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Effect of Transannular Patching on Outcome After Repair of Tetralogy of Fallot

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Among 814 patients undergoing repair of tetralogy of Fallot with pulmonary stenosis between 1967 and May 1986, transannular patching in the current era was a weak risk factor for death early postoperatively (predicted 30-day mortality, 4% with a transannular patch and 1.4% without) and is not a risk factor for instantaneous risk of death late postoperatively (predicted 20-year survival including early death, 94% with a transannular patch and 96.5% without). Ninety-six percent of surviving patients were in New York Heart Association functional class I at last follow-up, and the slight decline in this percentage as the interval between operation and last follow-up lengthened could have been due to chance alone (p = 0.24) and was no different in patients with a transannular patch. Transannular patching was a risk factor for reoperation for pulmonary regurgitation late postoperatively, but only a 7% incidence within 20 years is predicted when mild residual stenoses are beyond the patch: the incidence rises to about 20% with important distal stenoses. Inferences from the study are relevant to the indications for transannular patching and insertion of allograft semilunar valves at the time of repair.

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Controversy has continued over the indications for transannular patching as a part of the repair of tetralogy of Fallot with pulmonary stenosis, in large part because of insufficient information on the potentially detrimental effect on outcome of the resulting pulmonary regurgitation. Therefore a study has been made of the effect of transannular patching in the repair of tetralogy of Fallot on early and intermediate-term survival, functional status, and freedom from reoperation. The data are also relevant to the recent upsurge of interest in using semilunar valve allografts rather than transannular patches when the pulmonary annulus is hypoplastic.

Material and Methods

Patient Population

Between January 1, 1967, and May 1, 1986, 814 patients underwent repair of tetralogy of Fallot with pulmonary stenosis. Age at operation ranged between 2 months and 57 years. Ten percent of the patients were 1.0 year of age or less at operation, 25% were 2.3 years of age or less, 50% were 5.3 years of age (median age) or less, and 75% were 11 years of age or less.

The event "reoperation" included all reoperations early and late after the repair and excluded only reoperations for bleeding in the perioperative period. Patients who underwent percutaneous balloon valvoplasty of the pulmonary valve or angioplasty of the pulmonary trunk or right or left pulmonary artery stenoses were included among those considered to have undergone reoperation. The event was tabulated whether the reoperation was performed in this institution (28 reoperations, 1 hospital death) or elsewhere (4 reoperations, 1 hospital death). During the same period, 34 additional reoperations were performed in this institution (1 hospital death) in patients whose initial repair had been done elsewhere.

Intraoperative Methods

The surgical methods used [1] and the indications for placing a transannular patch [2] have been described previously. The repair was performed from the right atrium or by a combined right atrial and pulmonary arterial approach in 107 patients [3–5] and through a right ventriculotomy in 707. A simple repair (infundibular dissection, pulmonary valvotomy, or both, with or without an enlarging patch limited to the right ventricle, the pulmonary trunk, or both) was used in 538 patients, a transannular patch (or a nonvalved conduit, 2 patients) in 255 (31% of 814 patients), and a valved conduit in 21. Throughout the experience, the transannular patch was tailored to be of adequate width but not billowing. Most of the patches were made of Dacron, but pericardial patches were used early in the experience in some patients and throughout the experience in small patients.

The postrepair ratio between the peak pressure in the right ventricle and that in the left ventricle (postrepair $P_{RV/LV}$) was measured in the operating room (postrepair (OR) $P_{RV/LV}$) about 20 minutes after the discontinuance of cardiopulmonary bypass. A thin-walled needle was passed across the free wall and into the right ventricle; after the right ventricular peak pressure was obtained, the needle was advanced across the ventricular septum and into the left ventricular cavity. In general, a simple repair

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was used when the predicted postrepair (OR) $P_{RV/LV}$ was 0.85 or less. A transannular patch usually was placed if the predicted or measured ratio without a patch was greater than this [6].

Study Methods

All documents pertaining to the original operation and the postoperative period, all documents concerned with interval events including reoperations performed at this institution or elsewhere, and all information obtained directly from patients and their physicians were studied in detail. The pertinent information was extracted and placed in computer storage.

Follow-up

A formal follow-up of all patients not known to be dead was made by letter and by telephone during July, August, and September 1986. All but 68 patients were traced during follow-up or were previously known to be dead. Of the 68, 10 had 10 to 16 years of complete follow-up as a result of previous inquiry, return visits, correspondence, or a combination of these, 17 had 5 to 10 years, 18 had 2 to 5 years, 4 had 1 year to 2 years, 8 had 30 days to 1 year, and 11 had less than 30 days. The mean follow-up after initial repair was 9 ± 5.4 years. Ten percent of the patients were followed 16 or more years; 25%, 14 or more years; 50%, 10 (median follow-up) or more years; 75%, 4.4 or more years; and 95%, 1 year or more.

Analytical Methods

The time-related freedom from death was estimated actuarially and by parametric methods [7, 8]. The hazard function was derived using a method previously described [8]. Multivariate analyses were performed in the hazard function domain to search for incremental risk factors [8]. A variable was retained as a risk factor if its p value was less than 0.1. The time-related freedom from reoperation of any kind and the time-related freedom from reoperation for pulmonary regurgitation were similarly analyzed, but patients receiving valved conduits (mostly xenograft valved) were excluded. Ordinal logistic regression analysis was used to estimate parametrically the change in New York Heart Association functional class across time [9].

All differences were examined by appropriate methods for the likelihood that they were due to something other than chance alone.

Results

Survival

Transannular patching was a risk factor for death early after repair of tetralogy of Fallot but not thereafter (Table 1). The effect is much weaker in operations performed in recent years, and the trends suggest that currently any differences could be due to chance alone (Fig 1).

Functional Class Late Postoperatively

Ninety-six percent of surviving patients were in New York Heart Association functional class I at the time of the last follow-up. A slightly reduced prevalence of patients in class I when there was a longer interval between operation and last follow-up could have been due to chance alone (Fig 2). Thus, there are no risk factors (including transannular patching) for declining functional status in surviving patients (Appendix Table B-1).

Table 1. Incremental Risk Factors for Death After Repair of Tetralogy of Fallot With Pulmonary Stenosis[a,b]

Incremental Risk Factor for Death (All Deaths = 81)	Hazard Phase: Early	Hazard Phase: Constant
Demographic		
Body surface area (m^2) (smaller)	Yes	No
Age (yr) (older)	Yes	Yes
Clinical		
Hematocrit (%) (higher)	Yes	No
Previous Potts' anastomosis	No	Yes
More than one previous palliative operation	Yes	No
Previous palliative direct relief of RVOTO	No	Yes
Morphological		
Absence of unbranched hilar portion of one pulmonary artery	Yes	No
Multiple ventricular septal defects	Yes	No
Dextrocardia	Yes	No
Surgical		
Date of operation (years since 1/1/67) (earlier)	Yes	No
Transannular patch	Yes	No
Postrepair (OR) $P_{RV/LV}$ (higher)	Yes	Yes

[a] Variables with no notation in parentheses as to the direction or units of the risk factor are simply yes/no variables. [b] See Appendix A for the variables entered into the analysis and the parameter estimates, coefficients, and p values.

OR = operating room; $P_{RV/LV}$ = ratio between peak pressure in right ventricle and that in left ventricle; RVOTO = right ventricular outflow tract obstruction.

Reoperations

Transannular patching was not a risk factor for reoperation in general after repair of tetralogy of Fallot (Table 2). Transannular patching clearly was a risk factor for reoperation for pulmonary regurgitation (Fig 3). However, the strength of its effect was dependent on the postrepair (OR) $P_{RV/LV}$ (Table 3), and the probability of reoperation within 20 years was very low when residual stenosis was mild (Fig 4). Thus, transannular patching rarely resulted in reoperation for pulmonary regurgitation within 20 years when an obstructing lesion beyond the transannular patch was not present (Table 4).

Comment

Critique of Study

A strength of the study is that two of the outcome events, death and reoperation, are specific and are objectively

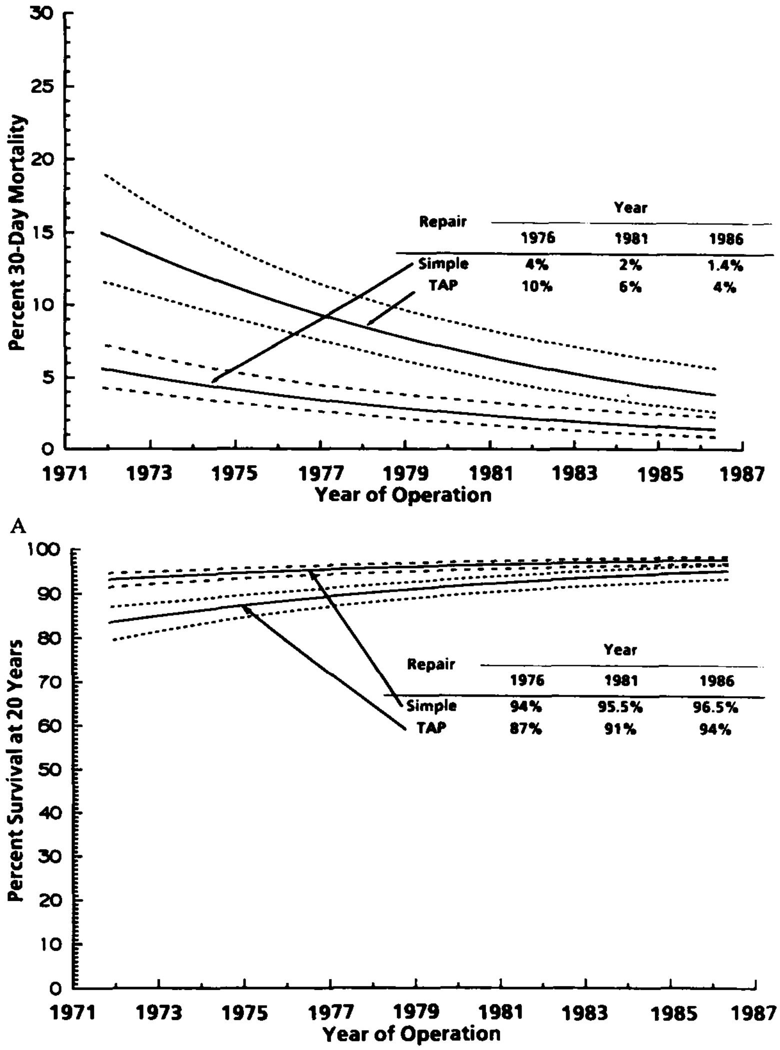


Fig 1. The effect on (A) 30-day mortality and (B) 20-year survival of use of a transannular patch (TAP) rather than a simple procedure (dissection or valvotomy, with or without infundibular or pulmonary artery patching). Time zero is the time of operation, and thus hospital deaths are included. Patients 2 years of age at repair are represented. The solid lines *are the continuous point estimates, and the* broken lines *enclose the 70% confidence intervals. Notice that the 70% confidence intervals of (A) death and (B) survival are nearly touching when the repair, whether simple or with a patch, was done in 1986, thus indicating that the difference by that date may be due to chance alone. The depictions are specific solutions of the multivariate risk-factor equation shown in Table 1 (see Appendix A for details).*

determined. The third, New York Heart Association functional class, is specific but is subjectively determined, and on occasion, patients who believe themselves to have no limitation on their activities are found to be subnormal by objective exercise testing. However, in the setting of the current study, the data concerning the functional class over a long follow-up would seem to be useful, particularly as there is no evidence out to 20 years of deteriora-

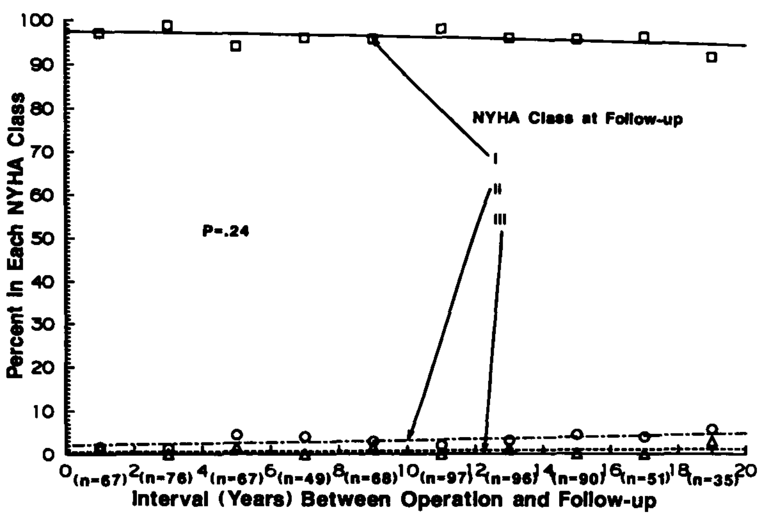


Fig 2. New York Heart Association (NYHA) *functional class after repair of tetralogy of Fallot according to the interval between operation and last follow-up. The numbers in parentheses along the horizontal axis are the number of patients available for functional class categorization at the odd-numbered interval below which the number is positioned. The* squares *represent the actual proportion of patients in functional class I at each interval; the* circles, *those in class II; and the* triangles, *those in class III. The* solid line *represents the actual slope of the solution of the ordinal logistic regression analysis, although the* p *value of 0.24 for the difference from zero slope indicates that change across time in the distribution of patients according to their NYHA functional class could be due to chance alone (see Appendix B for details).*

Table 2. Incremental Risk Factors for Reoperation of Any Type After Repair of Tetralogy of Fallot[a,b]

Incremental Risk Factor for Reoperation of Any Type (n = 32)	Hazard Phase: Early	Hazard Phase: Constant
	p value	*p* value
Demographic		
Body surface area (m^2) (smaller)	No	Yes
Previous operation		
Potts' anastomosis	No	Yes
Palliative direct relief of RVOTO	No	Yes
Surgical		
Valved extracardiac conduit	No	Yes
Postrepair (OR) $P_{RV/LV}$ (higher)	Yes	Yes

[a] The depiction is as in Table 1. [b] See Appendix C for details.

OR = operating room; $P_{RV/LV}$ = ratio between peak pressure in right ventricle and that in left ventricle; RVOTO = right ventricular outflow tract obstruction.

Table 3. Incremental Risk Factor for Reoperation for Important Pulmonary Regurgitation After Repair of Tetralogy of Fallot[a]

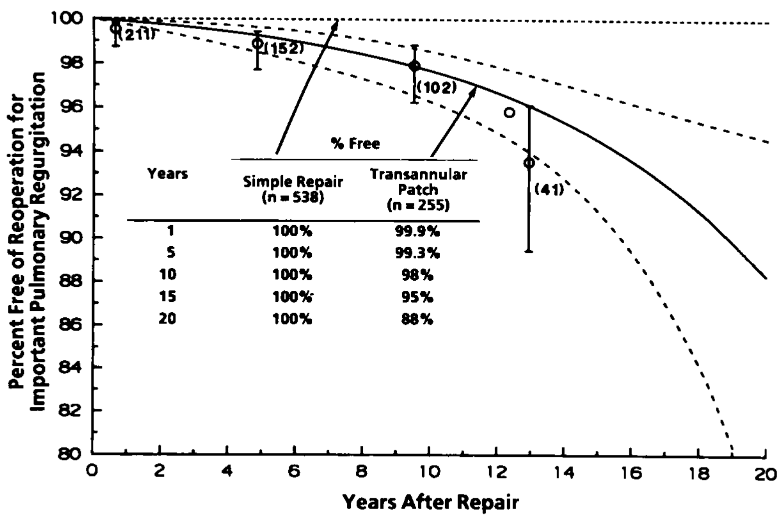
Incremental Risk Factor for Reoperation for Important Pulmonary Regurgitation (n = 5)	Single Hazard Phase
	p value
Postrepair (OR) $P_{RV/LV}$ (higher)	0.1

[a] See Appendix D for details.

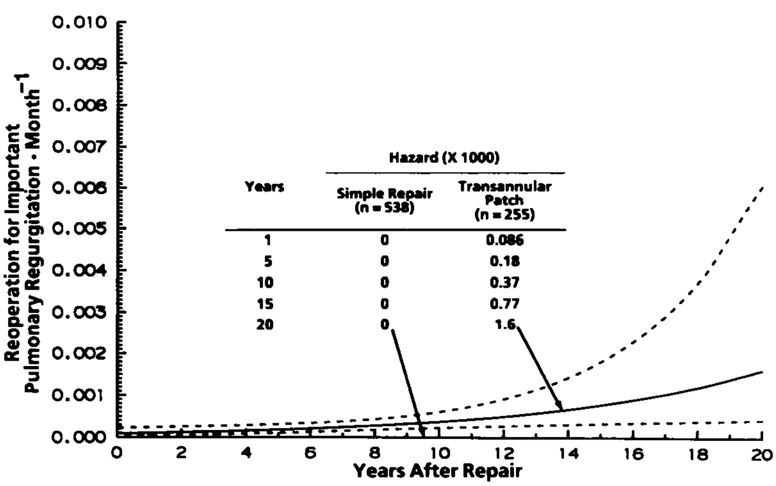
OR = operating room; $P_{RV/LV}$ = ratio between peak pressure in right ventricle and that in left ventricle.

tion in the functional capabilities of the patients. The reliability of the outcome data is enhanced by the completeness and length of the follow-up.

Ideally, late postoperative hemodynamic and objective exercise testing should be included in the outcome events studied for the determination of a possible unfavorable effect of transannular patching. These data are, however, almost impossible to obtain on anything more than a small fraction of the patient population, and this severely



A



B

Fig 3. (A) Actuarial and parametric depiction of percent freedom from reoperation for important pulmonary regurgitation according to whether the repair was simple or was performed using a transannular patch. Among the patients who underwent simple repair, no reoperations were performed for important pulmonary regurgitation, and this is shown by the straight broken line. Note the markedly expanded vertical axis. (B) Hazard function (see Appendix C for details).

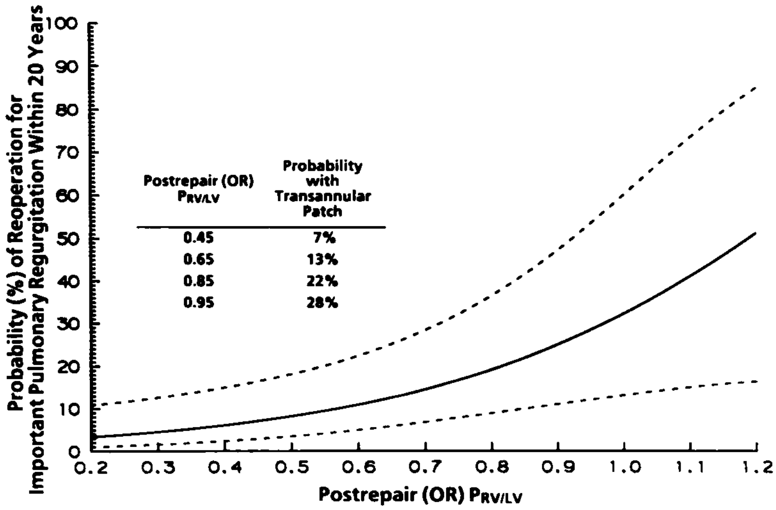


Fig 4. Specific solution of the multivariate equation relating the postrepair ratio between the peak pressure in the right ventricle and that in the left measured in the operating room (Postrepair (OR) $P_{RV/LV}$) *to the probability of reoperation for important pulmonary regurgitation within 20 years in patients in whom the repair had been performed using a transannular patch (see Appendix D for details).*

limits the inferences that can be drawn about the total patient population undergoing operation. The hemodynamic and exercise data available are compatible with the inferences derived from the current study.

Inferences as to the Detrimental Effect of Transannular Patching

It seems self-evident that pulmonary regurgitation and right ventricular volume overload follow the insertion of a transannular patch, even when the patch is not excessive in width. The time of greatest instantaneous hazard to survival must be when the volume overload is first evident after cardiopulmonary bypass and in the early hours thereafter, when only the functional myocardial reserve of the right ventricle is available for adaptation. The declining hospital mortality experienced in recent years among patients in whom a transannular patch has been used and the favorable experience with transannular patching in other institutions [10] are probably related to better protection of the myocardial reserves during operation. Thereafter, increase in right ventricular volume and change in wall characteristics aid in adaptation. However, the course of patients with isolated congenital pulmonary valve incompetence indicates that, although approximately 40 years of successful adaptation are usually allowed, the adaptive process ultimately fails in the face of continuing pulmonary regurgitation [11].

During the period of successful adaptation, as shown by this study, the patient's functional capacity is usually excellent, and hence, the probability of survival is not reduced, and reoperation is usually not indicated. Mild increase in right ventricular volume is part of the adaptive process [11]. The adaptive process is sufficiently robust that in most patients it is effective for at least 20 years, as seen in the present study and an earlier one by Fuster and colleagues [12]. However, objective exercise testing has

Table 4. Data on the 5 Patients Undergoing Reoperation (Insertion of Pulmonary Valve) for Pulmonary Regurgitation

Age at Repair	Operation Before Repair	Coexisting Anomalies	Postrepair (OR) $P_{RV/LV}$	Interval to Reoperation	$P_{RV/LV}$ Before Reoperation	RV Before Reoperation	Postreoperation (OR) $P_{RV/LV}$
19 mo	Right B-T shunt	Mild stenosis at LPA origin	0.42	8 mo	0.43	Dilatation grade 4/6	0.35
6 yr	Waterston shunt	Long stenosis in RPA	0.67	13 yr	. . .	. . .	0.63
4 yr	Palliative transannular patch	Severe RPA and LPA hypoplasia; large right collateral from innominate	0.68	9.5 yr	1.0 (same in PA)	Dilatation grade 4/6	(Inserted pulmonary valve was obstructive and removed)
7 yr	Waterston shunt	Obstruction of RPA	0.73	12 yr	0.52	Dilatation grade 6/6	0.41
8 yr	Potts' shunt	Stenosis at RPA origin; stenosis in mid-LPA	1.0	5 yr	0.8	Dilatation grade 5/6	1.05

B-T = Blalock-Taussig; LPA = left pulmonary artery; OR = operating room; PA = pulmonary artery; $P_{RV/LV}$ = ratio of peak pressure in right ventricle to that in left ventricle; RPA = right pulmonary artery; RV = right ventricle.

shown something less than normal capacity even during this period in nearly all patients in whom a transannular patch has been inserted [13].

As could be expected, there is some variability in the length of the period of successful adaptation, which in part probably accounts for a small proportion (12% in this study) of patients requiring reoperation within 20 years. The rising hazard function for reoperation in this group of patients (see Fig 3B) is consistent with the hypotheses developed here.

The success and duration of adaptation appear to be lessened by residual stenotic lesions beyond the transannular patch, including pulmonary vascular disease, according to the present study. This may relate to a possible increase in the regurgitant flow or an increase in right ventricular afterload. Because there is no certainty as to which mechanism is more responsible for the relations illustrated in Figure 4, there is no certainty that the presence of a pulmonary valve would change that relation.

When adaptation begins to fail, considerable benefit is provided by relieving the volume overload by orthotopic insertion of an allograft semilunar valve [14, 15], provided that this is not delayed until irreversible right ventricular damage has occurred.

Inferences as to Indications for Transannular Patching

Because clinical evidence of the detrimental effects of transannular patching is delayed for at least 20 years in most patients, efforts to preserve or substitute for the pulmonary valve should have at least as favorable an outcome. The relative risks of transannular patching, on the one hand, and of avoidance of transannular patching and preservation of the patient's pulmonary valve, albeit with a somewhat higher postrepair $P_{RV/LV}$, on the other, have not been clearly defined, but the strong unfavorable effect on outcome of increased resistance to right ventricular outflow must be taken into account [16]. Until these relative risks are specifically compared, transannular patching can be considered indicated when the predicted postrepair $P_{RV/LV}$ late postoperatively is greater than about 0.65. Also, the early and intermediate-term risks of insertion of an allograft valve have not as yet been determined to be as low as those of transannular patching. Consequently, until more information is available, the widespread use of this technique in the repair of tetralogy of Fallot with pulmonary stenosis is not indicated.

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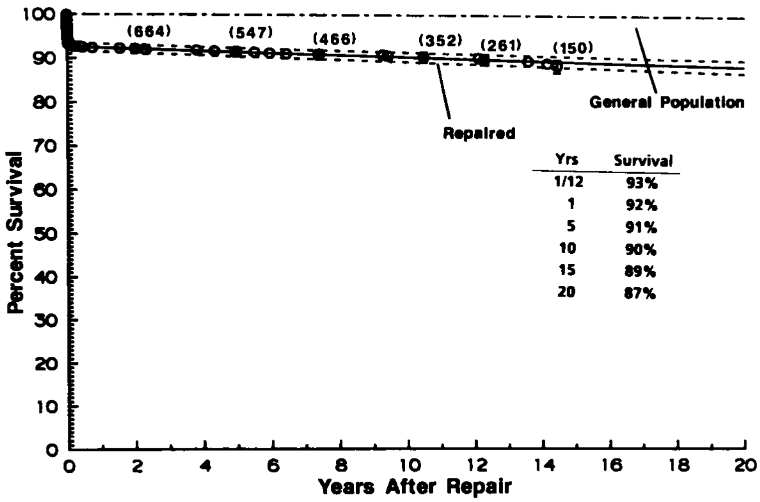
Appendix A. Analysis of Survival

The parameter estimates for the survivorship and hazard function were: Early phase: $\mu_1 = 0.07604$, $\delta = 0$, $\rho = 0.02600$, $\upsilon = 1$, and $m = -0.5420$; Constant phase: $\mu_2 = 0.0002557$ (Appendix Figs A-1, A-2).

Variables entered into the multivariate risk-factor analysis for death included *demographic and clinical variables*—age (years) at repair, body surface area (square meters) and weight (kilograms) at repair, sex, race, preoperative hematocrit; *previous operation variables*—previous operative procedure (yes/no, number, more than one), previous shunting procedure (classic Blalock-Taussig or Gore-Tex interposition shunt, single classic, right or left classic, Waterston, Potts', other), previous palliative direct relief of right ventricular outflow tract obstruction (Brock procedure [n = 13] or palliative transannular patch [n = 4]); *morphological variables*—anomalous origin of left anterior descending coronary artery from right coronary artery, patent ductus arteriosus, left superior vena cava, low-lying infundibular pulmonary stenosis, subarterial location of ventricular septal defect, large aortopulmonary collateral arteries, straddling tricuspid valve, multiple ventricular septal defects, dextrocardia (of the 5 patients,

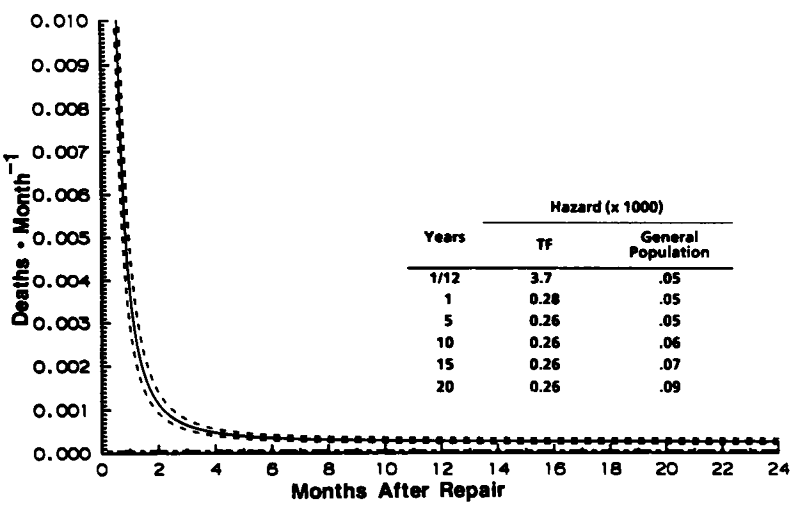


Appendix Fig A-1. Survival after repair of tetralogy of Fallot with pulmonary stenosis (1967–May 1986) (n = 814). The circles represent a death, and are positioned along the horizontal axis according to the interval between the time of operation (time zero) and the death, and along the vertical axis actuarially. The vertical bars *represent the 70% confidence intervals (± 1 standard deviation). The* solid line *represents the parametric estimate of survival, and the* broken lines *enclose its 70% confidence intervals. The numbers in parentheses indicate the number of patients surviving and traced to the interval since operation. The* dash-dot-dash *line is the survival of an age-sex-race–matched general population (US Life Tables, 1976).*

2 had situs inversus totalis), severe tricuspid valve incompetence, partial anomalous pulmonary venous connection; *morphology of the pulmonary arteries variables*—left or right pulmonary artery stenoses, bifurcation stenosis, absence of unbranched hilar portion of one pulmonary artery, anomalous origin of a pulmonary artery from the ductus; *surgical variables*—atrial approach to ventricular septal defect, right ventriculotomy, type of repair (simple, transannular patch, or nonvalved extracardiac conduit, orthotopic valve, or valved extracardiac conduit), repair of left or right pulmonary artery stenosis, date of operation (years since January 1, 1967), use of total circulatory arrest, use of cardioplegia, global myocardial ischemic time using cardioplegia; and *postrepair (OR)* $P_{RV/LV}$.

Parameter estimates, coefficients, and p values for the equation representing the incremental risk factors for death resulting from the multivariate analysis in the hazard function domain were: Early phase: $\delta = 0$, $\rho = 0.02275$, $v = 1$, m $= -0.4806$, intercept $= -6.729$, *age at repair* $= 0.006755 \pm 0.0022$ ($p = 0.002$), *body surface area* (natural logarithmic transformation) $= -2.976 \pm 0.57$ ($p < 0.0001$), *hematocrit* $= 3.554 \pm 1.35$ ($p = 0.008$), *more than one previous palliative operation* $= 1.719 \pm 0.45$ ($p = 0.0001$), *multiple ventricular septal defects* $= 1.404 \pm 0.43$ ($p = 0.001$), *dextrocardia* $= 2.346 \pm 1.04$ ($p = 0.02$), *absence of unbranched hilar portion of one pulmonary artery* $= 1.241 \pm 0.38$ ($p = 0.001$), *date of operation* $= -0.09877 \pm 0.034$ ($p = 0.004$), *use of transannular patch* $= 1.035 \pm 0.30$ ($p = 0.0006$), *postrepair (OR)* $P_{RV/LV}$ *(square transformation)* $= 1.373 \pm 0.48$ ($p = 0.004$); Constant phase: intercept $= -9.950$, *age at repair* $= 0.005298 \pm 0.00113$ ($p < 0.0001$), *previous Potts' anastomosis* $= 1.269 \pm 0.59$ ($p = 0.03$), *previous palliative direct relief of right ventricular outflow tract obstruction* $= 1.928 \pm 0.60$ ($p = 0.001$), *postrepair (OR)* $P_{RV/LV}$ *(squared transformation)* $= 1.599 \pm 0.79$ ($p = 0.04$).

The nomogram in Figure 1 is a specific solution of the multivariate equation, and the values entered for each risk factor are as follows: *age*, 24 months; *body surface area*, 0.50 m^2; *hematocrit*, 0.5; *previous Potts' anastomosis*, *previous palliative direct relief of right ventricular outflow obstruction*,



Appendix Fig A-2. Hazard function for death after repair of tetralogy of Fallot (TF) with pulmonary stenosis (1967–May 1986). The depiction is the same as in Appendix Figure A-1.

Appendix Table B-1. New York Heart Association Functional Class at Last Follow-up After Repair of Tetralogy of Fallot

	Category of Repair							
	Simple		Transannular Patch		Valved Conduit		Total	
Functional Class at Follow-up	No.	% of 478	No.	% of 201	No.	% of 17	No.	% of 696
I	459	96	196	98	14	82	669	96
II	15	3	4	2	3	18	22	3
III	4	1	1	0.5	0	0	5	1
IV	0	0	0	0	0	0	0	0
Subtotal	478	100	201	100	17	100	696	100
Dead	36		42		3		81	
Unknown	24		12		1		37	
Total	538		255		21		814	

more than one previous palliative operation, all No; *morphological risk factors* (see Table 1), all No; *date of operation*, 1986.

Appendix B. Functional Class Late Postoperatively

The Appendix Table B-1 contains the contingency table of New York Heart Association functional class at the time of the last follow-up. The ordinal logistic regression analysis was: intercept 1 = −3.669, intercept 2 = −5.389, *interval between repair and latest follow-up* (months) = 0.003734 ± 0.0032 (p = 0.24).

Appendix C. Reoperations

The indications for reoperation are shown in Appendix Table C-1.

Appendix Table C-1. Indications for Reoperation After Repair of Tetralogy of Fallot

Indication for Reoperation (n = 31) or Balloon Dilation (n = 1)	No. of Patients
Persistent or recurrent RVOTO[a]	17
Important pulmonary regurgitation	5
Residual or recurrent VSD	3
Large left-to-right shunt[b]	1
Valved conduit obstruction	2
Miscellaneous (one each)	4
Total	32

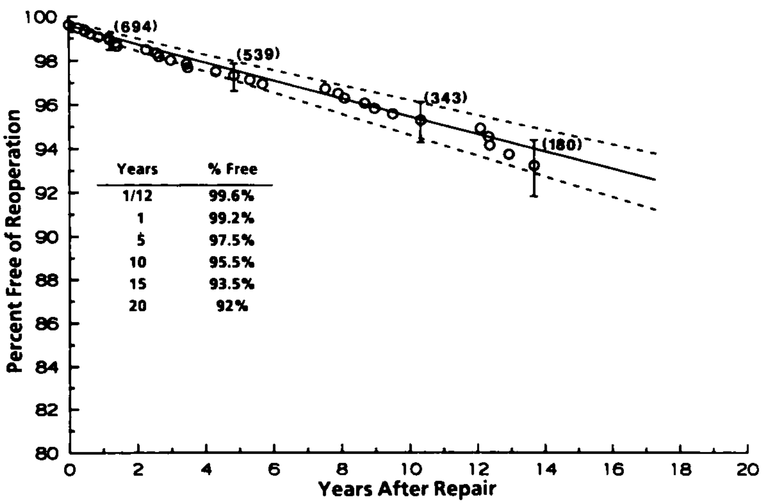
[a] In 13, this was the only abnormality at the time of reoperation; the obstruction was in the infundibulum in 4 patients, pulmonary annulus in 1, pulmonary artery bifurcation in 2, origin of the right and/or left pulmonary artery in 2, and multiple sites in 4. In 1 patient each, the RVOTO was associated with a small residual VSD, a small VSD and right ventricular aneurysm, a right ventricular aneurysm, and tricuspid incompetence. [b] Shunt was through a patent Blalock-Taussig shunt and a residual VSD.

RVOTO = right ventricular outflow tract obstruction; VSD = ventricular septal defect.

Parameter estimates for time-related depiction of reoperation of any kind (Appendix Fig C-1): Two hazard phases for reoperation of any kind were found. The shaping parameters for these were: Early phase: μ_1 = 0.003889, δ = 0, ρ = 0.03422, ν = 1, m = 0; Constant phase: μ_2 = 0.0003523.

Multivariate analysis of reoperation of any kind: The variables entered into the risk-factor analysis for reoperation of any kind included *demographic and clinical data*—age (years) at repair, sex, race, body surface area (square meters), hematocrit; *previous palliative procedures*—previous palliative procedures (yes/no, more than one, number), previous shunting procedures (classic, single classic, left classic, right classic, Waterston, Potts'), right ventricular outflow tract procedure (Brock or transannular patch); *morphological variables*—anomalous origin of left anterior descending coronary artery from right coronary artery, anomalous origin of one pulmonary artery, straddling tricuspid valve, patent ductus arteriosus, left superior vena cava, low-lying infundibular pulmonary stenosis, subarterial ventricular septal defect, large aortopulmonary collateral arteries, pulmonary artery morphology variables (left pulmonary artery stenosis, right pulmonary artery stenosis, bifurcation stenosis); *surgical variables*—atrial approach to ventricular septal defect, right ventriculotomy, type of repair (simple, transannular patch, valved conduit), repair of left pulmonary artery stenosis, repair of right pulmonary artery stenosis, date of operation (years since January 1967); and postrepair (OR) $P_{RV/LV}$ both as a numerical ratio and as a yes/no variable indicating a $P_{RV/LV}$ greater than or equal to 1.

Parameter estimates, coefficients, and p values for the multivariate risk-factor equation were: Early phase: δ = 0, ρ = 0.03487, ν = 1, m = 0, intercept = −7.448, *postrepair (OR)* $P_{RV/LV}$ (squared transformation) = 3.970 ± 1.11 (p = 0.0003); Constant phase: intercept = −9.686, *body surface area* (natural logarithmic transformation) = −1.004 ± 0.47 (p = 0.03), *previous Potts' anastomosis* = 1.468 ± 0.78 (p = 0.06), *previous palliative direct relief of right ventricular outflow tract obstruction* (closed or open Brock) = 2.182 ± 0.76 (p =



Appendix Fig C-1. Actuarial and parametric depiction of percent freedom from reoperation of any kind after repair of tetralogy of Fallot with pulmonary stenosis (1967 to May 1986; n = 814; reoperations = 32). The circles, *actuarially positioned, represent individual patients undergoing reoperations and the* vertical bars, *the 70% confidence intervals. The patients at risk at certain actuarial time intervals are indicated by the numbers in parentheses. The* broken lines *represent the 70% confidence intervals around the* solid line, *which is the parametric estimate. Also shown are the parametric estimates at certain intervals since the original operation (see Appendix C for details).*

0.004), *valved extracardiac conduit* = 2.106 ± 0.74 (p = 0.005).

Appendix D. Reoperations for Important Pulmonary Incompetence

Parameter estimates for the time-related depiction of reoperation for important pulmonary regurgitation (the analysis was made only for the 255 patients in whom a transannular patch was used, as no reoperations for important pulmonary regurgitation were performed in patients in whom a transannular patch was not used): A single hazard-phase for reoperation for important pulmonary regurgitation was found: $\mu_3 = 0.004306$, $\tau = 134.3$, $\gamma = 1$, $\alpha = 0$, $\eta = 1$.

Variables entered into the multivariate analysis: The risk factors entered into the analysis were the same as in Appendix C except those describing repair of the pulmonary outflow tract were omitted.

Parameter estimates, coefficients, and p values for the multivariate risk factor equation were: Single phase: $\tau = 83.04$, $\gamma = 1$, $\alpha = 0$, $\eta = 1$, intercept = −6.819, *postrepair (OR)* $P_{RV/LV} = 3.040 \pm 1.85$ ($p = 0.1$).

This risk factor equation was solved for various postrepair (OR) $P_{RV/LV}$ values for Figure 4.

Effect of transannular patching on outcome after repair of tetralogy of Fallot

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