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An International Survey of Corticosteroid Use for the Management of Low Cardiac Output Syndrome

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Abstract

Objective—Limited evidence exists on use of corticosteroids in low cardiac output syndrome (LCOS) following cardiac surgery. We sought to determine physicians' practices and beliefs with regard to corticosteroids therapy for LCOS.

Design—Multi-national internet-based survey.

Setting—Pediatric Cardiac Intensive Care Society member database.

Subjects—Pediatric cardiac intensive care physicians.

Interventions—None

Measurements and Main Results—We received 188 responses from 85 centers throughout the world including 57 U.S. congenital heart centers, 8 Canadian centers and 20 international centers. The majority of respondents (51%) reported performing at least 200 bypass cases per year and had separate dedicated cardiac intensive care units (57%). Most physicians (89%) rarely or never prescribe corticosteroids for mild LCOS (single vasoactive agent and mildly decreased perfusion) while 94% of those surveyed sometimes or always administer corticosteroids to patients with severe LCOS (2 or more vasoactive agents and persistent hypotension). Hydrocortisone was the most commonly used corticosteroids (88%) but there was no consensus on dosage used. There

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was a variable approach to cortisol level measurement and cortisol stimulation testing to inform therapy with corticosteroids. A majority of respondents (75%) stated they would be willing to randomize patients with severe LCOS into a trial of corticosteroids efficacy.

Conclusion—Our survey demonstrates considerable practice variability with regard to the type of patients in whom corticosteroids are administered, adrenal axis testing is performed and dosage of hydrocortisone used. The majority of physicians, however, stated their willingness to randomize patients with severe LCOS in a corticosteroids trial. This survey identified multiple areas for future research on use of corticosteroids for LCOS.

Keywords

Corticosteroids; Cardiac surgery; Low Cardiac Output Syndrome; Hydrocortisone; Congenital heart disease; Adrenal insufficiency

Introduction

Low Cardiac Output Syndrome (LCOS) refers to the decrease in cardiac output that occurs following cardiac surgery, which affects up to 25% of neonates and young children(1–3). The presence of LCOS may result in prolonged duration of mechanical ventilation, increased intensive care and hospital length of stay, and increased risk of other morbidities and mortality(1). Current management of this clinical syndrome is supportive and includes the use of vasoactive agents and fluid administration (3). However, some patients appear to have a suboptimal response to these agents despite escalating doses of vasoactive agents. The identification and treatment of this subset of patients has not been well studied.

It has been hypothesized that patients with inotrope refractory LCOS may have relative adrenal dysfunction (4–6) raising the possibility that corticosteroids might be useful in this setting. Nonetheless, there are no randomized controlled trials on the use of corticosteroids for LCOS in children post cardiac surgery and recent large adult-based trials in septic shock have provided conflicting data with some suggesting more harm than benefit (7,8). There are currently no evidenced-based guidelines for the use of corticosteroids in LCOS in children post-cardiac surgery. As such current physician practices in this setting appear to be extrapolated from the guidelines from the American College of Critical Care Medicine for the use of hydrocortisone for children with septic shock(9).

An understanding of current physician practices and beliefs is essential to inform future studies of corticosteroids in LCOS after pediatric cardiac surgery. To this end, we performed a survey of cardiac critical care physicians who are members of the Pediatric Cardiac Intensive Care Society (PCICS) to discern beliefs, current practice patterns, and the equipoise to engage in future randomized studies.

Materials and Methods

Study Design and Population

This was a prospective study utilizing a custom-designed survey. The target population was practicing pediatric cardiac intensive care physicians worldwide who were post-fellowship

training. Population members were identified through the current membership list from the Pediatric Cardiac Intensive Care Society (PCICS) (10). The survey was sent via email to all 394 cardiac intensivists identified representing a total of 148 institutions and 17 countries. This study was reviewed and approved for exempt status by the Cincinnati Children's Hospital Medical Center Institutional Review Board (IRB).

Survey Development

The survey items were generated through an iterative process by the study investigators with input from a panel of senior intensivists from the U.S. and Canada. These reviews established content validity by ensuring direct correspondence between the research objectives and survey questions. Each version of the survey was also reviewed to identify and address issues that might undermine validity including question clarity, response option appropriateness, and ease of completion. The survey was then pre-tested using the Question Appraisal System (QAS)(11) as a framework to identify and address any remaining problems that might undermine the validity of the survey data. The survey includes ordinal, categorical, and open-ended questions. Most of the ordinal questions pertained to the frequency of various self-reported behaviors (e.g., initiating steroid therapy for treatment of LCOS). For these frequency questions the initial version of the survey included response options that offered percentage ranges for the respondents to estimate the percentage of cases in which they engaged in the behavior. Through pre-testing it was found that respondents considered this to be too difficult; many felt they either couldn't or found it very difficult to recall accurately. The response options for these questions were changed to "Never", "Rarely", "Sometimes", and "Usually/always." While these response options are more difficult to interpret than percentage estimates, the threats to validity posed by the latter in terms of recall error, respondent fatigue, item non-response, and dropout were too high(12).

The final version of the survey is provided for online viewing (Supplement 1).

Regarding LCOS, respondents were asked to consider the following descriptions of mild, moderate, and severe LCOS comprised of commonly used clinical parameters when determining LCOS:

- Mild - single vasoactive agent, slightly decreased urine output and cool extremities
- Moderate - Two or more vasoactive agents, tachycardia and slightly elevated lactate
- Severe - Two or more vasoactive agents, tachycardia, elevated lactate and refractory hypotension

Survey Administration

The survey was administered using Qualtrics™ (Provo, Utah); a web-based survey application that provides respondent anonymity, question routing and display logic functionality. Respondents received an invitation and survey link via email that included a brief description of the purpose of the project along with assurance of anonymity. The

survey was conducted between July and September of 2014 and January and March of 2015 due to updates to the PCICS membership database. Respondents were given three weeks to complete the survey with a reminder sent at the end of each week to those who had not yet responded.

Statistical analysis

Univariate descriptive frequencies were calculated for all closed-ended questions. Bivariate descriptive cross-tabulations were calculated to show the frequency distributions between comparison variables. Differences in practices based on geographic location and PICU structure were examined with one-way between subjects ANOVA and chi-square analysis using SPSS (v. 19). A content analysis was conducted on the responses from the open-ended questions using a previously established technique which involved two of the investigators independently coding and then discussing each response to reach a consensus on the thematic code - or codes - for each response(13,14). Descriptive frequencies were then calculated based on the assigned codes. Intraclass correlation coefficient (ICC) was examined using proc mixed to assess consistency of responses (observer agreement) given by different respondents within a site for each survey item, if sites have more than three respondents. The ICC measures were: Less than 0.40 – poor; between 0.40 and 0.59 – fair; between 0.60 and 0.74 – good; between 0.75 and 1.00 – excellent (15).

Results

Demographics

Responses were received from 188 (48%) of the 394 physicians invited to participate. Respondents had practiced Cardiac Critical Care for a median of 9 years (IQR=4.3–16). Table 1 shows the distribution of board certification for all respondents. The most common board certification (51%) was in pediatric critical care medicine.

A total of 85 (71%) member institutions of the Pediatric Cardiac Intensive Care Society (PCICS) were represented. A median of 2 physicians (IQR=1–3) from 57 U.S. centers, a median of 4 physicians (IQR=2–8) from 8 Canadian centers, and a median of 1 physician (IQR=1–1) from 20 international centers responded to the survey. The following international centers were represented: Asia - India (3), Israel (1), Jordan (1), Saudi Arabia (1), Qatar (1); South America - Argentina (2), Mexico (1), Brazil (1), Colombia (1); Europe – U.K. (2), Austria (1), Netherlands (1), Switzerland (1), France (1), Serbia (1), Australia – Australia (1). A median of 8 physicians (IQR=6–10) provide care for post-operative cardiac surgery patients at these centers. Institutional level respondent data are presented in Table 2.

Agreement with LCOS severity levels

The majority of respondents indicated that the definitions of mild, moderate, and severe LCOS used in the survey “Mostly” (52.1%) or “Completely” (25%) reflected their own views and all but 2 of the remaining respondents (0.5%) indicated that the descriptions “Partially” reflected their views. Respondents whose views were not “Completely” reflected in the descriptions were asked what they would change about each of the levels to completely reflect their own views. The most frequently mentioned theme across all severity

levels had to do with adding “decreased SVO₂ level” to the description with many including some specific threshold for each severity level. The next most frequently mentioned change was to include “low or no urine output” to the moderate and severe levels. Supplemental Digital Content – Supplementary Table 1 provides a summary of the thematic codes for those open-ended responses.

Corticosteroid use in LCOS

Respondents were asked how often they have initiated corticosteroid therapy for treatment of mild, moderate and severe LCOS. The majority reported that they “1-Never” (64.9%) or “2-Rarely” (24.5%) administer corticosteroids for mild LCOS and the vast majority reported that they “3-Sometimes” (35.6%) or “4-Usually/Always” (58%) administer corticosteroids to patients with severe LCOS. There was a statistically significant difference in how often corticosteroid therapy was initiated for mild LCOS based on PICU structure, with the frequency of initiating corticosteroid therapy significantly lower for those in combined PICU’s without dedicated staff compared to those in dedicated CICU’s ($p=.013$). No other statistically significant differences based on PICU structure or geographic locations were found. The responses are summarized in Table 3.

Hydrocortisone was reported as the most commonly used corticosteroid for LCOS by 162 (88%) of the respondents but there was variation among them regarding the dosage used with 27.5% reporting 50 mg/m²/day, 26.3% 100 mg/m²/day, 13.1% 2 mg/kg/day, and 5% 1 mg/kg/day. The remaining 28.1% reported that they most often used some dosage other than these with 1 mg/kg q6h being the most frequently mentioned.

Adrenal axis testing

Respondents were asked how frequently they measured serum cortisol levels and/or performed a cosyntropin stimulation test prior to the administration of corticosteroids. Respondents were also asked how often they initiated therapy before the results of these tests became available and how often they tailored corticosteroid therapy based on the results. Figure 1 provides the response frequencies for cortisol measurement and Figure 2 provides the frequencies regarding the cosyntropin stimulation test. ANOVA results indicated a significant geographic difference in how often cortisol levels were measured prior to the administration of steroids in patients with LCOS, $F(2,160) = 11.2, p < .001$. *Post hoc* analyses using the Scheffé *post hoc* criterion for significance revealed that physicians at U.S. institutions measure cortisol levels more frequently prior to corticosteroid administration ($M=3.36, SD=0.86$) compared to physicians in Canada ($M=2.63, SD=1.07$) and physicians practicing in other international countries ($M=2.5, SD=1.09$). No other statistically significant differences were found in terms of measuring cortisol levels or conducting a cosyntropin test prior to corticosteroid administration.

Of those who did measure cortisol level prior to administration, nearly half (48.7%) reported that their institutions used total cortisol, 24% reported using plasma free cortisol, and the remaining 27% did not know. In terms of the cosyntropin dose usually used for the stimulation test, 39.6% of respondents reported usually using 1 mcg, 15.6% usually used 125 mcg, 8.3% usually used 250 mcg, 29.2% did not know, and 7.3% indicated that they

used some other dosage with a majority of those mentioning that they would use 1 mcg for infants and 250 mcg for older children. Figure 3 provides data regarding the cortisol level thresholds respondents most often use when using cortisol levels or the cosyntropin stimulation test to determine therapy. Chi-square analyses did not reveal any statistically significant differences based on geographic location or PICU structure.

Willingness to randomize patients with LCOS

A majority of (56.7%) respondents stated they would be “very willing” to randomize patients with severe LCOS into such a study. A minority of (34.4%) respondents were both “very willing” to randomize for severe LCOS and “Usually or always” used corticosteroids for severe LCOS. All responses are summarized in Table 4.

Intraclass correlation coefficient

A total of 14 sites were examined. In general, low agreement was observed for various survey questions. Many questions had ICC=0 (i.e. no agreement). The highest observed agreement was ICC=0.47 for question 17 (How often do you start steroid therapy before cortisol testing results are available?).

Discussion

Our survey is the first to assess physician practices and beliefs with regard to the use of corticosteroids for LCOS. The study’s primary finding is that among a large and diverse sample of physicians and centers, corticosteroid use for LCOS is common, variable, and often not guided by testing. We also identified low agreement of responses within specific centers and highlights even further the lack of uniformity in corticosteroid use for LCOS. These results are consistent with those documented in corticosteroid use for hypotensive pediatric shock studies which have shown a similar degree of variability (16).

Adrenal function in the critical care setting is currently assessed by baseline cortisol levels and/or the cosyntropin stimulation test. We found significant variability with regard to the choice of test and the interpretation of the results in treatment of LCOS with corticosteroids. However, the most commonly identified threshold for corticosteroid initiation for a cortisol level was <9 mcg/dl which is consistent with the generally accepted definition by critical care physicians (4,17–20). This implies that in the absence of data on corticosteroid use in LCOS, physicians have developed treatment approaches by extrapolating from other hemodynamically compromising conditions. Furthermore, the utility of cortisol levels in the postoperative period remains questionable, as a recent study by Schiller et. al demonstrated that low cortisol levels did not impact the postoperative course as characterized by inotropic support, lactate level, urine output, length of mechanical ventilation, and length of ICU stay when compared with children with normal cortisol levels (21).

A high percentage of respondents reported measuring a cortisol level prior to administration of corticosteroids in the setting of LCOS, but the vast majority of respondents stated they would start corticosteroid therapy before cortisol testing results were available. Only a small percentage of respondents reported performing a cosyntropin stimulation test prior to the initiation of corticosteroids in the setting of LCOS, but similar to the baseline cortisol level,

most responded that they would start corticosteroid therapy before cosyntropin stimulation testing results are available likely due to the delay in obtaining cortisol results. A vast majority of respondents reported adjusting the corticosteroid therapy based on their test results. Another potential reason for this practice may be the considerable controversy in the literature regarding the definition of adrenal insufficiency in critically ill children and adults (7,8,22). Interestingly, a third of respondents that obtained adrenal axis testing prior to initiation of corticosteroid therapy either never or rarely tailored therapy based on those levels. The reasons for this practice are unclear and would be interesting to explore in a future study.

Determination of LCOS after cardiac surgery in children can be difficult. The traditional definition was based on hemodynamic data in the catheterization laboratory (23,24). We propose a LCOS definition to better assist clinicians and investigators in clinical trial design, which captures respondents' perceptions of what should be added to our provided definitions. Additionally, our provided definition was structured by determining different categories of LCOS. These categories could be helpful when initiating corticosteroids. Furthermore, the LCOS classification can help identify potential groups of patients with LCOS that will or will not receive corticosteroids and secondly to identify the group of patients who providers will be willing to randomize to receive or not receive corticosteroids for a potential clinical trial for the management of LCOS. As demonstrated by this survey, 78% of respondents in the moderate LCOS category and 75% in the severe LCOS category would be "somewhat willing" or "very willing" to randomize patients to receive corticosteroids or not in case of a clinical trial. However, 58% of providers would administer corticosteroids for severe LCOS, whereas only 6% for moderate LCOS. This suggests that a more likely group eligible for randomization would be patients with moderate LCOS to maximize provider compliance.

We found a significant variability in the use of corticosteroids for LCOS after congenital heart surgery. This may reflect a lack of clear evidence for or against the use of corticosteroids. For instance, a recent study of children undergoing congenital heart surgery failed to demonstrate a benefit from the perioperative use of corticosteroids, and instead found an association between corticosteroid use and more frequent infections, post-operative use of insulin, and prolonged length of stay (25). Conversely, Robert et al. demonstrated that prophylactic, postoperative hydrocortisone reduces LCOS, improves fluid balance and urine output, and decreases length of stay after neonatal cardiopulmonary bypass surgery (26). In addition, our study found that respondents reported increased frequency of corticosteroids use with greater severity of LCOS, whereas in the study by Vogt et. al (3) the use of corticosteroids was very low regardless of the LCOS category.

The variability in adrenal function testing and corticosteroid use in patients with congenital heart disease is likely driven by gaps in knowledge and highlights the need for further investigation. A well designed, multi-center, randomized controlled trial is needed to define the benefits and clinical significance of corticosteroids administration in critically ill patients following cardiac surgery. Ultimately this would allow for the development of guidelines and subsequently a significant reduction in practice variability.

Future studies should also attempt to determine cardiac surgeons' perceptions on the use of corticosteroids for the management of LCOS in this patient population. These perceptions can be assessed by utilizing scenario based surveys to address what may influence their responses incorporating other factors not included in our study, such as patient's age, the level of complexity of surgery, the use of hemofiltration, the perioperative administration of corticosteroids, the cardiopulmonary bypass time, etc. Furthermore, these studies should also attempt to capture the proportion and perceptions of providers who do not consistently use corticosteroids, even in severe LCOS.

The primary limitations of the study include the relatively low response rate of just under 50%. An additional limitation is that it reflects stated rather than actual physician practices from members of PCICS. However, we still believe that we were able to examine a diverse range of experiences and beliefs as evidenced by representation from 85 centers.

Conclusion

Our survey demonstrates considerable practice variability with regard to the type of patients in whom corticosteroids are administered, adrenal axis testing and dosage of hydrocortisone used. The majority of respondents stated their willingness to randomize patients with severe LCOS in a corticosteroid trial. This survey identified multiple areas for future research on use of corticosteroids for LCOS.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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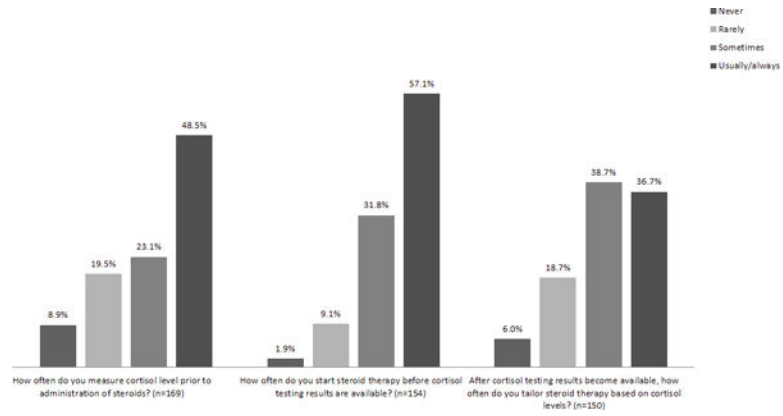


Figure 1.
Measurement and use of cortisol level in corticosteroid therapy

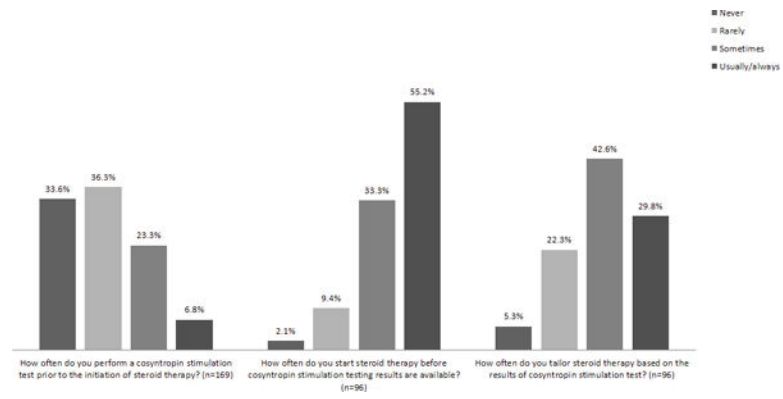


Figure 2.
Measurement and use of stimulation testing in corticosteroid therapy

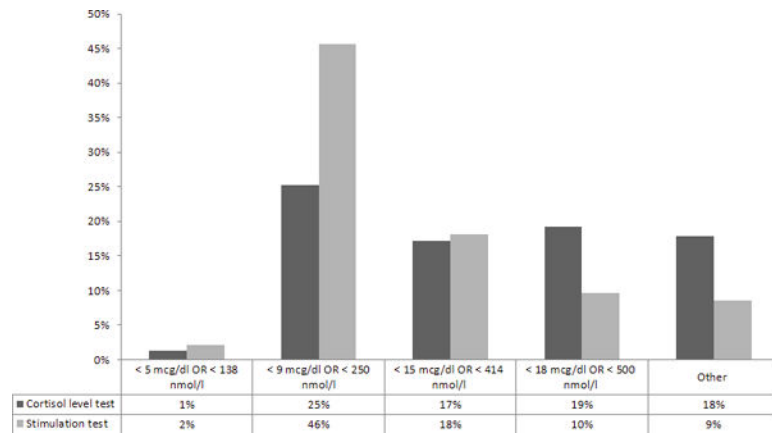


Figure 3.
Cortisol level threshold used to determine initiation of corticosteroid therapy

Table 1

Training Background of Respondents

Training Background	Frequency (%)
Pediatrics and Critical Care	96 (51%)
Pediatrics and Cardiology	34 (18%)
Pediatrics, Critical Care, and Cardiology	27 (14%)
Pediatrics, Critical Care, and Anesthesiology	18 (10%)
Pediatrics only	6 (3%)
Pediatrics, Critical Care, and Surgery	4 (2%)
Pediatrics, Cardiology, and Neonatology	3 (2%)

Table 2

Institutional Level Respondent Information (n=85)

Category	Frequency (%)
Geographic location	
U.S.A	57 (67%)
Canada	8 (10%)
Other international	20 (23%)
Bypass cases over the past 12 months	
0 to 100	14 (16%)
101–200	21 (25%)
201–300	22 (26%)
301–400	13 (15%)
>400	15 (18%)
Structure of Pediatric Intensive Care Unit	
Independent CICU	49 (58%)
Combined units (PICU/CICU) – with dedicated CICU staff [/]	18 (21%)
Combined units (PICU/CICU)- no dedicated CICU staff	18 (21%)
Bed Count	
If independent CICU	
0–10	13 (15%)
11–20	25 (29%)
More than 20	11 (13%)
If combined units	
0–10	20 (23%)
11–20	10 (13%)
More than 20	1 (1%)
No response	5 (6%)

[/] Staff includes nurses and physicians.

Table 3

Rate of Corticosteroid Therapy Initiation for each Level of LCOS Severity (n=188)

Category	Mild n=188	Moderate n=186, 2 skipped	Severe n=188
Never	122 (64.9%)	35 (18.8%)	4 (2.1%)
Rarely	46 (24.5%)	59 (31.7%)	8 (4.3%)
Sometimes	18 (9.6%)	80 (43.0%)	67 (35.6%)
Usually (or Always)	2 (1.1%)	12 (6.5%)	109 (58.0%)

Mild = Single vasoactive agent, slightly decreased urine output and cool extremities; Moderate = Two or more vasoactive agents, tachycardia and slightly elevated lactate; Severe = Two or more vasoactive agents, tachycardia, elevated lactate and refractory hypotension

Table 4

Willingness to Conduct a Corticosteroid Study given LCOS Severity Level of Patient (n=188)

Category	Mild n=179, 9 skipped	Moderate n=179, 9 skipped	Severe n=180, 8 skipped
Not at all willing	61 (34.1%)	14 (7.8%)	23 (12.8%)
Only slightly willing	35 (19.6%)	25 (14.0%)	23 (12.8%)
Somewhat willing	22 (12.3%)	65 (36.3%)	32 (17.8%)
Very willing	61 (34.1%)	75 (41.9%)	102 (56.7%)