR	TAVR	MVR	MV plasty	TVR
Operative death (%)	4.1 (3.8–4.3)	1.7 (1.3–2.2)	7.1 (6.3–7.7)	2.2 (1.9–2.4)	10.5 (7.3–14.5)
Stroke (%)	2.7 (2.5–2.9)	1.6 (1.2–2.1)	2.8 (2.4–3.3)	1.5 (1.3–1.7)	1.0 (0.2–2.85)
Renal failure (%)	4.1 (3.8–4.3)	2.2 (1.7–2.7)	3.2 (2.9–3.5)	3.2 (2.9–3.5)	13.4 (9.8–17.8)
Deep sternal infection (%)	1.4 (1.2–1.5)	0.0 (0–0.2)	2.0 (1.6–2.4)	1.0 (0.8–1.1)	3.0 (1.4–5.5)
Bleeding (%)	3.7 (3.5–3.9)	1.0 (0.7–1.4)	5.0 (4.5–5.6)	2.4 (2.2–2.7)	4.9 (2.8–8.0)
Pneumonia (%)	3.5 (3.2–3.7)	2.3 (1.8–2.8)	4.8 (4.2–5.4)	2.3 (2.1–2.6)	8.5 (5.6–12.2)
Re-admission (%)	0.7 (0.6–0.9)	0.8 (0.5–1.2)	0.8 (0.6–1.1)	0.7 (0.6–0.9)	0.7 (0.1–2.4)

AVR aortic valve replacement, *TAVR* transcatheter aortic valve replacement, *MVR* mitral valve replacement, *MV plasty* mitral valvuloplasty, *TVR* tricuspid valve replacement

(–) (lower limit of 95% confidence interval–higher limit of 95% confidence interval)

Operative mortality and morbidity in the years 2015 and 2016

Operative mortality and morbidity are reported in Table 5. In AVR, the operative mortality rate was 4.1%, stroke rate was 2.7%, renal failure rate was 4.1%, deep sternal infection rate was 1.4%, bleeding rate was 3.7%, pneumonia rate was 3.5%, and the re-admission rate was 0.7%. In the MVR, the operative mortality rate was 7.1%, stroke rate was 2.8%, renal failure rate was 3.2%, deep sternal infection rate was 2.0%, bleeding rate was 5.0%, pneumonia rate was 4.8%, and re-admission rate was 0.8%. In MV Plasty, the mortality rate was 2.2%, stroke rate was 1.5%, renal failure rate was 3.2%, deep sternal infection rate was 1.0%, bleeding rate was 2.4%, pneumonia rate was 2.3%, and re-admission rate was 0.7%.

The trend related to operative mortality of each procedure is shown in Fig. 4. There was decrease in mortality rate in MV Plasty procedures from 2.7% in the years 2013–2014 to 2.2% in the years 2015–2016 ($p < 0.05$). The mortality rate was 4.1% in AVR procedures (4.3% in years 2013–2014) and was 7.1% in MVR procedures (6.6% in years 2013–2014). The mortality rate following valve surgery in hemodialysis patients tended to be higher.

Discussion

The number of TAVR procedures was significantly increasing during 2015 and 2016. Much larger numbers of TAVR were performed compared to 2013 and 2014. The enrollment for the TAVR procedures in the JCVSD might be relatively under-represented because procedures are also performed by cardiologists in many institutions. Nonetheless, a total of 3350 cases were registered in the

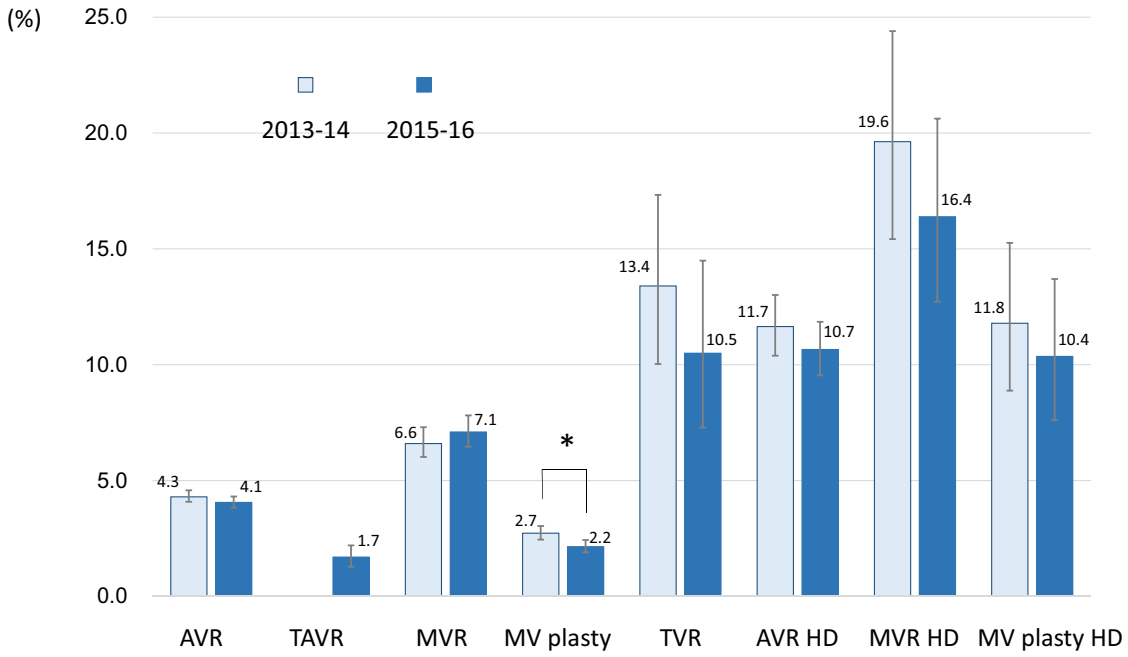

Fig. 4 Operative mortality in valve surgery in Japan in 2013–2014 and 2015–2016. *AVR* aortic valve replacement, *TAVR* transcatheter aortic valve replacement, *MVR* mitral valve replacement, *MV plasty* mitral valvuloplasty, *TVR* tricuspid valve replacement, *HD* hemodialysis. $*p < 0.05$. Error bars indicate 95% confidence intervals

JCVSD in the years 2015 and 2016; the true number could be approximately 5000 judged from sales number data. The number of surgical AVR in the years 2015 and 2016 showed a slight increase despite this significant number of TAVR. However, the number of AVR procedures did not dramatically decrease in Germany [3] or in United States [4]. The same trend in Japan may be observed in the present report. Future trends arouse interest.

There was not a significant change in the number of mitral valve surgeries over the study period; however, there was an increase in elderly patients on hemodialysis.

Regarding choice of the valve prosthesis, an increased use of bio-prostheses was favored. Statistically significant increases in the percentages of bio-prostheses in the AVR were shown for patients in their 60s–80s, while the percentage remained unchanged in younger patients (Fig. 1). Most AVR patients in their 70s and 80s on hemodialysis received bio-prostheses (Fig. 2).

Regarding operative mortality and morbidity, our data showed a slightly higher mortality rate in Japan compared to the recent Society of Thoracic Surgeons (STS) database report [5]. In the present and previous reports, we did not exclude concomitant surgeries that would not have influenced valve prosthesis choice because we considered the procedure and prosthetic valve selection as the primary interest. This fact appeared to be a reason why the results of this report were relatively poor. In the STS report, the operative mortality of isolated MVR was 4.7%, while the MVR and concomitant coronary artery bypass (CABG) showed 8.7% mortality. In the present report mortality following MVR procedures including concomitant CABG and aortic surgery showed 7.1%. When we exclude concomitant CABG and aortic surgery, the operative mortality rate was 6.1% (95% CI 5.4–6.8%), 4.5% for mechanical valves, and 7.1% for bio-prostheses. The mortality rate for isolated MVR might have been somewhat lower as this number included patients with concomitant tricuspid valve surgery. We are currently planning to investigate the contributing factors of operative mortality in valve replacement described in the JCVSD as a future research project.

The STS report indicated there was a 1.1% operative mortality following MV Plasty procedures while our results showed a rate of 2.2%. When we excluded concomitant CABG and aortic valve surgery, the operative mortality was 142 of 9895 or 1.4% (95% CI 1.2–1.7%) indicating a number that was not much different to the STS value.

Similarly, the STS report showed 2.1% operative mortality following isolated AVR procedures, while our results showed a rate of 4.1%. When we excluded concomitant CABG and aortic surgery, the operative mortality was 3.5% (95% CI 3.3–3.8%). The true operative mortality for isolated AVR could be somewhat lower because these patients also included concomitant mitral valve repair and tricuspid valve repair.

It is important for a national database to reflect the standard of medical care in the country. The JCVSD should

continue to evaluate the results of benchmark procedures based on robust definitions. Although international comparison is difficult, it may be meaningful to adopt the same definition for benchmark operations to allow easier comparison.

It was pleasing to see improving results with regard to operative mortality in MV plasty procedures. Since patient background may be evolving in the aging society of Japan, it may also be interesting to evaluate trends in patient backgrounds in future reports.

In this annual report, we analyzed 2 years' worth of data. In JCVSD, a penetration rate of participating hospitals all over Japan almost reached 100% in 2013. We started writing the annual reports in 2014, when we were already lagging behind by 4 years. In order to catch up with the latest year, we combined and analyzed the data of 2 years.

We have finished the report for the first 2 years (2013–2014) and are now preparing the same for 2015–2016. As we gradually catch up with the real-time year, we will analyze each year separately.

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