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Intraoperative Steroid Use and Outcomes Following the Norwood Procedure: An Analysis of the Pediatric Heart Network's Public Database

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Abstract

Objective—Data supporting the use of perioperative steroids during cardiac surgery are conflicting and most pediatric studies have been limited by small sample sizes and/or diverse cardiac diagnoses. The objective of this study was to determine if intraoperative steroid administration improved outcomes following the Norwood procedure.

Design—A retrospective analysis was performed on the 549 neonates who underwent a Norwood procedure in the publicly available datasets from the Pediatric Heart Network's Single Ventricle Reconstruction (SVR) trial. Groups were compared to determine if outcomes differed between intraoperative steroid recipients (n=498, 91%) and non-recipients (n=51, 9%).

Results—Baseline characteristics and intraoperative variables were similar between groups with the exception of a shorter duration of cross clamp and cardiopulmonary bypass time in the group that received steroids. Subjects who did not receive intraoperative steroids had improved hospital survival (94% vs 83%, p=0.03), but longer intensive care unit stays (16 days (IQR 12–33) vs 14 days (IQR 9–28), p=0.04) and hospital stays (29 days (IQR 21–50) vs 23 days (IQR 15–40, p=0.01) than steroid recipients. In multivariate analysis lengths of stay associations were no longer significant but hospital survival trended towards favoring the non-steroids group with an odds ratio of 3.52 (95% confidence interval 0.98–12.64, p=0.054).

Conclusions—In the large multi-centered SVR trial there was widespread use of intraoperative steroids. Intraoperative steroid administration was not associated with an improvement in outcomes and may be associated with a reduction in hospital survival in neonates undergoing the Norwood procedure. This study highlights the need for a randomized control trial.

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Keywords

Cardiopulmonary bypass; Cardiac surgical procedures; Norwood procedures; Perioperative care; Steroids; Anti-inflammatory agents

INTRODUCTION

Cardiopulmonary bypass (CPB) is known to incite an inflammatory cascade that is believed to contribute to post-operative morbidity (1–4). Utilization of corticosteroids in an effort to attenuate this response dates back to the 1960s (5). Over time the empirical use of perioperative steroids as prophylactic anti-inflammatory therapy has become a common practice in pediatric cardiac surgery (6,7). Despite demonstrated benefits of steroids in reducing the post-bypass inflammatory response, data to support an association with improved clinical outcomes have yielded contradictory results, with recent research calling into question the benefit of this routine practice (8–20).

Examination of the utility of corticosteroids in CPB has been hindered by widespread variability in dosing regimens and protocols. Studies to evaluate this practice in patients with congenital heart disease have been further limited by small sample sizes and/or heterogeneous patient populations (16,21). This is especially true of neonates, in whom the systemic inflammatory response may be exacerbated by morbidity factors such as smaller patient size, greater hemodilution, hypothermia, and longer bypass times.

The Pediatric Heart Network's Single Ventricle Reconstruction (SVR) Trial is one of the most robust studies examining outcomes of neonates undergoing cardiac surgery. This randomized, multi-center trial examined a homogenous group of 549 neonates undergoing the Norwood procedure for single right ventricular anomaly. Other than shunt type utilized, perioperative care, including utilization of intraoperative steroids, was carried out at the discretion of each institution. The publicly available datasets from the SVR Trial provide the opportunity to determine if the administration of intraoperative steroids is associated with improved outcomes in a large cohort of neonates undergoing the Norwood procedure.

MATERIALS AND METHODS

The details of the SVR trial design and outcomes have been described previously (22,23). In brief, the study was conducted across 15 centers from 2005 through 2009. Inclusion criteria consisted of a diagnosis of hypoplastic left heart syndrome (HLHS) or other single right ventricle anomaly and a planned Norwood procedure. Subjects were randomly assigned to receive either the modified Blalock-Taussig shunt or the right ventricular-pulmonary artery shunt. The institutional review board at each center approved the protocol and written informed consent was obtained from a parent/guardian prior to randomization. Other than the type of shunt placed, the remainder of the perioperative care was per institutional standard.

The publicly available SVR datasets were utilized to compare demographics and outcome measures during the Norwood hospitalization in subjects who received intraoperative

steroids to those who did not. Intraoperative administration of steroids was documented as a dichotomous outcome without specification of type of steroid, number of doses given or specific dosages. As a publicly available dataset, no link to an identified or de-identified center or surgeon is reported.

Grouped data was analyzed using the chi-square or Fischer exact test as appropriate. The chi square test for independence was used to determine if observed frequencies were significantly different from expected frequencies; standardized residuals z-scores less than -1.96 or greater than 1.96 were considered significant. The Shapiro-Wilk test was used to determine that the continuous data were not normally distributed between the steroid and non-steroid groups. As such, non-parametric (Mann Whitney U) statistics were utilized to assess for differences between groups. The results are reported as medians with interquartile ranges (IQR).

In order to control for potential confounders, multivariable logistic and linear regression was performed using risk factors previously shown to have an effect on hospital morbidity and mortality in the SVR Trial (24). Candidate variables were ECMO utilization, open sternum, presence of total anomalous pulmonary venous return, ascending aorta diameter, deep hypothermic circulatory arrest (DHCA), bypass, and cross-clamp time, shunt type, weight, center volume, and intraoperative steroid administration. Candidate variables were included in the initial model if their association with outcome upon univariate analysis revealed a $p < 0.2$. Variables were removed from the multivariable model if their inclusion resulted in $p > 0.1$ or if their inclusion did not benefit the explanatory power of the model. A p-value of 0.05 was considered statistically significant. Statistical analysis was performed using SPSS v. 22 (IBM, New York, NY, USA).

RESULTS

The presence or absence of intraoperative steroid use was documented in all 549 evaluated subjects in the SVR trial of which 498 (90.7%) received intraoperative steroids. Compared with those who received intraoperative steroids, the cohort who did not receive steroids was similar in baseline preoperative characteristics, including weight and ascending aorta size (Table 1). There was no difference in diagnosis of a genetic syndrome or other genetic abnormality. There was no difference in shunt type or delayed sternal closure between the two groups. Those who did not receive steroids had longer bypass and cross-clamp times than those who did receive steroids, although those who received steroids had longer duration of DHCA. The use or non-use of intraoperative steroids spanned the spectrum of both surgeon and center volume, but not with equal distribution (Table 2). For example, 65% of the non-steroid group compared to 34% of the steroid group originated from centers with a volume of ≥ 20 /year. Conversely, 28% of the non-steroid group compared to 42% of the steroid group came from surgeons performing ≥ 10 /year.

In unadjusted analysis, 48 of the 51 patients (94%) who did not receive intraoperative steroids survived to hospital discharge compared to 411 of the 498 patients (83%) who did receive intraoperative steroids ($p=0.03$, Table 3). There was no difference in days of mechanical ventilation between the groups. Those who did not receive steroids did have

longer intensive care unit (ICU) stays compared to those receiving steroids (16 days (IQR 12–33) versus 14 days (IQR 9–28), $p=0.04$) as well as longer total hospital stay (29 days (IQR 21–50) versus 23 days (IQR 15–40), $p=0.01$). Other outcome measurements were not different between the groups, although extracorporeal membrane oxygenation and cardiopulmonary resuscitation utilization trended towards a reduction in the cohort of patients who did not receive intraoperative steroids.

As there was significantly increased mortality in the steroid-receiving cohort outcomes for those patients who survived to hospital discharge after Norwood were analyzed separately. Results were unchanged when considering only hospital survivors (Supplemental Table). However, the persistent findings of shorter ICU and hospital lengths of stay in the steroid group may have been influenced by fewer deaths in the non-steroid group.

In multivariate analysis including center volume, there was a trend towards an increased risk of hospital mortality in the steroid recipients (odds ratio 3.52 with 95% confidence interval of 0.98 – 12.64, $p=0.054$) (Table 4). There was no difference in duration of mechanical ventilation or ICU and hospital lengths of stay between groups.

Neurodevelopmental outcomes have been monitored as part of the SVR Trial (25). 14-month neurodevelopmental outcomes were available on 317 subjects (277 subjects (56%) who received steroids and 40 (78%) who did not receive steroids). There was no difference between the two groups detected by assessment with either the Psychomotor Development Index or Mental Development Index of the Bayley Scales of Infant Development-II (Table 3).

DISCUSSION

The vast majority of neonates undergoing a Norwood procedure in the large, multi-center SVR trial received intraoperative steroids. Despite this, the 51 neonates who did not receive steroids in the operating room represents one of the largest and most homogenous cohorts to date for whom outcomes have been compared to neonates receiving steroids during CPB (16). Similarly to results seen in previously published research, the use of intraoperative steroids in the SVR trial was not definitively associated with improved clinical outcomes. In unadjusted analysis, patients receiving steroids had shorter durations of ICU and hospital stay but exhibited increased hospital mortality compared to neonates who did not receive intraoperative steroids. In adjusted analysis, the improvements in ICU and hospital lengths of stay did not persist but a strong trend towards an increased risk of hospital mortality did. Other outcomes were not statistically different between the two groups, although several outcomes, including need for cardiopulmonary resuscitation or extracorporeal membrane oxygenation, showed a trend towards improvement in those patients not receiving steroids.

Previous studies have shown post-operative renal function to be adversely affected in patients receiving perioperative steroids (15,26). In this cohort, there was not a significant difference in the post-operative diagnosis of acute renal failure between the two groups. Other post-operative markers of renal function were not assessed.

Increased risk of infection remains a potential adverse effect of steroid administration (27). Infectious complications were divided into 13 categories and their timing relative to Norwood procedure was not recorded as part of the SVR trial. While the timing of increased infectious risk would likely be in the period soon after steroid administration, this information could not be ascertained from the SVR data, thus limiting the ability to assess for increased risk due to steroids. As such, the documentation of any infectious complication during Norwood hospitalization was compared between the groups. It is worth noting that over 40% of all patients had some infectious complication during their hospitalization, although there was no demonstrable increased risk in those who received intraoperative steroids.

There are several patient and procedure-related variables shown to be risk factors for morbidity and mortality in the SVR Trial (24). These include lower birth weight, presence of genetic abnormality, need for ECMO, open sternum, and lower center/surgeon volume. The 51 neonates who did not receive intraoperative steroids were similar to their counterparts who did receive steroids in several important pre- and intra-operative variables, including weight, ascending aorta diameter, presence of genetic syndrome or other abnormality, need for other cardiac procedures at time of Norwood, and open sternum at the end of procedure. Of note, the patients who did not receive steroids had significantly longer bypass and cross-clamp times than patients receiving steroids. Theoretically these longer times may predispose neonates to a more severe inflammatory response that steroids may potentially attenuate. Despite this, outcomes were not worse for patients not receiving steroids. It is worth noting that in the SVR Trial duration of DHCA was an independent risk factor for 30-day mortality, and subjects receiving steroids did have significantly longer periods of DHCA than patients who did not receive steroids.^{11–13,15,20,21}

Study Limitations

Despite utilizing the robust publicly available datasets from the largest pediatric cardiac surgical trial to date, this study has some important limitations. As steroid use was not controlled for in the SVR Trial, it is difficult to retrospectively assess for confounding variables between patients who did and did not receive steroids. Although important differences were not noted for most variables shown to impact morbidity and mortality, administration of preoperative and/or postoperative steroids was not recorded.

Another important consideration, especially given the numeric imbalance between the groups, is the role of institution-specific perioperative practices are likely to play in many outcomes. Given the distribution of non-steroid recipients across the spectrum of center and surgeon volume, it appears at a minimum that this cohort originated from several of the SVR sites. As a publicly available dataset, no link to an identified or de-identified center or surgeon is reported and therefore cannot be incorporated in statistical analysis. Center volume, which was thought to vary less than surgeon volume from year to year, was included in multivariable analysis to account for this. Interestingly, a majority of the non-steroid recipients came from centers with a volume of <20/year where the majority of the steroid group came from centers with a higher volume.

There was an imbalance in sample sizes between patients receiving steroids and those not receiving steroids. While equal samples would be preferable for comparison, the sample of 51 neonates who did not receive steroids still qualifies as one of the largest groups studied to date, and the homogeneity of the population is an important strength that has not been achieved in other studies.

Certain measurements often assessed in studies comparing outcomes related to steroids were not obtained in the SVR Trial, including inflammatory biomarkers, post-operative renal function, immediate post-operative infectious complications, and evidence of reduced cardiac output (19,20,28). These morbidities may have important consequences and should continue to be assessed in future studies.

CONCLUSIONS

The SVR Trial provides one of the largest, most homogenous cohorts of neonates undergoing CPB studied to date. This study was unable to demonstrate a significant benefit associated with the use of intraoperative steroids and found that intraoperative steroids may be associated with increased hospital mortality following the Norwood procedure. Given the study limitations, it is not possible to definitively describe the risks and benefits of intraoperative steroids use. However, this information provides further support for a multi-centered, randomized control trial for steroid use in neonates requiring CPB.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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TABLE 1

Pre- and intraoperative patient characteristics

	Steroids (n=498)	No steroids (n=51)	p-value
Weight (kg)	3.2 (2.7–3.5)	3.1 (2.9–3.5)	0.25
Identifiable syndrome (n)*	22 (6.7%)	4 (8.7%)	0.76
Identifiable abnormality (n)*	91 (27.7%)	15 (32.6%)	0.6
Ascending aorta (mm)	2.5 (2.0–4.0)	2.4 (2.0–3.8)	0.72
Modified Blalock-Taussig shunt (n)	247 (50%)	28 (55%)	0.47
Cross-clamp time (minutes)	52 (40–66)	65 (52–83)	<0.001
Bypass time (minutes)	137 (103–170)	152 (136–191)	0.001
DHCA (n)	462 (93%)	50 (98%)	0.24
DHCA (minutes)	35.5 (16–47)	16.5 (11–45)	0.03
DHCA+bypass time (minutes)	162 (131–193)	182 (152–211)	0.004
Other procedures during Norwood (n)	52 (10%)	9 (18%)	0.19
Open sternum (n)	388 (78%)	38 (75%)	0.49

Data are reported as median (interquartile range) or number and percent as appropriate.

* Only 374 subjects had recorded genetic evaluations to assess history of any syndrome or other non-syndromic abnormality (328 patients who received steroids (66%), 46 patients who did not receive steroids (90%))

DHCA – deep hypothermic circulatory arrest

‘Other procedures during Norwood’ include atrioventricular valve repair, pacemaker insertion, branch pulmonary arterioplasty, and repair of anomalous pulmonary veins.

TABLE 2

Surgical center and surgeon volume

	Steroids (n=498)	No steroids (n=51)	p-value
Center volume			
15/year	91 (18%)	2 (4%) ^b	<0.001
16–20/year	78 (16%) ^b	31 (61%) ^a	
21–30/year	160 (32%)	16 (31%)	
> 30/year	169 (34%)	2 (4%) ^b	
Surgeon volume			
5/year	98 (20%)	10 (20%)	<0.001
6–10/year	109 (22%)	4 (8%) ^b	
11–15/year	204 (41%)	35 (68%) ^a	
> 15/year	87 (17%)	2 (4%) ^b	

^a higher than expected frequency based on standardized residuals using chi square test for independence

^b lower than expected frequency based on standardized residuals using chi square test for independence

TABLE 3

Outcomes in steroid recipients versus non-recipients during the Norwood Procedure

	Steroids (n=498)	No steroids (n=51)	p-value
Discharged alive (n)	411 (83%)	48 (94%)	0.03
Mechanical ventilation (days)	7 (5–13)	7 (5–11)	0.85
Intensive care unit stay (days)	14 (9–28)	16 (12–33)	0.04
Hospital stay (days)	23 (15–40)	29 (21–50)	0.01
Extracorporeal membrane oxygenation (n)	54 (11%)	2 (4%)	0.15
Cardiopulmonary resuscitation (n)	92 (19%)	5 (10%)	0.13
Any infectious complication (n)	197 (40%)	23 (45%)	0.44
Acute renal failure (n)	44 (9%)	2 (4%)	0.30
Total hospital complications (n)	2 (1–4)	2 (1–3)	0.25
Psychomotor Development Index	72 (54–92)	75 (62–94)	0.14
Mental Development Index	92 (77–101)	95 (84–103)	0.22

Data are reported as median (interquartile range) or number and percent as appropriate

TABLE 4

Multivariable logistic regression predictors of hospital mortality accounting for center volume

	Odds Ratio	95% CI	p-value
Intraoperative steroid use	3.52	0.98–12.64	0.054
Norwood weight	0.43	0.26–0.72	<0.01
Open sternum	4.72	1.4–15.85	0.01
Extracorporeal membrane oxygenation	6.98	3.53–13.8	<0.01
Cardiopulmonary bypass time	1.01	1.01–1.02	<0.01