Vancomycin Dosing and Monitoring in the Treatment of Cystic Fibrosis: Results of a National Practice Survey

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OBJECTIVES Vancomycin is commonly used in patients with cystic fibrosis (CF) to treat acute pulmonary exacerbations, but few guidelines exist to help dose and monitor patients. The objective of this study was to assess vancomycin use and monitoring strategies at Cystic Fibrosis Foundation (CFF)–accredited centers in hopes of developing and implementing vancomycin dosing and monitoring standards.

METHODS An anonymous national cross-sectional survey of pharmacists affiliated with CFF-accredited pediatric and/or adult centers was performed by using SurveyMonkey.com. The survey consisted of 3 sections: (1) CF Center Demographic Information (10 questions); 2) vancomycin use in pediatric CF patients (31 questions); and 3) vancomycin use in adult CF patients (29 questions); it was administered from March 9, 2015, to April 13, 2015.

RESULTS The survey was completed by 31/69 (45%) pharmacists and 28 (90.3%) reported using vancomycin in the pediatric population. The most common initial starting dose for pediatric patients was 15 mg/kg/dose (57.1%) and every 6 hours was the most common dosing frequency (67.9%). The most common monitoring strategy was collection of a trough concentration (92.9%) with 57.7% of pharmacist targeting a range of 15 to 20 mg/L. The most common initial starting vancomycin dose in adults with CF was 15 mg/kg/dose (61.5%), and initial frequency of every 8 hours (73.1%). The most common monitoring strategy was a trough concentration (96.2%) with 83.3% of pharmacists reporting a goal trough range of 15 to 20 mg/L.

CONCLUSIONS The most common vancomycin dosing reported was 15 to 20 mg/kg/dose every 6 hours (pediatric) and 15 to 20 mg/kg/dose every 8 to 12 hours (adults). Serum concentrations measured to meet monitoring parameters of trough concentrations of 15 to 20 mg/L, or area under the curve to minimum inhibitory concentration ratio > 400, were the same in both pediatric and adult patients.

ABBREVIATIONS AUC, area under the curve; BMP, basic metabolic panel; BUN, blood urea nitrogen; CF, cystic fibrosis; CFF, Cystic Fibrosis Foundation; IV, intravenous; MIC, minimum inhibitory concentration; MRSA, methicillin-resistant *Staphylococcus aureus*; NACFC, North American Cystic Fibrosis Conference; SCr, serum creatinine

KEYWORDS antibiotics; cystic fibrosis; pediatrics; pharmacokinetics; vancomycin

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Introduction

Cystic fibrosis (CF) is an autosomal recessive disorder caused by a defective chloride transport channel in multiple organ systems, including the lungs and gastrointestinal tract.^{1–3} Detrimental effects of thick, dehydrated secretions; bacterial infections; and inflammation result in bronchiectasis and progressive obstructive airway disease.^{1–3} Acute pulmonary exacerbations are managed with either oral, aerosolized antibiotics (mild exacerbations) or with intravenous (IV) antibiotics (moderate to severe exacerbations) that can be administered in the hospital and/or at home.^{1–3} Vancomycin is a commonly used antibiotic in CF patients to treat acute pulmonary exacerbations due to chronic methicillin-resistant *Staphylococcus aureus* (MRSA) infection, but few guidelines exist to aid in dosing and

monitoring vancomycin in these patients.

In 2009, the Cystic Fibrosis Foundation (CFF) released guidelines for the treatment of acute pulmonary exacerbations.⁴ These guidelines provided recommendations for treatment of exacerbations associated with *Pseudomonas aeruginosa*; however, they did not address treatment of exacerbations in patients with chronic MRSA infection.⁴ In the most recent CFF Patient Registry Annual Data Report for 2014, the reported infection rates among CF patients for MRSA was 25.9%.⁵ According to a recent survey of CFF-accredited care center directors and clinical coordinators on exacerbation treatment in patients with chronic MRSA infection, IV vancomycin was the second most commonly used antibiotic in hospitalized pediatric and adult patients at 31% and 30%, respectively.⁶ This survey also reported

a wide range in vancomycin dosing strategies with dosing reported as 20 to 200 mg/kg/day IV every 6 to 12 hours in pediatric patients and 500 to 2000 mg IV every 6 to 12 hours in adult patients.⁶ Despite the variability in dosing, most respondents noted a goal of a trough serum concentration between 15 to 20 mg/L.⁶

Although there are limited guidelines and data specific to the treatment of acute pulmonary exacerbations in CF patients with chronic MRSA, 2 recently published review articles both recommended vancomycin or linezolid as first-line treatment options.^{7,8} The limited data and variable dosing reported in a recent survey suggest further research is needed to identify optimal vancomycin dosing and monitoring strategies specifically in CF patients.

One approach to address these concerns is through the involvement of pharmacists in CF care. According to a European Consensus statement and the United Kingdom CF Trust Standard, pharmacists are considered primary members of the multidisciplinary CF care team with specific duties.^{9,10} One of these duties is to individualize drug and dosage requirements (e.g., optimization of medications through maximizing therapeutic benefit and minimizing toxicity; therapeutic drug monitoring of aminoglycosides and vancomycin, based on individual patient pharmacokinetic parameters).^{9,10}

Pharmacists play a key role in recommending and monitoring antibiotics for the treatment of acute pulmonary exacerbations, which may aid in the optimization of dosing strategies. A survey of CF center directors in the United States reported 61/105 (58%) of these centers having a dedicated CF pharmacist.¹¹

This is the first survey designed to obtain information from pharmacists who practice at CFF-accredited centers. The aim of the survey is to identify the frequency of vancomycin use for MRSA-associated pulmonary exacerbations, and to determine the dosing regimens and monitoring strategies being used. Information obtained from this survey will be used to promote future study that will allow implementation of standardized vancomycin dosing and monitoring strategies in patients with CF.

Materials and Methods

This study was approved by the Indiana University Institutional Review Board. An anonymous survey was distributed to pharmacists affiliated with CFF pediatric and/or adult accredited centers via email on March 9, 2015, using SurveyMonkey.com. Pharmacists were identified by those enrolled in the CF Foundation Pharmacist listserv and those attendees at the previous 2 North American Cystic Fibrosis Conferences who registered as a pharmacist. A cover letter that explained the survey purpose and confidentiality statement was included. The survey consisted of 3 sections (survey questions available from RSP): CF Center Demographic Information (10 questions), vancomycin use in pediatric CF patients, (31 questions), and vancomycin use in

Table 1. Percentage Use of Vancomycin in Pediatric Patients by Age Group

Patient Age	n (%) [*]
Neonate (<1 mo)	12 (42.9)
Infant (1–12 mo)	21 (75)
Young children (1–5 yr)	26 (92.9)
Older children (6–12 yr)	27 (96.4)
Adolescent (13–18 yr)	28 (100)

^{*} Respondents who report using vancomycin (n = 28).

adult CF patients (29 questions). Skip logic was used to direct pharmacists to appropriate sections, based on previous answers. Respondents were required to answer demographic questions (i.e., location, center size, number of pediatric and adult patients). Questions aimed to capture starting doses/frequencies, monitoring parameters/goals, and monitoring frequency. Respondents were given the opportunity to respond in free text and check all that apply when appropriate. Reminder emails were sent on March 23, 2015, and April 6, 2015. The survey was closed on April 13, 2015.

Results

A total of 69 pharmacists at 69 CFF-accredited centers were contacted and 31 pharmacists responded for a response rate of 45%. The pharmacists represented CF centers across the United States, with the largest response from centers located in the Midwest (42%), West (25.8%), and South (25.8%). Only 9.7% of responses came from pharmacists at centers located in the Northeast. All 31 pharmacist respondents reported using IV vancomycin in their CF population.

Pediatric Use. Twenty-eight of 31 pharmacists (90.3%) reported routinely using vancomycin in pediatric CF patients. Of all survey responders, most reported using vancomycin in all patients older than 1 month (Table 1). Survey results for vancomycin dosing in pediatric CF patients are summarized in Table 2.

Twelve pharmacists reported vancomycin use in CF patients younger than 1 month (neonates). Seventy percent of these reported using an initial dose of 15 mg/kg, while others (20%) reported dosing based on postmenstrual age and degree of prematurity, or a dose of 20 mg/kg (10%). The initial dosing interval most commonly reported was “other” (40%) and depended on the patient’s gestational and postnatal age. Others reported dosing vancomycin every 12 hours (30%), every 6 hours (20%), and every 8 hours (10%) in neonates with CF.

Of the 28 pharmacists using vancomycin for pediatric patients, the most common initial vancomycin dose used was 15 mg/kg (57.1%), followed by 20 mg/kg (35.7%). One pharmacist (3.6%) reported using 15 to 20 mg/kg/dose or based dosing on a previous admission, and another (3.6%) reported an initial dose of 10 mg/kg. Most

Table 2. Pediatric Vancomycin Dosing and Monitoring Data

Question (No. of Respondents)	Most Common Response (%)	Second Most Common Response (%)
What initial dosing regimen do you most commonly use? (n = 28)	15 mg/kg/dose (57.1)	20 mg/kg/dose (35.7)
What vancomycin frequency do you most commonly use? (n = 28)	Every 6 hr (67.9)	Every 8 hr (28.6)
What is the duration of infusion for administering vancomycin dosing within your CF center? (n = 28)	60 min (85.7)	120 min (7.1)
What therapeutic drug monitoring concentrations does your CF center collect? (n = 28)	Trough serum concentration only (78.6)	2 random serum concentrations (14.3)
When do you check the first vancomycin concentration in pediatric CF patients? (n = 22)	Prior to the fourth dose (63.6)	Prior to the third dose (13.6) Prior to the fifth dose (13.6)
When do you check vancomycin random concentrations? (n = 4)	After the third dose (50)	After the fourth dose (50)
Pharmacokinetic parameters calculated to adjust dosing? (n = 28)	Trough serum concentration (92.9)	AUC (17.9)
What is your goal trough with vancomycin dosing? (n = 26)	15–20 mg/L (57.7)	Other (19.2) – variety of ranges all within 10–20 mg/L
If AUC is calculated: what is your goal AUC/MIC ratio? (n = 5)	>400 (100)	-----
How frequently are vancomycin concentrations drawn following attainment of a therapeutic dose? (n = 28)	Every 7 days (35.7)	Based on clinical judgement (35.7)
What follow-up levels do you collect for monitoring? (n = 28)	Trough only (92.9)	Peak and trough serum drug concentrations (3.6) Two random serum drug concentrations (3.6)
What MAXIMUM vancomycin dosing regimen do you MOST COMMONLY utilize in PEDIATRIC CF patients? (n = 27)	120 mg/kg/day (22.2)	100 mg/kg/day (14.8) 60 mg/kg/day (14.8)
What laboratory test(s) do you order to aid in the monitoring of possible adverse reactions that may occur with the use of intravenous vancomycin? (n = 28)	Basic metabolic panel (60.7)	BUN and/ or serum creatinine (57.1)
How often do you check a basic metabolic panel when the PEDIATRIC CF patient is on vancomycin PLUS an aminoglycoside? (n = 17)	Twice a week (35.3)	Three times a week (17.6) Weekly (17.6)
How often do you check a basic metabolic panel when the PEDIATRIC CF patient is on vancomycin WITHOUT an aminoglycoside? (n = 17)	Weekly (47.1)	Twice a week (41.2)

AUC, area under the curve; BUN, blood urea nitrogen; CF, cystic fibrosis; MIC, minimum inhibitory concentration

pharmacists reported using a dosing interval of every 6 hours (67.9%). The maximum dose of vancomycin reported ranged from 80 mg/kg/day to 200 mg/kg/day, with 22.2% reporting dosing as large as 120 mg/kg/day. The most common initial duration of infusion reported was 60 minutes (85.7%) followed by 120 minutes (7.1%).

All 28 pharmacist respondents reported monitoring vancomycin serum concentrations. Twenty-two of 28 respondents (78.6%) reported monitoring vancomycin trough concentrations (i.e., prior to the fourth dose), 4 respondents (14.3%) reported collecting 2 random vancomycin concentrations (i.e., after the third dose

and prior to the fourth dose), and 2 pharmacists (7.1%) reported monitoring both peaks and trough vancomycin serum concentrations. The trough concentration, area under the curve (AUC) to minimum inhibitory concentration (MIC) ratio (AUC:MIC), and extrapolated maximum concentration were the most commonly used parameters to determine goal serum vancomycin concentrations, reported by 92.9%, 17.9%, and 10.7%, respectively. The most common monitoring goal for serum trough concentrations reported was 15 to 20 mg/L (57.7%). When AUC:MIC was monitored, all respondents (n = 5) reported a goal AUC:MIC of >400.

Table 3. Adult Vancomycin Dosing and Monitoring Data

Question (No. of Respondents)	Most Common Response (%)	Second Most Common Response (%)
What initial dosing regimen do you most commonly use? (n = 26)	15 mg/kg/dose (61.5)	20 mg/kg/dose (38.5)
What vancomycin frequency do you most commonly use? (n = 26)	Every 8 hr (73.1)	Every 12 hr (19.2)
What is the duration of infusion for administering vancomycin dosing within your CF center? (n = 26)	60 min (69.2)	Other/dose dependent (23.1)
What therapeutic drug monitoring concentrations does your CF center collect? (n = 26)	Trough only (84.6)	Two random concentrations (11.5)
When do you check the first vancomycin concentration in adult CF patients? (n = 22)	Prior to fourth dose (72.7)	Prior to third dose (18.2)
When do you check vancomycin random concentrations? (n = 3)	After the fourth dose (66.7)	After the third dose (33.3)
Pharmacokinetic parameters calculated to adjust dosing? (n = 26)	Troughs (96.2)	AUC (23.1)
What is your goal trough with vancomycin dosing? (n = 26)	15–20 mg/L (83.3)	10–15 mg/L (8.3)
If AUC is calculated: what is your goal AUC/MIC ratio? (n = 5)	>400 (100)	—
How frequently are vancomycin concentrations drawn following attainment of a therapeutic dose? (n = 25)	Every 7 days (44)	Based on clinical judgment (32)
What follow-up concentrations do you collect for monitoring? (n = 25)	Trough ONLY (96)	Two random concentrations (4)
What maximum vancomycin dosing regimen (mg/day) do you most commonly use in adult CF patients? (n = 22)	4000 mg/day (22.7)	4500 mg/day (9.1) 60 mg/kg/day (9.1) 80 mg/kg/day (9.1)
What laboratory test(s) do you order to aid in the monitoring of possible adverse reactions that may occur with the use of intravenous vancomycin? (n = 24)	Basic metabolic panel (62.5)	BUN and/or serum creatinine (62.5)
How often do you check a basic metabolic panel when the adult CF patient is on vancomycin <i>plus</i> an aminoglycoside? (n = 15)	Twice a week (33.3)	Every other day (20)
How often do you check a basic metabolic panel when the adult CF patient is on vancomycin <i>without</i> an aminoglycoside? (n = 15)	Twice a week (40)	Weekly (33.3)

AUC, area under the curve; BUN, blood urea nitrogen; CF, cystic fibrosis; MIC, minimum inhibitory concentration

No pharmacists reported using a nomogram to determine the appropriate vancomycin dose for pediatric CF patients. Follow-up monitoring of vancomycin concentrations varied, but most respondents commonly reported weekly monitoring (35.7%), or was based on clinical judgment (35.7%).

When queried about laboratory monitoring to screen for possible vancomycin-associated adverse effects, 100% of respondents reported using either a basic metabolic panel (BMP) consisting of a serum sodium, potassium, chloride, blood urea nitrogen (BUN), creatinine (SCr), glucose, and calcium or a BUN and SCr

to monitor renal function. In patients on vancomycin plus an aminoglycoside, 35.3% reported checking these laboratory parameters twice a week, followed by three times a week (17.6%) and weekly (17.6%). When vancomycin was given to pediatric patients without an aminoglycoside, a BMP was checked weekly by 47.1% and twice weekly by 41.2%.

Adult Use. Of the 31 pharmacists who responded, 26 answered the survey questions related to vancomycin use in adults with CF. These results are summarized in Table 3. Sixteen respondents (61.5%) reported using an initial dose of 15 mg/kg, while 10 pharmacists (38.5%)

reported an initial dose of 20 mg/kg. Every 8-hour dosing was the most commonly reported interval used by pharmacists (73.1%), followed by every 12 hours (19.2%), and every 6 hours (7.7%). The initial duration of infusion of 60 minutes was reported by 18 pharmacists (69.2%). There was variability in the maximum dose of vancomycin given with 4000 mg/day reported by 5 respondents (22.7%). Other respondents noted a range of 2000 to 6000 mg/day, 60 to 120 mg/kg/day, or 20 mg/kg/dose. One respondent did not use a specific maximum dose but dosed on the basis of clinical judgment.

All respondents reported using vancomycin serum concentrations to monitor therapy. Of the 26 responses, the most common vancomycin concentrations collected were trough concentration only (i.e., prior to the fourth dose) (84.6%) and 2 random concentrations (i.e., after the third dose and prior to the fourth dose) (11.5%). Serum trough concentrations (range, 15–20 mg/L) were the most commonly reported pharmacokinetic parameter (96.2%) used to adjust dosage, followed by AUC (23.1%). Similar to pediatrics, when AUC was monitored, all respondents ($n = 5$) reported an AUC:MIC goal of >400 .

When respondents were asked about laboratory monitoring to screen for possible adverse effects with vancomycin, 100% of respondents reported using either a BMP or a BUN and SCr to monitor renal function. In patients on vancomycin plus an aminoglycoside, 33.3% reported checking these tests twice a week, followed by 20% reporting assessment every other day. When vancomycin was given without an aminoglycoside, a BMP was checked twice a week by 40% and weekly by 33.3%.

Discussion

To our knowledge, this is the first study to survey pharmacists about vancomycin use in CF patients experiencing a pulmonary exacerbation. In results of a previous study, about 30% of respondents noted the use of vancomycin in pediatric and adult CF patients.⁶ To date, no studies have determined the safety and efficacy of vancomycin in patients with CF. Two pharmacokinetic analyses examined vancomycin pharmacokinetics in those with CF.^{12,13} The first study performed in adult patients used a dosing strategy of 15 mg/kg every 8 to 12 hours.¹² This study showed no difference in pharmacokinetic parameters between adult CF patients and controls, suggesting that standard vancomycin dosing strategies would be sufficient.¹² The second study was performed in pediatric patients with CF and used a dosing strategy of 15 to 20 mg/kg every 6 to 12 hours.¹³ The results of this study noted that vancomycin clearance increased with body weight, thus indicating that vancomycin dosing is affected over time as a patient ages.¹³

Our survey results differ from the previous survey with 90% and 84% of respondents reporting use of

vancomycin in pediatric and adult patients with CF, respectively.⁶ The most common initial vancomycin dose in both pediatric and adult respondents was 15 mg/kg every 6 to 8 hours, with a maximum dose of 120 mg/kg/day or 4000 mg/day. This dosing strategy is consistent with guideline recommendations from the United Kingdom and published literature.^{6,12–14}

Existing literature does not provide recommendations for best timing of serum concentrations, frequency of serum concentrations, or other monitoring recommendations. With the lack of standardized monitoring recommendations, respondents reported several different vancomycin monitoring strategies. The most common strategy was to check a vancomycin serum trough concentration prior to the fourth dose (64% pediatric; 73% adult) with a goal of 15 to 20 mg/L (58% pediatric, 83% adult). This vancomycin trough target is consistent with the previous survey that showed that 84% of respondents used a goal trough of 15 to 20 mg/L to adjust vancomycin.⁶ Some respondents (about 20%) reported checking 2 random vancomycin concentrations (i.e., after the third dose and prior to the fourth dose), which aided in the calculation of a 24-hour AUC (AUC_{24}) with a goal AUC:MIC ratio of >400 . Follow-up monitoring was similar between pediatric and adult respondents with both measuring only trough concentrations every 7 days. Laboratory monitoring of BMP, and BUN and SCr were routinely performed by most respondents.

A limitation of the study is the low response rate (45%) of pharmacists affiliated with CFF-accredited care centers; however, the response rate is comparable to that of previous antibiotic utilization surveys (42%–58%).^{6,15–18} Since over half of the pharmacists did not respond, the results may not be generalized.

Conclusion

Pediatric Recommendations. The most common vancomycin dosing reported in the survey was 15 to 20 mg/kg every 6 hours infused over 1 to 2 hours. Serum concentrations were measured to assess the need for dosage adjustment with a target of a trough concentration of 15 to 20 mg/L, or an AUC:MIC > 400 . Maximum doses ranged from 80 to 200 mg/kg/day.

Adult Recommendations. The most common adult vancomycin dosing reported in those with CF was 15 to 20 mg/kg every 8 to 12 hours infused over 1 hour. Serum concentrations were monitored to assess for a trough concentration of 15 to 20 mg/L, or AUC:MIC > 400 . The maximum doses ranged from 2000 to 6000 mg/day.

This survey describes the previously unknown prevalence of vancomycin utilization, dosing, and monitoring strategies as described by pharmacists in CFF-accredited centers in the United States. With the information from this survey, the establishment of future consensus recommendations by pharmacists for optimal and consistent vancomycin dosing and monitoring strategies needs to be considered.

ARTICLE INFORMATION

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