European Journal of Cardio-Thoracic Surgery 59 (2021) 333–340
doi:10.1093/ejcts/ezaa346 Advance Access publication 17 November 2020

ORIGINAL ARTICLE

CONGENITAL

Cite this article as: Ferraz Cavalcanti PE, Sá MPBO, Lins RFA, Cavalcanti CV, Lima RC, Cvitkovic T *et al.* Three-step preoperative sequential planning for pulmonary valve replacement in repaired tetralogy of Fallot using computed tomography. Eur J Cardiothorac Surg 2021;59:333–40.

Three-step preoperative sequential planning for pulmonary valve replacement in repaired tetralogy of Fallot using computed tomography

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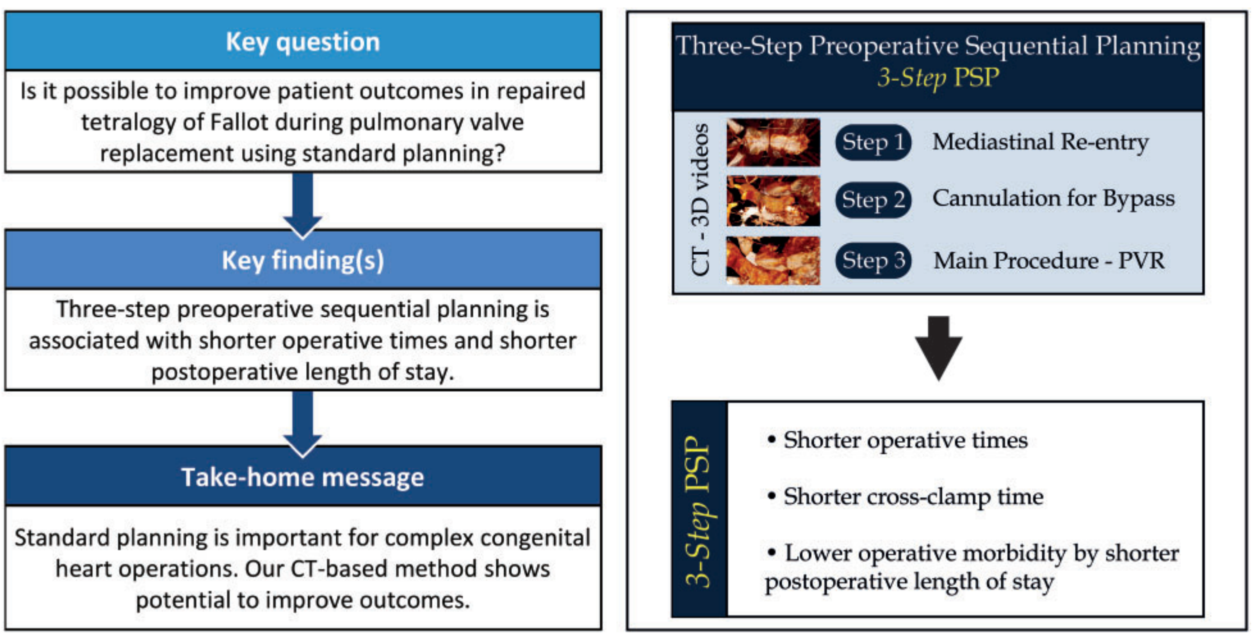
Received 11 April 2020; received in revised form 25 June 2020; accepted 12 July 2020



Abstract

OBJECTIVES: Our goal was to compare results between a standard computed tomography (CT)-based strategy, the 'three-step preoperative sequential planning' (3-step PSP), for pulmonary valve replacement in repaired tetralogy of Fallot versus a conventional planning approach.

METHODS: We carried out a retrospective study with unmatched and matched groups. The 3-step PSP comprised the planning of mediastinal re-entry, cannulation for cardiopulmonary bypass (CPB) and the main procedure, using standard 3-dimensional videos. Operative times (skin incision to CPB, CPB time, end of CPB to skin closure and cross-clamp time) as well as postoperative length of stay and in-hospital mortality were compared.

RESULTS: Eighty-two patients (49% classical tetralogy of Fallot) underwent an operation (85% with pulmonary homograft) with 1.22% in-hospital mortality. The 3-step PSP ($n = 14$) and the conventional planning ($n = 68$) groups were compared. There were no statistically significant differences in the preoperative characteristics. Differences were observed in the total operative time ($P = 0.009$), skin incision to CPB ($P = 0.034$) and cross-clamp times (74 ± 33 vs 108 ± 47 min; $P = 0.006$), favouring the 3-step PSP group. Eight matched pairs were compared showing differences in the total operative time (263 ± 44 vs 360 ± 66 min; $P = 0.008$), CPB time (123 ± 34 vs 190 ± 43 min; $P = 0.008$) and postoperative length of stay ($P = 0.031$), favouring the 3-step PSP group.

CONCLUSIONS: In patients with repaired tetralogy of Fallot undergoing pulmonary valve replacement, preoperative planning using a standard CT-based strategy, the 3-step PSP, is associated with shorter operative times and shorter postoperative length of stay.

Keywords: Tetralogy of Fallot • Pulmonary valve replacement • Computed tomography • Surgical planning • Three-step preoperative sequential planning

ABBREVIATIONS

CI	Confidence interval
CPB	Cardiopulmonary bypass
CT	Computed tomography
PVR	Pulmonary valve replacement
TOF	Tetralogy of Fallot
3D	3-Dimensional
PSP	Preoperative sequential planning

INTRODUCTION

Repeat sternotomy in heart surgery poses a major risk for undesired outcomes. This is particularly the case in congenital heart diseases in which the patients usually undergo multiple operations during their lifetime [1]. The surgical risk is considerable in developed countries and exceedingly high in some developing countries in which these patients have their surgical procedures denied, because the risk of the surgical treatment surpasses that of the do-not-treat approach.

With the advent of new multidetector computed tomography (CT) scanners, as well as modern techniques of post-processing imaging, CT-based strategies have gained ground in providing 3-dimensional (3D) images (printed models or not) and an easy interface for surgeons to use in preoperative planning [2–4]. A recent systematic review points to the need for conducting research through comparative studies in order to measure the additional value of the 3D models in relation to the usual surgical planning [5].

Considering that tetralogy of Fallot (TOF) represents the most studied congenital heart disease in history due to its high prevalence and the need for follow-up throughout the patient's life, this complex condition was chosen in order to gather a homogeneous sample. It is well known that, in the natural history of the 'repaired right hearts', pulmonary insufficiency is common, leading to impaired functional capacity and increased risk of death [6–8].

Bearing in mind these facts, our goal was to perform a study whereby we used our straightforward imaging and CT-based post-processing method, 'three-step preoperative sequential planning' (3-step PSP), in which we compared the use of this method with the conventional approach of preoperative planning for pulmonary valve replacement (PVR), considering intraoperative data and surgical outcomes.

MATERIALS AND METHODS

Patients

We conducted a retrospective analysis of outcomes in consecutive patients with repaired TOF (the full clinical spectrum) who underwent PVR at the Hannover Medical School, Hannover, Germany, from August 2012 to July 2017. A comparison between 3-step PSP (July 2016–July 2017) and conventional planning (August 2012–July 2016) groups was made. Patients who had concomitant aortic or aortic valve procedures were excluded. All patients in both groups underwent preoperative CT.

Most surgical procedures were elective, and the indications for PVR were those from the 2015 guidelines of the German Society of Paediatric Cardiology and other international guidelines [9, 10].

This research was registered and followed the necessary procedures; the project was approved by the ethics committee under the registration number CAAE: 82276418.0.0000.5192. The ethical standards were fulfilled because the patients were also participants in an ongoing study at the Hannover Medical School. They had a decellularized homograft implanted and participated in a trial registered at ClinicalTrials.gov under the identifier number: NCT02035540, the ESPOIR (European Clinical Study for the Application of Regenerative Heart Valves). The surgical PVR at the Hannover Medical School is the conventional surgical technique described in a previous publication [11].

Three-step preoperative sequential planning using computed tomography

So that we could obtain post-processing CT images for analysis, the patients (3-step PSP group), underwent a contrast-enhanced thorax examination on a 64-slice CT scanner (SOMATOM Force; Siemens Healthcare, Forchheim, Germany), with no electrocardiographic synchronization, without sedation, with slices thickness of 0.5–1.0 mm thick and using non-ionic low-osmolar contrast material.

The techniques for post-processing imaging were performed using the OsiriX MD (OsiriX MD. v7.0 64-bit. Pixmeo SARL, 2003,

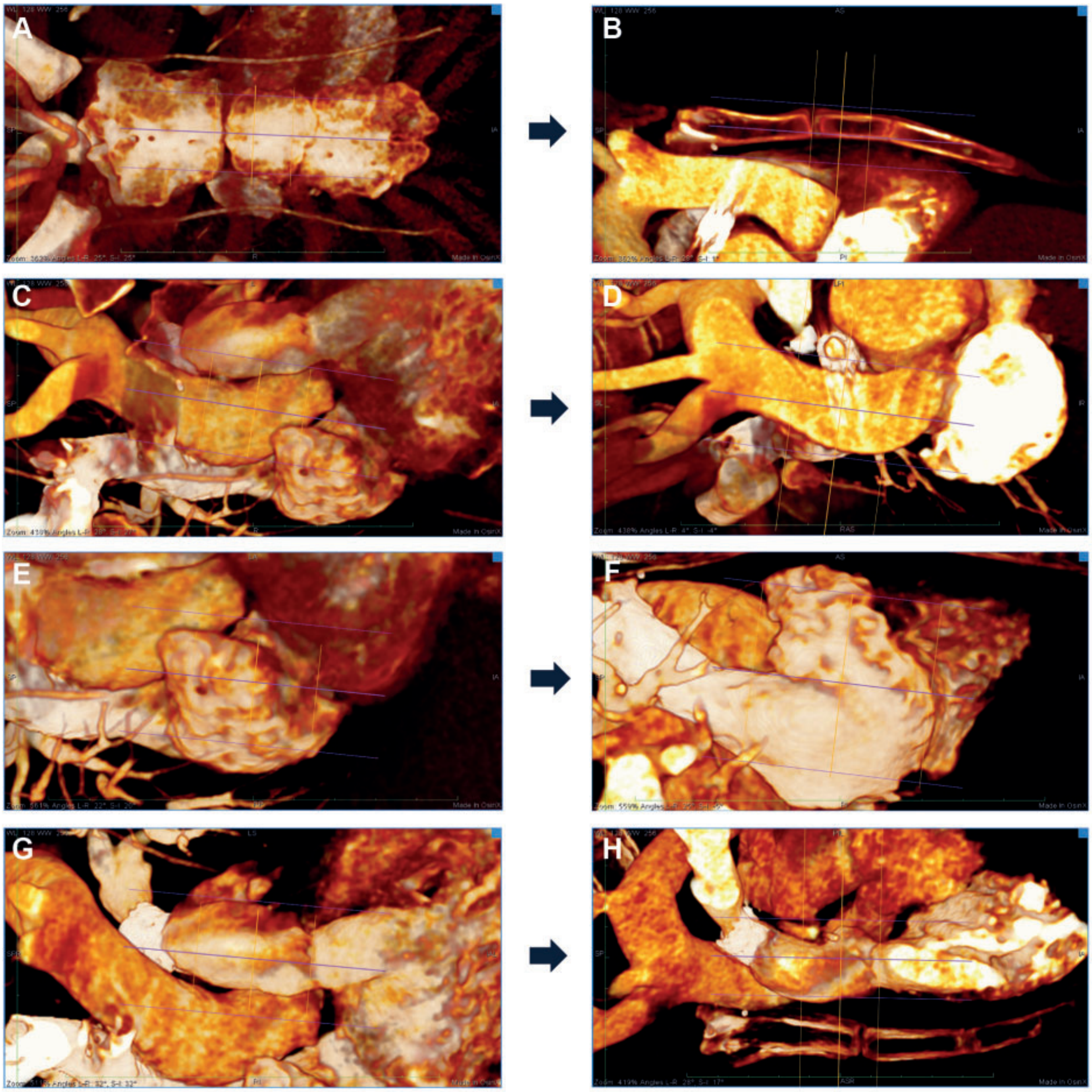
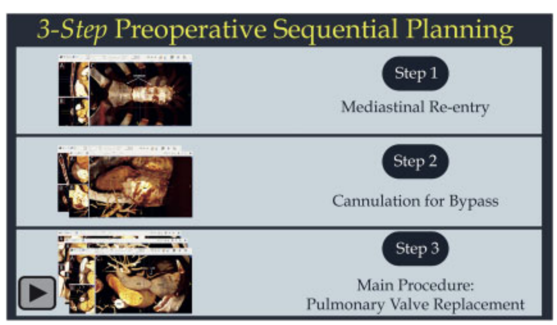


Figure 1: Volume-rendered sample images of the three-step preoperative sequential planning. Step 1: planning the mediastinal re-entry: panel (**A**) shows the surgeon's view and panel (**B**), the substernal anatomy. Step 2: planning the arterial and venous cannulation for cardiopulmonary bypass: panel (**C**) shows the ascending aorta and panel (**D**), a 90° rotation in the longitudinal axis; panel (**E**) shows the right atrium and (**F**), a 90° rotation in the longitudinal axis. Step 3: planning the pulmonary valve replacement: panel (**G**) shows the surgeon's view of the main pulmonary artery and the right ventricular outflow tract; panel (**H**) shows a 90° rotation in the longitudinal axis.

Geneva, Switzerland). The videos created from the three-step PSP strategy were analysed for qualitative validation by the paediatric and surgical teams.

To simulate a 'step-by-step' surgical procedure, a 3-step sequential planning strategy was performed, comprised of mediastinal re-entry (step 1), cannulation for cardiopulmonary bypass (CPB) (step 2) and the main procedure (step 3), briefly demonstrated in Fig. 1 and in the Video 1 (Supplementary Material). Ultimately, a total of 2160 images composed of CT-based 3D reconstructions (6 videos, 360 images/video) were displayed at a rate of 20 images per s. The videos were produced through a 360° loop around the longitudinal axis of the surgical site at each



Video 1: Videos of the three-step preoperative sequential planning.

step in an attempt to enhance the depiction of 3D anatomical relationships that could help the surgical team mentally visualize the patient's mediastinal anatomy.

Outcomes

The variables chosen to represent the difficulty of the procedure were total operative time, time from the skin incision to CPB (skin-to-CPB time), CPB time, time from the end of CPB to skin closure (CPB-to-skin time) and cross-clamp time. The variables chosen to represent the safety of the procedure were the number of unplanned operative events and redoing any surgical step. The in-hospital mortality and the operative morbidity expressed by the postoperative length of stay were also assessed.

Statistical analyses

Data were described using absolute and percentage frequencies for categorical variables and means, standard deviations, medians and ranges for numerical variables.

For the inferential analysis through statistical tests, the differences between the groups or categories were evaluated using Pearson's χ^2 test or Fisher's exact test for categorical variables and the Mann–Whitney test for the numerical variables. The exact Fisher's test was used when the condition for use of the χ^2 test was not found. The Mann–Whitney test was chosen when there was a lack of normality in at least 1 of the groups or categories. Normality was verified using the Shapiro–Wilk normality test.

For a more reliable comparison between 3-step PSP and conventional planning groups, a paired analysis was performed by matching the patients for the following variables: non-beating-heart surgery, diagnosis of TOF (except for associations with atrioventricular septal defect, absent pulmonary valve syndrome, post-Rastelli or post-Ross status), same age range and homograft implantation. Pairing procedures in cases of more than 1 possible matching partner were established on a random basis, and the comparison was performed using the McNemar's test in relation to the categorical variables or the Wilcoxon test paired for the numerical variables. The paired Wilcoxon test was chosen because of the reduced number of paired samples. The statistical analysis was performed to obtain the largest number of similar pairs in terms of preoperative characteristics, considering the limitations of the available sample size.

The data were plotted in double entry in Microsoft Excel for Mac software, version 16.11 (180311) and then analysed using IBM SPSS software (IBM SPSS Statistics for Windows, Version 23.0, released 2015. IBM Corp., Armonk, NY, USA). *P*-values were considered statistically significant if lower than 0.05.

Table 1: Preoperative characteristics: univariate analysis of categorical data

Variables	3-Step PSP (n = 14), n (%)	Conventional planning (n = 68), n (%)	Total sample (n = 82), n (%)	*P*-value
Gender				P^a = 0.543
Male	7(50)	40 (59)	47 (57)	
Female	7(50)	28 (41)	35 (43)	
Age range (years)				P^b = 0.419
<6		7 (10)	7 (8)	
6–12	4 (29)	22 (32)	26 (32)	
13–18	2 (14)	16 (24)	18 (22)	
>19	8 (57)	23 (34)	31 (38)	
Weight range (kg)				P^b = 1.000
<10		2 (3)	2 (2)	
10–20	1 (7)	8 (12)	9 (11)	
21–80	12 (86)	51 (75)	63 (77)	
>81	1 (7)	7 (10)	8 (10)	
Diagnosis				P^b = 0.068
TOF/PS	6 (43)	34 (50)	40 (49)	
TOF/PA		5 (7)	5 (6)	
TOF/DORV		6 (9)	6 (7)	
TOF/AVSD or TOF/APV or post-Rastelli or post-Ross	2 (14)	16 (24)	18 (22)	
VSD/PS or PS/PI	6 (43)	7 (10)	13 (16)	
Previous operations				P^b = 0.102
1	12 (86)	38 (56)	50 (61)	
2	2 (14)	18 (26)	20 (24)	
3 or more		12 (18)	12 (15)	
Previous interventional catheter procedures				P^b = 0.301
0–1	13 (93)	48 (70)	61 (75)	
2		10 (15)	10 (12)	
3 or more	1 (7)	10 (15)	11 (13)	

[a]Pearson's χ^2 test.

[b]Fisher's exact test.

*Statistically significant (P < 0.05).

PS/PI: pulmonary stenosis and insufficiency; TOF/APV: tetralogy of Fallot with absent pulmonary valve; TOF/AVSD: tetralogy of Fallot associated with atrioventricular septal defect; TOF/DORV: double outlet right ventricle Fallot type; TOF/PA: tetralogy of Fallot with pulmonary atresia; TOF/PS: tetralogy of Fallot with pulmonary stenosis; VSD/PS: ventricular septal defect with pulmonary stenosis.

Table 2: Preoperative characteristics: univariate analysis of numerical data

Variables	3-Step PSP (n = 14), mean ± SD (median)	Conventional planning (n = 68), mean ± SD (median)	Total sample (n = 82), mean ± SD (median)	P-value
Age (years)				
<18	12.8 ± 4.5 (11.8)	10.5 ± 5.3 (10)	10.7 ± 5.2 (10.2)	P^a = 0.258
>18	32.6 ± 7.1 (32.3)	34.9 ± 15.8 (29.9)	34.3 ± 14 (29.9)	P^a = 0.700
Valve size (mm)	26 ± 3 (25)	24 ± 4 (24)	24 ± 4 (24)	P^a = 0.216
BSA (m^2)	1.7 ± 0.4 (1.7)	1.4 ± 0.5 (1.5)	1.4 ± 0.5 (1.5)	P^a = 0.060

[a]Mann–Whitney U-test.
*Statistically significant (P < 0.05).
BSA: body surface area; SD: standard deviation.

Table 3: Intraoperative characteristics: univariate analysis of categorical data

Variables	3-Step PSP (n = 14), n (%)	Conventional planning (n = 68), n (%)	Total sample (n = 82), n (%)	P-value
Bypass temperature (°C)				P^a = 0.059
>35	4 (29)	5 (7)	9 (11)	
32–35	2 (14)	16 (24)	18 (22)	
28–32	6 (43)	21 (31)	27 (33)	
<28	2 (14)	26 (38)	28 (34)	
Valve type				P^a = 0.825
TE homograft	12 (86)	47 (69)	59 (72)	
Homograft	2 (14)	9 (13)	11 (13)	
Contegra®		4 (6)	4 (5)	
Hancock®		6 (9)	6 (7)	
RVOT conduit		1 (1.5)	1 (1)	
Vascutek RVOT ElanConduit®		1 (1.5)	1 (1)	
Maze procedure				P^a = 1.000
Yes		4 (6)	4 (5)	
No	14 (100)	64 (94)	78 (95)	
PA or PA branches arterioplasty				P^a = 0.724
Yes	2 (14)	16 (24)	18 (22)	
No	12 (86)	52 (76)	64 (78)	
Tricuspid valve plasty				P^a = 0.680
Yes	1 (7)	10 (15)	11 (13)	
No	13 (93)	58 (85)	71 (87)	
Concomitant procedures				P^a = 0.869
0	10 (71)	38 (56)	48 (58)	
1	3 (21)	22 (32)	25 (31)	
2	1 (7)	6 (9)	7 (9)	
3		1 (1.5)	1 (1)	
4		1 (1.5)	1 (1)	
Unplanned events[b]				P^a = 1.000
0	12 (86)	57 (84)	69 (84)	
1	2 (14)	9 (13)	11 (13)	
2		2 (3)	2 (3)	

[a]Fisher's exact test.
[b]The need to repeat any surgical movement (for example, the changing cannulation site for the bypass) was also considered.
*Statistically significant (P < 0.05).
PA: pulmonary artery; RVOT: right ventricular outflow tract; TE: tissue-engineered.

RESULTS

Between August 2012 and July 2017, a total of 82 patients underwent PVR. Almost half of the patients (49%) had the classical form of TOF. Thirty-nine patients (47%) were operated on with the beating-heart technique. From April 2015 to July 2017, the beating-heart technique was less prevalent: we had only 4 patients. Preoperative characteristics are described in Tables 1 and 2.

Eighty-five percent of the patients had a pulmonary homograft implanted, and 72% of all valves implanted were tissue-engineered homografts. Sixteen percent of the patients had at least 1 unplanned operative event. One in-hospital death occurred in this consecutive series over a 5-year period. Intraoperative characteristics are described in Table 3.

Eleven patients had 1 unplanned operative event, and 2 patients had 2 events. Two patients required conversion from the beating-heart technique to cardioplegic cardiac arrest due to the risk of an air embolism from the left chambers of the heart detected by transoesophageal echocardiography; 3 patients required conversion to undergo an unplanned additional procedure.

Four patients had cardiac injuries (1 lesion in the left atrium, 2 lesions in the right ventricular outflow tract and 1 lesion in the aortic homograft in the pulmonary position), and 1 patient had ventricular fibrillation requiring emergency femoral cannulation. Two patients needed arterial or venous cannulation once more, and 1 patient required reinspection of the pulmonary valve homograft after implantation.

Hospital morbidity was based on postoperative length of stay, the median of which was 7 days (interquartile range 6–10.2).

Three-step preoperative sequential planning versus conventional planning

Fourteen patients (17%) were operated on from July 2016 to July 2017 (3-step PSP group), and 68 patients (83%) were operated on from August 2012 to July 2016 (conventional planning group).

There were no statistically significant differences in the preoperative characteristics between the groups regarding sex, age, weight range, valve size, body surface area, diagnosis of the underlying disease, number of previous operations or number of previous catheter interventions (Tables 1 and 2).

There were no statistically significant differences in the intraoperative characteristics between the groups regarding bypass temperature, number of concomitant procedures, prevalence of repair of the pulmonary artery or pulmonary branches, prevalence of tricuspid valve repair, the Maze procedure and unplanned events (Table 3).

We observed a 1.22% hospital mortality rate in the total sample, with only 1 death (conventional planning group).

Statistically significant differences were observed between groups regarding some operative times, with the 3-step PSP group presenting a shorter total time ($P = 0.009$), shorter skin-to-CPB time ($P = 0.034$) and shorter cross-clamp time ($P = 0.006$). There was also a decrease in CPB and CPB-to-skin times, but without a statistically significant difference ($P = 0.062$ and $P = 0.083$, respectively) (Table 4). The complete distribution of patients' operative times is shown in Fig. 2.

No statistically significant differences in hospital morbidity were observed between the 3-step PSP and conventional planning groups in relation to the postoperative length of stay [(>7 days; $P = 0.563$), (>14 days; $P = 1.000$), (>21 days; $P = 0.597$)].

In the matched comparison analysis, perfect matching was obtained in the 8 pairs. Statistically significant differences were observed between the groups regarding CPB, CPB-to-skin and total times, with correspondingly lower means and medians in the 3-step PSP group. Differences were also observed in the postoperative length of stay, also favouring this group. No statistically significant differences in lowest temperature in CPB or implanted valve size were observed (Table 5).

Table 4: Intraoperative characteristics: univariate analysis of numerical data

Variables	3-Step PSP ($n = 14$), mean ± SD (median)	Conventional planning ($n = 68$), mean ± SD (median)	*P*-value
Skin-to-CPB time (min) (skin incision to CPB)	73 ± 25 (77)	89 ± 32 (90)	$P^a = 0.034^*$
CPB time (min)	145 ± 57 (126)	186 ± 94 (164)	$P^a = 0.062$
CPB-to-skin time (min) (from end of CPB to skin closure)	68 ± 28 (63)	73 ± 25 (69)	$P^a = 0.083$
Total time (min) (skin incision to skin closure)	285 ± 71 (268)	348 ± 107 (318)	$P^a = 0.009^*$
Cross-clamp time (min)	74 ± 33 (57)	108 ± 47 (89)	$P^a = 0.006^*$

[a]Mann–Whitney *U*-test.

*Statistically significant ($P < 0.05$).

CPB: cardiopulmonary bypass; SD: standard deviation.

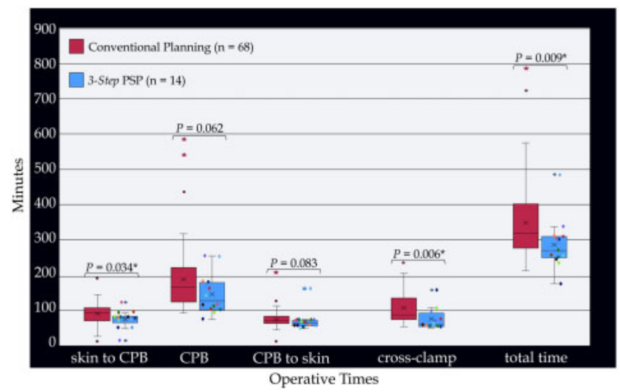


Figure 2: Conventional planning versus 3-step PSP. Box-and-whiskers plots of operative times in min. Each pair of box plots shows the distribution of the measures. The line in the middle of the box indicates the median. The first (Q1) and third (Q3) quartiles are the lower and upper edges of the box, respectively. The upper and lower whiskers show ±1.5 times IQR. The mild (farther than 1.5 times IQR) and the extreme (farther than 3.0 times IQR) outliers are shown as dots and asterisks, respectively. Because the number of measurements is <15 in the 3-step PSP group, each of the data points is plotted as a differently coloured dot. Median comparisons between the 3-step PSP and the conventional planning groups were made according to Mann–Whitney (statistical significance at $P < 0.05$). 3-Step PSP: three-step preoperative sequential planning; CPB: cardiopulmonary bypass; IQR: interquartile range.

DISCUSSION

Preoperative planning using computed tomography data

Our findings are in accordance with those of Goldstein *et al.* [12], whose study of using or not using preoperative CT-based planning (364 patients, 137 vs 227) did not show differences in mortality but revealed statistically significant differences in CPB time (90.1 ± 34.2 vs 110.1 ± 63.8; $P = 0.002$) and cross-clamp time (62.6 ± 23.7 vs 74.8 ± 38.0; $P = 0.003$), even without a standard protocol based on 3D images.

Table 5: Intraoperative characteristics: matched comparison analysis

Variables	3-Step PSP (*n* = 8), mean ± SD (median)	Conventional planning (*n* = 8), mean ± SD (median)	*P*-value
Lowest temperature in CPB (°C)	31 ± 4 (31)	28 ± 5 (29)	P^a = 0.148
Valve size (mm)	26 ± 3 (26)	25 ± 3 (24)	P^a = 0.273
Skin-to-CPB time (min) (skin incision to CPB)	80 ± 21 (78)	97 ± 27 (99)	P^a = 0.313
CPB time (min)	123 ± 34 (113)	190 ± 43 (187)	P^a = 0.008*
CPB-to-skin time (min) (from end of CPB to skin closure)	61 ± 11 (61)	73 ± 15 (68)	P^a = 0.047*
Total time (min) (skin incision to skin closure)	263 ± 44 (261)	360 ± 66 (351)	P^a = 0.008*
Cross-clamp time (min)	62 ± 14 (56)	83 ± 30 (77)	P^a = 0.078
Postoperative length of stay (days)	8 ± 5 (6)	13 ± 11 (8)	P^a = 0.031*

[a]Wilcoxon test (paired samples).
*Statistically significant ($P < 0.05$).
CPB: cardiopulmonary bypass; SD: standard deviation.

In a meta-analysis by Kirmani *et al.* [13] including 4 retrospective cohort studies that compared the use of preoperative CT for surgical planning ($n = 369$) versus no-CT ($n = 531$), all patients were included consecutively and had undergone a previous median sternotomy. On the one hand, no statistically significant differences were found in the risk of death, re-entry injury, renal failure or extracorporeal perfusion/cross-clamp times. On the other hand, the risk was reduced for stroke [relative risk 0.42, 95% confidence interval (CI) 0.19–0.93; $P = 0.03$] and major complications as a composite (relative risk 0.65, 95% CI 0.47–0.88; $P = 0.006$). The authors recommended preoperative cross-sectional imaging to reduce the risk of complications following cardiac reoperation.

It is important to highlight that patients included in both studies [12, 13] were operated on more than 10 years ago. Since then, CT scanners and 3D post-processing techniques have evolved considerably, making it common to use 3D reconstructions for surgical planning in several centres, including the use of printing technology [4, 5].

Considering the aforementioned studies, as well as our findings, we believe that the use of surgical planning using CT represents an important tool for improving surgical care.

Preoperative planning using 3-step preoperative sequential planning

Patients operated on using the 3-step PSP showed shorter total operative times and skin-to-CPB times, as well as shorter cross-clamp times, without any increase in the number of unplanned operative events. In addition, in our matched-comparison analysis, patients who underwent 3-step PSP showed shorter CPB and CPB-to-skin times as well as postoperative lengths of stay.

Despite the evolution in perioperative care of adult congenital heart patients in recent years, CPB and cross-clamp times are still being identified as independent predictors of negative outcomes, as demonstrated by Haapanen *et al.* [14]. In their cohort of 1093 consecutive patients (from 1998 to 2015), including 280 PVRs in patients with TOF, CPB time was a predictor in both multivariate logistic regression (OR 1.11, 95% CI 1.06–1.16; $P < 0.001$) and the receiver operating characteristic curve (area under the curve 0.716, 95% CI 0.65–0.78; $P = 0.001$).

The shorter operative times found in the 3-step PSP group may reflect the greater confidence of the surgical team in view of greater exposure to preoperative imaging anatomical data provided by this method. We believe that exposure to anatomical imaging data may have prompted a more fluent course of the procedure, resulting in shorter times. Additionally, neither the main surgeon nor the assistants were aware that operative times would be closely evaluated. This fact reinforces the idea that our surgical planning method may have contributed to shortening operative times without increasing the number of intraoperative surgical complications.

Taking into account that our technique was developed by collaborating surgeons from Brazil and Germany, we speculate that a shortening in the operative times as well as in the postoperative length of stay might represent potential areas of improvement for clinical outcomes when this procedure is used with patients in developing countries.

Three-step preoperative sequential planning in everyday practice

The surgical complexity of patients with congenital heart disease worldwide has been growing over the years and requiring both more preoperative information and improvement in the quality of imaging examinations [15]. There is an increasing need for an inter-stage moment between the diagnosis and the procedure, especially in centres involved in training new generations of surgeons. In our opinion, surgical planning has a great educational value, and our 3-step method is focused on creating a true roadmap of the entire procedure based on images.

The 3-step PSP method was developed based on 3D reconstructions using volume rendering, a well-known post-processing technique widely used in clinical practice for diagnosis. From our perspective, our method might play an important role in creating a 'common language' between clinical and surgical teams. The discussion about patients at weekly interdisciplinary meetings with intuitive images provides an environment of learning and cooperation, thereby strengthening the heart team.

As part of the natural process of the evolution of imaging, with the increasing availability of post-processing software and powerful laptop computers that bring 3D reconstruction technology closer to surgeons, we see a favourable scenario for the reproducibility of our 3-step PSP protocol worldwide, including in developing countries. Such a tool, combined with the growing development of high-definition monitors, will represent a real revolution in the way we preoperatively explain details to patients (and sometimes to their parents) and in the manner of planning and operating.

Risk of bias and limitations

This is a retrospective study that includes data from a single centre in Germany, which evaluated the preoperative and operative characteristics of 2 similar groups of patients who were operated on at different times. Nevertheless, the effect of this limitation was somewhat mitigated because no changes in clinical handling occurred during the entire period. The high prevalence of implanted homografts in both groups of our sample also contributed to their comparability, added to the fact that the surgical team was the same. There are inherent limitations with retrospective and small sample studies; consequently, robust statistical analyses are not possible. No adjustments were made for multiple comparisons. We believe that these limitations are relevant and can only be overcome by designing a new, prospective, randomized study that involves a dedicated multidisciplinary team for patient selection and recruitment in order to homogenize the samples as much as possible.

CONCLUSION

Surgical PVR using the 3-step PSP in patients with repaired TOF is associated with low hospital mortality and a low rate of unplanned operative events. In comparison with conventional planning, the 3-step PSP was associated with shorter operative times including cross-clamp time and lower operative morbidity expressed by a shorter postoperative length of stay.

Conflict of interest: none declared.

Author contributions

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European Journal of Cardio-Thoracic Surgery thanks Tim Attmann and the other, anonymous reviewer(s) for their contribution to the peer review process of this article.

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