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DEVICES

A manual synchronous low energy shock impedance as a predictor of successful defibrillation testing during subcutaneous ICD implantation

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Abstract

Background: Guidelines recommend defibrillation testing (DFT) during subcutaneous implantable cardioverter-defibrillator (S-ICD) implantation. Implant position, patient characteristics and device factors, such as shock impedance, influence defibrillation success. To evaluate the shock impedance, a manual synchronous 10J shock (low energy synchronous shock [LESS]) can be delivered, without the need to induce ventricular fibrillation (VF).

Objective: To compare LESS and DFT impedance values and to evaluate the diagnostic accuracy of LESS impedance for predicting a successful DFT during S-ICD implantation.

Methods: Consecutive S-ICD implantations were included. Shock impedances were compared by paired *t*-tests. Univariate analysis was performed to investigate factors associated with successful DFT. A prediction model of successful DFT based on LESS impedance was assessed by logistic regression. Receiver operating characteristic (ROC) curve, area under the ROC curve and the Hosmer–Lemeshow tests were used to evaluate the accuracy of LESS impedance.

Results: Sixty patients were included (52 ± 14 years; 69% male). LESS and DFT impedance values were highly correlated ($r^2 = 0.97$, $p < .01$). Patients with a failed first shock had higher body mass index (BMI) (30 ± 3 vs. 25.7 ± 4.3, $p = .014$), higher mean LESS (120 ± 35Ω vs. 86. ± 23Ω, $p = .0013$) and DFT impedance (122 ± 33Ω vs. 87 ± 24Ω, $p = .0013$). ROC analysis showed that LESS impedance had a good diagnostic performance in predicting a successful conversion test (AUC 84% [95% CI: 0.72–0.92]) with a cutoff value of <94Ω to identify a successful DFT (sensitivity 71%, specificity 73%).

Abbreviations: BMI, body mass index; DFT, defibrillation testing; LESS, low energy synchronous shock; S-ICD, subcutaneous implantable cardioverter defibrillator; TV-ICD, transvenous implantable cardioverter defibrillator; VF, ventricular fibrillation.

Conclusion: LESS impedance values without the need to induce VF can intraoperatively predict a successful DFT.

KEYWORDS
defibrillation testing, shock impedance, subcutaneous implantable cardioverter defibrillator, ventricular fibrillation

1 | INTRODUCTION

The subcutaneous implantable cardioverter defibrillator (S-ICD) was developed to overcome the complications associated with traditional transvenous implantable cardioverter defibrillators (TV-ICDs) such as venous thrombosis, cardiac perforation, lead fracture, and lead-related infective endocarditis. The S-ICD is increasingly being used for the prevention of sudden cardiac death, and studies have demonstrated high rates of successful defibrillation for both induced and spontaneous ventricular arrhythmias with acceptably low rates of complications.[1–3]

Randomized clinical trials[4,5] and current society recommendations support implantation of a TV-ICD without conversion testing of ventricular fibrillation (VF); however, current guidelines advocate for defibrillation testing (DFT) at the time of S-ICD implantation, based on the lack of evidence suggesting that it is safe to avoid DFT.[6] However, VF induction and subsequent defibrillation is associated with various complications, albeit with a low incidence rate.[7] Therefore, it would be worth to avoid the risk of DFT when it is not necessary.

Both suboptimal device position and lead impedance have been associated with higher DFTs on computer modeling.[8] Several factors such as a higher shock impedance, higher body mass index (BMI), device position or white race have been associated with lower conversion success. More recently, The PRAETORIAN score, a chest radiograph-based method that assesses the determinants of the DFT has been retrospectively validated to predict the probability of successful S-ICD conversion testing.[9–12]

Given the increasing adoption of S-ICDs for the prevention of sudden cardiac death, the decision whether to perform routine DFT may be clinically relevant. The ability to predict defibrillation efficacy at the time of S-ICD implantation without the need to induce VF may eliminate the need for such testing.

The impedance of the shocking electrode is typically determined during the 65-J VF conversion testing performed at implant but can also be obtained with manual delivery of a 10-J shock; as it has been demonstrated that a 10 J shock impedance in sinus rhythm correlates well with a 65 J defibrillation impedance during intermuscular subcutaneous ICD implantation.[13] In order to avoid VF induction, some physicians prefer to deliver a manual synchronous 10-J shock to evaluate the shock impedance.[14] If this value is <90 Ω, the device is considered to have been placed correctly.[15] However, to date there are no studies evaluating this parameter as a reliable tool for predicting shock efficacy and the value of 90 Ω threshold has been established as a rule of thumb, without any clinical evidence.

The objectives of our study were: (i) to compare the impedance values obtained after a low energy synchronous shock (LESS) of 10 J and after DFT, and (ii) to evaluate the diagnostic accuracy of LESS impedance for predicting a successful DFT.

2 | MATERIALS AND METHODS

2.1 | Study population

This was a prospective study of consecutive patients receiving an S-ICD at our institution from September 2018 to May 2022. Our local institutional Review Board approved the study and all patients provided written informed consent.

2.2 | Study population and S-ICD implantation

The study population included all patients aged > 18 years old who met the criteria for S-ICD implantation for primary or secondary prevention. Patients undergoing S-ICD implantation but in whom DFT was not performed were excluded from the analysis. The reasons provided for abstinence from testing included an inability to induce sustained VF, known left ventricular thrombus, the presence of atrial fibrillation with inadequate anticoagulation or the presence of hemodynamic instability during implantation.

Medical history, demographic data, etiology of cardiomyopathy, echocardiographic measurements, and indications for ICD implantation were recorded for each individual.

2.3 | Implantation technique

Screening ECG test was performed in two postures (lying down and sitting) for all patients with at least one of the three sensing configurations being considered acceptable in both postures.

The procedure was performed in the electrophysiology laboratory under standard sterile conditions and conscious or general anesthesia. The generator was placed within the virtual space between the latissimus dorsi and serratus anterior muscles (intermuscular implantation), at the level of the VII and VIII costal arches (intermuscular technique). Electrode positioning was performed following the two-incision technique described by Knops and co-workers[16] in either the left or right parasternal locations based on preprocedural screening evaluation results. Finally, the incision and pocket sites were irrigated and massaged for deairing and wound closure was performed.

A fluoroscopic image of the chest was obtained following implant completion to confirm appropriate electrode and generator positioning.

Device analysis with the patient lying down and sitting was performed to choose the best sensing vector.

The conditional shock zone and shock zone were programmed based on patient characteristics at 190–200 and 220–250 beats per minute, respectively.

2.4 | DFT protocol

All patients were under deep sedation before DFT.

A first manual synchronous 10 J shock (LESS) was delivered during the baseline rhythm. Immediately after the LESS, DFT was performed according to the local clinical practice:

1. VF was induced through the device delivering a 50 Hz transthoracic current. The initial shock energy output from the device was set at 65 J. Any successful first 65 J shock was considered a successful test and was not repeated;
2. If the first 65 J shock failed to convert VF, a second shock at 80 J output with reverse polarity was delivered through the device. External direct current (DC) defibrillation was immediately available for rescue if S-ICD shocks failed to terminate VF.

A failed conversion test was defined as any induced VF that failed to convert at the first 65J shock.

2.5 | STATISTICAL ANALYSIS

Descriptive statistics are reported as mean ± standard deviation for normally distributed continuous variables, or medians with corresponding interquartile range (IQR) in the case of skewed distribution. Categorical variables are reported as percentages. Differences were compared by means of a *t*-test for Gaussian variables and Wilcoxon's nonparametric test for non-Gaussian variables. The Chi-square test or Fisher's exact test were used to compare proportions, as appropriate.

Spearman's correlation analysis was performed to show the relationships between continuous variables. A two-tailed *p*-value of $< .05$ was considered statistically significant.

Univariate analysis was performed to investigate the association between predictors and failure of standard 65J DFT. A prediction model of successful DFT based on LESS impedance was assessed by logistic regression. Receiver operating characteristic (ROC) curves, sensitivity, specificity, positive and negative likelihood ratios (PLR and NLR) and positive and negative predictive values (PPV and NPV) were used to evaluate the diagnostic accuracy of the final model. Calibration was evaluated using Hosmer–Lemeshow goodness-of-fit statistic test and the McFadden's R2. Concordance among LESS and DFT impedance was assessed using intra-class correlation coefficients.

Analysis was using STATA 14.0 (StataCorp LLC, College Station, TX).

TABLE 1 Baseline demographic data.

Age (years)	**51.1 ± 14.8**
Sex (men) (%)	70
BMI	26.1 ± 4.4
Heart disease (%)	
Ischemic cardiomyopathy	31.75
Hypertrophic cardiomyopathy	22.22
Dilated cardiomyopathy;	14.29
Idiopatic cardiomyopathy;	6.35
Brugada síndrome	3.17
Long QT síndrome	3.17
Arrhythmogenic cardiomyopathy	7.94
Myocarditis	3.17
Adult congenital heart disease	1.59
Non compacted cardiomyopathy	3.17
Chemotherapy induced cardiomyopathy	1.59
Catecholaminergic polymorphic ventricular tachycardia;	1.59
Indication (%)	
Primary prevention	82.54
Secondary prevention	17.46
LESS impedance (Ω)	89.4 ± 26.4
Shock impedance (Ω)	90.7 ± 26.4

Abbreviations: BMI, body mass index; LESS, manual synchronous 10J shock.

3 | RESULTS

3.1 | Baseline population characteristics

During the study period, 73 patients received an S-ICD at our center. In 60 of these patients, a LESS was delivered during the baseline rhythm and a sustained VF was then induced through the device and constituted the study cohort. The baseline demographic data are listed in Table 1. The mean age of the study population was 52 ± 15 years, 70% were men, the average BMI was 26 ± 4 kg/m^2 and the average LVEF was 48% ± 15%. Ischemic cardiomyopathy (30%) was the most frequent heart disease, followed by hypertrophic cardiomyopathy (22%) and non-ischemic cardiomyopathy (15%). A total of 10 patients (17%) were implanted for secondary prevention.

3.2 | DFT

The first shock failed in six patients (10%). A second 80J shock with reverse polarity was required for adequate defibrillation in four of

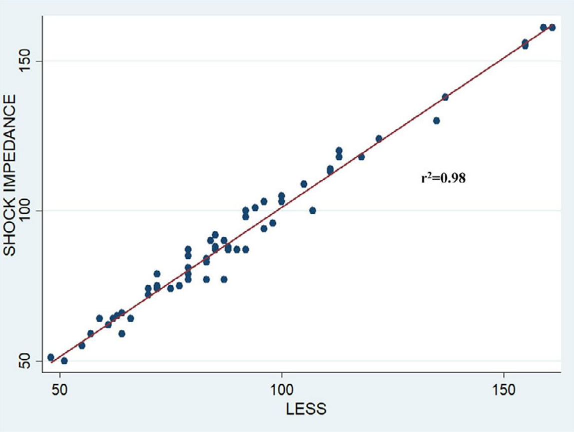

FIGURE 1 Scatter plot of paired impedance tests showing the high correlation. [Color figure can be viewed at wileyonlinelibrary.com]

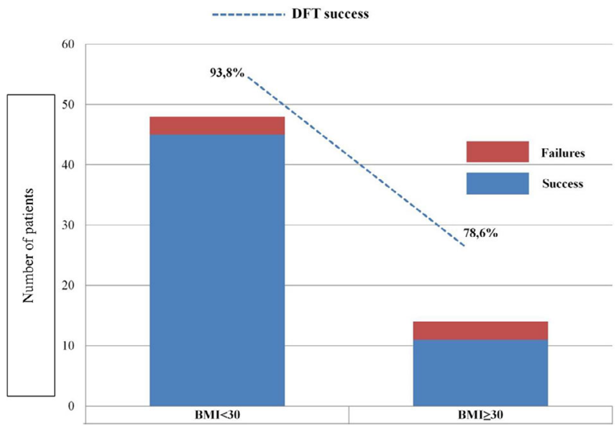

FIGURE 2 DFT success according to BMI. BMI, body mass index; DFT, defibrillation testing. [Color figure can be viewed at wileyonlinelibrary.com]

these patients, whereas successful defibrillation could not be achieved in the remaining two patients, who were rescued by an external DC shock. In these two cases, the fluoroscopy revealed an optimal position of the generator in the midline of the lateral chest view with no significant amount of fat between the generator and the thoracic wall. However, a wide amount of tissue was observed between the coil and sternum, so the lead was repositioned. Once repositioned, a 65J shock was successful in both cases.

3.3 | LESS versus DFT impedances and DFT success

There were no significant differences in the average impedance value between the manual synchronous 10 J shock (LESS) and DFT (89.41 ± 26.27 vs. 90.68 ± 26.4 respectively) and these impedance values were highly correlated (Figure 1) (r^2 = 0.97, p < .01). LESS impedance showed excellent reliability compared to DFT impedance (intra-class correlation coefficient = 0.99, [CI 0.989–0.997]).

In patients in whom DFT was ineffective, the average value of the manual synchronous 10J shock impedance was 119.84 ± 35.1 Ω and the average DFT impedance was 122.33 ± 33.2 Ω (p = .90).

In patients with a successful first shock, the average manual synchronous 10J shock impedance value was 86.21 ± 32.32 Ω and 87.4 ± 23.57 Ω for DFT impedance (p = .80).

Patients with a failed first shock had a higher mean LESS impedance and DFT impedance values than patients with a successful conversion test (p = .0013).

A second shock with reverse polarity was necessary and effective in four patients. The mean LESS impedance in patients for whom the second shock was effective was 113.33Ω, compared to 158 Ω in those for whom it was ineffective. This difference approached statistical significance (p = .086). Similarly, the difference in mean DFT impedance between patients with an effective second shock (116 Ω) and those with an ineffective second shock (158.5 Ω) also approached statistical significance (p = .083).

TABLE 2 Univariate analysis for predictors of successful defibrillator test.

	Univariate OR (95% CI)	p
Sex	2.31 (0.25–21.22)	.460
Body mass index	0.77 (0.60–0.98)	.036
LVEF	1.02 (0.97–1.07)	.482
Heart disease	1.18 (0.91–1.54)	.21
LESS impedance	0.96 (0.93–0.99)	.009
Shock impedance	0.96 (0.93–0.99)	.007

Abbreviations: LESS, manual synchronous 10J shock; LVEF, left ventricular ejection fraction.

3.4 | Clinical determinants of first shock success

Patients with a failed first shock had a higher BMI compared to those with successful initial shock (30 ± 3 vs. 25.7 ± 4.3, p = .014). Figure 2 shows DFT success in patients with BMI < 30 kg/m^2 compared to those with BMI ≥ 30 kg/m^2.

There were no statistically significant differences in mean LVEF between patients with a failed (LVEF 43 ± 19%) or successful DFT (LVEF 48 ± 15%) (p = .49).

3.5 | Predictors of DFT success

Table 2 shows the results of univariate logistic regression analysis. BMI, LESS impedance and DFT impedance were significant predictors of an ineffective DFT (p < .05). On the contrary, sex, etiology of cardiomyopathy, and LVEF did not meet statistical significance to predict a failed first shock.

ROC-curve analysis revealed that LESS impedance showed significant specificity and sensitivity to distinguish between a successful or unsuccessful conversion test. The AUC value was 83.42% (95% CI: 0.67–0.996) (Figure 3).

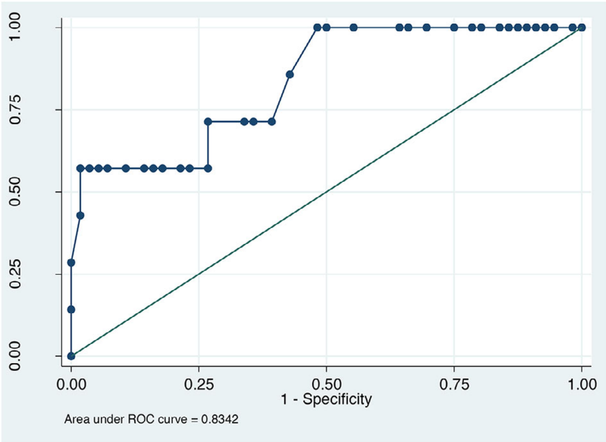

FIGURE 3 Receiver operating characteristic (ROC) curve for the overall performance of LESS impedance for the prediction of successful test. [Color figure can be viewed at wileyonlinelibrary.com]

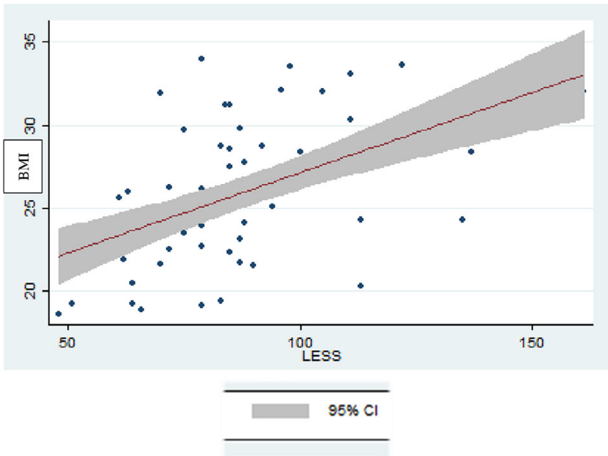

FIGURE 4 Correlation between BMI and LESS impedance for patients with a successful or a failed first shock ($r = 0.5841$, $p > .05$). [Color figure can be viewed at wileyonlinelibrary.com]

The optimal cut off value for LESS impedance based on ROC-curve to detect those passing or failing DFT was 94 Ω.

The negative predictive value, which represents the percentage of patients with a LESS impedance of <94 Ω who passed conversion testing was 95.6%. The positive predictive value, that is, the percentage of patients with a LESS impedance ≥94 Ω who failed conversion testing was 25%. The sensitivity and specificity values for a LESS impedance ≥94 Ω were 71.4%, and 74.1%, respectively. Cut-off values of LESS impedance with respective sensitivity, specificity, PPV and NPV are shown in the supplementary material. The model was calibrated ($p = .85$ for the Hosmer–Lemeshow goodness-of-fit test, with a McFadden's R^2 of 0.27).

On the other hand, a positive correlation between increasing BMI and LESS impedance was present ($p < .05$) (Figure 4, with an average LESS impedance of 82.5 Ω for patients with a BMI of <30 kg/m^2, and 113.64 Ω for patients with a BMI > 30 kg/m^2.

3.6 | Complications related to DFT

All inducible VF episodes were appropriately detected by the S-ICD without dropout or under-sensing. There were no complications attributable to DFT testing, including absence of stroke, myocardial infarction, pulmonary embolism, or death. One patient experienced left shoulder dislocation probably secondary to inadequate arm bracing during the DFT, which was successfully resolved by closed reduction following the procedure.

4 | DISCUSSION

The main findings of our study may be summarized as the following: (i) manual synchronous low energy shock impedance values do not significantly differ from those obtained during DFT, and (ii) high LESS impedance values are associated with a higher risk of failed conversion test after S-ICD implantation.

DFT has traditionally been part of the implant procedure of the ICD to ensure adequate device functionality. However, since the SIMPLE and NORDIC[4,5] trials demonstrated that omission of routine DFT was non-inferior to standard of care in terms of arrhythmic death and first shock efficacy in left-sided TV-ICDs, the omission of routine DFT during routine implantation of left-sided TV-ICDs is included in current guidelines with a class IIa recommendation and DFT is now rarely performed.

On the contrary, due the lack of outcomes data on the safety and efficacy of not performing DFT during S-ICD procedures, current guidelines recommend that intraprocedural DFT should be performed following S-ICD implantation (Class I, Level of Evidence: C).[6]

Previous studies have reported an association between increased shock impedance and failed conversion testing.[17–19] An analysis in the IDE study, demonstrated that the likelihood of defibrillation success in converting VF was inversely related to the system impedance. In this study, with impedances ≤89 Ω, conversion efficacy at 65 J was 95% whereas with impedances > 90 Ω, the conversion efficacy decreased to 77%.

More recently, in order to avoid VF induction, some physicians prefer to deliver a manual synchronous 10 J shock to evaluate the shock impedance and, as a rule of thumb, a high-voltage impedance > 90 Ω is generally considered a risk factor for lower shock efficacy.[14] However, there are no previous studies analyzing the association between this value and the conversion success. In a previous small study, Payne et al.[14] analyzed the relationship of shock energy to impedance during S-ICD DFT. They observed a high correlation between impedance at low and high energy shocks and, unlike in our study, a significantly higher impedance for 10 J shocks compared with 65 J shocks were described. However, as the authors state, the mean difference between groups was small (2.8 Ω) and unlikely of clinical difference. In our population, we did not observe significant differences in the average impedance value between the manual synchronous 10 J shock and DFT and these impedance values were highly correlated. Furthermore, to the best of our knowledge, this is the first study that demonstrates that the LESS impedance value is a strong determinant of VF conversion success. We propose a value < 94 Ω as a cut-off point to safely predict a successful DFT. This value may select patients in which DFT may not be necessary, similar to contemporary TV-ICD implant procedures. We will emphasize that all our patients received a S-ICD using an intermuscular technique. This consistent approach ensures that our findings regarding impedance and defibrillation efficacy are applicable to this specific implantation method, thereby strengthening the validity and relevance of our study.

BMI has also been reported as a predictor of DFT.[11,20] Do et al. found that the average BMI of those patients with high DFT was significantly higher than that of the normal DFT group (37.7 kg/m^2 vs. 29.4 kg/m^2; $p = .02$). A positive correlation between increasing BMI and DFT was present ($p = .03$) with an average DFT of 36.9 J for patients with a BMI < 30 kg/m^2, 43.8 J for patients with a BMI of 30–35 kg/m^2, and 72.5 J for patients with a BMI ≥ 35 kg/m^2 ($p = .006$).

In our study, patients with a failed first shock had a higher BMI compared to patients with successful DFT and BMI was associated with a failed conversion test in the univariate analysis

Since electrode tunneling in the subcutaneous fat along the sternum may be more apt to occur in obese patients, the increased shock energy required for defibrillation in obese patients could be related to the presence of increased adipose tissue, which is a poor electrical conductor. Heist et al.[8] showed through computer modeling with the S-ICD that sub-coil adipose tissue and adipose tissue between the generator and the thorax increased the DFT and shock impedance significantly. These data suggest that shock impedance during the procedure may be a good surrogate for estimating the electrode coil depth.

A previous retrospective study[9] reported a method to assess implant position to identify patients who are likely to fail their DFT (PRAETORIAN score). This score evaluates three factors of defibrillation success in S-ICD patients: sub-coil fat tissue, placement of the generator in the sagittal axis and sub-generator fat tissue. The authors found that the PRAETORIAN score showed a negative predictive value of 99.8%, positive predictive value of 51% and a sensitivity and specificity of 95% and 95%, respectively. Shock impedance also demonstrated a significant correlation with conversion success, although with lower positive and negative predictive values. The positive predictive value of a high-voltage impedance of ≥100 U was 23% whereas the negative predictive value of a high-voltage impedance of <100 U was 95%. The sensitivity and specificity values for a high-voltage impedance of ≥100 U were 50% and 86%, respectively. However, it should be noted that the PRAETORIAN score is limited by its retrospective nature and the fact that it is obtained postprocedurally. A randomized clinical trial aiming to provide a prospective validation of this score is currently underway.[21] One practical consideration limiting in the use of this score is that, although the anterior-posterior fluoroscopic images can be easily obtained during the implant procedure, obtaining a lateral fluoroscopic image may compromise the sterile field.

Finally, regardless of the strong recommendation in the current guidelines, recent studies have shown that many physicians omit DFT due to concern for the risk of complications and patients frailty.[12,22,23]

Therefore, a less invasive intraoperative test without the potential adverse effects related to DFT could have obvious benefits until data from randomized clinical trials may implement a method to safely omit DFT during S-ICD implantation.

4.1 | LIMITATIONS

This was an observational nonrandomized study with a relatively low incidence of ineffective shocks. The study is also limited by its single center nature. However, our results are consistent with the first published studies about S-ICD safety, which showed a high conversion success rate of DFT during S-ICD implants.[24–26]

The observed results need to be validated by larger prospective randomized clinical trials. However, to our knowledge, this is the first study that compares LESS impedance and shock impedance values, as well as the first to report an optimal LESS impedance cut-off value to identify patients with high risk of conversion failure after S-ICD implantation. This strategy could additionally provide an alternative to avoid potential DFT-related complications.

5 | CONCLUSIONS

LESS impedance values could intraoperatively predict the chance of successful conversion testing during S-ICD implantation. Additional randomized studies with larger sample sizes may be needed to further characterize the potential risk factors associated with a failed conversion test.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in Zaguán: Repositorio Institucional de la Universidad de Zaragoza at http://zaguan.unizar.es.

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