Cardiology in the Young

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Immunisation recommendations for children with single ventricle CHD

Sarah L. Tallent[1], Trudy A. Pierick[2], Jo Ann M. Davis[3], Sonali S. Patel[4], Sophia Marusic[5] and Andrew W. McCrary[1]

[1]Division of Paediatric Cardiology, Duke University Medical Center, Durham, NC, USA; [2]Division of Paediatric Cardiology, University of Iowa Stead Family Children's Hospital, Iowa City, IA, USA; [3]Heart Center, Nationwide Children's Hospital, Columbus, OH, USA; [4]Division of Paediatric Cardiology, University of Texas Southwestern Medical Center, Dallas, TX, USA and [5]Duke University School of Medicine, Durham, NC, USA

Brief Report

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Corresponding author: S. L. Tallent; Email: sarah.tallent@duke.edu

Abstract

Recommendations for immunisation practices in children with single ventricle CHD are lacking. A survey of 53 heart centres received responses from 40 centres (33 complete and 7 partial) revealing variability in immunisation recommendations. Only 11% have a written protocol. Immunisations were delayed before cardiopulmonary bypass in 94% (32/34) and after cardiopulmonary bypass in 97% (30/31), with 34% (13/38) re-dosing some immunisations post cardiopulmonary bypass. Further research is needed to develop guidelines.

Introduction

Infants and children with CHD face challenges in achieving optimal immunisation.[1,2] Only 60% of infants with CHD are fully vaccinated by one year of age, with cardiopulmonary bypass exposure emerging as a significant predictor of under-vaccination.[1] This is likely due to the lack of clear guidelines for immunisation schedules in this high-risk group. There is also concern for avoidable adverse events, despite some limited evidence that immunisation does not lead to adverse events in this population.[3] Specific concerns for infants who have undergone procedures with cardiopulmonary bypass include reduced immunisation titres and the exposure to antibody-containing blood products while on bypass reducing immunisation efficacy.[4–6] However, limited data support these concerns or guides immunisation practices.

A recent study by Gal et al.[5] characterising immunisation practices in the setting of congenital heart surgery found that 66% of paediatric heart centres surveyed deferred immunisations prior to surgery and 89% deferred for variable amounts of time after surgery with different practices for live virus vaccines. We sought to further characterise these practices specifically for infants (0–18 months) with single ventricle heart disease, as they are anticipated to have at least two procedures with cardiopulmonary bypass, long periods of hospitalisation, and increased morbidity and mortality.

Materials and methods

A qualtrics survey was sent to an email listserv of single ventricle programmes across the United States. Survey questions (Table 1) were sent via listserv with three reminders over four weeks. A single collaborative response per centre was requested. Duke Institutional Review Board deemed this study to be exempt, Pro00110663.

Responses were analysed based on centre size, procedure type, and immunisation type. The Society of Thoracic Surgeons definition of centre size by number of bypass cases per year was used to classify the respondent's programme size (small: <150, medium: 150–349, large: ≥350). Procedures were classified into five categories: surgical stage 1 palliation, hybrid stage 1 palliation, surgically placed shunt, interventional palliative procedure, and main pulmonary artery banding. Immunisations were divided into three groups. The first group included all non-live virus vaccines (hepatitis B, diphtheria, tetanus, and pertussis, *Haemophilus influenzae*, pneumococcal conjugate; inactivated polio, and hepatitis A), rotavirus, and palivizumab. The second group included all non-live virus vaccines and palivizumab. The third group only included palivizumab. This study was conducted prior to nirsevimab availability. Hepatitis A vaccine was also included since our patient population comprised children aged 0–18 months. Practices around measles, mumps, and rubella and varicella vaccination were collected with regard to delaying and re-dosing around cardiopulmonary bypass.

Descriptive statistics were performed; categorical data are presented as frequency (percentage) and non-normally distributed continuous data as median (interquartile range, range). All analyses were performed using Statistical Analysis Software, version 9.4 (SAS Corporation, Cary, NC).

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Table 1. Survey questions

What medical professionals provided input for this survey?
Do you have a written protocol for providing routine immunisations (as defined by the CDC) to patients with single ventricle heart disease?
What is your annual paediatric cardiac surgical volume?
Do you re-dose routine vaccines (as defined by the CDC) after bypass?
Select all that you re-dose: • All non live-virus vaccines (Hep B, DTaP, Hib, PCV13, IPV, and Hep A) • Rotavirus • MMR • Varicella • Influenza
How long after bypass do you re-dose (in weeks)?
Prior to cardiopulmonary bypass, how many weeks are vaccines held?
After cardiopulmonary bypass, how many weeks are vaccines delayed?
Do you recommend Synagis to those that qualify according to the 2014 AAP Guidelines for patients with haemodynamically significant CHD?
Do you re-dose Synagis after cardiopulmonary bypass for those that qualify according to the 2014 AAP Guidelines for patients with haemodynamically significant CHD?
When do you re-dose Synagis (in weeks) after bypass?
Do you recommend Synagis for a second season for patients with hemodynamically significant CHD?
In infants who have undergone Surgical stage 1 palliation: Defined as Norwood with Sano modification or Norwood with modified Blalock–Taussig–Thomas shunt (mBTTs), select all that you recommend the infant receive per routine schedule as defined by the CDC: • All non live-virus vaccines (Hep B, DTaP, Hib, PCV13, IPV, and Hep A) • Rotavirus • Palivizumab
In infants who have undergone Hybrid stage 1 palliation: Defined as bilateral pulmonary artery bands and ductal stent, select all that you recommend the infant receive per routine schedule (as defined by the CDC) • All non live-virus vaccines (Hep B, DTaP, Hib, PCV13, IPV, and Hep A) • Rotavirus • Palivizumab
In infants who have undergone a surgically placed shunt for other diagnoses excluding Norwood operation: select all that you recommend the infant receive per routine schedule (as defined by the CDC) • All non live-virus vaccines (Hep B, DTaP, Hib, PCV13, IPV, and Hep A) • Rotavirus • Palivizumab
In infants who have undergone an interventional palliative procedure: Defined as a ductal stent, RVOT stent, or other types of interventional palliation, select all that you recommend the infant receive per routine schedule (as defined by the CDC) • All non live-virus vaccines (Hep B, DTaP, Hib, PCV13, IPV, and Hep A) • Rotavirus • Palivizumab
In infants who have undergone main pulmonary artery banding ONLY: select all that you recommend the infant receive per routine schedule (as defined by the CDC): • All non live-virus vaccines (Hep B, DTaP, Hib, PCV13, IPV, and Hep A) • Rotavirus • Palivizumab
Do any of your answers above change if there was no cardiopulmonary bypass? • You answered “yes” that your practice is different if there is no cardiopulmonary bypass. Please tell us what is different:
For the MMR and Varicella vaccines, do you delay administration in infants who were exposed to antibody-containing blood products (immunoglobulin, whole blood, packed red blood cells, platelets, and plasma)?
You answered that you delay MMR and Varicella vaccines in infants who were exposed to antibody-containing blood products. How long in months after exposure do you delay administration of MMR and Varicella vaccinations?
Does your centre have any other special considerations related to immunisations?

Results

Of 53 surveyed centres, 40 responded (33 complete, 7 partial). Among the 37 centres that reported programme size, 49% (18/37) were medium, 35% (13/37) were large, and 16% (6/37) were small-sized programmes.

Immunisation recommendations are displayed in Table 2. Only 11% (4/38) of responding centres had a formal written protocol for immunisation recommendations in this population.

Practices for holding or re-dosing immunisations around cardiopulmonary bypass varied among centres (Table 2). Of the

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Table 2. Immunisation recommendations

Immunisation Practices by Centre size and Procedure				
Procedure/Immunisation approach	Small	Medium	Large	Totals by procedure (n = 33)
Surgical Stage 1 Palliation[1]				
• Palivizumab only	1 (16.7%)	1 (6.7%)	0 (0.0%)	2 (6.1%)
• Non-live virus immunisations, palivizumab	3 (50.0%)	3 (20.0%)	2 (18.0%)	8 (24.2%)
• Non-live virus immunisations, rotavirus, palivizumab	3 (33.3%)	11 (73.3%)	9 (82.0%)	23 (69.7%)
Hybrid Stage 1 Palliation				
• Palivizumab only	1 (16.7%)	1 (6.7%)	0 (0.0%)	2 (6.1%)
• Non-live virus immunisations, palivizumab	3 (50.0%)	3 (20.0%)	1 (10.0%)	7 (21.2%)
• Non-live virus immunisations, rotavirus, palivizumab	2 (33.3%)	11 (73.3%)	10 (90.0%)	24 (72.7%)
Surgically Placed Shunt				
• Palivizumab only	1 (16.7%)	0 (0.0%)	0 (0.0%)	2 (6.1%)
• Non-live virus immunisations, palivizumab	3 (50.0%)	4 (26.6%)	1 (10.0%)	7 (21.2%)
• Non-live virus immunisations, rotavirus, palivizumab	2 (33.3%)	11 (73.3%)	10 (90.0%)	24 (72.7%)
Interventional Palliative Procedure				
• Palivizumab only	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
• Non-live virus immunisations, palivizumab	3 (50.0%)	3 (20.0%)	1 (10.0%)	7 (21.2%)
• Non-live virus immunisations, rotavirus, palivizumab	3 (50.0%)	12 (80.0%)	10 (90.0%)	26 (78.8%)
Main PA Banding				
• Palivizumab only	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
• Non-live virus immunisations, palivizumab	3 (50.0%)	1 (6.7%)	1 (10.0%)	5 (15.2%)
• Non-live virus immunisations, rotavirus, palivizumab	3 (50.0%)	14 (93.3%)	10 (90.0%)	28 (84.8%)
Cardiopulmonary Bypass[2]				
Re-dose routine immunisations after bypass	–	–	–	13/38 (34.2%)
Immunisations re-dosed[3]	–	–	–	
• All non-live virus immunisations	–	–	–	3 (33.3%)
• Non-live virus, Rotavirus, MMR, Varicella, Influenza	–	–	–	1 (11.1%)
• Non-live virus, MMR, Varicella	–	–	–	4 (44.4%)
• Rotavirus, MMR, Varicella	–	–	–	1 (11.1%)
Timing for re-dose post-bypass in weeks	–	–	–	4 (IQR 3.0-6.0), (range 2.0-12.0)
Immunisations held pre-bypass in weeks (n = 34)	–	–	–	2 (IQR 2.0-4.0), (range 2.0-12.0)
Immunisations delayed post-bypass in weeks (n = 31)	–	–	–	4 (IQR 2.0-4.0), (range 2.0-6.0)
MMR/Varicella Delay[2]				
Delay MMR/Varicella?	–	–	–	Yes: 11/32 (34%) No: 21/32 (66%)
If yes, delay duration (months)	–	–	–	7 (IQR 6.0-8.0), (range 1.0-12.0)

Centre size was determined by annual paediatric cardiac surgical case volume, with data presented as n (%). There were 32 responses for each procedure except for Surgical Stage 1 palliation where there were 33 responses. Additionally, 33 centres reported interstage immunisation recommendations specific to each procedure, with data represented as n (%). There were 32 responses to the questions about MMR and Varicella immunisations. Some responses were incomplete, accounting for discrepancies between centre size reporting by procedure and reporting by procedure alone.

[1]Centre size $n = 33$ for Surgical Stage 1 Palliation and $n = 32$ for the remaining categories.

[2]Data in these sections are not stratified by centre size.

[3]Of the 13 centres that responded they re-dose immunisations; only 9 identified which ones and timing for dosing.

34 centres reporting pre-bypass immunisation timing, 32 (94%) held immunisations before bypass (median delay 2 weeks, interquartile range 2–4 weeks, range 2–12 weeks), and 2 (6%) did not delay. Among the 31 centres reporting post-bypass practices, 30 (97%) reported delayed immunisations after bypass (median delay 4 weeks, interquartile range 2–4 weeks, range 2–6 weeks). Post-cardiopulmonary bypass, 34% (13/38) of centres re-dose immunisations, and 9 centres provided immunisation-specific details (Table 2).

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For the centres responding about respiratory syncytial virus prophylaxis with palivizumab, it was recommended by 100% of centres (34/34). After cardiopulmonary bypass, 52% (17/33) of responding centres re-dose palivizumab and 82% (27/33) recommend palivizumab for a second season. Of the 32 centres that responded about MMR and Varicella immunisations, 11 (34%) reported they delay MMR and Varicella immunisations for a median of 7 months (interquartile range6–8 months, range 1–12 months). An additional 2 centres reported delaying all routine immunisations (except palivizumab) until after stage 2 surgery.

Six centres shared additional considerations in a free text response. Special consideration is given to patients at increased risk for immune compromise, such as patients with heterotaxy or 22q11.2 deletion syndromes. Those interventions included having immunology or infectious disease evaluations prior to giving live viruses or giving an extra meningitis vaccine. Two centres recommended scheduled, prophylactic acetaminophen for twenty-four hours post-vaccines. One centre reported limiting the number of vaccines given at one time.

Discussion

We found considerable variation in centre-level immunisation practices for infants with single ventricle CHD. Only 11% of centres have a written protocol for immunisations. Most centres held immunisations before and after cardiopulmonary bypass for a range of 2 to 12 weeks with varying practices regarding specific vaccinations. Infants with single-ventricle CHD undergo multiple surgical interventions, stacking periods of delay and prolonging vaccine preventable vulnerability. There are limited data to guide deferring and re-dosing immunisations for these high-risk infants leading to variations in practice evidenced by our survey responses. Further immunisation serologic titre studies are needed to guide deferral and re-dosing durations. Specific attention should be given to infants with single ventricle congenital heart disease, given their exposure to cardiopulmonary bypass and high morbidity and mortality. With increasing global access to surgical care, children with single ventricle physiology are especially vulnerable to severe outcomes from immunisation-preventable diseases, underscoring the urgent need for clear, timely immunisation protocols worldwide.

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