# [2-Year Outcomes After Complete or Staged Procedure for Tetralogy of Fallot in Neonates.](https://www.ncbi.nlm.nih.gov/pubmed/31537267)

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**Take-Home Points:**

* Complete repair has a higher mortality than a staged approach in neonates with tetralogy.
* Postoperative cardiac complications are the most likely mediator for this relationship.



**Commentary from Dr. Jared Hershenson (Greater Washington DC), section editor of Pediatric Cardiology Journal Watch:** Symptomatic/cyanotic infants with TOF require neonatal intervention. There has been debate as to the better strategy: palliation with a shunt or complete repair. Both have advantages and disadvantages. Shunt palliation will prolong cyanosis and require a 2nd surgery.  However, complete repair is a more complex procedure with a longer hospital course and less patients would be able to have a valve-sparing repair, which likely has much better long term consequences. It is known that neonatal repair has a higher morbidity and mortality than later complete repair, but it has not yet been clear which approach may result in the best outcomes in the neonatal population.

This was a retrospective cohort study using the Pediatric Health Information System (PHIS) database between 2004-2015. Primary outcome was death during the 2 year follow up after initial procedure. Somewhat complex statistics were necessary to control for patient and hospital based characteristics, as both could influence the choice of surgical approach. An inverse probability weighted Cox model was used to estimate the effect of the initial procedure on late mortality and a logistic regression was used to analyze mortality within the first hospitalization. To address unmeasured confounding variables and their relative strength, E values were calculated for the estimated hazard and odds ratios.

2363 patients were studied; 1032 had a complete repair and 1331 were staged. Table 1 showed good balance in the weighted sample, with no demographic or patient characteristics being significantly different (all < 10%). Surgeries were performed at 45 hospitals; 24% performed greater than ⅔ complete repairs, 33% performed greater than ⅔ staged repairs, and 42% had equal proportions. Median length of initial hospital stay was 16 days for the complete repair and 15 days for the staged repair. There were 239 deaths, 92 in the complete and 147 in the staged groups. Figure 1 shows the breakdown of each cohort. Complete repair had a greater risk for mortality within the 2 year follow up (HR 1.51) and is shown graphically below. There was no difference within the first week, but from day 7-30 (early), the complete group had an increased risk of mortality (HR 2.29). E-value calculations indicated that only the presence of very strong unmeasured confounders could explain the association of type of repair and survival. See Table 2.  At least one in-hospital cardiac complication was observed in 36.1% of the complete group and 15.4% of the staged group. This was shown to be the primary mediator between surgical approach and mortality, with 87% of the total effect attributable to early mortality and 80% to late mortality. Non-cardiac complications did not mediate the treatment-mortality relationship. However, subgroup analysis did not show a difference in mortality for patients who received a BT shunt versus complete repairs, nor were there differences in those that received an RV to PA conduit within the complete repair group. The authors write that the trend was similar for benefit of BT shunt over complete repair, but the study was possibly underpowered to detect a significant relationship.

As an accompanying editorial suggests, given the limitation of an administrative dataset, the most likely influence of this study will be on those considered to be higher risk. If there is a way to identify those that are more likely to have a cardiac complication, or a way to prevent that complication from occurring, then complete repair risk may be mitigated. Additionally, of those patients in the staged group that did not receive a BT shunt, was it improved catheter based therapy such as RVOT stenting or PDA stenting that led to the improved mortality? Overall, it does seem that a less-invasive initial approach should be favored, especially in the highest risk patients, and decision-making should be individualized to achieve the best possible results. A risk-stratification model may be the next logical step to help determine who may benefit the most from a given therapy.

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