Case Report

ISSN 2689-1093

Surgical Research

Monocusp is Worth It: Short- and Longterm-Outcome of TAP, Monocusp and Valve-sparing Strategies

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Received: 21 Jan 2025; **Accepted:** 18 Feb 2025; **Published:** 18 March 2025

Citation: Sarah Simona Rahlfs, Joerg S Sachweh, Sebastian Harms, et al. Monocusp is Worth It: Short- and Longterm-Outcome of TAP, Monocusp and Valve-sparing Strategies. Surg Res. 2025; 7(1): 1-6.

ABSTRACT

Background: *Right ventricular outflow tract obstruction (RVOTO) at the level of the pulmonary valve in patients with Tetralogy of Fallot (ToF) may be treated with a transannular patch (TAP), Monocusp implantation or valve-sparing repair, depending on the anatomy, degree of obstruction and surgical preferences. We sought to evaluate our data on the short- and mid-term function of RVOTO relief in ToF.*

Methods: *This retrospective cohort study is based on 83 consecutive patients with ToF-typical anatomy who underwent surgery at the University Medical Center Hamburg-Eppendorf (UKE) between 2007 and 2021. The median age at index surgery was 164 (37 - 475) days, the median weight 6.0 kg (3.8 - 9.3). Surgical approach to RVOTO was classified as transannular patch (n= 38), monocusp reconstruction (n= 11), commisuriotomy (n= 27) and primary infundibulectomy (n=7). The grouped comparison was made between patients undergoing annular incisional surgery and valve-sparing surgical strategies. In a second step, isolated TAP and monocusp repair was compared. The primary endpoint of the analysis is freedom from reintervention. Long-term data were collected.*

Results: *The comparison between annular incision and valve-sparing surgery revealed significant differences regarding more bicuspid valves (p=0.005), a smaller Z-value of the pulmonary valve annulus (p<0.001), lower preoperative oxygen saturation (p=0.015) and more palliative surgical interventions (p<0.001) in the annular incision group. There is a trend towards shorter ICU stay (p=0.066), significantly less moderate or severe pulmonary valve regurgitation postoperatively (17.6% vs. 73.5%; p<0.001) and no need for valve replacement and no subsequent reinterventions in the valve-sparing group. When comparing TAP and monocusp repair, there are no significant differences in terms of cardiac anatomy and functional data. There is significantly more frequent moderate or severe pulmonary valve regurgitation (PR) postoperatively in the TAP group (84.2% vs. 36.4%; p=0.002). There is a trend towards fewer reinterventions in the monocusp group after 5 years (38.5% vs. 0%, p=0.073) and a significant difference after 10 years (71.4% vs. 14.3%, p=0.024). Long-term freedom from severe PR and reinterventions are 57.1% after 5 years and 42.9% after 10 years in the monocusp group.*

Conclusion: *Our data have shown that valve-preserving techniques require fewer reinterventions and are therefore preferable to other methods when anatomically possible. If a decision has to be made between TAP and monocusp due to identical anatomy, our data indicate that the use of a monocusp shows a better outcome in the long term due to the better result in terms of less PR postoperatively and fewer reinterventions.*

Keywords
Tetralogy of Fallot, Transannular Patch, Monocusp, Valve-sparing, Pediatric cardiac surgery.

Introduction
Surgical repair of Tetralogy of Fallot (ToF) has become a standard procedure with low mortality [1]. However, the relief of right ventricular outflow tract obstruction (RVOTO) at annular level has remained a debate in some cases [2,3]. Based on anatomy, degree of obstruction and surgical preferences, RVOTO at the level of the pulmonary valve may be dealed with transannular patch (TAP), monocusp implantation, or valve sparing repair. At one end of the surgical spectrum is TAP, which in most cases adequately relieves the RVOT obstruction but is associated with significant PV regurgitation leading to RV dilatation and ventricular arrhythmias [4,5]. On the other hand, the valve-preserving approach, which in most cases preserves valve function in the long term [6], often leaves an obstruction in the RVOT. These patients need to be treated with regular RVOT dilating procedures [6,7]. To circumvent the disadvantages of free pulmonary insufficiency with a TAP, the monocusp concept was developed as early as 1964 by W. Lillehei [8]. The concept is to augment a TAP with a single cusp made out of a homograft, xenograft or synthetic material [9], however, this procedure is more complex, time consuming and the result may not be as predictable as with other means of RVOTO repair [10]. On the first glance a reasonable approach, nevertheless, the results of moncusps, particular in terms of valve function, are not unison. We sought to evaluate our data of short- and mid-term function of RVOTO relief in ToF to contribute to the body of knowledge.

Material and Methods
Patients
This retrospective cohort study based on 83 consecutive patients with ToF-typical anatomy operated on University Medical Center Hamburg-Eppendorf (UKE) between 2007 and 2021. Patients characteristics are demonstrated in table 1. Exclusion criteria were pulmonary atresia, presence of a RVPA conduit, univentricular palliation and age at repair older than two years. Our classification of the surgical strategy was based on the priority intervention on the RVOT at the time of repair with closure of the VSD, classified as transannular patch (TAP), monocusp reconstruction, commisuriotomy and primary infundibulectomy.

Statistical Analysis
The data were retrospectively collected from surgery reports, discharge letters, echo findings and other clinical documents using Excel and analyzed using SPSS. Patients were grouped according to the surgical RVOT strategies applied. The primary endpoint for the analysis is freedom from reintervention, defined as surgical or catheter-based interventions on the RVOT or pulmonary arteries. The grouped comparison was conducted between patients who had undergone a procedure with annular incision (TAP and monocusp) and valve-sparing surgical strategies (primary commissurotomy and primary infundibulectomy). Delamination of the pulmonary valve annulus was not considered a separate group as it always occurred with commissurotomy. In the second step, isolated TAP and monocusp were compared (Figure 1).

Table 1: Patients Characteristics.

Variables	All patients (n=83)
Anatomy	
→ TOF	56 (67%)
→ DORV/TOF	27 (33%)
Male sex	49 (59%)
Genetic syndrome	
→ No syndrome	61 (74%)
→ Trisomie 18 or 21	5 (6%)
→ Di George	5 (6%)
→ Others	12 (14%)
Age at total correction (d)	164 (37 - 475)
Weight at total correction (kg)	6.0 (3.8 – 9.3)
Year of surgery	
→ 2007 – 2013	39 (47%)
→ 2014 – 2021	44 (53%)
RVOT-surgical strategy	
→ TAP	38 (45%)
→ Monocusp	11 (13%)
→ Commissuriotomy	27 (34%)
→ Infundibulectomy	7 (8%)
Palliative procedure	
→ No procedure	55 (66%)
→ Surgical (BT shunt/ TAP)	18 (22%)
→ Interventional (balloon dilatation/ stent)	8 (10%)
→ Combined	2 (2%)

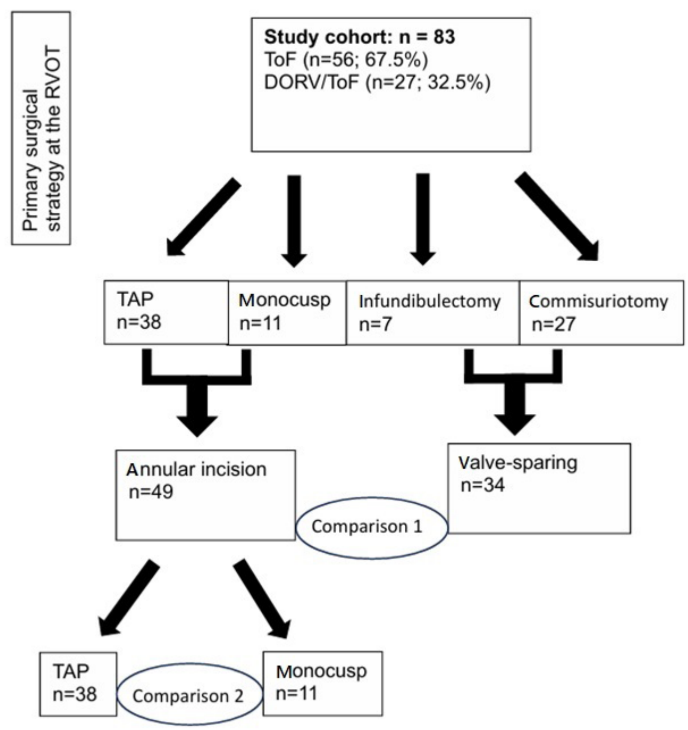

Figure 1: Group division: TAP = Trannsanular Patch.

For long-term follow-up data of the 4th to 6th year and of the 9th to 11th year follow up were grouped. For patients with a reintervention in this period, we only used echo data afterwards. Distribution was displayed using median (minimum-maximum). All continuous characteristics were tested for normal distribution using the Kolmogorov-Smirnov test. Normally distributed variables were compared using the T-test, non-normally distributed using the Mann-Whitney U test. For categorical variables, a Chi-Square test was performed. The Fisher's exact test was used for expected frequencies of less than five. A multivariate Cox regression was carried out according to content for each of the two initial comparisons to identify possible confounders on the time to the occurrence of reinterventions. All P-values given are two-sided with a first order error of 0.05 as a criterion for statistical significance.

Results

Comparison of Annular incision vs. Valve-sparing

Patient characteristics are summarized in table 2. There are no significant differences between the transannular and valve-sparing surgical strategies with respect to demographics (age, weigth, year (before and after 2014), sex) and preoperative maximum systolic gradient. However, the group with transannular incision was significantly more likely to have bicuspid valve leaflets (p=0.005), smaller pulmonary valve annulus Z-scores (p<0.001), lower preoperative oxygen saturations (p=0.015) and more frequent prior palliations (p<0.001).

There were no significant intraoperative differences in the time to aortic cross-clamping, mean postoperative residual gradient across the RVOT, or right ventricular function. There was a trend toward shorter postoperative ICU stay in the valve-sparing group (p=0.066) (7.29 d, annular incision: 8.83 d). Technique-related moderate to severe pulmonary valve regurgitation was significantly more frequent in the transannular incision group (73.5%; valve-preserving 17.6%; p<0.001). Long-term data are summarized in table 3. No significant differences were found for RV pressure, gradient across the RVOT, or TRs. At 5-year follow-up, 38.7% in the transannular incision group and 16.7% in the valve-sparing group had severe or free PR, and 28.5% and none, respectively, at 10 years. There was no significant difference in reinterventions. Cox regression in table 4 shows no significant confounders.

Comparison of TAP vs. Monocusp

Patient characteristics are summarized in table 2. There are no significant differences between TAP and monocusp with regard to the demografic data (age, weight, year, gender), cardiac anatomy and functional data (valve morphology, systolic gradient, PV-annulus, preoperative oxygen saturation, palliative surgical procedures) and surgery data (aortic cross-clamp time, intensive care stay, residual RVOT gradient and right ventricular function postoperative). At discharge, significantly more patients in the TAP group had moderate to severe PR (84.2% vs. 36.4%; p=0.002). Long-term follow-up data are summarized in table 3. No significant differences were found for RV pressure, gradient across the RVOT, or TRs. At long-term follow-up, 37.5% of patients in the TAP group and 42.9% in the monocusp group had severe to free PR at 5 years and 21.4% and 42.9%, respectively, at 10 years. Within the first 5 years, 38.5% of patients in the TAP group required

Table 2: Surgery data.

Variables	Annular incision (n=49)	Valve-sparing strategies (n=34)	P-value	TAP (n=38)	Monocusp (n=11)	P-value
Demographic data						
· Male sex	27 (55.1%)	22 (64.7%)	0.382	22 (57.9%)	5 (45.5%)	0.510
· Age at total correction (d)	172 (±72)	167 (±68)	0.643	172 (±73)	174 (±50)	0.923
· Year of surgery			0.183			0.911
→ 2007 – 2013	26 (53.1%)	13 (38.2%)		20 (52.6%)	6 (54.5%)	
→ 2014 – 2021	23 (46.9%)	21 (61.8%)		18 (47.4%)	5 (45.5%)	
Cardiac anatomy and functional data (preoperative)						
· Pulmonary valve morphology bicuspid[a]	35 (87.5%); n=40	20 (58.8%)	**0.005**	28 (87.5%); n=32	7 (87.5%); n= 8	1.000
· RVOT gradient (mmHg)	83.89 (±18.60)	79.88 (±24.16)	0.423	85.2 (±19.44)	79.73 (±15.70)	0.346
· PV Z-score	-3.99 (±2.56)	-1.41 (±1.87)	**<0.001**	-3.87 (±2.66)	-4.40 (±2.27)	0.555
· SpO2 (%)	91.61 (±7.28)	95.15 (±6.01)	**0.015**	91.58 (±7.38)	91.73 (±7.30)	0.895
· Palliative surgical procedures	25 (51.0%)	3 (8.8%)	**<0.001**	19 (50%)	6 (54.5%)	0.791
Corrective Surgery						
· Weight (kg)	6.079 (±1.279)	6.205 (±1.503)	0.682	6.148 (±1.363)	5.842 (±0.946)	0.490
· ACC time (mins)	109 (±32)	104 (±30)	0.469	111 (±35)	104 (±16)	0.411
Postoperative						
· ICU stay (d)	8.83 (±8.28)	7.29 (±7.80)	0.066	8.77 (±8.61)	9.00 (±7.51)	0.800
Discharge echocardiography						
· Mean RVOT gradient > 35 mHg	7 (15.2%); n=46	9 (31%); n=29	0.103	5 (13.9%); n= 36	2 (20%); n=10	0.634
· Moderate or severe PR	36 (73.5%)	6 (17.6%)	**<0.001**	32 (84.2%)	4 (36.4%)	**0.002**
· Reduced right ventricular function	9 (18.4%); n=45	11 (32.4%); n=31	0.132	7 (18.4%); n=34	2 (18.2%); n=11	1.000

[a]one valve monocuspid

Table 3: Long-term data.

Variables	Annular incision	Valve-sparing strategies	P-value	TAP	Monocusp	P-value
5-years-follow-up	n= 33	n= 14		n= 26	n= 7	
· RV-pressure (mmHg)	28.73 (±16.93); n=22	24.39 (±9.95); n=9	0.535	30.72 (±18.06); n=18	19.75 (±4.99); n=4	0.141
· Mean RVOT gradient > 35 mmHg	2 (6.1%)	2 (14.3%)	0.574	2 (7.7%)	0	1.000
· Severe or free PR	12 (38.7%); n=31	2 (16.7%); n=12	0.279	9 (37.5%); n=24	3 (42.9%)	1.000
· Moderate or severe TR	3 (9.1%)	0	0.543	3 (11.5%)	0	1.000
· Patients with reinterventions · Number of reinterventions → 1 → >1	10 (30.3%) 5 (15.1%) 5 (15.1%)	4 (28.6%) 4 (28.6%) 0	1.000 0.303	10 (38.5%) 5 (19.2%) 5 (19.2%)	0 0 0	0.073 0.555
10-years-follow-up	n= 21	n= 4		n= 14	n=7	
· RV-pressure (mmHg)	31.44 (±20.47); n=16	26.67(±13.73); n=3	0.487	33.14 (±24.44); n=11	27.70 (±7.24); n=5	0.913
· Mean RVOT gradient > 35 mmHg	1 (4.8%)	1 (25%)	0.300	1 (7.1%)	0	1.000
· Severe or free PR	6 (28.5%)	0	0.540	3 (21.4%)	3 (42.9%)	0.354
· Moderate or severe TR	4 (19.1%)	0	1.000	3 (21.4%)	1 (14.3%)	1.000
· Patients with reinterventions · Number of reinterventions → 1 → >1	11 (52.4%) 4 (19.0%) 7 (33.3%)	1 (25%) 1 (25%) 0	0.593 0.294	10 (71.4%) 4 (28.6%) 6 (42.9%)	1 (14.3%) 0 1 (14.3%)	**0.024** 0.337

at least one reintervention compared to none in the monocusp group (p=0.073). At the 10-year follow-up, reinterventions were significantly more frequent in the TAP group compared to the monocusp group (71.4% vs. 14.3%; p=0.024).

Table 4: Multivariate cox regression: Comparison Annular incision vs. Valve-sparing.

Variables	HR (95% KI)	P-value
Surgical procedure	1.336 (0.474; 3.763)	0.583
PV Z-score	0.922 (0.778; 1.092)	0.345
Age at total correction (d)	0.993 (0.985; 1.001)	0.080
Palliative surgical procedures	2.404 (0.990; 5.836)	0.053

The health status of all patients at the last follow-up in table 6 shows that a large proportion (72.7- 88.2%) of patients in all groups are fully resilient with no restrictions in daily activities. Only a small proportion of 5.3-9.1% per group had relevant limitations in functional capacity. There are no significant differences between the groups. We have attempted to identify possible confounders in table 5 using Cox regression. This only shows a significant influence of age at primary correction, which appears to be very small with an HR of 0.991.

Table 5: Multivariate cox regression: Comparison TAP vs. Monocusp.

Variables	HR (95% KI)	P-value
Surgical procedure	0.288 (0.063;1.307)	0.107
PV Z-score	0.927 (0.765; 1.123)	0.439
Age at total correction (d)	0.991 (0.982; 1.000)	**0.049**
Palliative surgical procedures	2.541 (0.877; 7.358)	0.086

Discussion

Our long-term data confirm that surgical correction of RVOTO in ToF can be performed with good long-term results [11], both with valve-sparing techniques and with transannular extensions. Patients who could be treated with a valve-sparing technique had fewer reinterventions at follow-up. The residual stenosis appears to be better tolerated by patients than the pulmonary insufficiency associated with transannular techniques. This was also shown in a study by Blais et al. in which a total of 683 patients with a follow-up of 30 years were examined. Patients who underwent valve-sparing surgery had a higher 30-year survival rate, fewer cardiovascular reinterventions, and fewer pulmonary valve replacements compared to patients who underwent TAP expansion, even in the presence of significant residual pulmonary stenosis [12]. Consistent with these results, patients in our cohort who underwent valve-sparing surgery had a trend towards shorter ICU stays and significantly less moderate or severe PR compared to patients who required transannular incisions. It is known that PR is

Table 6: Survival and endurance.

Condition at last follow-up	Annular incision (n=49)	Valve- sparing strategies (n=34)	TAP (n=38)	Monocusp (n=11)
Fully functional	38 (77.6%)	30 (88.2%)	30 (78.9%)	8 (72.7%)
Lightly restricted endurance	4 (8.2%)	1 (2.9%)	3 (7.9%)	1 (9.1%)
Restricted endurance	3 (6.1%)	2 (5.9%)	2 (5.3%)	1 (9.1%)
Deceased	4 (8.2%)	1 (2.9%)	3 (7.9%)	1 (9.1%)
	→ Chi-Square: p=0.552		→ Chi-Square: p= 0.964	

often well tolerated postoperatively but is associated with increased morbidity in the long term. Patients often have significantly poorer exercise tolerance, which is a sign of impaired right ventricular function and can ultimately lead to right heart failure with cardiac arrhythmias and even sudden cardiac death [4]. A tendency towards lower mortality of 2.9% vs. 8.2% is also evident in the valve-sparing group and in contrast to the group with annular incision, which experiences multiple repeated reinterventions, there are no subsequent reinterventions in the valve-sparing group. When choosing the best possible treatment for RVOTO, there is widespread agreement that valve-sparing surgery is preferable to transannular incision with loss of valve function, provided that this leaves only a minor stenosis component. For the surgical planning of the procedure, Z-values for the pulmonary valve annulus of greater -2, a suitable and non-dysplastic valve morphology and sufficient tissue properties are described as good prerequisites for a valve-sparing procedure [13,14]. In the present patient population, the mean Z-value for the pulmonary valve annulus was -3.99 in the transannular incision group (-1.41; valve-sparing group). The proportion of bicuspid and often dysplastic valve morphology was also higher in the transannular incision group at 87.5% (58.8% in the valve-sparing group), which was associated with a higher incidence of poorer preoperative oxygen saturation and a more frequent need for upstream palliation with systemic to pulmonary shunting. Thus, our data suggest that if anatomic conditions allow and a sufficient reduction of RVOTO is possible, a valve-sparing approach is preferable.

Based on the present data, a subgroup analysis was performed to determine whether a more surgically demanding integration of a monocuspid valve design into the RVOT is favorable in terms of the need for reinterventions when a transannular incision is required. Between both groups there are no differences in preoperative anatomy and function, making the outcome of these strategies particularly interesting for surgeons' decision-making. Although likely, we did not find a longer aortic cross-clamp time in the monocusp group due to the more complex surgical procedure [10]. This could be attributed to individual surgeon experiences or to additional surgical procedures not included here. Therefore, we attach less importance to this observation. In the short-term outcome the monocusp technique may contribute to a lower postoperative morbidity [15] attributed to lower PR and the resulting less complicated postoperative course [10]. Our data show a reduction in moderate to severe PI in the monocusp group, but do not reflect a shorter ICU stay. The latter may be due to the good tolerability of PR in the early post-operative phase, as described earlier. When regard to the long-term outcome, previous studies show different results. In terms of long-term outcome, other studies have shown that PR also increases over time in patients with monocusp, but the time to onset of severe PR varies. Overall, however, there is an advantage in terms of the need for RVOT intervention compared to TAP [16-18]. Our data show a long-term freedom from severe PR and reinterventions in 57.1% of all patients after 5 years and 42.9% after 10 years in the monocusp group. This shows that a relevant proportion of patients in the monocusp group do not develop severe PR even in the long-term course. In the TAP group there is a limited significance to the severe PR according to multiple reinterventions. Regarding reinterventions, current literature provides different statements. Jang et al. hypothesize that a monocusp prolongs the time to pulmonary valve replacement [16]. Park et al. argue that a monocusp offers no advantages regarding reintervention rate [19]. In our data, no reinterventions occurred in the monocusp group after 5 years, while 42,9% of the TAP group underwent at least one reintervention. After 10 years, there was a significant difference of 71.4% to 14.3%. This suggests that the use of a monocusp in corrective surgery has a positive influence on the occurrence of reinterventions in our cohort.

Conclusion

In summary, surgical treatment of RVOTO in patients with a ToF or ToF-like congenital heart defects is associated with excellent long-term results. Whenever possible, a valve-sparing procedure should be preferred. In cases where this is not possible, the available data suggest an advantage for monocusp procedures compared to TAP procedures. This advantage is mainly due to a lower need for intervention in the long-term follow-up.

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