

Evaluation of Methicillin-Resistant *Staphylococcus aureus* Eradication in People With Cystic Fibrosis

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OBJECTIVE People with cystic fibrosis (pwCF) have impaired bacterial mucociliary clearance, which can result in colonization with pathogens like *Pseudomonas aeruginosa* and methicillin-resistant *Staphylococcus aureus* (MRSA) in the lower airway. Although guidelines for the eradication of *P. aeruginosa* in CF are well-established, MRSA eradication guidelines are lacking. This study aimed to determine the rates of MRSA eradication in pwCF based on a prescribed antibiotic regimen.

METHODS This retrospective chart review included pwCF with a first lifetime positive MRSA respiratory culture or first positive MRSA respiratory culture after at least 1 year of MRSA negativity (minimum of 4 negative respiratory cultures) obtained at Nationwide Children's Hospital between August 1, 2012, and February 28, 2022. Secondary outcomes assessed the impact of adding topical decontamination on MRSA eradication and the time to a subsequent MRSA-positive respiratory culture after completing the eradication regimen.

RESULTS Sixty-two patients were included, and 16% achieved MRSA eradication. Intravenous vancomycin transitioned to oral trimethoprim-sulfamethoxazole achieved the highest eradication rate of 75% ($p = 0.008$). Antibiotics consisting of dual therapy with rifampin and topical decontamination had a higher rate of eradication (25%) compared with antibiotics alone, antibiotics with topical decontamination, or no antibiotics. Four patients had no subsequent MRSA-positive cultures, including 2 patients who did not receive antibiotics.

CONCLUSIONS The transition from intravenous vancomycin to oral trimethoprim-sulfamethoxazole had the highest rate of MRSA eradication. Overall rates of MRSA eradication at 12 months in patients CF using antibiotics with or without topical decontamination are low.

ABBREVIATIONS CF, cystic fibrosis; CFTR, cystic fibrosis transmembrane conductance regulator; ETI, elexacaftor/tezacaftor/ivacaftor; MRSA, methicillin-resistant *Staphylococcus aureus*; NCH, Nationwide Children's Hospital; pwCF people with cystic fibrosis; Pa, *Pseudomonas aeruginosa*; TMP-SMX, trimethoprim-sulfamethoxazole

KEYWORDS antibiotics; cystic fibrosis; eradication; methicillin-resistant *Staphylococcus aureus*

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Introduction

Impaired bacterial mucociliary clearance caused by the production of abnormally thick, sticky mucus in the respiratory tract is a key clinical feature of cystic fibrosis (CF). In healthy individuals, the lower respiratory tract supports minimal bacterial replication. Owing to the changes in the airway environment caused by the defect in the CF transmembrane conductance regulator (CFTR) protein, people with CF (pwCF) can host microorganisms in the lower airway, including pathogens capable of colonization and long-term survival, such as *Pseudomonas aeruginosa* (Pa) and methicillin-resistant *Staphylococcus aureus* (MRSA).^{1,2}

Based on the 2022 Cystic Fibrosis Foundation patient registry, 26% and 15.6% of pwCF had positive respiratory cultures for Pa and MRSA, respectively.² Chronic infection with Pa and MRSA in CF is associated with poor outcomes, including increased morbidity and mortality.^{3,4} Eradication of colonized bacteria may prevent chronic infection in pwCF. There are well-established guidelines for the eradication of Pa, yet MRSA eradication guidance is lacking.⁵ United States guidelines do not address the eradication of MRSA.⁶ The United Kingdom Cystic Fibrosis Trust recommends attempting to eradicate MRSA, although it states that the optimal eradication method remains unclear.⁷

The STAR-too randomized trial is considered the first randomized trial in the United States studying a MRSA eradication regimen in pwCF.⁸ Forty-five pwCF

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between the ages of 4 and 45 years with a positive MRSA respiratory culture were randomized to receive either observation or undergo an eradication protocol. The eradication protocol included the following: oral trimethoprim-sulfamethoxazole (TMP-SMX) or minocycline plus rifampin for 2 weeks; nasal mupirocin and whole-body cleansing with chlorhexidine wipes for 5 days; twice daily gargling with 0.12% chlorhexidine gluconate for 14 days, and enhanced household cleaning. The primary endpoint was MRSA eradication by day 28.⁸ The study found that 82% of patients in the treatment group had MRSA-negative respiratory cultures compared with 26% in the observation group on day 28, with a difference of 52% after adjusting for interim reviews ($p < 0.001$). On day 84, 54% of the treatment group were MRSA negative compared with 10% in the observation group.⁸

The duration of the endpoints in the STAR-too trial may not be adequate for assessing the long-term clinical response of MRSA eradication attempts. In comparison, the endpoints of trials evaluating *Pa* eradication in pwCF are considerably longer than the STAR-too trial. The EPIC and ELITE trials followed patients over 18 and 27 months after initiation of treatment, respectively.^{9,10} The ability of a pwCF to sustain long-term eradication may lead to improved outcomes. A cohort study of children in the EPIC trial found that patients who were *Pa*-free in all quarterly cultures in the preceding 12 months, defined as sustained eradicators, had improved microbiologic outcomes, increased time to *Pa* chronic infection, and increased time to developing mucoid *Pa*.¹¹

The CF Center at Nationwide Children's Hospital (NCH) is a Cystic Fibrosis Foundation–accredited cystic fibrosis center serving more than 500 pediatric and adult pwCF. At our center, the incidence of methicillin resistance within CF respiratory cultures growing *S. aureus* has decreased from 45% (555/1228) in 2012 to 25% (214/862) in 2022. NCH does not have a standardized MRSA eradication protocol in CF, although many providers will follow part or all of the STAR-too protocol. This study aimed to determine the rates of MRSA eradication within 12 months after treatment based on the prescribed antibiotic regimen.

Materials and Methods

Study Design and Participants. This retrospective study included pwCF with an index MRSA isolation from a respiratory culture obtained at NCH between August 1, 2012, and February 28, 2022. An index MRSA culture was defined as the first lifetime positive MRSA respiratory culture or first positive MRSA respiratory culture after at least 1 year of MRSA negativity. Patients included after at least 1 year of MRSA negativity were required to have a minimum of 4 negative respiratory cultures during that period. Respiratory cultures included bronchoalveolar lavage and CF respiratory cultures (expectorated or oropharyngeal). Patients were excluded if the index culture was a small

colony variant or TMP-SMX resistant MRSA, if they received systemic antibiotics with MRSA coverage within 30 days before index culture, if they received antibiotics their MRSA isolate was resistant to, if they had less than 1 year of documented follow-up, or if the index MRSA culture was identified from outside of the NCH electronic health record. Antibiotics considered as having MRSA susceptibility included TMP-SMX, minocycline, doxycycline, linezolid, and vancomycin. As this study was intended to demonstrate the ability to achieve routine MRSA eradication, TMP-SMX resistance was chosen as an exclusion criterion because it indicates a MRSA strain would be a small colony variant and, therefore, difficult to eradicate.

Measures. This study aimed to determine the rates of MRSA eradication within 12 months after treatment based on the prescribed antibiotic regimen. Antibiotics with MRSA susceptibility received within 1 year of the index culture, whether prescribed for intentional MRSA eradication or received incidentally for CF exacerbation, were recorded. Antibiotics with MRSA susceptibility were defined as previously listed in the exclusion criteria. If no antibiotics with MRSA sensitivity were prescribed within 1 year of the index culture, patients who otherwise met inclusion criteria were included to assess for rates of self-eradication. Eradication was defined as at least 4 consecutive MRSA-negative respiratory cultures within a minimum of 12 months. Secondary objectives included the eradication rates with the addition of topical decontamination (nasal mupirocin, chlorhexidine mouthwash, or chlorhexidine body wipes or wash) and time to subsequent positive MRSA respiratory culture after completion of the initial eradication regimen. An exploratory analysis examined the likelihood of eradication associated with patient age, type of *CFTR* mutation, *CFTR* modulator therapy, and timing of treatment in relation to the index culture.

Data were obtained through retrospective chart review within the NCH electronic health record. Demographics collected at the date antibiotics were prescribed included age and *CFTR* modulator therapy. If a patient was not prescribed antibiotics, age and *CFTR* modulator therapy were collected on the date of index MRSA culture. The authors also collected data on sex assigned at birth, *CFTR* gene profile, duration of antibiotics, addition of rifampin to the eradication regimen, addition of topical decontamination to the eradication regimen, results of respiratory cultures 12 months after antibiotics for MRSA eradication, and time to a subsequent MRSA-positive respiratory culture after antibiotics for MRSA eradication.

Statistical Analysis. Descriptive statistics are reported as mean $\pm$ SD, median (IQR), or total number and percentage. For the group comparisons, a 2-sample *t*-test or Wilcoxon sum rank test was used for the continuous variables, and χ^2 or Fisher's exact test were used for the proportions as appropriate. The

significance level was set at $\alpha \leq 0.05$. The data were analyzed using SAS, version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

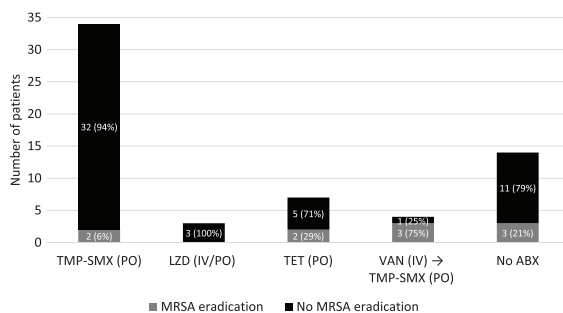
Demographics. There were 74 patients who met inclusion criteria with an index MRSA respiratory culture between August 1, 2012, and February 28, 2022. Twelve patients were excluded for having less than 1 year of follow-up ($n = 8$), receipt of antibiotics with MRSA coverage within 30 days before index culture ($n = 3$), or having an index culture that was a small colony variant or TMP-SMX-resistant strain ($n = 1$). Lung transplant patients were not specifically excluded; however, none were identified. Of patients, 47% were assigned male at birth. The median patient age was 9 years (IQR, 4–23) at the time of antibiotic receipt, with a range of 1 month to 65 years. *CFTR* gene profiles included F508del homozygous ($n = 31$, 50%), F508del heterozygous ($n = 22$, 35%), other ($n = 8$, 13%), and unknown ($n = 1$, 2%). Of patients, 74% ($n = 46$) were not prescribed a *CFTR* modulator at the time of the MRSA index culture positivity.

Antibiotic Regimen. Forty-eight patients (77%) received antibiotics with MRSA susceptibility, and 14 (22%) did not receive antibiotics. Antibiotic regimens prescribed included oral TMP-SMX ($n = 34$), oral and intravenous linezolid ($n = 3$), oral tetracycline (minocycline and doxycycline; $n = 7$), and intravenous vancomycin transitioned to oral TMP-SMX ($n = 4$). Figure 1 shows eradication rates stratified by the prescribed antibiotic regimen. The overall MRSA eradication rate at 1 year was 16%. The antibiotic regimen with the highest rate of eradication was intravenous vancomycin, which was followed by oral TMP-SMX, yielding a

75% eradication rate ($p = 0.008$). These patients received a range of 4–12 days of vancomycin therapy, with a median duration of 8.5 days before transitioning to oral TMP-SMX. Of 48 patients who received antibiotics, 25 (52%) were prescribed antibiotics for the intentional eradication of MRSA, and 23 (48%) received antibiotics with MRSA susceptibility incidentally for a CF exacerbation. Antibiotics used for intentional MRSA eradication were as follows: TMP-SMX ($n = 21$), oral linezolid ($n = 1$), oral minocycline ($n = 1$), and intravenous vancomycin transitioned to oral TMP-SMX ($n = 2$). The eradication of those who intentionally received antibiotics for MRSA eradication was 12% ($n = 3$) compared with 17% ($n = 4$) in those who received antibiotics for a CF exacerbation. The median duration of antibiotics was 14 days (IQR, 14–14) and did not differ between those who intentionally received antibiotics for eradication compared with those who received antibiotics incidentally for a CF exacerbation. All but 8 patients received 14 days of antibiotics.

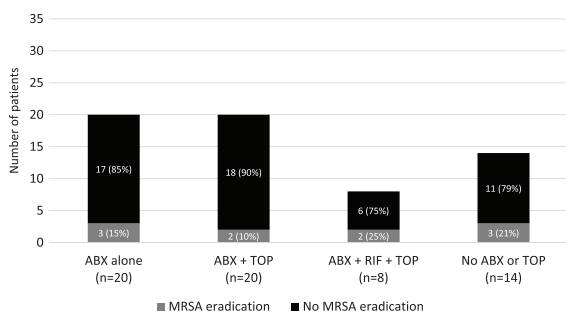
Rifampin and Topical Decontamination. Figure 2 outlines the eradication rates based on the addition of rifampin and topical decontamination. Patients who underwent intentional MRSA eradication ($n = 25$) were prescribed individual topical products at varying rates as follows: 100% were prescribed nasal mupirocin ($n = 25$), 84% were prescribed chlorhexidine body wash or wipes ($n = 21$), and 40% were prescribed chlorhexidine mouthwash ($n = 10$). Eight patients (32%) were prescribed rifampin and topical decontamination as part of their antibiotic regimen consistent with the STAR-too protocol. These patients received TMP-SMX ($n = 7$) and minocycline ($n = 1$).

Figure 1. Number of patients who did or did not achieve MRSA eradication stratified by antibiotic regimen. MRSA eradication was defined as MRSA negativity at 12 months after initiation of antibiotic treatment with a minimum of 4 consecutive MRSA-negative respiratory cultures.



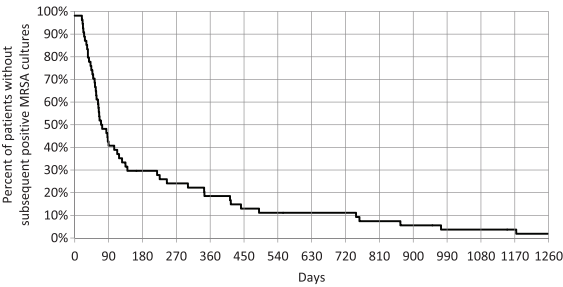
ABX, antibiotics; IV, intravenous; LZD, linezolid; TET, tetracycline; TMP-SMX; trimethoprim-sulfamethoxazole; PO, oral.

Figure 2. Number of patients who did or did not achieve MRSA eradication stratified by antibiotics with or without the addition of rifampin or topical decontamination. Topical decontamination is reported as the addition of at least 1 of the following: nasal mupirocin, chlorhexidine mouthwash, or chlorhexidine body wash/wipes. MRSA eradication was defined as MRSA negativity at 12 months after initiation of antibiotic treatment with a minimum of 4 consecutive MRSA-negative respiratory cultures.



ABX, antibiotics; RIF, rifampin; TOP, topical decontamination

Figure 3. Kaplan-Meier curve of the percentage of patients without subsequent positive MRSA cultures following the index culture.



Time to Subsequent MRSA-Positive Respiratory Culture. Patients had a median follow-up of 4.4 years (IQR, 3.1–7.5) from their index MRSA culture. Figure 3 depicts MRSA culture negativity survival after index MRSA culture. Four patients had no follow-up cultures that were positive for MRSA, including 1 patient who received vancomycin and transitioned to oral TMP-SMX, 1 patient who received oral minocycline, and 2 patients who did not receive any antibiotics.

Exploratory Analysis. The exploratory analysis in the Table assessed MRSA eradication rates stratified by age, *CFTR* gene profile, and *CFTR* modulator therapy. Overall, MRSA eradication rates were found to be higher in patients aged ≥ 18 years of age, those with *F508del* heterozygosity, and those on either ivacaftor or elexacaftor/tezacaftor/ivacaftor (ETI), although the differences were not statistically significant.

Discussion

Despite increased mortality and morbidity from MRSA infection in pwCF, the optimal regimen for MRSA

eradication remains unclear. Our study retrospectively evaluated the rates of MRSA eradication at 12 months, based on the antibiotics used in clinical practice. The primary endpoint of 12 months was chosen to assess sustained MRSA eradication, which may be more relevant than initial early eradication (ie, 28 days) to morbidity and mortality outcomes of chronic MRSA infection. The STAR-too protocol uses TMP-SMX or minocycline plus rifampin as the antibiotic regimen for MRSA eradication.⁸ Most patients included in our study received oral TMP-SMX (55%) and tetracycline derivatives (11%). Eradication rates with these antibiotics were 6% and 29%, respectively. The transition from intravenous vancomycin to oral TMP-SMX had the highest eradication rate of 75% ($n = 4$). During the study period, vancomycin therapeutic drug monitoring utilized within our institution targeted serum trough concentrations of 15–20 mcg/mL in pwCF. Area under the curve/minimum inhibitory concentration monitoring for vancomycin was not performed. All vancomycin therapy was initiated while inpatient. Other studies have found varying success in using nebulized vancomycin in combination with oral antibiotics and topical decontamination for MRSA eradication. However, evidence for intravenous vancomycin for MRSA eradication is lacking.^{12,13}

In our study, 8 patients followed regimens comparable to the STAR-too protocol. The 12-month eradication rate for these patients was 25%. In comparison, Belarski et al¹⁴ found that the percentage of negative cultures at 12 months in 10 CF patients who completed MRSA eradication using the STAR-too protocol was 70%. The feasibility of using all components of the STAR-too protocol has been impacted by the development of *CFTR* modulator therapy as a standard of care in pwCF. Rifampin is a strong inhibitor of CYP3A4, which induces the metabolism of *CFTR* modulators, including ETI.¹⁵ Concurrent use of rifampin with *CFTR* modulators

Table. Exploratory Analysis of Factors Impacting MRSA Eradication			
Demographics	Number of Patients (N = 62)		p value
	Achieved Eradication (n = 10)	Did Not Achieve Eradication (n = 52)	
Age			
<18 yr	5 (12%)	34 (87%)	0.19
≥18 yr	5 (21%)	18 (78%)	
CFTR gene profile			
F508del homozygous	3 (10%)	28 (90%)	0.358
F508del heterozygous	6 (27%)	16 (72%)	
Other	1 (13%)	7 (87%)	
Unknown	0 (0%)	1 (100%)	
CFTR modulator therapy			
None	5 (11%)	41 (89%)	0.076
Ivacaftor	3 (43%)	4 (57%)	
Lumacaftor/ivacaftor	0 (0%)	3 (100%)	
Tezacaftor/ivacaftor	0 (0%)	1 (100%)	
Elexacaftor/tezacaftor/ivacaftor	2 (40%)	3 (60%)	

is not recommended.¹⁵ Patients in our study more commonly received single antibiotic regimens (not including rifampin) with topical decontamination than antibiotics consisting of dual therapy with rifampin and topical decontamination, which had a lower eradication rate (10% vs 25%). The more frequent use of a single antibiotic regimen at our institution was likely due to our study period largely preceding the publication of the STAR-too trial in 2017. Before this, no MRSA eradication protocol was used at our CF center, and MRSA eradication attempts were not routinely attempted. Cunningham et al¹⁶ published a protocol for the STAR-ter trial, which compared MRSA negativity at 28 days between a treatment group given 2 courses of a single oral antibiotic regimen (without rifampin) plus nasal mupirocin and the control group from the STAR-too trial. At the time of publication, the results of this study were not yet available, and additional studies may help determine the optimal eradication regimen for pwCF on *CFTR* modulator therapy.

Of note, the results of our study call into question the effectiveness of antibiotics in eradicating MRSA. The overall rates of sustained MRSA eradication at our center at 12 months were quite low. Only 10 patients (16%) achieved eradication by any method according to our study's definition. Of these 10 patients, 3 received no antibiotics with MRSA susceptibility within 1 year of their index MRSA culture. Self-eradication was identified in the STAR-too study, as 5 of 19 patients (26%) in the observational group were MRSA negative at day 28.⁸ Patients in both our study and the STAR-too trial may have had a transient MRSA infection, which is thought to impact up to 30% of patients with MRSA positive culture.¹⁷ In addition, the use of ETI, a highly effective *CFTR* modulator, may impact a patient's ability to self-eradicate or could prevent MRSA colonization altogether. ETI has been found to have a positive impact on MRSA respiratory cultures in pwCF. A retrospective chart review revealed that patients initiated on ETI experienced a decrease in MRSA culture positivity from 31% to 24% (−6.5%, $p = 0.0963$) 12 months after starting ETI.¹⁸ Another prospective cohort study found that the rate of MRSA-positive cultures decreased from 43.8% at baseline to 27.5% (−37.2%, $p = 0.003$) 12 months after ETI initiation.¹⁹ Of 3 patients who self-eradicated within our study, 1 was not receiving a *CFTR* modulator at the time of the index MRSA culture, 1 was prescribed ivacaftor, and 1 was prescribed ETI. Our study was unable to fully describe the impact of *CFTR* modulators on MRSA eradication. Only 23% of index cultures occurred after the approval of ETI in our study. Before that, very few patients would have been eligible for highly effective ivacaftor therapy. Last, it is important to note that although it has been established that chronic MRSA infection leads to a decline in lung function in pwCF, there is a lack of data to show that achieving MRSA eradication improves long-term clinical outcomes. Our

study did not assess the clinical impact of achieving or sustaining MRSA eradication, and larger database studies are needed to determine the long-term effects of MRSA eradication in pwCF.

Limitations of this study include its retrospective chart review design and small sample size. The dose and frequency of antibiotic regimens were not assessed. Antibiotic regimens were recorded based on prescriptions within the electronic health record; however, it was not determined whether the prescriptions were filled or picked up by the patient. Evidence of therapeutic vancomycin trough levels was not assessed. It is unknown in our study if patients may have received antibiotics during this period that were not documented in the NCH electronic health record. Adherence to recommended environmental decontamination strategies could not be determined. Our study did not assess for clinical outcomes associated with MRSA eradication or adverse effects of MRSA eradication therapies.

Conclusions

The transition from intravenous vancomycin to oral TMP-SMX had the highest rate of MRSA eradication in our single-center, retrospective study. Future studies are needed to determine the impact of intravenous versus oral antibiotic regimens on MRSA eradication. Patients presenting with an index MRSA culture during an acute pulmonary exacerbation should be treated according to exacerbation guidelines and be considered as having completed a MRSA eradication attempt. Of note, the overall rates of MRSA eradication in pwCF using antibiotics with or without topical decontamination are low. The lack of long-term effectiveness studies supports the need to weigh the risks and benefits when considering antibiotics for eradication following the patient's first MRSA culture, especially in patients on ETI who may be able to achieve self-eradication. More data are needed to determine the impact of *CFTR* modulator therapies on their ability to prevent initial MRSA colonization, enhance MRSA self-eradication, and achieve sustained MRSA eradication with an optimal protocol.

Article Information

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study and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors attest to meeting the four criteria recommended by the ICMJE for authorship of this manuscript.

Ethical Approval and Informed Consent. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant international guidelines on human experimentation and have been approved by the appropriate committees at our institution. However, given the nature of this study, informed consent was not required by our institution.

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