Better Than You Think—Appropriate Use of Implantable Cardioverter-Defibrillators at a Single Academic Center: A Retrospective Review

Nikhil H. Shah (iD), MD[1], Steven J. Ross, MD[1], Steve A. Noutong Njapo, MD[2], Justin Merritt (iD), MD[1], Andrew Kolarich, MD[3], Michael Kaufmann (iD), MD[4], William M. Miles, MD[1], David E. Winchester (iD), MD[1], Thomas A. Burkart, MD[5] and Matthew McKillop, MD[6]

[1]*UF Division of Cardiovascular Medicine, 1600 SW Archer Rd, PO Box 100277, Gainesville, FL 32610, USA*
[2]*UVA Division of Cardiovascular Medicine, PO Box 800158 1215 Lee St. Charlottesville, VA 22908-0158, USA*
[3]*The Johns Hopkins Hospital Department of Radiology, 601 N Caroline St, Baltimore, MD 21287, USA*
[4]*The Heart Center, 930 Franklin Street SE, Huntsville, AL, 358015, USA*
[5]*Intermountain Medical Center, 1380 E Medical Center Dr, Ste 1500, St. George, UT 847906, USA*
[6]*Carolina Cardiology Consultants, Prisma Health, 1005 Grove Road, Greenville, SC 29605, USA*

Abstract

Background: Implantable cardioverter-defibrillators (ICDs) can be life-saving devices, although they are expensive and may cause complications. In 2013, several professional societies published joint appropriate use criteria (AUC) assessing indications for ICD implantation. Data evaluating the clinical application of AUC are limited. Previous registry-based studies estimated that 22.5% of primary prevention ICD implantations were "non-evidence-based" implantations. On the basis of AUC, we aimed to determine the prevalence of "rarely appropriate" ICD implantation at our institution for comparison with previous estimates.

Methods: We reviewed 286 patients who underwent ICD implantation between 2013 and 2016. Appropriateness of each ICD implantation was assessed by independent review and rated on the basis of AUC.

Results: Of 286 ICD implantations, two independent reviewers found that 89.5% and 89.2%, respectively, were appropriate, 5.6% and 7.3% may be appropriate, and 1.8% and 2.1% were rarely appropriate. No AUC indication was found for 3.5% and 3.4% of ICD implantations, respectively. Secondary prevention ICD implantations were more likely rarely appropriate (2.6% vs. 1.2% and 3.6% vs. 1.1%) or unrated (6.0% vs. 1.2% and 2.7% vs. 0.6%). The reviewers found 3.5% and 3.4% of ICD implantations, respectively, were non-evidence-based implantations. The difference in rates between reviewers was not statistically significant.

Conclusion: Compared with prior reports, our prevalence of rarely appropriate ICD implantation was very low. The high appropriate use rate could be explained by the fact that AUC are based on current clinical practice. The AUC could benefit from additional secondary prevention indications. Most importantly, clinical judgement and individualized care should determine which patients receive ICDs irrespective of guidelines or criteria.

Keywords: Appropriate use; appropriate use criteria; implantable cardioverter-defibrillator

Correspondence: Nikhil H. Shah, MD, Division of Cardiovascular Medicine, University of Florida, PO Box 100277, 1600 SW Archer Rd, Gainesville, FL 32610, USA, E-mail: nikhil.shah@medicine.ufl.edu

Background

Implantable cardioverter-defibrillators (ICDs) can be life-saving devices. They can be implanted in

patients who have experienced sudden cardiac death or those who may be at elevated risk of sudden cardiac death. Despite their life-saving potential, they are expensive and carry the risk of serious complications, such as pneumothorax, lead displacement, infection, and inappropriate device therapies [1].

In 2013, the American College of Cardiology, the Heart Rhythm Society, and the American Heart Association published joint appropriate use criteria (AUC) outlining clinical scenarios in which ICDs are indicated. The criteria were decided upon by an expert panel who rated clinical scenarios on a scale from 1 to 9 as rarely appropriate (1–3), may be appropriate (4–6), and appropriate (7–9). Clinical scenarios are assigned an appropriateness score (from 1 to 9), which was determined by a consensus of the AUC authors [2].

Prior investigators have discussed that certain clinical scenarios in the AUC are not currently covered by the Medicare national coverage determination. Consequently, submitting such ICDs for reimbursement may be construed as fraudulent despite their being clinically indicated and appropriate [3]. The inability to receive indicated ICD implantation due to coverage and funding discrepancies could be the difference between life and death.

Previous registry-based studies used various criteria to assess appropriateness of ICD implantation. One study found that 22.5% of primary prevention ICD implantations were non-evidence-based implantations if they met any of four criteria: New York Heart Association class IV symptoms, myocardial infarction within 40 days, revascularization within 3 months, or newly diagnosed heart failure at the time of implantation [4]. A later study found that 86% of all primary prevention ICD implantations met the inclusion criteria of major ICD trials [5]. Generally, although the criteria were published in 2013, clinical data evaluating the real-world application of AUC are sparse.

We aimed to determine the prevalence of AUC-deemed rarely appropriate ICD implantation at our facility and then compare these data with previously published estimates, such as those by Al-Khatib et al. [4] and Kaiser et al. [5]. We hypothesized that we would have a high rate of appropriate ICD implantations, with very few rarely appropriate ICD implantations. Furthermore, as reimbursement is often based on clinical guidelines, we aimed to assess the validity of the AUC should these be a determination of reimbursement in the future.

Methods

We performed an Institutional Review Board–approved retrospective medical record review of 286 patients (Figure 1) at our institution. Patients were identified through the McKesson Cardiology system (McKesson Corporation, Las Colinas, TX, USA), which is used in the electrophysiology
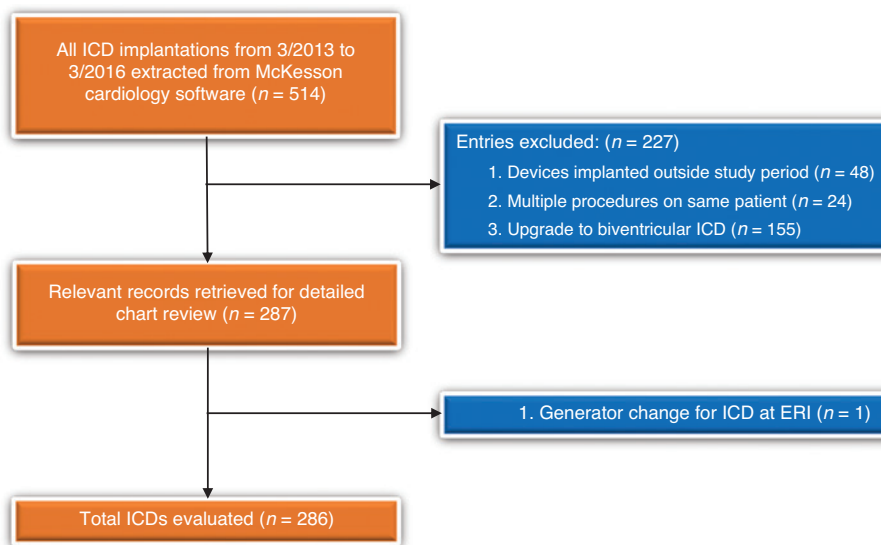
Figure 1: Search and Exclusion Criteria.
ERI, elective replacement indicator; ICD, implantable cardioverter-defibrillator.

laboratory. Patients aged at least 18 years with single-chamber or dual-chamber ICDs implanted at our institution in the 3 years following publication of the AUC (March 2013 to March 2016) were evaluated. Patients who were identified as having biventricular ICD upgrades in the McKesson Cardiology system and those who only underwent generator change were excluded. Data collection was supervised by a staff electrophysiologist, and data were entered by several resident physicians and a medical student into an institutional research electronic data capture (REDCap) database [6].

Two physicians independently reviewed and assessed the appropriateness of all 286 ICD implantations on the basis of the AUC and were blinded to the other physician's assessments. Deidentified data were exported into an Excel spreadsheet, and were then sorted by indication and appropriateness of each ICD implantation for tallying.

Statistical analysis was performed by a chi-square analysis to compare the appropriateness rates by each reviewer.

Results

Baseline demographics are reported in Table 1. The patient population included approximately 70% males with a mean age of 58 years. Seventy percent were white, 2.8% had a myocardial infarction within 40 days, 72% had heart failure at implantation, and the average ejection fraction was 31%. Most patients had New York Heart Association class I symptoms (26%) or class II symptoms (34%). The indications for which ICDs were implanted are listed in Table 2.

The reviewers (reviewer 1 and reviewer 2, respectively) determined that 89.5% ($n = 256$) and 89.2% ($n = 255$) of implantations were appropriate, 5.6% ($n = 16$) and 7.3% ($n = 21$) may be appropriate, and 1.8% ($n = 5$) and 2.1% ($n = 6$) were rarely appropriate. For the remaining 3.2% ($n = 9$) and 1.4% ($n = 4$), respectively, there was no ICD indication listed in the AUC (Figure 2, Table 3) (P = 0.44 by chi-square analysis for all comparisons).

Of the total 286 ICD implantations, the reviewers (reviewer 1 and reviewer 2, respectively) deemed 170 and 176 ICDs to be implanted for primary

Table 1 Baseline Characteristics of Patients.

Characteristic	Value
Mean age (years)	58
Male	201 (70.28%)
White	201 (70.28%)
Alcohol abuse	19 (6.64%)
Beta blocker	247 (86.35%)
ACE or ARB	219 (76.57%)
Nitrates	17 (5.94%)
Inotropes	14 (4.90%)
Hypertension	197 (68.88%)
Hyperlipidemia	151 (52.80%)
Diabetes mellitus	93 (32.52%)
CKD stage 3 or higher	65 (22.73%)
Coronary artery disease	168 (58.74%)
MI within past 40 days	8 (2.80%)
Heart failure at implantation	216 (72.52%)
Systolic heart failure	198 (69.23%)
Mean ejection fraction	31%
GDMT for at least 3 months	177 (61.89%)
NYHA class I disease	75 (26.22%)
NYHA class II disease	97 (33.92%)
NYHA class III disease	5 (1.75%)
NYHA class IV disease	23 (8.04%)

ACE, angiotensin-converting enzyme; ARB, angiotensin-receptor blocker; CKD, chronic kidney disease: GDMT, guideline-directed medical therapy; MI, myocardial infarction; NYHA, New York Heart Association.

prevention. They found that 89.4% ($n = 152$) and 88.6% ($n = 88.6\%$) of implantations were appropriate, 8.2% ($n = 14$) and 9.7% ($n = 17$) may be appropriate, 1.2% ($n = 2$) and 1.1% ($n = 2$) were rarely appropriate. For 1.2% ($n = 2$) and 0.6% ($n = 1$) of ICD implantations, the reviewers were unable to find any ICD indication in the AUC document (Figure 3, Table 4). Per the criteria of Al-Khatib et al. [4] for "non-evidence-based" ICD implantation, the reviewers found that only 3.5% ($n = 6$) and 3.4% ($n = 6$) were "non-evidenced-based" implantations (P = 0.90 by chi-square analysis for all comparisons).

The reviewers (reviewer 1 and reviewer 2, respectively) deemed 116 and 110 ICDs to be implanted for secondary prevention. They found 89.7% ($n = 104$) and 90.0% ($n = 99$) of implantations to be appropriate, 1.7% ($n = 2$) and 3.6% ($n = 4$) may be appropriate, and 2.6% ($n = 3$) and 3.6% ($n = 4$)
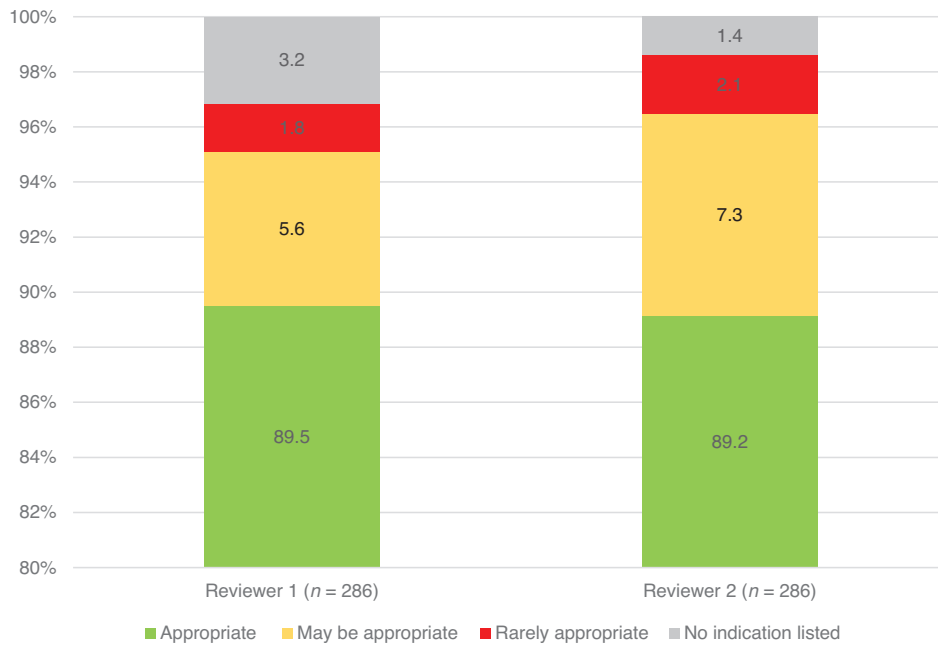
Table 2 Implantable Cardioverter-Defibrillator (ICD) Indications.

	Primary prevention	Secondary prevention
Cardiac allograft vasculopathy	LV dysfunction	Nonsustained VT Syncope
Ischemic cardiomyopathy/ coronary artery disease	<40 days after MI with EF <40% and pacing indication	VF
	>40 days after MI with EF <35%	Hemodynamically unstable VT
	EF <40% despite optimal GDMT	Sustained hemodynamically stable VT
		Unrevascularizable disease with VT/ VF
		Acute MI without revascularization and VT/VF
		Acute MI with revascularization and VT/VF
		Syncope with inducible sustained VT/ VF
		EF <40% with syncope
		Sustained VT after VT ablation
Nonischemic cardiomyopathy	EF <35% <3 months since diagnosis	VT/VF associated with cocaine abuse
	EF <35% despite optimal GDMT	Sustained hemodynamically stable monomorphic VT
		Syncope
Idiopathic arrhythmias		VF
		Hemodynamically unstable VT
		Outflow tract tachycardia with normal LV function and unexplained syncope
Generator change	Persistently reduced LV function	Clinically relevant ventricular arrhythmias since implantation
	Normalized LV function	Improved LV function but clinically relevant ventricular arrhythmias since implantation
	CRT-D system with improved LV function	Normalized LV function but clinically relevant ventricular arrhythmias since implantation
		Initial secondary prevention ICD with no ventricular arrhythmia since implantation
Inherited disorders		
Cardiac sarcoidosis	Primary prevention	
Myotonic dystrophy	Primary prevention	
Hypertrophic cardiomyopathy	Risk factors meeting criteria for primary prevention	Sustained VT/VF
		Syncope
LV noncompaction	Primary prevention with EF >35%	EF <40% and syncope
Brugada syndrome		Sustained VT/VF
Arrhythmogenic right ventricular cardiomyopathy		Sustained VT/VF Sustained VT/VF after VT ablation

Table 2 (continued)

	Primary prevention	Secondary prevention
Congenital disorders		
Tetralogy of Fallot		EF <50% and nonsustained VT during exercise testing
Congenital long QT syndrome		Sustained VT/VF Unexplained syncope
Catecholaminergic polymorphic VT		Sustained VT/VF
Mitochondrial myopathy		Syncope and nonsustained VT

CRT-D, cardiac resynchronization therapy—defibrillator; EF, ejection fraction; GDMT, guideline-directed medical therapy; LV, left ventricular; MI, myocardial infarction; VF, ventricular fibrillation; VT, ventricular tachycardia.

Figure 2: Appropriateness of All Implantable Cardioverter-Defibrillator Implantations ($n = 286$).

Table 3 Appropriateness of All Implantable Cardioverter-Defibrillator Implantations.
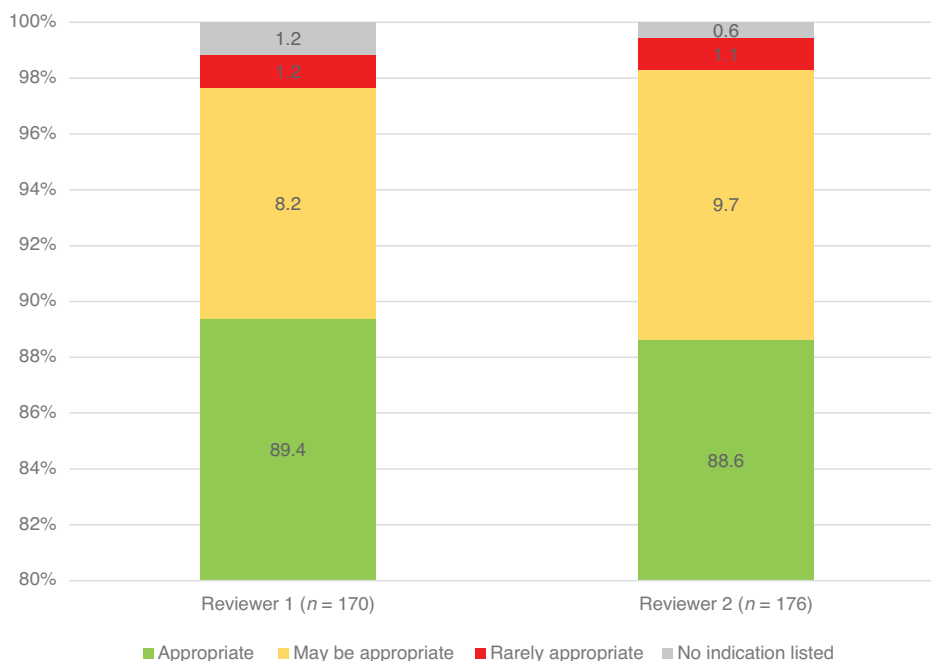
	Reviewer 1	Reviewer 2
Appropriate	256 (89.5%)	255 (89.2%)
May be appropriate	16 (5.6%)	21 (7.3%)
Rarely appropriate	5 (1.8%)	6 (2.1%)
No indication listed	9 (3.2%)	4 (1.4%)

were rarely appropriate. Six percent ($n = 7$) and 2.7% ($n = 3$) had no listed indication in the AUC document (Figure 4, Table 5) (P = 0.50 by chi-square analysis for all comparisons).

There was some interreviewer variability in appropriateness. In 5.24% of cases ($n = 15$), the reviewers disagreed on the level of appropriateness of the ICD indication. In 2.80% of cases ($n = 8$), one reviewer deemed an ICD implantation appropriate and the other deemed it rarely appropriate.

Discussion

There was a high proportion of appropriately implanted ICDs and a very low proportion of rarely appropriate ICD implantations for both primary and secondary prevention indications. Our

Figure 3: Appropriateness of Primary Prevention Implantable Cardioverter-Defibrillator Implantations.

Table 4 Appropriateness of Primary Prevention Implantable Cardioverter-Defibrillator Implantations.

	Reviewer 1 (n = 170)	Reviewer 2 (n = 176)
Appropriate	152 (89.4%)	156 (88.6%)
May be appropriate	14 (8.2%)	17 (9.7%)
Rarely appropriate	2 (1.2%)	2 (1.1%)
No indication listed	2 (1.2%)	1 (0.6%)

high appropriate implantation rate suggests that the AUC accurately reflect current clinical practice.

Comparing these data with data from prior studies (Table 6), we found an average of 89.4% of ICD implantations in this study were appropriate compared with 86% from a study that assessed ICD implantation on the basis of major ICD trial inclusion criteria [5]. Per the criteria of Al-Khatib et al., only 3–4% of ICD implantations for primary prevention in our study were "non-evidence-based" implantations compared with 22.5% in their study [4]. One drastic difference is that the previous studies were registry analyses with more than 100,000 patients in all practice settings, compared with 286 patients in this study. Furthermore, all ICDs in our study were implanted by electrophysiologists in a university academic center, and thus the familiarity of the implanters with current evidence and guidelines likely contributed to the high appropriateness rate.

The low rarely appropriate implantation rate (1.2% and 1.1%) of primary preventions is likely due to clear primary prevention indications. Secondary prevention ICDs may have had a higher rate of rarely appropriate implantations (2.6% and 3.6%) as the AUC may not fully reflect complex clinical scenarios often seen at university centers, such as patients with transplant vasculopathy, rare genetic disorders, or congenital heart disease.

The relatively high number of unrated secondary prevention implantations (6.0% and 2.7%) indicates that there are gaps in the AUC. Specific examples include patients with hemodynamically unstable ventricular tachycardia without syncope in a structurally normal heart, as well as cardiac arrest in patients too unstable to undergo ischemic evaluation. In addition, the AUC do not address whether patients with a newly discovered cardiomyopathy who require permanent pacing should also receive an ICD at the time of device implantation, although for these clinical scenarios most clinicians would likely consider ICD implantation as the benefit likely outweighs the risk in this circumstance.

The greatest limitation of this study is the small sample size (n = 286) and the subsequent limitation in power, which may limit generalizability. Baseline
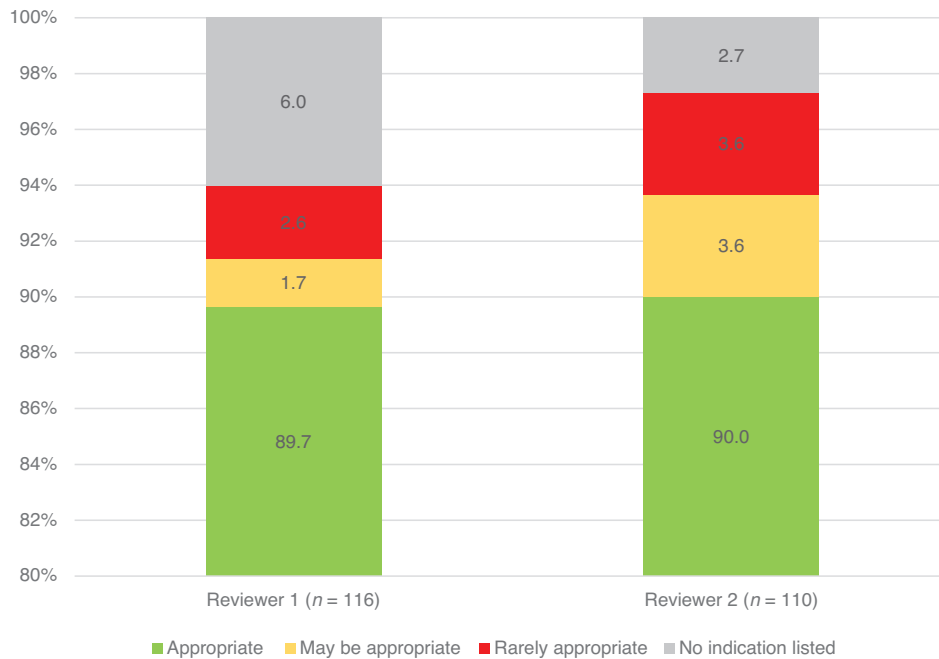
Figure 4: Appropriateness of Secondary Prevention Implantable Cardioverter-Defibrillator Implantations.

Table 5 Appropriateness of Secondary Prevention Implantable Cardioverter-Defibrillator Implantations.

	Reviewer 1 (*n* = 116)	Reviewer 2 (*n* = 110)
Appropriate	104 (89.7%)	99 (90.0%)
May be appropriate	2 (1.7%)	4 (3.6%)
Rarely appropriate	3 (2.6%)	4 (3.6%)
No indication listed	7 (6.0%)	3 (2.7%)

demographics were similar to those of other major ICD trials [7–9]. Furthermore, as this study examined ICD implantation in a university setting in which ICDs are implanted only by electrophysiologists, it may not represent clinical practice in settings in which ICDs may be implanted by nonelectrophysiologists, such as general cardiologists and thoracic surgeons [4, 5].

Some patients had ICDs implanted for secondary prevention, but if there were no clear or appropriate secondary prevention indications, the reviewers may have instead listed a primary prevention indication, which would falsely decrease the rate of rarely appropriate or unrated secondary prevention ICD implantation. Similarly, the differences in appropriateness rates between reviewers may have been due to differences in how strictly each reviewer interpreted the AUC. For example, the reviewers

disagreed on whether class IV symptoms were a contraindication, regardless of whether the patient was listed for transplantation. Of note, the most recent ICD guidelines [10], which were published in 2018 after the reviewers had assessed appropriateness for this study, recommend ICD implantation in patients who are candidates for transplantation or ventricular assist device implantation; however, this recommendation was not included in prior guidelines [11]. The updated guidelines also expand recommendations for ICD implantation in patients with genetic, neuromuscular, and congenital heart disorders [10], some of which were not included in the AUC [2].

Lastly, given that the reviewers were physicians at the academic center studied, there may have been a degree of observer bias involved in rating appropriateness. The differences in appropriateness rates between reviewers were not statistically significant, with P = 0.44 for all ICD implantations, P = 0.90 for primary prevention ICD implantations, and P = 0.50 for secondary prevention ICD implantations.

The Medicare national coverage determination determines reimbursement for ICDs based on indication. It is based on major ICD trial criteria from MADIT, MADIT II, MUSTT, and SCD-HeFT [3], although indications were last added in 2005 [12]. Should the Medicare national coverage determination be based on AUC in the future, any gaps or

Table 6 Comparison with Prior Registry-Based Studies.

	Al-Khatib et al. [4]	Kaiser et al. [5]	This study
Appropriate primary prevention ICD implantations	NA	86%	Reviewer 1: 89.5% Reviewer 2: 89.2%
Non-evidence-based primary prevention ICD implantations	22.5%	NA	Reviewer 1: 3.4% Reviewer 2: 3.5%
Study size (n)	111,707	150,264	286
Hospital setting	University Government Private/community	University Government Private/community	University
Implanter specialty	Electrophysiology Cardiology Thoracic surgery Other	Electrophysiology Cardiology Surgery Other	Electrophysiology

ICD, implantable cardioverter-defibrillator, NA, not applicable.

inadequacies of the AUC would negatively impact patients, clinicians, and hospitals if clinically indicated ICDs are not reimbursable.

When one is considering the application of these findings to clinical practice, it is important that each patient receive individualized care, irrespective of the guidelines. Although the AUC may aid clinical practice and decision-making, they cannot provide guidance in every scenario for every patient. If an indication is not listed or rarely appropriate, clinical judgment must determine whether a specific patient would benefit from ICD implantation.

Conclusion

Compared with prior registry data reports, the prevalence of rarely appropriate ICD implantation at our facility was very low. Our high appropriate use rate could be explained by appropriate clinical practice or by the AUC being evidence based and reflecting clinical practice. The AUC have gaps and could benefit from additional indications regarding secondary prevention. Most importantly, clinical judgement and individualized care should determine which patients receive ICDs irrespective of guidelines or criteria.

Acknowledgements

None.

Ethics Approval and Consent to Participate

This study was approved by the University of Florida Institutional Review Board (ID no. IRB201600095). Given the deidentified data used in this study, patient consent was not required.

Consent for Publication

Not applicable.

Availability of Data and Material

The datasets generated and/or analyzed during the current study are not publicly available as they were extracted from University of Florida Health electronic medical records and entered into a REDCap database. Deidentified data were used for subsequent analysis but are available from the corresponding author on reasonable request.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Author Contributions

The implantable cardioverter-defibrillators studied were implanted by MK, TAB, WMM, and MM. NHS, DEW, and MM were responsible for study design. NHS, SJR, SANN, JM, and AK were responsible for data collection, which was supervised by MM. NHS analyzed the final dataset. DEW was responsible for statistical analysis. NHS was responsible for drafting the manuscript, and SJR, DEW, TAB, and MM were involved in editing the manuscript. All authors read and approved the final manuscript.

REFERENCES

1. Ezzat VA, Lee V, Ahsan S, Chow AW, Segal O, Rowland E, et al. A systematic review of ICD complications in randomised controlled trials versus registries: is our 'real-world' data an underestimation? Open Heart 2015;2(1):e000198.

2. Russo AM, Stainback RF, Bailey SR, Epstein AE, Heidenreich PA, Jessup M, et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. J Am Coll Cardiol 2013;61(12):1318–68.

3. Fogel RI, Epstein AE, Mark Estes NA, Lindsay BD, DiMarco JP, Kremers MS, et al. The disconnect between the guidelines, the appropriate use criteria, and reimbursement coverage decisions: the ultimate dilemma. J Am Coll Cardiol 2014;63(1):12–4.

4. Al-Khatib SM, Hellkamp A, Curtis J, Mark D, Peterson E, Sanders GD, et al. Non-evidence-based ICD implantations in the United States. J Am Med Assoc 2011;305(1):43–9.

5. Kaiser DW, Tsai V, Heidenreich PA, Goldstein MK, Wang Y, Curtis J, et al. Defibrillator implantations for primary prevention in the United States: inappropriate care or inadequate documentation: insights from the National Cardiovascular Data ICD Registry. Heart Rhythm 2015;12(10):2086–93.

6. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377–81.

7. Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med 2005;352(3):225–37.

8. Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002;346(12):877–83.

9. Buxton AE, Lee KL, Fisher JD, Josephson ME, Prystowsky EN, Hafley G. A randomized study of the prevention of sudden death in patients with coronary artery disease. N Engl J Med 1999;341(25):1882–90.

10. Al-Khatib SM, Stevenson WG, Ackerman MJ, Bryant WJ, Callans DJ, Curtis AB, et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm 2018;15(10):e73–189.

11. Zipes DP, Camm AJ, Borggrefe M, Buxton AE, Chaitman B, Fromer M, et al. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). J Am Coll Cardiol 2006;48(5):e247–346.

12. US Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4). Baltimore: US Centers for Medicare & Medicaid Services [cited 2017 August 30]. Available from: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId---equalsym---110&ncdver---equalsym---3&bc---equalsym--AAAAgAAAAAAAAA%3d%3d&amp.