Tetralogy of Fallot
Transannular and Right Ventricular Patching Equally Affect Late Functional Status

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Background—In tetralogy of Fallot, transannular patching is suspected to be responsible for late right ventricular dilatation.

Methods and Results—In our institution, 191 patients survived a tetralogy of Fallot repair between 1964 and 1984. Transannular patching was used in 99 patients (52%), patch closure of a right ventriculotomy in 35, and direct closure of a right ventriculotomy in 55. Two had a transatrial-transpulmonary approach. To identify predictive factors of adverse long-term outcome related to right ventricular dilatation, the following events were investigated: cardiac death, reoperation for symptomatic right ventricular dilatation, and NYHA class II or III by Cox regression analysis. Mean follow-up reached 22±5 years. The 30-year survival was 86±5%. Right ventricular patching, whether transannular or not, was the most significant independent predictor of late adverse event (improvement x^2=16.6, \( P<0.001 \)). In patients who had direct closure, the ratio between end-diastolic right and left ventricular dimensions on echocardiography was smaller (0.61±0.017 versus 0.75±0.23, \( P=0.007 \)), with a smaller proportion presenting severe pulmonary insufficiency (9% versus 40%, \( P=0.005 \)). There was no difference between right ventricular and transannular patching concerning late outcome (log rank \( P \) value=0.6), right ventricular size (0.70±0.28 versus 0.76±0.26, \( P=0.4 \)), or incidence of severe pulmonary insufficiency (30% versus 43%, \( P=0.3 \)).

Conclusions—In tetralogy of Fallot, transannular patching does not result in a worse late functional outcome than patching of an incision limited to the right ventricle. Both are responsible for a similar degree of long-term pulmonary insufficiency and right ventricular dilatation. (Circulation. 2000;102[suppl III]:III-116-III-122.)

Key Words: heart defects, congenital ▪ tetralogy of Fallot ▪ surgery ▪ follow-up studies

Excellent long-term survival has been demonstrated after surgical repair of tetralogy of Fallot, and nowadays, surgeons should not restrict their efforts to this goal.1-2 In the 20 years after the initial repair, 10% to 15% of the patients will need a reoperation on their right ventricular outflow tract, most of them for limited exercise capacity, ventricular dysrhythmias, or more severe symptoms of heart failure.2,3 Although some patients operated on for tetralogy of Fallot are athletes, most have physical performance inferior to those of the general population. All these symptoms are related to right ventricular dilatation.4-7 We should focus on the improvement of the late functional status of these patients by trying to limit the number of those who will suffer from late right ventricular dilatation. This policy might even decrease the small number of those who suffer sudden death years after the operation. To achieve this goal, an understanding of the exact mechanism of right ventricular dilatation and the refinement of our surgical techniques are crucial elements.

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TABLE 1. Distribution of Palliation and Commissurotomy Among Surgical Techniques

<table>
<thead>
<tr>
<th>Technique</th>
<th>No. of Patients</th>
<th>No. of Palliated Patients (%)</th>
<th>Concomitant Commissurotomy, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct closure RV</td>
<td>55</td>
<td>18 (33)</td>
<td>31 (56)</td>
</tr>
<tr>
<td>RV patching</td>
<td>35</td>
<td>8 (23)</td>
<td>24 (69)</td>
</tr>
<tr>
<td>Transannular patching</td>
<td>99</td>
<td>32 (32)</td>
<td>99 (100)</td>
</tr>
<tr>
<td>Transatrial-transpulmonary</td>
<td>2</td>
<td>0</td>
<td>1 (50)</td>
</tr>
</tbody>
</table>

RV indicates right ventricle.

evaluate the potential long-term deleterious consequences of the different surgical techniques, the patients were split into 3 groups: those who had a transannular patch, those who had a patch closure of a right ventriculotomy, and those who had a direct closure of their right ventriculotomy. The 2 patients who had a transpulmonary-transatrial approach were assimilated into the group who had a direct closure of the right ventricle. The following Kaplan-Meier curves of freedom from adverse events that might be related to right ventricular dilatation were calculated: (1) freedom from cardiac death, (2) freedom from reoperation for symptomatic right ventricular dilatation and cardiac death, and (3) freedom from NYHA class II or III status, from reoperation for right ventricular dilatation, and from cardiac death. Independent contributions to prognosis of preoperative and operative variables were then assessed with Cox regressions. All tests were 2-tailed, and a value of $P<0.05$ was considered significant.

Results

Follow-Up

The completeness of follow-up was 95%: 2 Belgian and 7 non-Belgian patients could not be traced. The mean follow-up time was 22±5 years (range, 13 to 34 years), for a total of 3773 patient-years.

Survival

During follow-up, 15 deaths occurred. Nine patients had a cardiac-related death: 3 died in congestive heart failure and 6 had a sudden unexpected death. Six patients died of unrelated causes: 2 of a motor vehicle accident, 1 of chronic glomerulonephritis, 1 of chronic viral hepatitis, 1 after a reoperation for tracheal stenosis, and 1 in septic shock probably related to a GI tract infection. The 2 motor vehicle accidents did not appear to be due to a sudden death of the patients. The 30-year survival was 86±5% (Figure 1A).
Cardiac Reoperation
Twenty-three patients needed a cardiac reoperation. Fifteen had a homograft pulmonary valve implantation: 14 for symptomatic right ventricular dilatation due to pulmonary insufficiency and 1 for a mixed stenosis and insufficiency. One patient underwent an orthotopic heart transplantation for end-stage heart failure and massive right ventricular dilatation, 2 had a closure of a residual ventricular septal defect, 2 had a prosthetic aortic valve replacement (1 for endocarditis, 1 for aortic insufficiency), 1 had a repair of partial anomalous pulmonary venous drainage, 1 had a closure of a major aortopulmonary collateral, and 1 had a cryoablation of right ventricular scarring. One patient who had a pulmonary valve implant and 1 who had a closure of a residual ventricular septal defect had a concomitant prosthetic aortic valve replacement for aortic regurgitation. The 30-year survival without cardiac reoperation was 76±5% (Figure 1B). Symptomatic right ventricular dilatation was the indication for reoperation in the 15 patients who had a pulmonary valve implant and in the patient who had an orthotopic heart transplantation.

Interventional Catheterization
Five patients underwent an interventional catheterization from 6 to 22 years after the repair. Two had a pulmonary valve balloon dilatation, 2 had a balloon angioplasty of the origin of pulmonary arteries, and 1 had a coil embolization of a right coronary artery to right ventricle fistula. One dilatation of the pulmonary valve gave unsatisfactory results, and the patient subsequently underwent a pulmonary valve implantation.

Pacemaker Insertion
Eight patients needed a pacemaker implantation: 1 in the immediate postoperative period, 1 at 16 months after the operation, and the remaining patients from 11 to 25 years after the tetralogy repair. Indications for implantation were complete AV block in 6 patients, sick sinus syndrome in 1, and unknown in the last. The patient who had his pacemaker inserted 16 months after the repair died suddenly 7 years after the initial operation.

Functional Status
One hundred fifty-nine survivors at the time of the follow-up were classified in the following NYHA functional class: 111 patients (70%) were in NYHA class I, 42 (26%) in class II, and 6 (4%) in class III. Patients who were categorized in NYHA class II were experiencing ≥1 of the following symptoms: exertional dyspnea (29 patients), grade II dyspnea (2 patients), tiredness (26 patients), and frequent episodes of palpitations (18 patients). Occupation was determined in 141 patients: 116 (82%) were working, seeking employment, or students. Half of them had an occupation requiring physical strength. The degree of unemployment was determined in 124 patients in NYHA class I and II. Twelve of 35 NYHA class II patients (34%) and 9 of 89 in class I (10%) had no professional activities (P=0.001). The sporting practice was investigated in 128 patients. Fifty-six (44%) practiced a sport at least occasionally: 52 of 94 patients in NYHA class I (55%) and 4 of 34 patients in NYHA class II (12%) (P<0.001).

Late Adverse Events Related to Right Ventricular Dilatation
The 30-year freedom from cardiac death was 90±5%. The only predictive factor of late cardiac death was the existence of a preoperative palliative procedure (P=0.02) (Figure 2). The 30-year freedom from (1) cardiac death and (2) reoperation for right ventricular dilatation was 79±5%. Again, preoperative palliation was the only predictive factor of cardiac death or reoperation for late ventricular dilatation. The 30-year freedom from (1) cardiac death, (2) reoperation for right ventricular dilatation, and (3) NYHA class II or III was 42±5%. The variables that were studied for their impact on all adverse events related to right ventricular dilatation are listed in Table 2. Direct closure of the right ventriculotomy achieved far better late freedom from all adverse events than transannular or right ventricular patching (P<0.01). There was no difference between the patients who had a transannular and a right ventricular patch (P=0.59) (Figure 3). Two variables were independently associated with a poorer prognosis after multivariate Cox regression analysis: right ventricular patching, whether transannular or limited to the right ventricle (improvement χ²=16.6, P<0.001), and palliation before repair (improvement χ²=6.8, P=0.009). Right ventricular patching remained a significant prognostic factor when considered together with age at the time of the repair within a multivariate Cox regression analysis (P<0.001).

No statistically significant differences were noted in the distribution of pulmonary commissurotomy between patients with direct closure of the right ventricle and patients with right ventricular patching (P=0.25). Nonetheless, to rule out the possibility that the observed long-term deleterious effects of right ventricular and transannular patching had in fact been masking the influence of the potential pulmonary insufficiency created by pulmonary commissurotomy, its impact on freedom from all adverse events was investigated. Pulmonary
TABLE 2. Freedom From All Adverse Events Related to RV Dilatation

<table>
<thead>
<tr>
<th>Variables</th>
<th>15 Years, %</th>
<th>20 Years, %</th>
<th>Log-Rank P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>88±3</td>
<td>77±4</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>93±3</td>
<td>77±5</td>
<td>0.58</td>
</tr>
<tr>
<td>Previous palliation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>82±5</td>
<td>66±7</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>94±2</td>
<td>83±4</td>
<td>0.005</td>
</tr>
<tr>
<td>Type of previous palliation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blalock</td>
<td>83±8</td>
<td>70±10</td>
<td></td>
</tr>
<tr>
<td>Waterston</td>
<td>88±6</td>
<td>66±10</td>
<td>0.24</td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct closure of RV</td>
<td>94±3</td>
<td>90±4</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>RV patching</td>
<td>97±3</td>
<td>70±10</td>
<td>0.59</td>
</tr>
<tr>
<td>Transannular patching</td>
<td>86±4</td>
<td>70±15</td>
<td></td>
</tr>
<tr>
<td>Nature of the patch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Autologous pericardium</td>
<td>91±4</td>
<td>77±6</td>
<td>0.12</td>
</tr>
<tr>
<td>Others</td>
<td>90±3</td>
<td>77±4</td>
<td></td>
</tr>
<tr>
<td>Immediate postoperative RV/LV pressure ratio</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤0.75</td>
<td>88±3</td>
<td>71±5</td>
<td>0.08</td>
</tr>
<tr>
<td>&gt;0.75</td>
<td>89±10</td>
<td>. . .</td>
<td></td>
</tr>
</tbody>
</table>

RV indicates right ventricle; LV, left ventricle; and . . . means that <10 patients remained at risk at that time.

commissurotomy had no effect on patients who had a direct closure of a right ventriculotomy. Within the group of patients who had a pulmonary commissurotomy, the same deleterious effect of right ventricular and transannular patching was observed (Table 3).

Late Echocardiographic Follow-Up

The transthoracic echocardiographic studies obtained in the last follow-up were collected. If the patients had been reoperated on for symptomatic right ventricular dilatation, the last echocardiogram performed before reoperation was taken into consideration. Echocardiographic studies before death were also included. One hundred twenty-five patients had an echocardiogram after a mean of 21±5 years.

![Figure 3. Kaplan-Meier curve of freedom from all adverse events related to right ventricular (RV) dilatation.](graphic)

TABLE 3. Late Effect of Pulmonary Commissurotomy and Surgical Techniques on Freedom From All Adverse Events

<table>
<thead>
<tr>
<th>Surgical Technique</th>
<th>Commissurotomy</th>
<th>Log-Rank P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct closure of RV</td>
<td>No</td>
<td>0.37</td>
</tr>
<tr>
<td>Direct closure of RV</td>
<td>Yes</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>RV patching</td>
<td>Yes</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Transannular patching</td>
<td>Yes</td>
<td>0.65</td>
</tr>
</tbody>
</table>

RV indicates right ventricle.

One hundred two studies were performed in our institution. No patient had significant residual ventricular septal defect. Six had a residual right ventricular outflow tract gradient >25 mm Hg (range, 27 to 45 mm Hg).

Ventricular dimensions were evaluated in the short axis in 104 patients: the mean ratio between the end-diastolic dimensions of the right and the left ventricles was 0.72±0.25. In patients in NYHA class I, this ratio was significantly smaller than in those with unfavorable outcome (NYHA class II or III, cardiac death, or reoperation for right ventricular dilatation): 0.65±0.22 versus 0.86±0.26 (P<0.001). Patients who had a patch, whether transannular or limited to the right ventricle, had a larger ratio than the ones who had a direct closure of a right ventriculotomy (0.75±0.26 versus 0.61±0.17, P=0.007), but there was no difference between the patients who had a transannular patch and those who had a patch closure of the right ventricle (0.76±0.26 versus 0.70±0.28, P=0.4).

The severity of pulmonary regurgitation was assessed by color Doppler in 109 patients: 26 had no or minimal regurgitation, 47 had moderate regurgitation, and 36 had severe regurgitation. The patients who suffered from severe pulmonary insufficiency had a larger ratio between their right and left ventricular end-diastolic dimensions (0.87±0.26 versus 0.65±0.21, P<0.001). Two of 23 patients (9%) who had a direct closure of a right ventriculotomy and 34 of 86 patients (40%) who had a right ventricular patch, whether transannular or limited to the right ventricle, suffered severe pulmonary insufficiency (P=0.005). Seven of 23 patients (30%) with a right ventricular patch and 27 of 63 patients with a transannular patch (43%) had severe pulmonary regurgitation (P=0.4).

The existence of restrictive physiology was investigated in 53 patients, and 17 appeared to have a forward flow in the pulmonary artery during atrial systole, indicating existence of restrictive right physiology. There was a difference in the ratio between right and left ventricular dimensions in patients with or without restrictive physiology, but this difference did not reach statistical significance (0.49±0.56 versus 0.68±0.2, P=0.08). Four patients with restrictive physiology had a ratio >0.75. Thirteen of 17 patients (76%) with restrictive physiology and 27 of 36 (75%) without it were in NYHA class I (P=0.5).

ECG Studies

Among 110 patients who had an ECG at the last follow-up, 106 had a right bundle-branch block. The mean QRS duration
of the patients in NYHA class I was 147±31 ms, whereas it was 161±31 ms in patients who had an unfavorable outcome (NYHA class II or III, reoperation for right ventricular dilatation, or cardiac death) (P=0.03). An ECG was obtained in 90 survivors not reoperated on for ventricular dilatation. QRS duration correlated significantly with the ratio between the end-diastolic dimensions of the right and the left ventricles (r=0.23, P<0.05).

The mean QRS duration was 146±29 ms in patients with restrictive physiology and 155±33 ms in patients without it (P=0.4). Twenty patients had a recorded QRS duration ≥180 ms. The clinical status of these patients with long QRS duration was the following: in 2 of these patients, the ECG was obtained before their death: 1 died of sudden unexpected death and 1 of progressive congestive heart failure. Five patients had a previous pulmonary valve implant for right heart dilatation. Five of the remaining patients were in NYHA class II and 8 in class I. Patients who had a QRS duration ≥180 ms had large right ventricles, but the ratio between right and left ventricular dimensions was not significantly different from the ratio of the patients with a QRS duration <180 ms (0.85±0.31 versus 0.72±0.23, P=0.2). In 13 of these 20 patients with long QRS duration, the ECG was long enough to perform QRS, QT, and JT dispersion measurements. Twelve of them had a QT dispersion >60 ms, a QRS dispersion >35 ms, or a JT dispersion >60 ms.

Discussion
Transannular patching gives excellent relief of the right ventricular outflow tract of patients operated on for tetralogy of Fallot but invariably causes pulmonary insufficiency. We initially planned to evaluate the late impact of the long-term pulmonary insufficiency related to the use of transannular patching on the late functional status and the right ventricular dilatation of patients operated on for tetralogy of Fallot.

Limitations of the Study
The first difficulty was to identify those patients who suffered an adverse outcome because of right ventricular dilatation. Death and reoperation for right ventricular dilatation were obvious adverse consequences, but physical limitations were much more difficult to assess. We chose the NYHA classification to differentiate good from poor functional status. We estimated that young adults physically limited by right ventricular dilatation would fall into the NYHA class II category and considered it a poor outcome. The assignment of a patient to NYHA class I or II remains a subjective appreciation, but from the description of their symptomatology, we are convinced that our class I and II patients were different.

The short-axis echocardiogram is far from being the ideal examination for the estimation of right ventricular dimensions, and use of this method of investigation could be considered the second limitation of the study. The QRS duration is known to increase with right ventricular dimensions, and in our study, the QRS durations correlated significantly with our echocardiographic estimations of right ventricular sizes.12 Therefore, we tend to believe in the reliability of our echocardiographic measurements. We were comforted in our conclusion that the poor functional status of the patients was related to right ventricular dilatation by the fact that the relationship between functional status and QRS length of the patients perfectly matched the differences observed with the estimation of right ventricular dimensions.

Ideally, all patients should have been submitted to exercise testing and to MRI, but these examinations are expensive and time-consuming. Because most of our patients were young active adults who would comply only with a quick, noninvasive procedure, choosing these investigations would have greatly decreased the number of gathered data.

Surgical techniques may vary greatly from one center to another, especially when muscle resection is considered. Therefore, our surgical approach may not be representative of the approach used in other centers.

Finally, this historical patient population was much older and had more palliation at the time of corrective surgery than the children operated on nowadays.

Late Survival and Functional Status
Neonatal palliation has already been shown to increase the risk of cardiac-related death during follow-up, and our study of the whole cohort of all our hospital survivors clearly confirms that fact.13 It has been hypothesized that the poorer survival of the patients who had a palliative shunting procedure before definitive repair was related to the distortion of the pulmonary arteries by the shunts. Although Waterston shunts were supposedly more harmful to the pulmonary arteries than Blalock shunts, we were unable to demonstrate any difference between these shunts in freedom from any adverse events. Therefore, the more likely explanation for the worse outcome of palliated patients is that they are born with smaller pulmonary arteries.

We initially expected to confirm the deleterious effects of transannular patching on late right ventricular dilatation and late functional status and thought that the patients who had their tetralogy repaired through a right ventriculotomy without a transannular incision would be spared late dilatation of their right ventricle. Surprisingly, only the patients who had a right ventriculotomy closed by direct suture were spared late dilatation and had a better late functional status. These patients are most probably the “pink Fallots” who had only moderate obstruction of their right ventricular outflow tract, and this would confirm that patients with the more severe disease have the worst long-term prognosis.

There was no difference in the proportion of patients with pulmonary insufficiency, the degree of right ventricular dilatation, and the freedom from late adverse consequences related to right ventricular dilatation between patients with transannular and right ventricular patching. The similarity between the outcomes of patients with a right ventricular and those with a transannular patch has already been described, although not clearly pointed out: Nollert et al2 showed that mortality risk was linear in the first 25 years after the repair but increased significantly after that. Long-term survival was impaired in patients with a right ventricular patch, but there was no difference between transannular and right ventricular patching. Exercise testing of patients with or without pulmonary regurgitation late after a repair of tetralogy of Fallot has
shown that those who had a ventricular patch, whether transannular or limited to the right ventricle, had a lower cardiac output both at rest and on exercise.9

We have to conclude that in our hands, limiting the incision to the right ventricle and preserving the pulmonary annulus failed to protect our patients from progressive right ventricular dilatation. It is difficult to conclude from the long-term consequences of operations of the past what should be changed in operations performed today. Clearly, surgeons now achieve much smaller ventriculotomies, and direct closure of a right ventriculotomy is an abandoned operation. Nonetheless, our findings may have some technical implications. If a right ventriculotomy is necessary to relieve the right ventricular outflow tract obstruction, there is probably no point in struggling to leave the pulmonary annulus intact, because it does not appear to influence the long-term physical capacity of the patients and its influence on operative mortality is still controversial.14

If the intimate relationship between pulmonary regurgitation and right ventricular dilatation has largely been demonstrated, their causal relationship has not been clearly proven, and other factors might play an important role.15,16 Because pulmonary commissurotomies did not affect the long-term outcome of our patients and because of the similarity in the long-term fate of our patients with transannular and right ventricular patching, we believe that long-term pulmonary insufficiency is not the only factor causing right ventricular dilatation. The resection of the parietoventricular and parietoparietal muscle bundles of the right ventricular outflow tract might well destabilize the muscular cylinder that supports the pulmonary valve and by itself cause dilatation of the pulmonary infundibulum. It is possible that the more the muscular mass of the pulmonary infundibulum is resected, the more its contractility and its ability to keep its shape are impaired. Dilatation of the pulmonary infundibulum might in turn cause pulmonary insufficiency. The surgeons working in our unit at that time, when asked in more detail about their technique, described their relief of the right ventricular outflow tract as a real “emptying out” of the pulmonary infundibulum. The large extent of muscle resection performed in our patients is demonstrated by the very high proportion of our patients having a right bundle-branch block on the last follow-up ECG and the extremely low incidence of reoperation for right ventricular obstruction. The influence of the muscle resection on subsequent right ventricular dilatation has already been proved clinically. A technique of transatrial closure of the ventricular septal defect and minimal resection of the right ventricular outflow tract muscle bundles reduced the incidence of late right ventricular dilatation in patients with transannular patching.9

Restrictive Physiology
It is difficult to evaluate from our study the impact of restrictive physiology on the long-term outcome of the patients, because our sicker patients were the ones who had died or those who had been reoperated on and therefore were not accessible to or suitable for this investigation. Patients with restrictive physiology had smaller right ventricles, but this difference was not statistically significant, probably because the number of patients was too small. Surprisingly, some patients had restrictive physiology and dilated right ventricles. This finding was carefully double-checked and confirmed. Our only interpretation of these facts is that these right ventricles might become so dilated that they are no longer compliant at the end of the diastole. It is probably for that reason and because of the design of the study that no relationship between restrictive physiology and functional status could be evidenced.

ECG Studies
In our study, increased QRS duration seemed to be a good index of worse outcome and of right ventricular dilatation. It is still unclear from the literature, however, what should be offered to the patients whose QRS duration is >180 ms. In our hands, QRS, QT, and JT dispersion measurements brought no further contribution: 12 of 13 patients examined had criteria predictive of sustained ventricular tachycardia. Whether it is justified to perform electrophysiological studies, cryoablation therapy, and/or defibrillator implantation even in those who are asymptomatic is an unresolved question.

Progeny
The 5% incidence of congenital heart defects in the offspring of our patients tends to confirm the previously predicted incidence of 7.5% in parents with congenital cardiovascular defects.17

Conclusions
In tetralogy of Fallot, transannular patching does not result in a worse late functional outcome than patching of an incision limited to the right ventricle. Resection of right ventricular outflow tract muscle bundles might contribute more to late ventricular dilatation than does chronic pulmonary insufficiency; therefore, we advocate limited subvalvar muscle incision. Because previous palliative procedures were responsible for late cardiac death and transannular patching did not worsen the late fate of our patients, we would tend to support a policy of early repair of tetralogy of Fallot.

References
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