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Research Article

Post-operative Course of Total Repair of Tetralogy of Fallot in Infancy: What about Renal Function?

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Abstract

Aims: The main objective was to describe the incidence of Acute Kidney Injury (AKI) specifically in the population of infants less than one year old in the post-operative course of total surgical repair of Tetralogy of Fallot (TOF) with cardiopulmonary bypass. The secondary objectives were to identify risk factors for AKI occurrence and for increased respiratory morbidity.

Methods: For this, 72 consecutive patients were retrospectively included and analyzed, about pre-operative, intra-operative and post-operative course, in one Tertiary French Cardiac Surgery Center.

Results: Based on the validated pRIFLE score, incidence of AKI was 25%. Among the 18 AKI+ patients, 9 (50% of them) required renal replacement therapy without complications. Bivariate analysis highlighted a link between AKI and post-operative lactate level (p= 0.014), intra-operative urine output (p=0.0003) and positive input-output balance at H12 (p=0.0129). In multivariate logistic regression analysis, intraoperative urine output was the only independent factor associated with the occurrence of post-operative AKI (OR 0.83 CI 95% [0.63; 0.98] p= 0.02. Besides, strong association was found between the duration of mechanical ventilation and, respectively, CPB time (OR 6.11, CI 95% [2.09; 17.99] p=0.001) and fluid balance at H12 (OR 1.39, CI 95% [1.05;1.84], p=0.008).

Conclusion: This cohort is the second one studying postoperative course exclusively in the homogeneous population of infants after total repair of TOF.

Keywords: Renal function; Acute kidney injury; Cardiopulmonary bypass; Tetralogy of fallot

Background

Post-operative management of total repair of Tetralogy of Fallot (TOF) is challenging for intensivists [1] firstly due to the young age of correction (infancy is more associated with Low Cardiac Output Syndrome (LCOS [2]), secondly, the specific complications related to the pathology presenting as arrhythmias, right diastolic ventricular dysfunction and Acute Kidney Injury (AKI) [3].

AKI is a common complication after pediatric cardiac surgery with Cardiopulmonary Bypass (CPB) [4,5] and has been found to cause a high rate of short term morbidity [6-8]. Studies showed a prevalence of AKI ranging from 5 to 50% [9]. This high variability can be explained by the fact that the definition of AKI varies between studies and that the patient populations are highly heterogeneous. Prevalence of AKI in the population of TOF patients after total surgical repair is thus not widely known: indeed, only one published study [1] was specifically dedicated to the renal function of these infants (about 41 patients). Pan et al. [10] reported 164 patients with right ventricular outflow tract obstructive lesions: among them 64% were TOF. Besides, even if intensivists know that, in general, high fluid volumes are needed to maintain a high central venous pressure and permit an adequate right ventricular filling, to our knowledge nobody reported the objective post-operative course of TOF, especially concerning renal function, but also the deleterious side effects of fluid overload (especially on the duration of mechanical ventilation).

Aims

The main objective of this study was to describe the incidence of AKI in the selected population of infants less than one year old in the post-operative course of total surgical repair of TOF with CPB.

The secondary objectives were to

- Identify risk factors for AKI occurrence
- Identify risk factors for increased duration of mechanical ventilation

Methods

All consecutive cases of TOF undergoing complete repair (either primary or following a palliative procedure) at University Children's Hospital of Toulouse, France, between January 1, 2009 and December 31, 2016 were retrospectively reviewed.

Care was not impacted by the investigation, thus for ethical standards it was only necessary to report and record the study to the CNIL (Commission Nationale de l'Informatique et des Libertés), number 2168083v0.

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All cases coded under « Tetralogy of Fallot » were identified beforehand using the Toulouse hospital internal database (Orbis) during the chosen period. Were excluded patients aged more than one year.

The medical records of the selected patients were analyzed: preoperative, intraoperative (meaning in the operating room) and postoperative data were collected. Among them:

- Patient's characteristics: age at surgery, gender, weight, morphology of TOF, associated cardiac and non-cardiac comorbidity (for example syndromic condition)
- Surgical and anesthesia details: CPB and Aortic Cross Clamp (ACC) times, need for transannular patch, urine output in the operating room
- Postoperative course in PICU: LCOS, as lactate level at H0 (hour of patient admission in PICU), H4, H10, renal function, requirement of Renal Replacement Therapy (RRT) such as Peritoneal Dialysis (PD) or Continuous Venovenous Hemofiltration (CVVHF), fluid balance in percentage of bodyweight at H12, H24, H48, duration of mechanical ventilation and of stay in PICU, mortality status at day 15.

Renal function

Modified pediatric RIFLE criteria (pRIFLE) were used to assess renal function: according to the literature [11-14] patients at stage « I »= Injury, « F »= failure, « L »= Loss, « E »= end-stage renal disease, were considered to have AKI (AKI+). This score takes into account postoperative (in PICU, just after H0) urine output and serum creatinine level and, in our study, was evaluated at H12, H24, H48: when the scores differed between the 3 recording times, the worst score was retained.

In accordance with the design of the study, indication of RRT wasn't based on the pRIFLE score: RRT was instaured after failure of maximal dose of diuretics if the patients presented an association between oliguria (less than one millimeter per kilogram per hour: ml/kg/h) and the requirement of high fluid volume administration (more than 10 ml/kg/h) to maintain adequate cardiac output; or if renal function was impaired due to abdominal compartment syndrome with ascites [15], or if hydroelectrolytic disorders were threatening [16]. With the exception of this last reason, PD was preferred in first intention, requirement of CVVHF was considered in case of contraindication for PD or failure of this technique. Prophylactic PD [17,18] wasn't used.

Mechanical ventilation

Weaning of mechanical ventilation was realized if the hemodynamic and respiratory status of the patient was stable with a minimal inotropic and pressure ventilatory support. Requirement of continued RRT wasn't a reason to continue mechanical ventilation if precedent criteria were reached.

Statistical analysis

Statistical analysis was performed using STATA Software version 11.2 (Stata Statistical Software: Release11. Tx:StataCorpLP). Descriptive data analysis was performed using standard conventional methods. A position indicator (mean or median) and a dispersion index (standard deviation SD or interquartile range IQR) were used for quantitative data, according to their Gaussian distribution. Statistical tests were performed using a bilateral approach with a 5% alpha risk of error. Student's t-test was used when the variable distribution was Gaussian and application conditions were met: if not, a non parametric Wilcoxon Mann Whitney test was chosen.

Qualitative data were expressed as percentages with a 95% confidence interval (CI 95%). Qualitative variables were compared using the Chi-2 square test (if theoretical number more than 5) or the exact Fisher test, as appropriate.

Multivariate analysis was performed using a logistic regression model: covariates univariably associated with the duration of mechanical ventilation and AKI (or known in the literature to be associated with them) were entered into the multivariate model. Variables were log-transformed when necessary.

Results

Demographics

Seventy-two patients were included in the study (Figure 1). The sex ratio was 1.3 in favor of males. Seven of the 72 patients (10%) were syndromic babies (22q.11 syndrome, Down syndrome). The median age of the patients at the time of the surgery was 6 months (IQR [5; 7]) and median weight was 6400 grams (IQR [5660; 7000]). Preoperative pulsatile oxygen saturation (SpO2) was 95% [88; 98.5]. Renal function was evaluated with a preoperative serum level of creatininemia at 22 micromoles per liter (µmol/l) [20; 26], and an estimated Glomerular Filtration Rate (eGFR) at 105.8 [90.3; 119] ml/min/1.73 m^2. All patients presented a RACHS score of 2 [19]. All the children survived until discharge from PICU, with an average length of stay of 8.7 days [7; 15].

Operative details

Of the 72 cases, 8 (11%) had previously undergone a Blalock-Taussig shunt. Placement of a transannular patch was necessary for 26 patients (36%). Median CPB time was 95 minutes IQR [85; 113] and ACC time was 63 minutes IQR [54; 77]. In the operative room, adequate medical inotropic support was administered to all patients. Intraoperative urine output was 33 ml [20; 59] and was not counted in the realization of pRIFLE score (begun in PICU at H0).

Postoperative course in PICU

Main objective: Incidence of AKI was 25%: 18 patients of 72. Most of them (17, 23.6% of the total population) were in stage "I"= Injury, 1 patient was "F"= Failure. We observed that 38 patients (52.77%) were at risk (stage "R"), but non AKI+.

Among the 18 AKI+ patients, 9 (50% of them) required RRT without complications. Of these, 7 were treated by PD, and 2 by CVVHF. Median time of initiation of RRT was H14 [7; 22], with a median duration of 35 h [22; 96]. Every patient recovered a normal renal function before discharge.

Secondary objectives: identification of risk factors for AKI occurrence

Patients were classified into two groups: 18 in the AKI+ group and 54 in the AKI- group. Patients' basal characteristics were comparable except for gender. Results of bivariate analysis are reported in Table 1.

As fluid overload was associated at H12 (but not at H24 nor H48) with AKI, we were interested in the evolution of fluid balance which is represented in Figure 2.

In multivariate logistic regression analysis (Table 2) intraoperative urine output was the only independent factor associated with the

occurrence of post-operative AKI (OR 0.83 CI 95% [0.63; 0.98] p=0.02): this factor was protective so the greater the intraoperative urine output, the lower the risk for the child to present AKI. Figure 3 depicts the Receiver Operating Characteristic curve (ROC curve) for intra-operative urine output level in the prediction of the occurrence of AKI. Area under curve was 0.22 (inverted ROC curve, 95% confidence interval 95% [0.14; 0.34]. Youden index indicated a urine output smaller than 15 milliliters to discriminate risk of occurrence of AKI with a sensibility of 83%, a specificity of 8%.

Secondary objectives: identification of risk factors for increased respiratory morbidity

Median duration of mechanical ventilation was 85.5 hours IQR [48; 125]. While median duration was higher in the AKI+ group (106.5 h) than in the AKI- group (74 h), the difference wasn't significant. Strong association was found between the duration of mechanical ventilation and, respectively CPB time and fluid balance at H12. For each additional minute of CPB time, mechanical ventilation time was increased by 1.35 hours (p=0.001). Besides, for each 1% of bodyweight of additional positive fluid overload at H12, mechanical ventilation time was increased by 5.52 h. Table 3 synthesizes the results of multivariate regression for predicting the duration of mechanical ventilation.

Discussion

Our study is the second that is exclusively dedicated to the description of AKI in the postoperative course of infants after complete surgical repair of TOF.

We highlighted an incidence of 25% of AKI, and an RRT requirement for 12.5% of the 72 infants, without any complication. These results can be compared with those of Griksaitis [1], who considered about 41 patients in a similar course: 17% required PD (incidence of AKI wasn't specified). As evoked in the review of Krawczeski [3], 2017, even if it is now well-established that AKI is

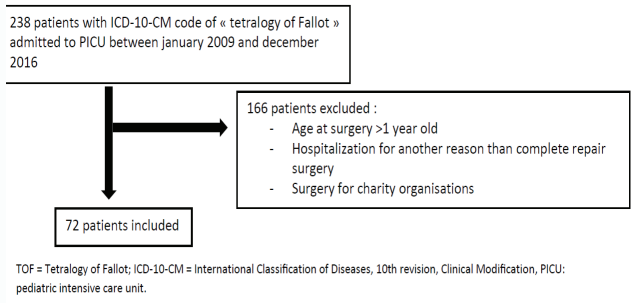

Figure 1: Flow chart.

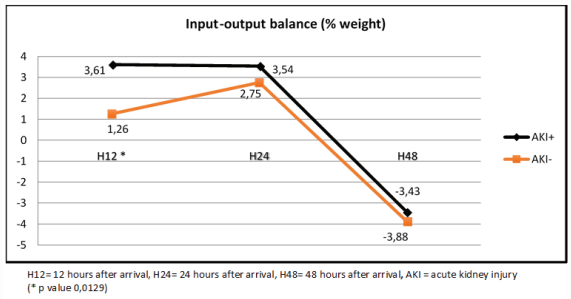

Figure 2: Evolution of input-output balance in percentage of body weight (% weight).

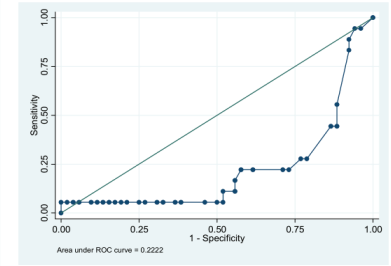

Figure 3: Receiver Operating Characteristic curve (ROC curve) for intra-operative urine output level in the prediction of the occurrence of AKI. Area under curve was 0.22 (inverted ROC curve, 95% confidence interval [0.14; 0.34]. Youden index indicated a urine output smaller than 15 milliliters to discriminate risk of occurrence of AKI with a sensibility of 83% and a specificity of 8%.

a common complication following CPB, and despite the advances of our understanding of the pathogenesis of the disease, almost all trials about the subject can't conclude to evident bundles.

The only one randomized controlled trial (RCT) treating of the interest of use PD versus furosemide in postoperative course of cardiac surgery in infants [20] included 73 patients (all together Norwood procedures, arterial switch operation, TOF…).

Our descriptive study of about 72 homogenous patients could be the first step to more ambitious studies, and it permits to progress about understanding of AKI in postoperative course of TOF. Comparisons can be made with the incidence in the literature: most pediatric studies report an incidence of 30% to 50% with higher rates, until 80% in neonates [3,21,22]. Our incidence is in line with these data but the range is large in the literature, probably with regard to the definition itself of AKI. Many scores can be used to diagnose AKI (KDIGO, AKIN, pRIFLE [11]: we chose pRIFLE, which appeared to be the most sensitive [23]. It seems important to detect early AKI because studies have demonstrated that early fluid overload was associated with a worse outcome and precedes AKI [24], that early initiation of RRT was beneficial [25] and even more if PD was prophylactic [26] . In our study, even if a PD catheter wasn't systematically inserted in the Operating Room (OR), the median time for beginning of RRT was H14, which is earlier than in the literature, except the studies treating of prophylactic PD. Our data don't permit us to conclude whether early RRT is better than prophylactic PD or intense diuretic treatment, but it was interesting to highlight that only 12.5% of infants required RRT with often restrictive right ventricular physiology [27,28]: the first hypothesis, at beginning this study, was, to the contrary, that TOF could more often have AKI compared with other pathologies (except neonates) because of requirement of filling and risk of abdominal compartment syndrome. Our data didn't permit to make an evident link between restrictive Right Ventricle (RV) physiology markers and AKI: it will be the subject of a specifically dedicated study.

Our secondary objectives were to identify whether possible risk factors of AKI occurrence in this population. Even if the mechanism of AKI after cardiac surgery is complex and multifactorial, (significant association with lactate level at H0 H4 and H10 could suggest a link with LCOS [29] our results highlighted an association between AKI with early fluid overload (H12) as Hassinger [24] As the only significant factor in the multivariate regression was the quantity of

Table 1: Characteristics of patients, univariate analysis.

Variable	AKI-	AKI+	
	Median (CI 95%)	Median (CI 95%)	p-value*
Patients (n)	54	18	
Sex Ratio (M/F)	1.35	1.25	**0.0189***
Birth term (WGA)	39 (37-40)	39 (36-40)	0.26
Height (cm)	63 (60-66)	62,5 (58-66)	0.59
Weight (g)	6,4 (5.6-7.0)	6,350 (5.8-7.0)	0.96
Preoperative SpO2 (%)	95 (88-99)	93 (90-97)	0.72
Age at surgery (month)	5,75 (4-7)	6 (5-6)	0.12
Preoperative eGFR	104,3 (90.3-116)	114,5 (90.3-138.9)	0.87
Mechanical ventilation duration	74 (48-120)	106,5 (56-189)	0.10
CPB time	92,5 (88.5-114.5)	105 (92-118)	0.21
ACC time	63 (54-74)	67,5 (55-79)	0.491
Transannular patch	17 (31.5%)	9 (50%)	0.157
Intraoperative urine output, ml (in OR)	46,5 (25-70)	17 (15-25)	**0.0003***
Priming, ml	325 (310-450)	320 (240-400)	0.154
Ultrafiltration, ml	300 (200-400)	380 (250-500)	0.056
Lactate level H0 (mmol/l)	1,65 (1.3-2.1)	2,15 (1.8-2.6)	**0.014***
Lactate level H4 (mmol/l)	1,75 (1.3-2.2)	2,50 (1.9-3.2)	**0.0033***
Lactate level H10 (mmol/l)	1,50 (1.3-1.8)	1,75 (1.5-2)	**0.0363***
Epinephrin support duration (h)	47	66.5	**0.26**
Input-output balance H12 (% weight)	+1,26 (-0.35-3.2)	+3,61 (1.5-5.7)	**0.0129***
Input-output balance H24 (% weight)	+2,75 (0.5-4.6)	+3,54 (0.6-6.0)	0.33
Input-output balance H48 (% weight)	-3,88 (-6.86 - -1.2)	-3,43 (-7- 1.5)	0.645
PICU duration of stay (days)	8,5 (7-12)	9 (7-15)	0.58

N: Number of Patients; WGA: Weeks of Gestational Age; cm: centimeters; g:grams; h:hours; AKI: Acute Kidney Injury; CI: Confidence Interval; SpO2: Pulsatile Oxygen Saturation; eGFR: estimated Glomerular Filtration Rate; M: Male/ F: Female; CPB: Cardio Pulmonary Bypass; ACC: Aortic Cross Clamp; ml: milliliters; OR: Operating Room; mmol/l: millimol by liter; PICU: Pediatric Intensive Care Unit; H0: on arrival in PICU; H4/H10/H12/H24/H48:4 /10/12/24/48 hours after arrival in PICU; *=p-value less than 0.05

Table 2: Results of multivariate logistic regression for prediction of AKI.

Variable	OR	95% CI	p-value*
Input-output balance H12 (% weight)	1.04	(0.86;1.27)	0.64
CPB time	1.5	(0.71;3.35)	0.26
Mechanical ventilation duration	0.99	(0.81;1.23)	1
Intraoperative urine output	0.83	(0.63;0.98)	**0.02***

CPB: Cardio Pulmonary Bypass; AKI: Acute Kidney Injury
*= p-value less than 0.05

Table 3: Results of multivariate linear regression for prediction of mechanical ventilation duration.

Variable	OR	95% CI	p-value*
CPB time	6.11	(2.09 ; 17.99)	**0.001***
Intraoperative urine output	0.96	(0.73 ; 1.26)	0.23
Input-output balance H12 (% weight)	1.39	(1.05;1.84)	**0.008***
AKI	0.99	(0.60; 1.65)	0.57

urine output in the operating room (before transfer to PICU) it can be really interesting to adapt protocols for TOF: according the local practices, several centers routinely place PD catheter intraoperatively at the time of cardiac surgery, using a trans-diaphragmatic approach [3]. Even if complications of PD catheters are rare [20] many surgeons are reluctant to place prophylactic catheter: this is the reason why easy risk factor (such as intra-operative oliguria in the OR as found in our results) could be a good tool to decide. Basing on the ROC curve, we could suggest that if the patient presents an intra-operative urine output less than 15 ml just before closing the chest, a PD catheter should be inserted. As we know serum creatininemia at the end of surgery isn't reliable [30], an objective cut off urine should be more easy to use.

Among our secondary objectives we aimed to identify risk factors for increased respiratory morbidity. AKI wasn't associated with an increased duration of mechanical ventilation: these results are different from some other studies probably in relation with a lack of power. However, there is agreement with the association between duration of mechanical ventilation and CPB time: for each additional minute of CPB time, mechanical ventilation duration was increased by 1.35 hours, even in adjusted multivariable regression [31].

We can interpret these data taking into account the precocity of instauration of RRT: indeed AKI wasn't associated with prolonged mechanical ventilation, but fluid overload at H12 (and not at H24) was (OR 1.39 CI 95% [1.05; 1.84] p=0.008. Thus, we can make the hypothesis that RRT, permitting balanced then negative fluid count, had an influence on the duration of mechanical ventilation.

Finally, what is different in TOF instead of in general heterogeneous population of children in postoperative course of congenital heart surgery with CBP? As for other pathologies, duration of mechanical ventilation is linked with the condition of surgery: CPB time, and early overload. But concerning AKI, and in accordance with the only study treating about AKI and TOF [1] we have pointed out that the injury was independent of CBP and ACC time and of the presence of a transannular patch. Besides, in bivariate analysis, AKI was correlated with lactate level, probably reflecting a moderate degree of LCOS, even if inotropic support wasn't different.

But intuitively we can speculate that the eventual restrictive RV physiology is involved in these different results. In the literature, adult patients were considered to show evidence of RV restriction after TOF repair if antegrade diastolic flow was detected in the main pulmonary artery, coinciding with atrial systole, throughout the respiratory cycle [32]. We can make the hypothesis that in immediate pediatric postoperative course, the less compliant the RV is, the higher the amount of fluid will be needed, and the higher the Venous Pressure (VP) will be. It has been published [33] that the decrease of the glomerular filtration rate because of a high VP could be involved in oliguria and postoperative AKI. Dedicated studies, including VP measure but mostly echocardiographic markers (A wave) of restrictive RV are needed, in association with the evaluation of the specific link with occurrence of AKI.

This is important to improve this challenging management for pediatric intensivist, but also in the long term to understand and anticipate mechanisms that leads to kidney injury during adulthood [34].

Conclusion

Even homogeneous by pathology and age, children following total repair of TOF remain a complex cohort. We have described postoperative course of these patients whose incidence of AKI isn't different from other patients after congenital cardiac surgery. However, an analysis of AKI risk factors and prolonged mechanical

ventilation suggested pathophysiological particularities that could be interesting to study in larger prospective cohorts.

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