Title

Effects of tricuspid valve surgery on tricuspid regurgitation in patients with hypoplastic left heart syndrome: a non-randomized series comparing surgical and non-surgical cases

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Keywords

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Abstract

OBJECTIVES: Tricuspid regurgitation (TR) remains a significant risk factor affecting the survival of patients with hypoplastic left heart syndrome (HLHS). We performed this study to investigate differences in the clinical course based on the timing of the development of TR and the effects of tricuspid valve surgery (TVS).

METHODS: One hundred and five patients of classic HLHS underwent staged operations from May 1991 to July 2010. Forty-four patients (41.9%) exhibited moderate or greater TR during follow-up. We defined the early TR group (30 patients, around the first palliative surgery) and the late TR group (14 patients, the later period) based on the timing of the appearance of moderate or greater TR. We performed TVS when moderate or greater TR was detected in 28 patients. The follow-up period was 5.5±5.1* years (range: 0.01 to 14.6 years) after the first palliative surgery and 4.9±4.4 years (range: 0.01 to 13.3 years) after TVS.

RESULTS: The early TR group exhibited poorer survival than the late TR group (42.9% vs 92.9% at five years, p=0.003). However, in the early TR group, the TVS significantly improved survival compared with that observed in the non-TVS cases (52.1% vs 23.3% at five years, p=0.046). The right-ventricular ejection fraction (RVEF) significantly decreased (62.7±11.4→57.2±12.6%*, p=0.040) and the right-ventricular

end-diastolic diameter (RVDd) became significantly enlarged (27.7±7.6→36.7±3.4mm, p<0.001) in association with deterioration of the TR degree. TVS significantly improved the degree of TR (2.5±0.5→1.5±0.9°, p<0.001) and RVDd (37.7±7.4→30.4±5.0mm, p=0.007); however, the RVEF was not improved one month after surgery (54.4±12.1→54.3±12.4%, p=0.931) or at the latest follow-up (53.7±14.9%, p=0.836).

CONCLUSION: The survival of HLHS patients who develop moderate or greater TR around the time of the first palliative surgery is worse than that of HLHS patients who develop moderate or greater TR at a later time. In this study, TVS for early TR improved survival, and decreased right ventricular dimensions during the 4.9-year follow-up period.

*Plus-minus values are means±SD

Word Count: 324 words

Key words: Hypoplastic left heart syndrome; Tricuspid valve; Tricuspid regurgitation

INTRODUCTION

The surgical results of the patients with hypoplastic left heart syndrome (HLHS) have

dramatically improved over the past two decades. However, tricuspid regurgitation (TR) remains an important risk factor that affects their survival, and there have been many reports regarding the negative impact of TR to the clinical course of HLHS [1-8]. Some patients show significant TR at birth, which may be diagnosed prenatally by fetal echocardiography [9,10], and tend to present a difficult clinical course. Others show a gradual increase in TR as they grow.

Regarding the timing of tricuspid valve surgery (TVS), there have been some reports that recommend that TVS should be performed at the same time as bidirectional Glenn procedure (BDG) when moderate or greater TR is present [7,8,11]. However, there have not been any reports about the timing of TVS for significant TR present at birth.

This series included patients with early TR. We performed this study in order to investigate differences in the clinical course based on the timing of development of significant TR and the effects of TVS with regard to survival and the right ventricular function.

MATERIALS AND METHODS

Study population

Staged operations were performed for 105 classic HLHS patient between May 1991 and

July 2010. Of these, 44 patients (41.9%) who had moderate or greater TR during their overall clinical course were targeted. We performed TVS when significant TR of moderate or greater degree was detected. The follow-up period after the first palliative surgery was 5.5±5.1* years. This study was performed retrospectively and was non-randomized. Operations were performed by a single surgeon at a single institute.

*Plus-minus values are means±SD

Classification of the early TR group / late TR group, and TVS cases / non-TVS cases

Forty-four patients were classified into two groups according to the timing of the appearance of significant TR of moderate or greater degree. The early TR group included 30 patients with significant TR that appeared around the time of the first palliative surgery (bilateral pulmonary artery banding or Norwood procedure). The late TR group included 14 patients whose significant TR appeared immediately before or after the BDG (including Norwood with Glenn procedure).

In the early TR group, 20 patients underwent TVS at 6.5±9.0 months (TVS cases), while 10 did not (non-TVS cases). In the late TR group, eight patients underwent TVS at

11.2±7.5 months (TVS cases), while six did not (non-TVS cases). In the early TR group, because of historical reasons and after considering the surgical risks, we did not attempt to perform TVS simultaneously with the Norwood procedure in some cases, even if moderate or greater TR was found, particularly between 1991 and 2001. Such patients are indicated to undergo TVS according to the current criteria; these patients were designated as non-TVS cases. In the late TR group, some patients whose cardiac function and hemodynamics were well maintained were observed without TVS; these patients were designated as non-TVS cases.

Echocardiography

Transthoracic echocardiography was performed for all patients, and the changes in the degree of TR and cardiac function could be followed at each stage of surgery. The grade of TR was classified by the echocardiographic examination. It was classified as none (0°), mild (1°, narrow regurgitant jet), moderate (2°, wide jet that reaches the back wall of the atrium) or severe (3°, wide jet that bound at the back wall of the atrium). Moreover, the right-ventricular ejection fraction (RVEF) and right-ventricular end-diastolic diameter (RVDd) were measured to indicate the right ventricular function and size. The changes of the TR degree, right ventricular function and right ventricular

size were compared between before TVS and one month after the surgery, and the RVEF was evaluated based on the latest data (4.9±4.4 years after TVS).

Chest X-rays

Chest X-rays were performed for all patinets, and the changes in cardiothoracic ratio (CTR) could be followed as an indicator of cardiac size at each stage of surgery.

Statistics

Early death was defined as death within 30 days following surgery and late death was defined as death 30 days or more after surgery.

The results are expressed as the mean±SD. A paired Student's *t*-test was used to compare the differences in continuous variables between the two groups for the same subject. Estimates of cumulative survival were calculated according to the Kaplan-Meier method and compared using the log-rank test. A two-sided $p<0.05$ was considered to be statistically significant.

RESULTS

Clinical course

Figure 1 shows the clinical courses of 44 patients who developed moderate or greater TR during follow-up. These patients underwent their first palliative surgery at a median age of 10.0 days (range, 0 to 31.0 days). In detail, the Norwood procedure was performed in 35 patients at a median age of 9.5 days (range, 0 to 31.0 days; RV-PA conduit in 21 patients, Blalock-Taussig shunt in 14 patients) and bilateral pulmonary artery banding (bPAB) was performed in nine patients at a median age of 13.5 days (range, 6.0 to 28.0 days). After the first palliative surgery, there were 12 deaths until the second palliative surgery, these included two early deaths and seven late deaths after the Norwood procedure, and two early deaths and one late death after bPAB. Twenty-four patients underwent the bidirectional Glenn procedure (BDG) as a second palliative surgery at a median age of 7.1 months (range, 4.2 to 12.1months), while six patients underwent the Norwood with Glenn procedure at a median age of 3.6 months (range, 2.7 to 4.0 months). After the second palliative surgery, there were four late deaths after BDG before the Fontan procedure. Twenty-four patients underwent the extra-cardiac total cavopulmonary connection procedure (TCPC) at a median age of 2.3 years (range, 1.1 to 3.8 years). There was one early death after TCPC.

The timing of TVS for TR

The timing of the first TVS was as follows: At the time of the Norwood procedure in nine patients, at the second palliative surgery in 13 patients (BDG in 10 patients, Norwood with Glenn procedure in three patients), before TCPC in three patients and at TCPC in three patients.

Re-operations for TR were performed in three patients. These were before TCPC in one patient and at TCPC in two patients.

Types of TVS

For central TR primarily caused by annular dilatation, we performed annuloplasty according to the De Vega method. We chose to perform commissure closure in patients with commissural gap and valvuloplasty, including edge-to-edge repair, in patients with structural valve abnormalities, such as a prolapsed leaflet.

The types of first TVS were as follows: Annuloplasty alone was performed in 15 patients (DeVega method in 14 patients, Kay method in one patient), annuloplasty (DeVega method) + commissure closure in seven patients, commissure closure alone in two patients, edge-to-edge repair in two patients and tricuspid valve replacement (TVR) was performed in two patients.

Re-operations for TR were performed in three patients, which were a tricuspid valve

repair in two patients (annuloplasty+commissure closure in one case, commissure closure alone in one case) and TVR in one patient.

Morphological findings of the tricuspid valve

The morphological findings of the tricuspid valve during the operations are showed in Table 1. This series focused on classic HLHS; therefore, the atrioventricular valve morphology included only the tricuspid valve, not other valves, such as the common atrioventricular valve. Morphological abnormalities were frequently observed in both of early and later TR group. There was no significant difference about incidence of tricuspid valve abnormalities between two groups. In four patients, we found hypoplasia of the septal leaflet with shortening of the chordae as a severe structural abnormality. The three of these four patients also had prolapsed anterior leaflet, and the three patients underwent edge-to-edge repair, but two of them converted to TVR during the same operation.

Survival

The survival among all 44 patients was 71.8% at one year, 62.0% at three years and 62.0% at five years. The early TR group exhibited a poorer survival than the late TR

group (57.6% vs 100% at one year, 42.9% vs 92.9% at three years and 42.9% vs 92.9% at five years, p=0.003, Figure 2. A). However, in the early TR group, the TVS cases showed significantly superior results compared to the non-TVS cases (73.7% vs 23.3% at one year, 52.1% vs 23.3% at three years and 52.1% vs 23.3% at five years, p=0.046, Figure 2. B). On the other hand, late TR cases showed favorable result in both of TVS and non-TVS cases.

Freedom from recurrent TR following TVS

The rates of freedom from recurrence of moderate or greater TR following TVS of all patients with significant TR, the early TR group and the late TR group was 50.9%, 50.9%, 50.0% at one year, 42.0%, 44.5%, 33.3% at three years, respectively. Recurrence of TR occurred at a similar incidence in both groups and there were no significant differences between the early and the late TR group (p=0.474, Figure 3).

The percentage of moderate or greater TR in clinical course of the early TR group

Figure 4.A showed the clinical course of the percentage of moderate or greater TR in early TR group. In the patients without TVS, seven of 10 patients (70%) showed moderate TR at birth. Five of these seven patients underwent the Norwood procedure

alone (two cases underwent bPAB), and four of the five patients died. Two patients who showed moderate or greater TR after Norwood procedure also died after the surgery. One moderate TR patient who underwent bPAB died after the surgery.

On the other hand, the patients who underwent TVS simultaneously with Norwood procedure were also difficult cases. All of the five severe TR patients died after the Norwood procedure, because of acute or chronic heart failure. However three of the five moderate TR patients survived.

In the patients who underwent TVS between BDG and TCPC, though severe TR patients prior to TVS also showed poor survival, moderate TR patients including the patients who underwent the Norwood with Glenn procedure following bPAB showed relatively stable clinical course.

The percentage of moderate or greater TR in clinical course of the late TR group

In the late TR group, the patients who underwent TVS showed relatively satisfactory results, though there was one death in TVR case. The percentage of moderate or greater TR improved after BDG with TVS in many patients, however several patients showed recurrence of significant TR.

On the other hand, in the patients without TVS, many patients' TR were progressing

and they had moderate or greater TR after TCPC, but they exhibited relatively favorable results without death (Figure 4.B).

Correlation between the deterioration of TR and the cardiac function

The changes in the RVEF, CTR and RVDd corresponding to the degree of deterioration in TR over time in 25 patients who exhibited gradual deterioration of TR from none/mild to moderate/severe after birth are shown in Table 2. The RVEF significantly decrease with the deterioration of the TR degree ($p=0.040$). On the other hand, the CTR in chest X-rays showed a significant increase ($p=0.026$), and the RVDd also showed a significant increase ($p<0.001$, Table 2).

Changes in cardiac function after TVS

Compared to before TVS, the degree of TR improved significantly one month after the surgery ($p<0.001$). Although the CTR decreased significantly ($p=0.003$), and the RVDd also decreased significantly ($p=0.007$, Table 3), the RVEF did not show a significant change one month after TVS (54.5±12.2→54.3±12.4%, $p=0.931$) or at the latest follow-up (53.7± 14.9%, $p=0.836$).

DISCUSSION

The major findings of the present study are as follows: The patients with classic HLHS frequently exhibited moderate or greater TR in their clinical course after birth. The early TR group showed poorer survival than the late TR group. However, TVS when the moderate or greater TR was detected improved their survival significantly. TVS significantly improved the degree of TR and right ventricular dilatation, however the right ventricular systolic function was not improved one month after surgery or in the mid- to long-term results.

Survival, clinical courses of the TR and strategy for TR

In the early TR group, TVS cases showed significantly superior results than the non-TVS cases. The Norwood procedure alone for significant TR cases is supposed to burden the patients with a high volume load due to the systemic-pulmonary shunt, and may lead to increase of TR and acute heart failure in this situation.

Guleserian et al. [12] reported bPAB for high-risk single ventricle patients with moderate or greater atrioventricular valve regurgitation or other risks, as a bridge to conventional Norwood procedure or primary cardiac transplantation. We also performed bPAB for several patients with significant TR at birth and their clinical courses were

relatively stable, who performed TVS with Norwood with Glenn procedure at 2.5 to 4 months of age following bPAB [13].

Our current strategy is to perform the Norwood procedure within two weeks of age, with TVS for patients with only moderate TR as a risk factor at birth and bPAB for multiple-risk patients with both significant TR and other cardiac or non-cardiac complications as a first palliative surgery. If the TR deteriorates early after bPAB, we plan to perform the Norwood procedure with TVS, because this may indicate the presence of morphological abnormalities of the tricuspid valve.

We also perform TVS for the cases of moderate or greater TR at BDG. In the period at or after BDG, the surgical results in survival were relatively acceptable even in the early TR group, particularly in the moderate TR cases.

Hansen et al. [8] reported that more than moderate TR should be targeted at surgery simultaneously with BDG, as it is a risk factor for adverse outcomes, such as death or the need for cardiac transplantation [8]. Kasnar-Samprec et al. [11] showed that BDG in patients with HLHS promoted the remodeling of the systemic right ventricle but this did not improve the degree of TR. They also recommended that TVS should be considered at the time of BDG in the patients with moderate and severe TR.

Relationship between morphological abnormalities of the tricuspid valve and the development of TR

The relationships between morphological abnormalities and the development of TR have been described in previous studies [4,7,14,15]. Takahashi et al. [15] found that moderate TR is associated with the tethering and prolapse of the tricuspid valve leaflets in HLHS patients using three-dimensional echocardiography. Also in our findings, the patients with significant TR frequently had morphological abnormalities of the tricuspid valve in both the early TR group (60%) and late TR group (87.5%). Commissural gaps, prolapse of leaflets, hypoplasia of the septal leaflet and shortened chordae of the septal leaflet were associated with the development of significant TR. In three patients, we found hypoplasia of the septal leaflet and shortened chordae complicated with prolapsed anterior leaflet as severe abnormalities of tricuspid valve, and these three patients were difficult to correct by edge-to-edge repair and two of them needed TVR during the same operation.

Correlation between the deterioration of the TR and right ventricular function, and the timing of TVS

We observed a significant decrease in the right ventricular function and significant right

ventricular dilatation in association with the deterioration of the TR. After TVS, the right ventricular dilatation improved significantly, whereas the right ventricular systolic function did not change significantly within one month or 4.9±4.4 years after TVS.

In studies regarding mitral valve regurgitation as acquired valvular heart disease, it was indicated that when a decrease in the left-ventricular ejection fraction (<55%) or an increase in the left-ventricular end-systolic diameter (≥40mm) is detected, mitral valve repair should be considered to preserve the postoperative left ventricular function [16]. From the view point of the systemic ventricular function, it is also supposed that performing TVS before the deterioration of the right ventricular function would better help to preserve the function of the systemic right ventricle in HLHS patients. In this study, moderate or greater TR indicated the start of a decrease in the right ventricular function.

Regarding the right ventricular function after TVS, Elmi et al. [6] also described that immediately after surgery (24 hours after surgery), the right ventricular performance was no different or even slightly worse compared to that before TVS, and our findings were in agreement with this result. However, their findings indicated that the right ventricular performance improved in the long-term (median follow-up, 5.1 years). In contrast, our results indicated that patients might not show improvement of the right ventricular

function in the mid- to long-term after they exhibit functional deterioration.

In this study, TVS for early TR improved the survival of patients with HLHS and decreased the right ventricular dimensions during the 4.9-year follow-up period. Furthermore, to preserve the function of the right ventricle, it may be better for the patients who show moderate or greater TR to undergo TVS before the deterioration of the right ventricular function.

Study limitations

The present study was limited by the relatively small sample size and non-randomized design, particularly in the classification of the groups between TVS cases and non-TVS cases, and of the types of the first palliative surgery (Norwood procedure or bPAB). In addition, this study was performed retrospectively using surgical records, so it is likely that there were more structural abnormalities of the tricuspid valve than we noted. A study with more patients and a longer follow-up is needed to clarify the clinical course of TR and right ventricular function after TVS.

CONCLUSION

The patients with classic HLHS frequently exhibited moderate or greater TR in their

clinical course. The survival of patients who develop moderate or greater TR around the time of the first palliative surgery is worse than that of patients who develop this condition at a later time. In this study, TVS for early TR improved the survival and decreased the right ventricular dimensions during the 4.9-year follow-up period.

Funding

None.

Conflict of interest: none declared.

Table 1: Morphological findings of tricuspid valve during TVS

Causes of development of TR	Early TR group n=20 (%)	Late TR group n=8 (%)
Only annular dilatation	8 (40)	1 (12.5)
Structural abnormalities	12 (60)	7 (87.5)
Commissural gap	8 (40)	3 (37.5)
Thickening of leaflets	2 (10)	4 (50)
Prolapse of leaflets	2 (10)	2 (25)
Hypoplasia of the septal leaflet	2 (10)	2 (25)
Shortening of the chordae (septal leaflet)	2 (10)	2 (25)

TVS: tricuspid valve surgery

Table 2: Correlation between the deterioration of TR and the cardiac function.

TR	none-mild	moderate-severe	p value
RVEF (%)	62.7±11.4	57.2±12.6	0.040
CTR (%)	55.0±4.5	58.6±6.4	0.026
RVDd (mm)	27.7±7.6	36.7±3.4	<0.001

RVEF: right-ventricular ejection fraction; CTR: cardiothoracic ratio; RVDd: right-ventricular end-diastolic diameter.

Table 3: Changes in cardiac function after TVS

	Before TVS	One month after TVS	p value
TR (°)	2.5±0.5	1.5±0.9	<0.001
RVEF (%)	54.5±12.2	54.3±12.4	0.931
CTR (%)	62.2±7.2	57.0±7.0	0.003
RVDd (mm)	37.7±7.4	30.4±5.0	0.007

Degree of TR: none=0°; mild=1° (narrow regurgitant jet), moderate=2° (wide jet that

reaches the back wall of the atrium), severe=3° (wide jet that bound at the back wall of the atrium).

TVS: tricuspid valve surgery, TR: tricuspid regurgitation; RVEF: right-ventricular ejection fraction; CTR: cardiothoracic ratio; RVDd: right-ventricular end-diastolic diameter.

Figure legend

Figure 1:

Flow diagram of all 44 patients treated in this series.

The number in ( ) indicates the number of patients who underwent TVS. ( ) out of the box indicates the interstage operation.

TVS: tricuspid valve surgery, BDG: bidirectional Glenn procedure, TCPC: total cavo-pulmonary connection procedure

Figure 2:

(A) Survival comparing early TR group and late TR group

(B) Survival comparing TVS cases and non-TVS cases in the early TR group. TVS: tricuspid valve surgery.

Figure 3:

Freedom from recurrence of moderate or greater TR. TR: tricuspid regurgitation, TVS: tricuspid valve surgery

Figure 4:

Percentage of moderate or greater TR (A) in early TR group. (B) in late TR group. TVS: tricuspid valve surgery.

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Figure 1.

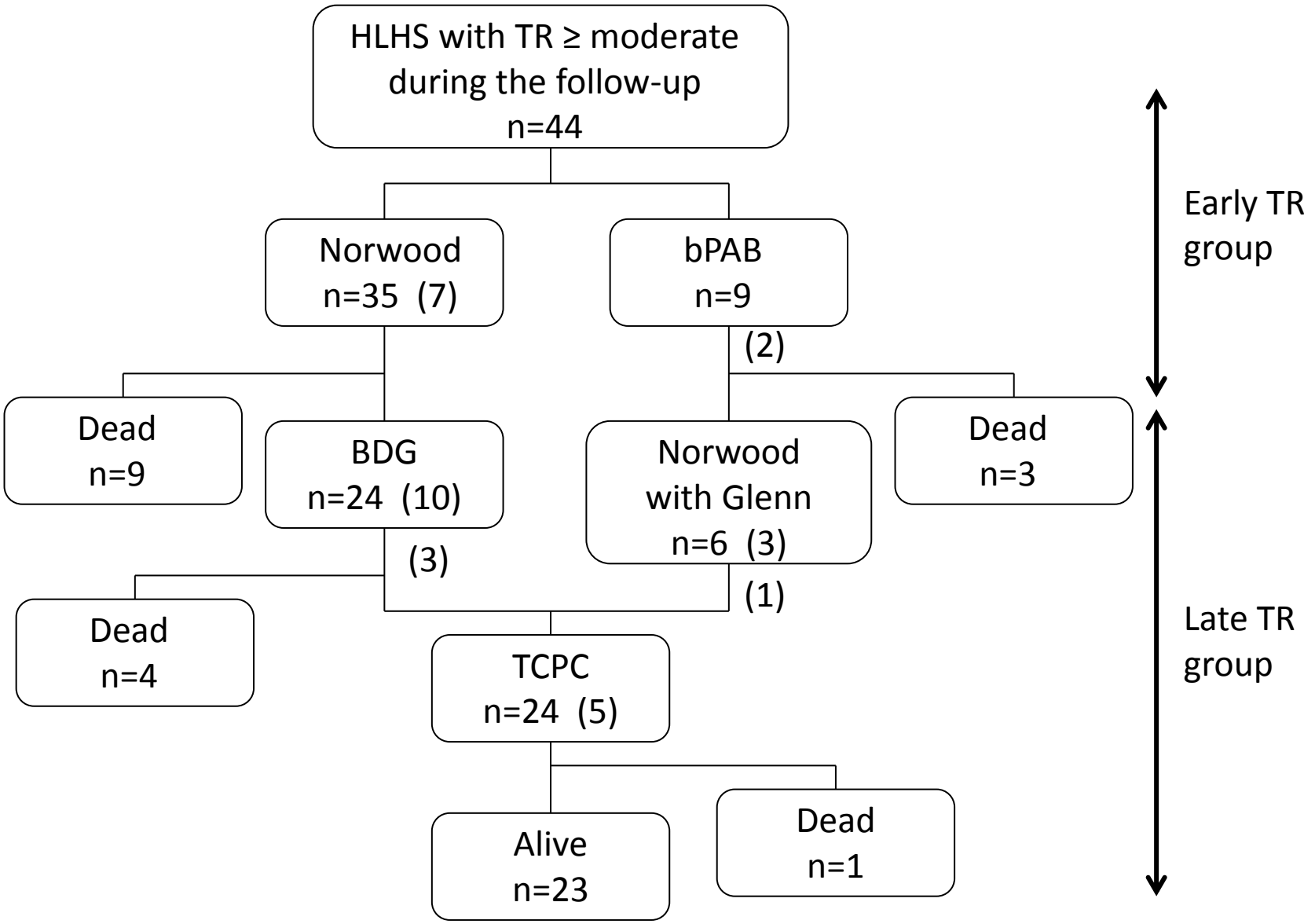

HLHS with TR ≥ moderate during the follow-up n=44
Norwood n=35 (7)
bPAB n=9
(2)
Dead n=9
BDG n=24 (10)
(3)
Norwood with Glenn n=6 (3)
(1)
Dead n=3
Dead n=4
TCPC n=24 (5)
Alive n=23
Dead n=1
Early TR group
Late TR group

Figure 2. A

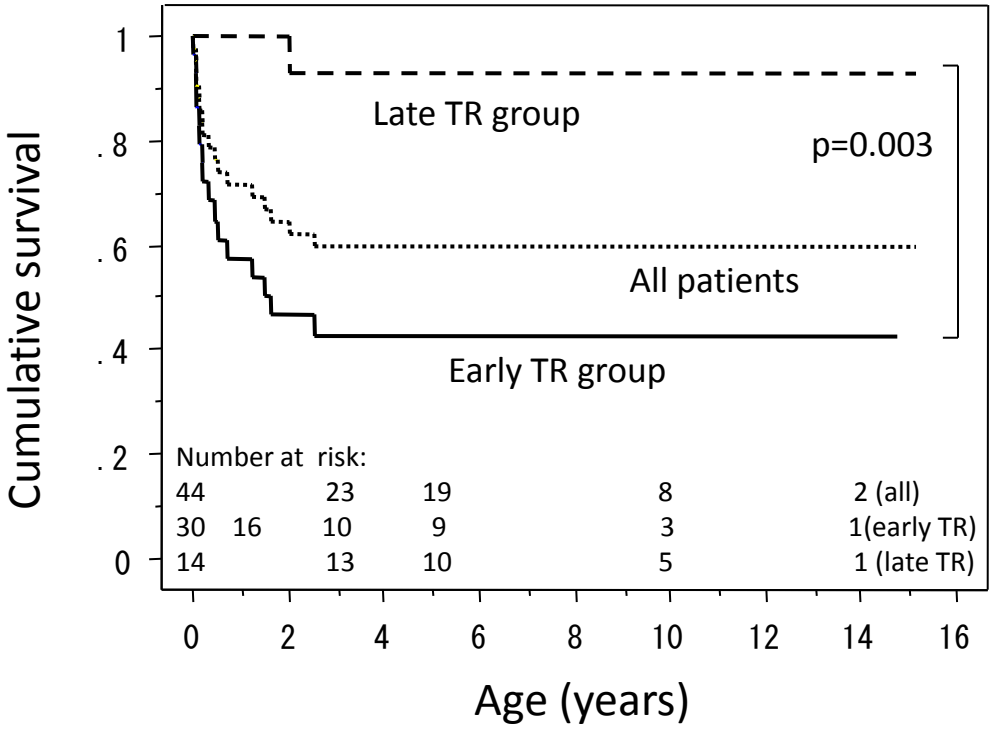
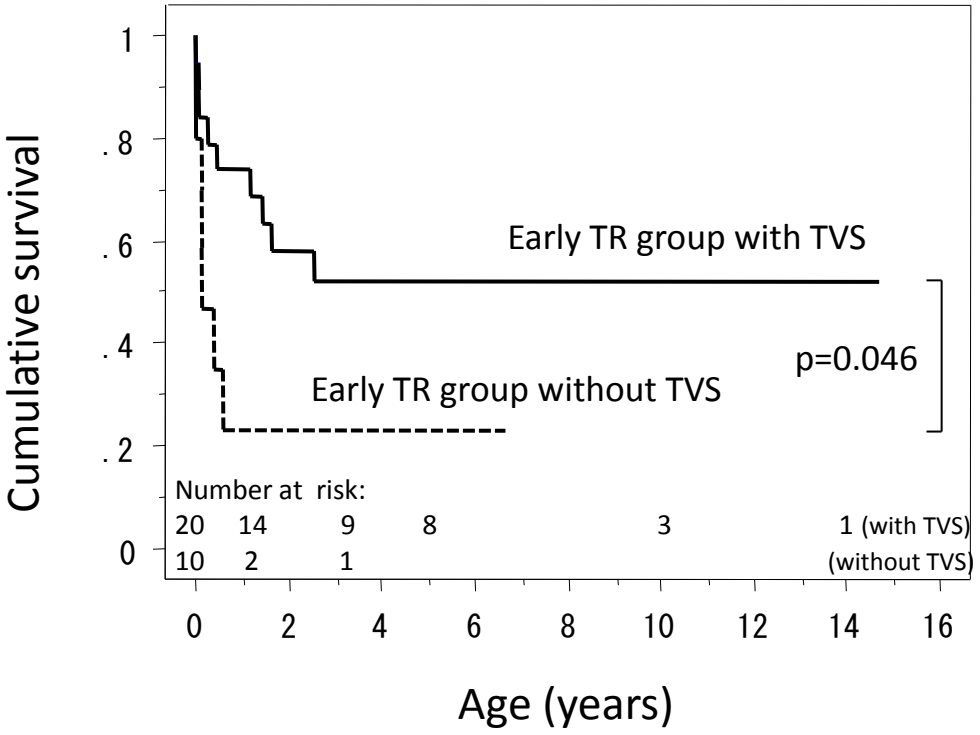

Cumulative survival
1
.8
.6
.4
.2
0
Late TR group
p=0.003
All patients
Early TR group
Number at risk:
44 23 19 8 2 (all)
30 16 10 9 3 1(early TR)
14 13 10 5 1 (late TR)
0 2 4 6 8 10 12 14 16
Age (years)

Figure 2. B


Cumulative survival
1
.8
.6
.4
.2
0
Early TR group with TVS
Early TR group without TVS
p=0.046
Number at risk:
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10 2 1 (without TVS)
0 2 4 6 8 10 12 14 16
Age (years)

Figure 3.

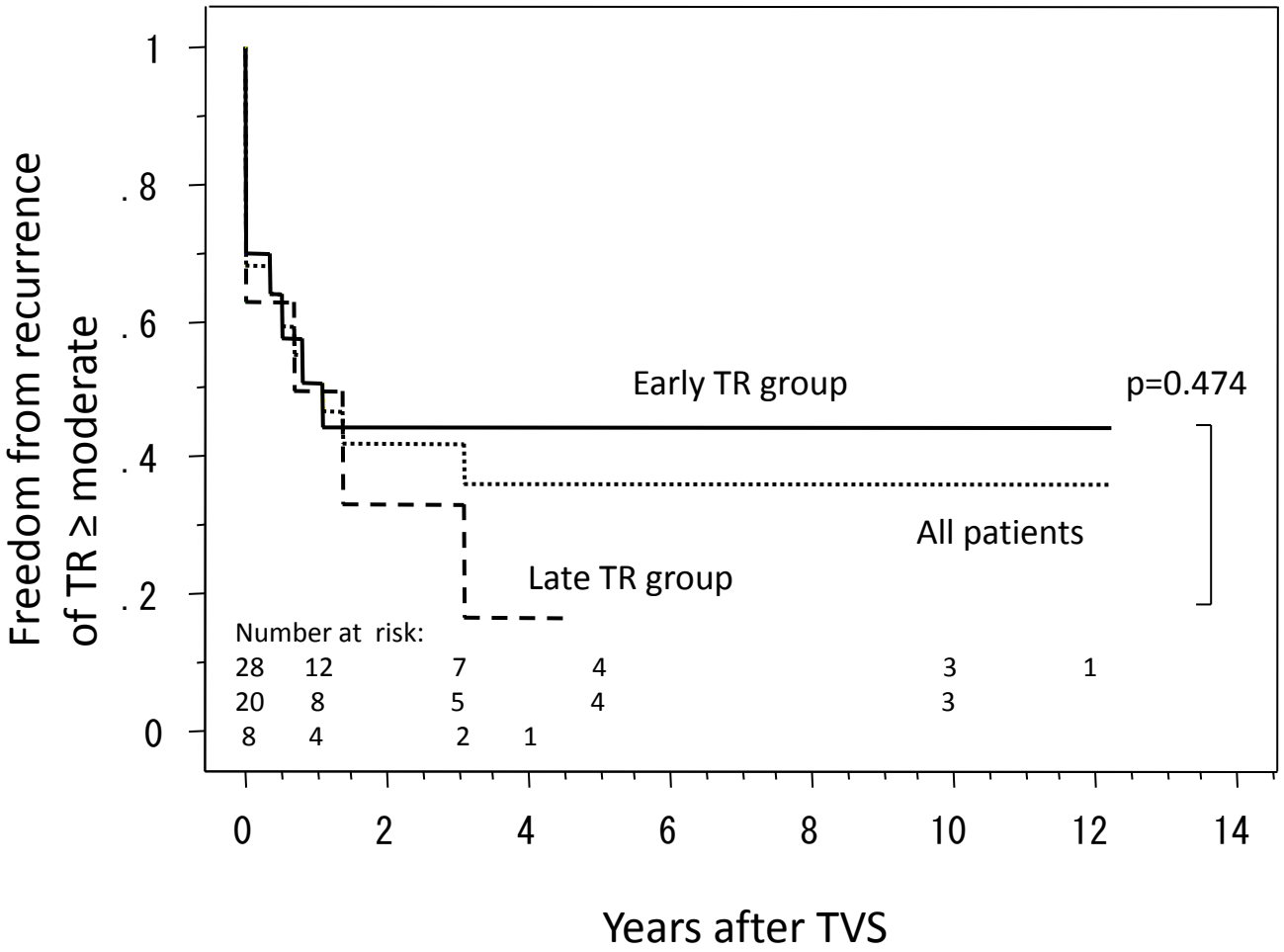
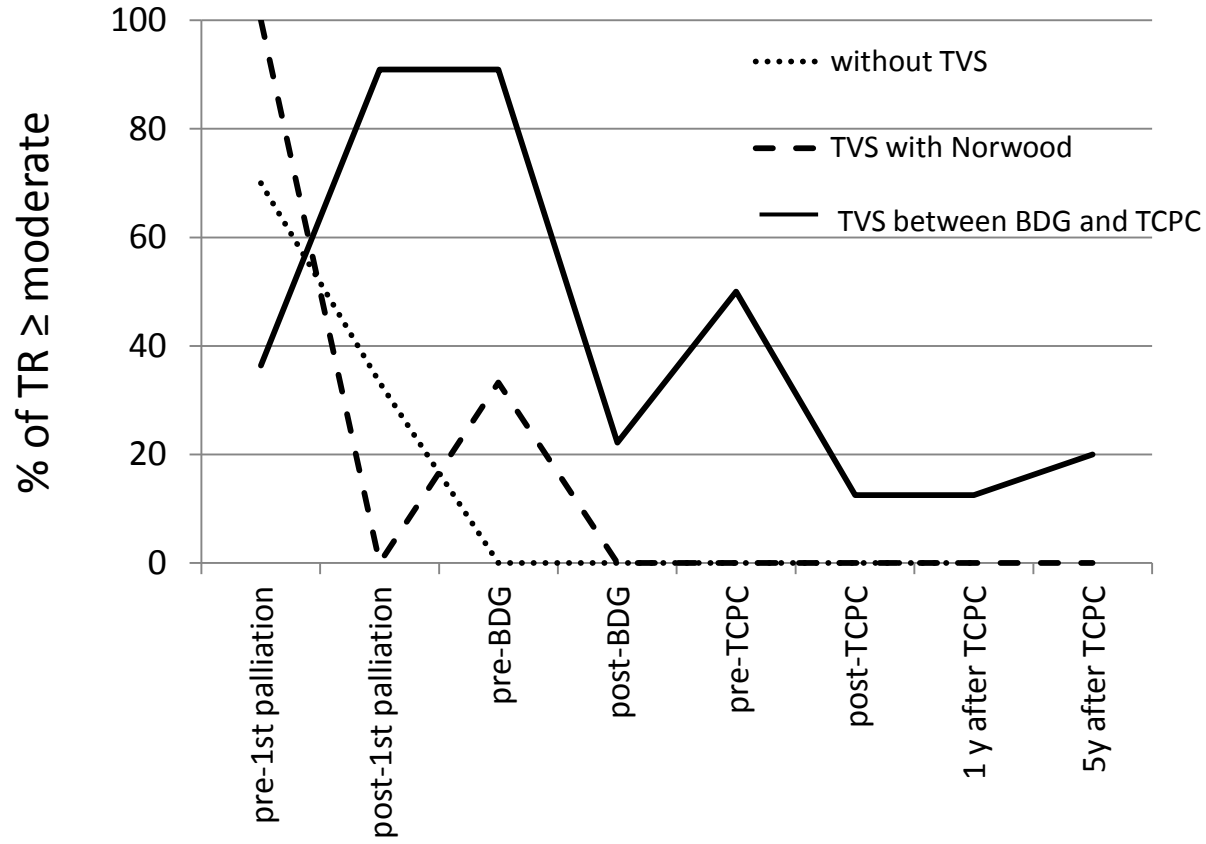

Freedom from recurrence of TR ≥ moderate
1
. 8
. 6
. 4
. 2
0
Early TR group
p=0.474
All patients
Late TR group
Number at risk:
28 12 7 4 3 1
20 8 5 4 3
8 4 2 1
0 2 4 6 8 10 12 14
Years after TVS

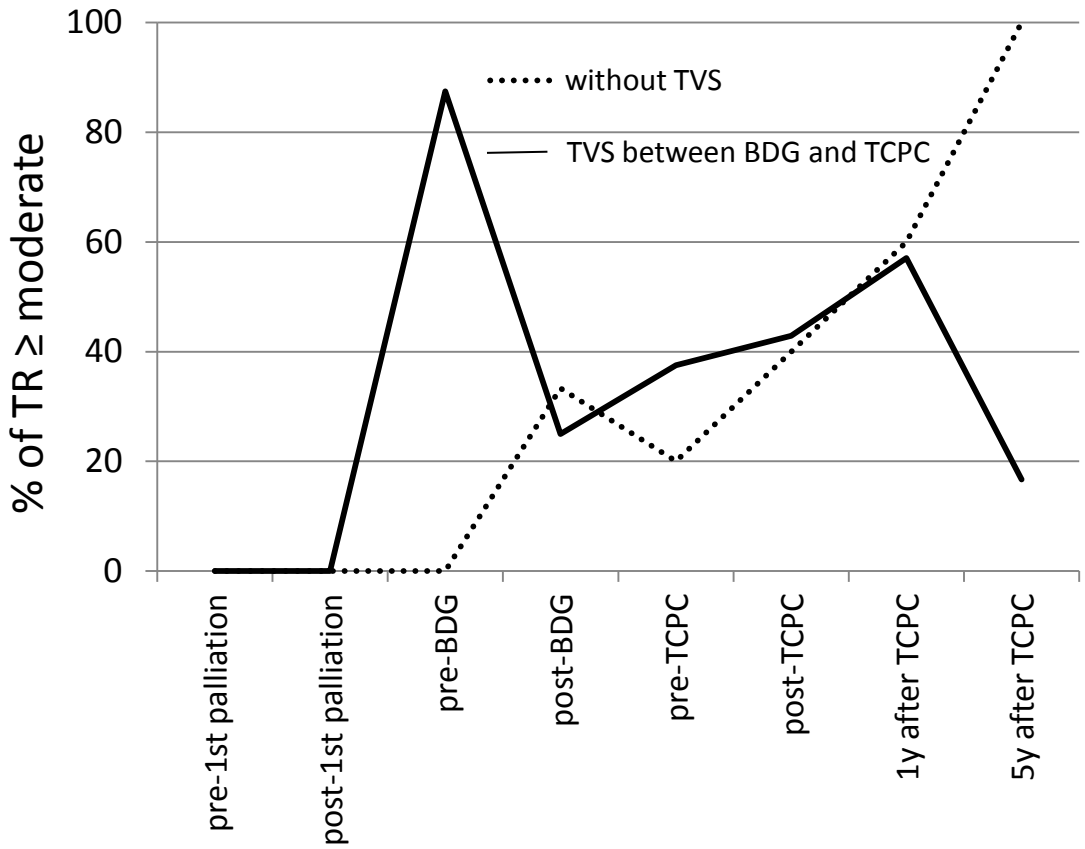
Figure 4. A



Number at risk:								
Without TVS	10	3	2					0
TVS with Norwood	9	4	3	2	1			
TVS between BDG and TCPC	11			9	8			5

Number of deaths:								
Without TVS		7						
TVS with Norwood		5		1				
TVS between BDG and TCPC				2	1			

Figure 4. B



Number at risk:							
Without TVS	6			5			2
TVS between BDG and TCPC	8				7		6
Number of deaths:							
Without TVS							
TVS between BDG and TCPC					1		