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Complete Versus Staged Repair for Neonates with Tetralogy of Fallot: Establishment and Validation of a Cohort of 2235 Patients Using Detailed Surgery Sequence Review of Health Care Administrative Data

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Abstract

Background: The surgical strategy for neonates with tetralogy of Fallot (TOF) consists of complete or staged repair. Assessing the comparative effectiveness of these approaches is facilitated by a large multicenter cohort. We propose a novel process for cohort assembly using the Pediatric Health Information System (PHIS), an administrative database that contains clinical and billing data for inpatient and emergency department stays from tertiary children's hospitals.

Methods.—A four-step process was used to identify neonates with TOF: 1) Screen neonates in PHIS with International Classification of Diseases-9 (ICD-9) diagnosis or procedure codes for TOF; 2) Include patients with TOF procedures prior to 30 days of age; 3) Exclude patients with missing two-year follow-up data; 4) Analyze patients' two-year surgery sequence patterns, exclude patients inconsistent with a treatment strategy for TOF, and designate patients as complete or staged repair. Manual chart review at one PHIS center was performed to validate this process.

Results: Between January 2004 and March 2015, 5862 patients were identified in Step 1. Step 2 of cohort assembly excluded 3425 patients (58%); step 3 excluded 148 patients (3%); and step 4 excluded 54 patients (1%). The final cohort consisted of 2235 neonates with TOF from 45 hospitals. Manual chart review of 336 patients showed a positive predictive value (PPV) for accurate PHIS identification of 44% after Step 1 and 97% after Step 4.

Conclusion: This systematic cohort identification algorithm resulted in a high PPV to appropriately categorize patients. This carefully assembled cohort offers a unique opportunity for future studies in neonatal TOF outcomes.

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Keywords

administrative database; comparative effectiveness; congenital heart disease

INTRODUCTION

Tetralogy of Fallot (TOF) is the most common form of cyanotic congenital heart disease, affecting approximately 1650 children in the United States every year.^{1,2} TOF is described by four classic anatomic characteristics: pulmonary stenosis, overriding aorta, ventricular septal defect, and right ventricular hypertrophy [see Figure, Supplemental Digital Content 1, which demonstrates the anatomic characteristics of tetralogy of Fallot]. There is wide variation in the degree of right ventricular outflow tract (RVOT) obstruction, from mild to severe pulmonary stenosis (PS), to its worst form, pulmonary atresia. This translates into a range of clinical presentations from asymptomatic detection to early post-natal cyanosis requiring urgent treatment.

There are multiple surgical strategies for how and when to repair TOF, and the ideal method is not known.³ Asymptomatic patients with mild PS typically undergo elective surgical repair in the first year of life.^{4,5,6} However, symptomatic patients with severe cyanosis require a neonatal procedure, consisting of either a complete repair or staged palliation. The approach of complete neonatal repair involves the simultaneous surgical relief of RVOT obstruction and closure of the ventricular septal defect (VSD) [see Figure, Supplemental Digital Content 2, which demonstrates the complete surgical repair for tetralogy of Fallot]. The staged approach involves an initial palliative intervention to augment pulmonary blood flow, followed by a complete surgical repair in subsequent months. Despite decades of experience with the surgical repair of TOF, the ideal treatment approach for symptomatic neonates continues to be highly debated.^{7,8,9}

To facilitate comparative effectiveness studies regarding staged versus complete surgical repair of TOF in the neonatal period, a valid administrative method of identifying patients with TOF who undergo these procedures is needed. To date, the majority of studies on patients with TOF requiring intervention in the neonatal period (before 30 days of age) have been single institution studies or small cohorts from a few centers.^{10,11} Previous studies using administrative databases have relied on International Classification of Diseases-9 (ICD-9) diagnosis and procedure codes alone to identify TOF cases, a method prone to misclassification.^{12,13} Therefore, we designed and validated an administrative algorithm for identifying a cohort of TOF patients who underwent staged versus complete repair in the neonatal period, an approach which mirrors prior cohort assembly processes in children with leukemia and neuroblastoma.^{14,15,16}

METHODS**Data Source**

Given the low incidence of TOF in the general population, national databases allow investigators to assemble large enough cohorts to study. PHIS is a comparative pediatric

administrative database that includes clinical and billing data for inpatient, emergency department, ambulatory surgery, and observation unit patient encounters from over 48 not-for-profit, tertiary children's hospitals affiliated with Children's Hospital Association. The PHIS database is particularly well-suited for comparative effectiveness studies for TOF, because the 48 children's hospitals are located in 46 geographically diverse areas in the United States, which provides a representative sample of the tertiary care centers where the majority of TOF patients receive their care.

Importantly, the patients in the PHIS database are assigned a unique identifier, which allows the individual patient records to be tracked longitudinally across multiple hospital admissions to PHIS contributing institutions. This ability to follow patients in PHIS over time differentiates it from the clinical registries that exist in pediatric congenital heart surgery, where data is often limited to within 30 days of a surgical procedure. Participating hospitals provide data which are subjected to a number of reliability and validity checks before being included in the database. Available data in PHIS includes patient-level demographics, up to 42 procedure code fields and 42 discharge diagnoses per discharge/encounter, and resource utilization data (e.g. pharmaceuticals, laboratory, and imaging) based on hospital billing.

Cohort Assembly

We designed a four-step process to establish a cohort of symptomatic neonates with TOF from the PHIS administrative database. The operational definition of the study population, "symptomatic neonates" with TOF, identifies patients who required a surgical or catheter-based intervention for TOF in the neonatal period (under 30 days of age). Once in the cohort, subjects were assigned into one of two surgical strategy treatment groups: the "complete neonatal repair" group, for patients with complete surgical repair in the neonatal period, and the "staged repair" group, for patients with an initial palliative intervention under 30 days of age (to be followed by complete surgical repair at a later date). Each step of this process was then validated by a manual chart review at one of the PHIS centers.

In step 1 of cohort assembly, we screened all PHIS inpatient admissions from January 2004 to March 2015 for neonates (less than or equal to 30 days of age) at the time of admission with either the discharge diagnosis code for TOF (ICD-9, 745.2) or the procedure code for total repair of TOF (ICD-9, 35.81). The primary search criteria of discharge diagnosis code and the secondary search criteria of procedure code were both used in this initial step, because every symptomatic neonate with TOF should theoretically have at least one of these two specific codes. The majority of patients who undergo complete TOF repair will have both codes; however, if a hospital does not code a patient as having TOF at discharge after the TOF was repaired, we expect that at least the patient would be given the procedure code for total repair of TOF. For patients who undergo a staged repair with initial palliative procedure, they would still be considered to have the underlying diagnosis of TOF and be given the diagnosis code for TOF at discharge (while not being given the procedure code for total repair of TOF).

In step 2 of cohort assembly, we established a list of *a priori*-defined ICD-9 procedure codes relevant to TOF [Table 1]. Then, only patients with at least one ICD-9 procedure code for

TOF surgery or intervention prior to or equal to 30 days of age were included for further review as potential “symptomatic neonates.”

In step 3, we excluded patients with incomplete or insufficient data within a two-year review period. For example, a patient who had a Blalock-Taussig (BT) shunt (ICD-9 procedure code 39.0) before 30 days of age, but then did not have any other TOF procedures in the subsequent 2 years, and did not die at a PHIS hospital, would be excluded from the cohort because that sequence of events is not clinically realistic. One would expect that patient to have received either a cardiac catheterization (to perhaps place a stent in the BT shunt) or a surgical procedure (to increase the size of the BT shunt), if the patient was expected to survive beyond 2 years with their initial neonatal BT shunt in place. This step was undertaken to avoid type I and type II error (the unknown outcome could be completion of repair/death or death without completion of repair). Subjects whose initial treatment included a palliative intervention (staged repair approach) and subsequently died before or after completion of repair, were included in the cohort because the outcome was known.

In step 4, we created a unique *surgery sequence pattern* for each patient, consisting of procedure codes from the *a priori*-defined list of ICD-9 procedure codes relevant to TOF, ordered chronologically by procedure date, hospitalization, and the 30-day age mark [Table 2]. We then performed a detailed analysis of the surgery sequence pattern for each of the remaining patient up to two years of age. This process involved a comprehensive manual review of all of the unique sequence patterns, in order to identify those which were consistent with TOF treatment practices. Only patients with surgery sequence patterns consistent with a treatment strategy for symptomatic neonates with TOF were included in the final cohort. For example, a patient with the tetralogy-type of double outlet right ventricle who was miscoded as tetralogy of Fallot in PHIS and initially underwent a palliative Blalock-Taussig shunt, but then had a Rastelli operation (specific for double outlet right ventricle), would be excluded in this step. Based on a manual designation of each unique surgery sequence pattern, the patients in the final TOF cohort were further designated as having either complete neonatal repair or staged repair [Table 2].

Cohort Validation

A subset of the finalized cohort and their treatment group assignments were validated by manual chart review. The medical records of all TOF patients that underwent treatment at the Children’s Hospital of Philadelphia (CHOP) during the study period (January 2004 to March 2015) were reviewed agnostic to their PHIS cohort designation. Study team members reviewed each patient’s operative notes, catheterization reports, discharge summaries, and clinic letters to determine if that patient was a symptomatic neonate with TOF and to categorize their surgical strategy treatment group as either complete neonatal repair or staged repair. This study was approved by the CHOP Internal Review Board and informed consent was not required.

The positive predictive value (PPV) of this four-step cohort assembly process was calculated based on the formula (true positives / true positives + false positives) as the ability to detect patients with TOF (confirmed in the CHOP database as the gold standard or true condition)

among those identified as TOF in the PHIS database (the test or predicted condition). This allowed us to estimate whether the PHIS designation was true positive or false positive.

The sensitivity was calculated based on the formula (true positives / true positives + false negatives). In order to determine the number of false negatives, the CHOP surgical database, which contains a list of every cardiothoracic surgical patient and procedure performed at CHOP, was queried to identify all symptomatic neonates with TOF during the study period. The CHOP surgical patient and procedure database does not use ICD or Current Procedural Terminology (CPT) codes, but records a list of all cardiac diagnoses and procedures for every cardiothoracic surgical patient. First, all patients with a diagnosis of tetralogy of Fallot were identified in the CHOP surgical database. Second, to be systematically comprehensive, all possible procedures related to TOF were identified, in order to create a list of potential subjects to include in the validation cohort. Third, manual retrospective chart review (gold standard or true condition) was performed to determine whether subjects underwent complete TOF repair or had a palliative procedure for staged TOF repair prior to 30 days of age. Patients who were found by chart review to be symptomatic neonates with TOF that were treated at CHOP during the study period, but who had been excluded from the PHIS cohort, were denoted as a false negative result. This allowed us to confirm if subjects were correctly categorized as a true positive result by the four-step cohort assembly process applied to the PHIS database, or if they were excluded from the PHIS cohort as a false negative result.

Alternative Cohort for Sensitivity Analysis

The cohort assembly process that was described above in steps 1 through 4 represents what we defined as the ideal methodology to accurately identify a cohort of symptomatic neonates with TOF and accurately classify into each treatment group. In step 3 described above, we excluded patients with incomplete or insufficient data within a two-year review period, whose outcome was not known and who were likely to belong to the staged group. This approach was undertaken to avoid misclassification of outcome bias, as patients could have achieved completion of repair at institutions outside of PHIS (and/or died thereafter), or could have died prior to achieving completion of repair. Documentation of death in PHIS predominantly represents in-hospital deaths and therefore out-of-hospital deaths may not be captured. However, in order to ensure that these subjects are accounted for in the group to which they would have been originally assigned, we set them apart as a secondary cohort for future sensitivity analyses. PPV and sensitivity for the cohort validation were calculated for the secondary cohort.

RESULTS

Between January 2004 and March 2015, 5862 neonates were identified in Step 1 as having been hospitalized at one of the 48 PHIS centers with either the ICD-9 discharge diagnosis code for TOF or the ICD-9 procedure code for repaired TOF [Figure 1]. After reviewing the surgery sequence patterns for each patient, Step 2 of cohort assembly excluded 3435 patients who did not have any TOF surgery or catheter-based intervention before 30 days of age. Step 3 of cohort assembly excluded 148 patients with missing follow-up data within a two-

year review, resulting in 2289 remaining patients as potential “symptomatic neonates” with TOF.

Over 800 unique surgery sequence patterns were identified among the patients remaining after Step 3. Many of these unique patterns were similar overall surgical strategies with slight variations based on the type of palliative intervention, the type of complete TOF repair, the number of different hospitalizations, the number of additional procedures, and the order in which those additional procedures were performed. Based on a detailed, manual review of all unique surgery sequence patterns, step 4 of cohort assembly further excluded 54 patients with sequence patterns that were not consistent with either treatment strategy for symptomatic neonates with TOF. The final TOF cohort consisted of 2235 patients from 45 hospitals, with 1032 designated as complete repair and 1203 designated as staged repair.

A subset of 336 patients generated from Step 1 of the PHIS cohort assembly process were identified as having undergone treatment at the Children’s Hospital of Philadelphia (CHOP) and their PHIS cohort designation was validated by manual chart review. As shown in Table 3, cohort identification with ICD-9 codes alone in Step 1 resulted in a positive predictive value (PPV) of 44% (95% CI 38 – 49) with a sensitivity of 94% (95% CI 89 – 97). After completing the cohort assembly process, the PPV of the final cohort increased to 97% (95% CI 93 – 99), which is the probability that a patient is a symptomatic neonate with TOF (*given that they were included in the cohort*), with a corresponding decrease in sensitivity to 85% (95% CI 78 – 90). Within the treatment groups for the final TOF cohort, validation of the surgical strategy designation found a PPV of 98% (95% CI 93 – 100) for the complete repair group, which is the probability that a patient is a symptomatic neonate with TOF *who underwent complete TOF repair in the neonatal period*, with a corresponding sensitivity of 88% (95% CI 80 – 93). Validation of the surgical strategy designation also found a PPV of 86% (95% CI 70 – 95) for the staged repair group, which is the probability that a patient is a symptomatic neonate with TOF *who underwent initial staged palliation in the neonatal period*, with a corresponding sensitivity of 70% (95% CI 55 – 83).

The final cohort has 2235 subjects with 56% males. Additional demographic characteristics are briefly reported in Table 4. Prematurity was present in 21%, while non-cardiac congenital or genetic defects were present in 32%. In short, overall death occurred in 69 subjects (3.1%) by 30 days of age and in 242 subjects (11%) by 2 years of age. These patient-level factors (among others) will be considered in the future analysis comparing outcomes for each treatment group. The number of patients in the final PHIS cohort by hospital and by year is detailed in the appendix [see Table, Supplemental Digital Content 3, which describes patients by hospital and by year].

Secondary cohort: upon further review of the surgery sequences for the 148 subjects included in the secondary cohort, an additional 20 were excluded because the PHIS encounters for the initial TOF procedure were emergency department visits and not immediately followed by any inpatient hospital stay. Therefore, 128 subjects will be available for future sensitivity analyses, resulting in 2363 subjects in the secondary TOF cohort. The PPV in the secondary cohort is 93% (95% CI 88 – 97) and sensitivity is 87% (95% CI 81 – 92).

DISCUSSION

In this study, we describe the methodology used to assemble a cohort of symptomatic neonates with TOF. By applying an innovative four-step process that combined ICD-9 discharge diagnosis codes, ICD-9 procedure codes, and detailed review of patients' surgical sequence patterns to a large pediatric database, we were able to establish a multicenter cohort of 2235 children with symptomatic TOF, with reassuring positive predictive value and sensitivity. This substantial cohort will enable us to investigate each therapeutic strategy without the limitation from surgeon/center preferences, which can limit comparisons. The large sample size will allow us to assess rare outcomes and address confounding by center, in order to investigate differences in outcomes associated with each treatment strategy.

The high false positives and low PPV found during the validation of Step 1 of the cohort assembly process confirms previous reports that cohort identification relying on ICD-9 diagnosis and procedure codes, without consideration of procedure sequence, has been linked with problematic case ascertainment in cardiac surgery patients. Pasquali et al. showed differences in case ascertainment when administrative data were compared to clinical registry data for children undergoing cardiac operations.¹³ For TOF repair, they demonstrated a positive predictive value of 74.2%, indicating that about one-quarter of patients were falsely designated as having a TOF repair. Reducing such misclassification is essential, as it can systematically bias a comparative effectiveness analysis either away from or towards the null, depending on the study question of interest. Therefore, creating and validating an effective cohort assembly process is a necessary foundation for subsequent analyses.

One distinctive feature of our methodology is that we established an *a priori*-defined list of TOF-relevant ICD-9 procedure codes and reviewed the surgery sequence patterns for each patient up to two years of age. In Step 2, only patients having received at least one of the surgical or catheter-based interventions on the TOF-relevant ICD-9 procedure code list before 30-days of age were eligible for further review. Furthermore, we included the additional Step 4, in which we performed a comprehensive manual review of each of the unique surgery sequence patterns. Validation with manual chart review demonstrated that this novel approach resulted in a high positive predictive value to identify symptomatic neonates with TOF from the PHIS database and to appropriately categorize patients as either complete neonatal repair or staged repair. The PPV for the staged repair group was lower as compared to the PPV for the complete repair group, probably a reflection of the fact that the staged repair group is a more heterogeneous population that is more difficult to define.

Future analysis of this cohort will include logistic regression to determine the risk of death at 30 days (primary outcome) from complete repair or palliative procedure (exposures), and the 2-year mortality to capture those who achieved completion of repair after 30 days of life and subsequently died. The logistic models will be constructed using purposeful selection of covariates as potential confounders or effect modifiers of the association between exposure (complete vs. staged repair) and outcome.

In addition to adjusted logistic regression, the authors will utilize an instrumental variable (IV) approach to account for hospital preference in the final analysis, with using hospital preference as the instrument. The instrumental variable approach is a common approach used to estimate causal relationships when randomization is not feasible and it is specifically designed to compensate for the lack of randomization. A proposed alternative to the IV approach involves using propensity score matching to account for bias that results from systematic differences between patients who receive complete versus staged repair. Based on this planned approach for data analysis, the authors seek to overcome the methodological difficulties of causal inference from retrospective data.

The PHIS administrative database was utilized for this study, because it enables investigators to sample a representative group of tertiary children's hospitals, provides longitudinal data to follow patients over time, reports on longer term outcomes, and provides additional data such as resource utilization. The results of this research study will be supplementary to the findings from clinical registries, such as the Society of Thoracic Surgeons Congenital Heart Surgery Database (STS CHSD), which primarily focuses on preoperative, intraoperative, and immediate postoperative factors.^{17,18} Despite these unique advantages, both types of databases have limitations, which must be considered when interpreting the results. The drawbacks inherent to analyses of large administrative datasets include misclassification of exposure, misclassification of outcome, and selection bias.

Limitations

While our method of cohort assembly addresses some of the issues found in previous studies, there are also some limitations. First, there is the potential of not capturing all patients with TOF in PHIS (false negative rate). Selection bias may theoretically have been introduced by how TOF was defined in step 1 of the cohort assembly process. Second, review of the two-year surgery sequence pattern relies on patients receiving treatment at the same hospital up to two years of age or until death. Therefore, an administrative database such as PHIS is unable to capture patients who transferred to (or died at) another non-PHIS hospital. Third, the systematic review of each patient's surgery sequence patterns based on ICD-9 procedure codes may limit the replicability of this exact cohort assembly process, especially given the recent transition from ICD-9 to ICD-10 codes.

The goal of our algorithm was to prioritize the maximization of PPV over sensitivity (thereby minimizing false positives), because including more false positives could have resulted in increased sensitivity, but would have potentially introduced misclassification bias. If an individual patient's surgery sequence pattern was not definitively consistent with a treatment strategy for symptomatic neonates with TOF, the patient was excluded from the cohort. This highlights the importance of establishing the list of relevant procedure codes and defining subgroup classifications prior to exploring the data. Lastly, cohort validation was only performed at a single institution, therefore it is possible that validation using clinical registries at other centers or validation by another institution would not result in the same high PPV or sensitivity. Future studies utilizing a multi-institutional approach combining clinical registries, administrative databases, and insurance claims data, are warranted.

CONCLUSION

The use of a systematic algorithm beyond just ICD-9 codes yielded a large multicenter cohort of symptomatic neonates with TOF from the PHIS administrative database. The subsequent categorization of patients into complete or staged repair groups showed high positive predictive values when compared to manual chart validation. This study cohort presents a unique opportunity to further investigate the differences in outcome between these surgical strategies.

In addition to comparative effectiveness studies in PHIS, this algorithm can be applied to identify symptomatic neonates with TOF in other databases that rely on ICD diagnosis and procedure codes, such as insurance claims data. This meticulous approach to cohort assembly and cohort validation is also relevant to broader audiences outside of pediatric cardiology, because the methodology can be generalized to many types of clinical research that utilize health care administrative data.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1 –.

Tetralogy of Fallot Cohort Assembly Process

Abbreviation: Pediatric Health Information System (PHIS), International Classification of Diseases Ninth Revision (ICD-9), Diagnosis (DX), Procedure (PX), Tetralogy of Fallot (TOF)

Table 1 –

Procedure Codes Related to Tetralogy of Fallot

ICD-9 Procedure Code	Description of Code
35.03	Closed heart valvotomy, pulmonary valve
35.13	Open heart valvuloplasty of pulmonary valve without replacement
35.25	Open and other replacement of pulmonary valve with tissue graft
35.26	Open and other replacement of pulmonary valve
35.53	Repair of ventricular septal defect with prosthesis
35.62	Repair of ventricular septal defect with tissue graft
35.72	Other and unspecified repair of ventricular septal defect
35.81	Total repair of tetralogy of Fallot
35.92	Creation of conduit between right ventricle and pulmonary artery
35.96	Percutaneous valvuloplasty
39.0	Systemic to pulmonary artery shunt
39.23	Other intrathoracic vascular shunt or bypass
39.50	Angioplasty or arterectomy of other non-coronary vessels

Abbreviation: International Classification of Diseases Ninth Revision (ICD-9)

Table 2 –

Patients' Two-year Surgery Sequence Pattern Examples

Treatment Group (Surgical Repair Strategy)	ICD-9 Procedure Code Examples of Surgery Sequence Patterns
Complete neonatal repair	35.81 - 35.81 – 39.50 - 35.81 - 39.50 35.81 - --- 39.50 --- 39.50 35.81 – 35.92 - 35.53 – 35.13 - 35.53 – 35.92 - 35.96 – 35.81 - 39.0 – 35.81 - 39.0 – 35.92 – 35.53 - 35.81 - Death 35.81 - Death
Staged repair	39.0 - 35.81 39.0 - --- 35.81 39.0 - --- 35.81 – 35.92 39.0 - --- 35.81 – 35.92 --- 39.50 39.0 - --- 35.81 – 35.92 --- 39.50 --- 39.50 39.0 - --- 39.50 --- 35.81 39.0 – 39.50 - --- 35.92 – 35.53 35.96 - --- 35.81 35.96 – 39.0 35.81 35.96 – 39.0 --- 35.92 – 35.53 39.0 - Death - 39.0 - Death 39.0 - --- Death 39.0 - --- 35.81 - Death

Abbreviations: International Classification of Diseases Ninth Revision (ICD-9), Symbol for 30-days of age (||), Symbol for one hospitalization (-), Symbol for multiple hospitalizations (---)

Table 3 –

Validation of Tetralogy of Fallot Cohort

Validation of Cohort Assembly Process							
Cohort Assembly Step	PHIS Cohort	CHOP Patients Identified	CHOP True Positive	CHOP False Positive	CHOP False Negative	Positive Predictive Value (95% CI) *	Sensitivity (95% CI) *
1	5862	336	147	189	10	44% (38 – 49)	94% (89 – 97)
2	2437	155	144	11	13	93% (88 – 96)	92% (86 – 96)
3	2289	145	140	5	17	96% (92 – 99)	89% (83 – 94)
4	2235	137	133	4	24	97% (93 – 99)	85% (78 – 90)
Validation of Surgical Strategy Designation							
Treatment Group	PHIS Cohort N = 2235	CHOP Patients Identified	CHOP True Positive	CHOP False Positive	CHOP False Negative	Positive Predictive Value (95% CI) *	Sensitivity (95% CI) *
Complete Repair	1032	101	99	2	14	98% (93 – 100)	88% (80 – 93)
Staged Repair	1203	36	31	5	13	86% (70 – 95)	70% (55 – 83)

* Exact Confidence Limits

Abbreviations: Pediatric Health Information System (PHIS), Children's Hospital of Philadelphia (CHOP), Confidence Interval (CI)

Table 4 –

Demographic Characteristics of Tetralogy of Fallot Cohort

Final PHIS Cohort: Demographics N = 2235	Patient Count (%)
Sex	
Male	1256 (56)
Race	
White	1446 (65)
Black	286 (13)
Asian	91 (4.1)
Other	345 (15)
Unknown	67 (3.0)
Insurance	
Private	917 (41)
Public	1104 (49)
Self-Pay	37 (1.7)
Other	155 (6.9)
Missing	22 (1.0)
Census Region	
Midwest	438 (20)
Northeast	475 (21)
South	714 (32)
West	608 (27)
Final PHIS Cohort: Variables of Interest	Median (Q1 - Q3) or Count (%)
Gestational age (weeks), N = 1524	38 (37 – 39)
Prematurity < 37 weeks, N = 1524	327 (21%)
Any congenital or genetic defect, N = 2235	713 (32%)
Age (days) at first TOF admission	1 (0 – 4)
Age (days) at first TOF procedure	8 (5 – 15)
Death by 30 days of age	69 (3.1%)
Death by 2 years of age	242 (11%)
Age (days) at death before 2 years, N = 242	64 (26 – 188)

Abbreviation: Pediatric Health Information System (PHIS), Quartiles (Q), Tetralogy of Fallot (TOF)