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CLINICAL INVESTIGATIONS

Diabetes mellitus is associated with increased acute kidney injury and 1-year mortality after transcatheter aortic valve replacement: A meta-analysis

George S. Mina | Priyanka Gill | Demiana Soliman | Pratap Reddy | Paari Dominic

Department of Cardiology, Louisiana State University Health Sciences Center–Shreveport, Shreveport, Louisiana

Correspondence
Paari Dominic, MD, Cardiology Department, LSUHSC-Shreveport, 1501 Kings Highway, Shreveport, LA 71103 (pdomi2@lsuhsc.edu).

Background: Diabetes mellitus (DM) is associated with adverse outcomes after surgical aortic valve replacement. However, there are conflicting data on the impact of DM on outcomes of transcatheter aortic valve replacement (TAVR).

Hypothesis: DM is associated with poor outcomes after different cardiac procedures. Therefore, DM can also be associated with poor outcomes after TAVR.

Methods: We searched PubMed and Cochrane Central Register of Controlled Trials for studies that evaluated outcomes after TAVR and stratified at least 1 of the studied endpoints by DM status. The primary endpoint was all-cause mortality at 1 year. Secondary endpoints were early (up to 30 days) mortality, acute kidney injury (AKI), cerebrovascular accident (CVA), major bleeding, and major vascular complications. Pooled odds ratio (OR) and 95% confidence interval (CI) were calculated using random effects models.

Results: We included 64 studies with a total of 38 686 patients. DM was associated with significantly higher 1-year mortality (OR: 1.14, 95% CI: 1.04-1.26, P = 0.008) and periprocedural AKI (OR: 1.28, 95% CI: 1.08-1.52, P = 0.004). On the other hand, there were no significant differences between diabetics and nondiabetics in early mortality, CVAs, major bleeding, or major vascular complications.

Conclusions: DM is associated with increased 1-year mortality and periprocedural AKI in patients undergoing TAVR. The results of this study suggest that DM is a predictor of adverse outcomes in patients undergoing TAVR.

KEYWORDS

Diabetes Mellitus, Transcatheter Aortic Valve Replacement, Meta-analysis

1 | INTRODUCTION

Diabetes mellitus (DM) is known to adversely affect outcomes of different cardiovascular diseases,[1,2] and it is considered one of the predictors of poor outcomes after cardiac surgery according to the Society of Thoracic Surgeons and the EuroSCORE II risk scores.[3,4] In patients with aortic stenosis (AS), DM was shown to have an adverse effect on left ventricular remodeling and ejection fraction,[5] and it was associated with rapid progression of aortic valve calcification.[6] DM is also associated with a higher mortality rate after surgical aortic valve replacement (SAVR).[7]

On the other hand, the impact of DM on outcomes after transcatheter aortic valve replacement (TAVR) is unclear. In a subgroup analysis of the PARTNER (Placement of AoRTic TraNscathetER Valve) trial, diabetics had favorable outcomes when compared to nondiabetics.[8] However, other studies showed DM had either adverse or no significant impact on TAVR outcomes.[9,10] Therefore, in this study we examined by meta-analysis the effect of DM on clinical outcomes of patients undergoing TAVR for severe AS.

2 | METHODS

The present meta-analysis was performed in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines for conducting systematic reviews and meta-analyses.[11]

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2.1 | Search strategy

We searched PubMed and Cochrane Central Register of Controlled Trials for all studies, whether retrospective, prospective, or randomized controlled trials (RCTs), evaluating outcomes after TAVR until May 2016. The following keywords were used in a search query: "transcatheter aortic valve replacement," "transcatheter aortic valve implantation," "TAVR," "TAVI," "diabetes," "outcomes," "mortality," "acute kidney injury," "cerebrovascular accidents," "cerebrovascular events," "bleeding," and "vascular complications." Only studies in English language or studies with English translation were included. No other search restrictions were applied. Citations were screened at the title/abstract level and relevant citations were retrieved as full reports. References from the included studies were also manually searched for relevant studies. In addition, the "similar articles" search feature on PubMed was also used.

2.2 | Study end points

The primary endpoint was all-cause mortality at 1 year. Secondary endpoints were early (up to 30 days) all-cause mortality, acute kidney injury (AKI), cerebrovascular accident (CVA), major bleeding, and major vascular complications. Definitions of AKI, bleeding, and vascular complications varied between studies and are shown in Supporting Tables 1 through 3 in the online version of this article).

2.3 | Inclusion and exclusion criteria

Studies were included if (1) they evaluated outcomes after TAVR for patients with severe aortic stenosis requiring aortic valve replacement, (2) patients were at intermediate, high, or prohibitive surgical risk, and (3) at least 1 of the studied outcomes was stratified by DM status. Studies were excluded if (1) they included duplicate cohorts, (2) outcomes of diabetic patients were not clearly available, (3) -diabetes-based outcomes were reported for a special subgroup of patients and not for the entire cohort, (4) patients had prosthetic aortic valves, and (5) access was exclusively transapical.

2.4 | Data extraction

Data were independently extracted from the included trials by the first and second authors (G.M. and P.G.) on a prespecified datasheet and were then cross-verified by the third author (D.S.). Any discrepancy was discussed until there was complete agreement on all the results in the final datasheet.

2.5 | Statistical analysis

Data were extracted as either odds ratio (OR) or event rate. If hazard ratio was available, it was considered as the best estimate of OR. If both univariate and multivariate analyses were available, data from multivariate analyses were taken. Pooled ORs and 95% confidence intervals (CIs) were calculated using the more conservative DerSimonian and Laird random effects model.[12] All tests were 2-sided, and a P value <0.05 was deemed significant. Heterogeneity was assessed by the I^2 statistic, which describes the percentage of total variation across studies that is due to heterogeneity rather than chance. I^2 > 50% was considered significant heterogeneity.[13,14] Potential publication bias was assessed by visual inspection of funnel plots, in which standard errors were plotted against log ORs, as well as Eggers regression intercept. All statistical analyses were performed using Comprehensive Meta-Analysis V3 (Biostat Inc., Englewood, NJ).

3 | RESULTS

The present meta-analysis included 64 studies with a total of 38 686 patients. DM was present in 29% of those patients. The process of citations screening and publication selection is demonstrated in a PRISMA flow chart (see Supporting Figure 1 in the online version of this article). Two studies were subgroup analyses of RCTs,[8,15] and the remaining 62 studies were either retrospective or nonrandomized prospective studies. The mean age of patients in each study ranged from 79 to 84 years old. Transfemoral access use ranged from 27% to 100% in the included studies. Other access sites used were transapical, transaortic, transaxillary, and trans-subclavian. A variety of valves were used for TAVR, but the majority of studies predominantly used CoreValve (Medtronic, Dublin, Ireland) and Sapien (Edwards Lifesciences Corp., Irvine, CA) valves. Detailed characteristics and references of of individual studies included in this meta-analysis are shown in Supporting Table 4 in the online version of this article.

3.1 | Study endpoints

3.1.1 | One-year mortality

The overall analysis of 1-year mortality was based on 22 studies with a total of 17 503 patients (Figure 1). There was a significant increase in 1-year mortality in diabetic patients compared to nondiabetics (OR: 1.14, 95% CI: 1.04-1.26, P = 0.008, heterogeneity I^2 = 14.01%).

3.1.2 | Early mortality

This analysis was based on 16 studies with a total of 23 296 patients (Figure 2). There was no significant difference between diabetics and nondiabetics in mortality up to 30 days after TAVR (OR: 1.00, 95% CI: 0.86-1.16, P = 0.99, heterogeneity I^2 = 33.71%).

3.1.3 | AKI

This analysis was based on 28 studies with a total of 11 845 patients (Figure 3). DM increased the risk of AKI development after TAVR (OR: 1.28, 95% CI: 1.08-1.52, P = 0.004, heterogeneity I^2 = 42.51%).

3.1.4 | CVA

This analysis was based on 7 studies with a total of 3765 patients (see Supporting Figure 2 in the online version of this article). There was no significant difference between diabetics and nondiabetics in the risk of CVA after TAVR (OR: 1.01, 95% CI: 0.63-1.64, P = 0.95, heterogeneity I^2 = 27.53%).

3.1.5 | Major bleeding

This analysis was based on 8 studies with a total of 3116 patients (see Supporting Figure 3 in the online version of this article). There

Study Name	Analysis Type	Statistics for each study					
		Odds ratio	Lower limit	Upper limit	Z-Value	p-Value	Relative weight
Abramowitz et al.	Univariate	0.991	0.628	1.563	-0.040	0.968	4.16
Adams et al.	Univariate	0.663	0.352	1.250	-1.270	0.204	2.28
Amabile et al.	Univariate	1.180	0.540	2.579	0.415	0.678	1.53
Berkovitch et al.	Univariate	0.662	0.352	1.242	-1.285	0.199	2.31
Chopard et al.	Univariate	1.085	0.906	1.299	0.887	0.375	16.27
Chorin et al.	Univariate	1.383	0.824	2.320	1.229	0.219	3.32
Conrotto et al.	Univariate	1.437	0.910	2.268	1.557	0.120	4.15
Debonnaire	Univariate	1.090	0.671	1.772	0.348	0.728	3.72
Heinz et al.	Univariate	1.737	0.707	4.267	1.204	0.229	1.17
Lindman et al.	Univariate	0.572	0.338	0.968	-2.082	0.037	3.22
Linke 2014	Univariate	1.180	0.862	1.615	1.035	0.301	7.77
Ludman et al.	Multivariate	1.240	1.002	1.534	1.983	0.047	13.41
Mok et al.	Univariate	1.200	0.788	1.826	0.851	0.395	4.80
Piazza et al.	Univariate	0.652	0.303	1.403	-1.094	0.274	1.60
Pyxaras et al.	Multivariate	1.311	0.642	2.677	0.744	0.457	1.82
Schymik et al.	Multivariate	1.333	0.886	2.005	1.380	0.168	5.04
Seiffert et al.	Univariate	1.105	0.783	1.559	0.569	0.570	6.70
Sinning et al.	Univariate	0.768	0.220	2.682	-0.414	0.679	0.62
Stahli et al.	Univariate	1.290	0.649	2.565	0.726	0.468	1.96
Stortecky et al.	Univariate	1.364	0.766	2.426	1.055	0.291	2.72
Tamburino et al.	Multivariate	2.450	1.187	5.057	2.424	0.015	1.77
Zahn et al.	Univariate	1.250	0.953	1.640	1.611	0.107	9.65
Overall		1.142	1.035	1.261	2.633	0.008	

$I^2 = 14.01\%$

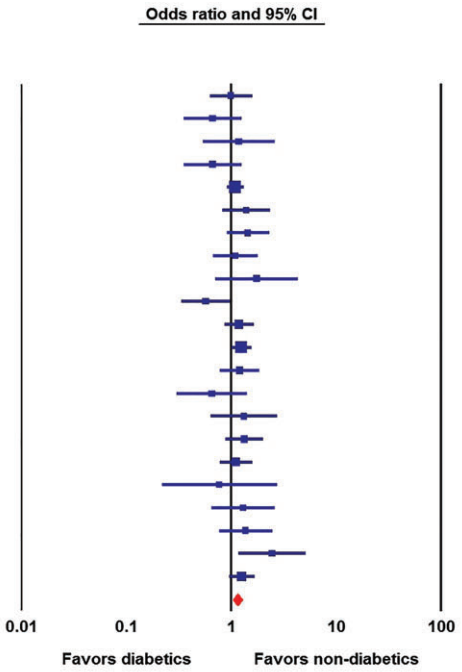

FIGURE 1 Forest plot showing that diabetes mellitus is associated with increased risk of 1-year mortality after transcatheter aortic valve replacement. Abbreviations: CI, confidence interval.

was no difference in major bleeding rates between diabetics and non-diabetics (OR: 1.03, 95% CI: 0.84-1.25, $P = 0.79$, heterogeneity $I^2 = 4.87\%$).

3.1.6 | Major vascular complications

This analysis was based on 6 studies with a total of 2447 patients (see Supporting Figure 4 in the online version of this article). DM had no significant impact on the occurrence of major vascular complications after TAVR (OR: 0.89, 95% CI: 0.65-1.22, $P = 0.47$, heterogeneity $I^2 = 0\%$).

Figure 5 illustrates the impact of DM on all studied outcomes. Sensitivity analysis was done by excluding 1 study at a time for each outcome, and there were no significant changes in the overall results. Visual inspection of funnel plots as well as Eggers test did not suggest any publication bias (see Supporting Figure 5 in the online version of this article).

Study Name	Analysis Type	Statistics for each study					
		Odds ratio	Lower limit	Upper limit	Z-Value	p-Value	Relative weight
Abramowitz et al.	Univariate	0.942	0.383	2.320	-0.129	0.897	2.37
Berkovitch et al.	Univariate	0.743	0.257	2.150	-0.547	0.584	1.75
Capodanno et al.	Multivariate	1.900	1.133	3.187	2.432	0.015	6.08
Conrotto et al.	Univariate	1.760	0.819	3.781	1.448	0.148	3.18
de Biasi et al.	Multivariate	0.810	0.459	1.428	-0.728	0.466	5.26
Halkin et al.	Univariate	1.006	0.541	1.872	0.020	0.984	4.54
Heinz et al.	Univariate	0.911	0.851	0.976	-2.666	0.008	24.72
Lauten et al.	Univariate	0.975	0.717	1.325	-0.162	0.872	12.09
Lindman et al.	Univariate	0.511	0.178	1.467	-1.248	0.212	1.78
Ludman et al.	Univariate	1.060	0.760	1.479	0.343	0.732	11.03
Lung et al.	Univariate	0.860	0.631	1.172	-0.955	0.340	11.98
Munoz-Garcia et al.	Univariate	1.016	0.638	1.617	0.066	0.947	7.13
Rodes-Cabau et al.	Univariate	0.630	0.252	1.574	-0.989	0.323	2.31
Stohr et al.	Univariate	0.459	0.129	1.641	-1.197	0.231	1.24
Tamburino et al.	Multivariate	2.660	1.256	5.633	2.556	0.011	3.29
Wenaweser et al.	Univariate	0.750	0.210	2.674	-0.443	0.657	1.25
Overall		0.999	0.864	1.156	-0.010	0.992	

$I^2 = 33.71\%$

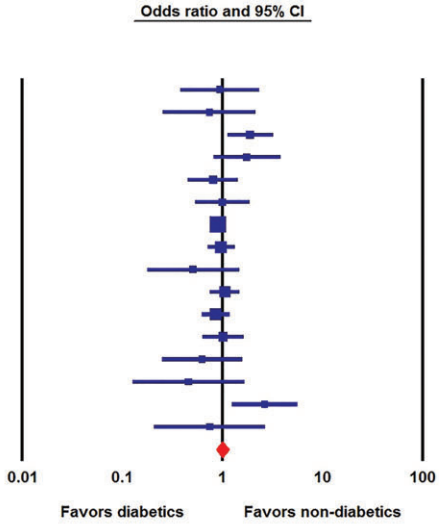

FIGURE 2 Forest plot showing that diabetes mellitus has no impact on early mortality after transcatheter aortic valve replacement. Abbreviations: CI, confidence interval.

Study Name	Analysis Type	Statistics for each study					
		Odds ratio	Lower limit	Upper limit	Z-Value	p-Value	Relative weight
Aalaei-Andabili et al.	Univariate	1.129	0.627	2.033	0.404	0.686	4.43
Abramowitz et al.	Univariate	1.355	0.439	4.185	0.529	0.597	1.78
Arai et al.	Multivariate	1.770	1.321	2.372	3.824	0.000	7.67
Aregger et al.	Univariate	2.571	0.670	9.866	1.377	0.169	1.32
Arsalan et al.	Univariate	1.418	0.930	2.164	1.622	0.105	6.09
Bagur et al.	Univariate	1.394	0.545	3.566	0.694	0.488	2.37
Barbanti et al.	Univariate	0.982	0.714	1.351	-0.111	0.912	7.34
Chatani et al.	Univariate	0.940	0.424	2.088	-0.151	0.880	3.02
Conrotto et al.	Univariate	1.137	0.718	1.800	0.546	0.585	5.67
Crowhurst et al.	Univariate	1.557	0.866	2.797	1.480	0.139	4.45
Elhmidi et al.	Multivariate	0.430	0.178	1.039	-1.876	0.061	2.61
Elmariah et al.	Univariate	1.533	0.346	6.794	0.563	0.574	1.10
Garcia-Lara et al.	Univariate	2.432	0.841	7.031	1.641	0.101	1.96
Goebel et al.	Univariate	1.662	0.825	3.351	1.421	0.155	3.59
Johansson et al.	Univariate	1.031	0.302	3.522	0.049	0.961	1.54
Khawaja et al.	Multivariate	3.170	1.665	6.034	3.513	0.000	3.99
Kong et al.	Univariate	7.556	1.574	36.267	2.527	0.012	1.00
Konigstein et al.	Univariate	1.262	0.735	2.167	0.845	0.398	4.86
Lindman et al.	Univariate	0.738	0.266	2.043	-0.585	0.558	2.09
Munoz-Garcia et al.	Univariate	0.546	0.297	1.003	-1.951	0.051	4.27
Nuis et al.	Univariate	0.978	0.693	1.380	-0.127	0.899	7.02
Saia et al.	Univariate	0.706	0.268	1.856	-0.706	0.480	2.27
Sinning et al.	Univariate	0.494	0.127	1.928	-1.015	0.310	1.29
Thongprayoon et al.	Univariate	1.520	0.968	2.386	1.820	0.069	5.77
van Rosendael et al.	Univariate	1.654	0.848	3.227	1.476	0.140	3.81
Vermi et al.	Univariate	1.056	0.162	6.873	0.057	0.955	0.72
Wessely et al.	Univariate	1.342	0.668	2.697	0.826	0.409	3.61
Yamamoto et al.	Univariate	1.680	0.923	3.059	1.697	0.090	4.34
Overall		1.275	1.080	1.504	2.873	0.004	

$I^2 = 42.51\%$

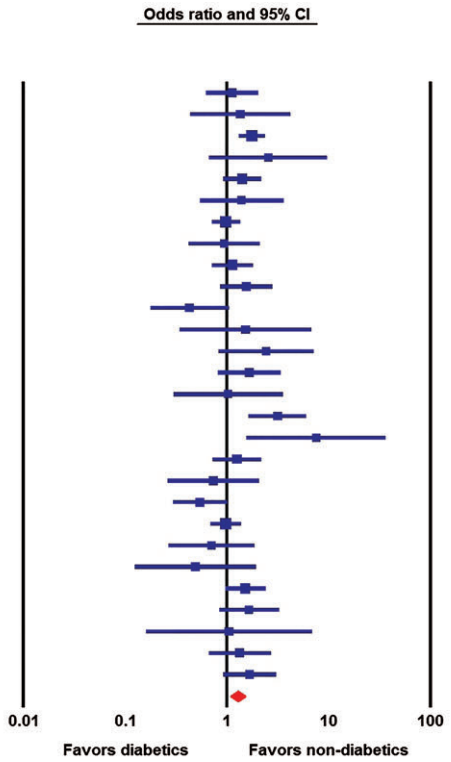

FIGURE 3 Forest plot showing that diabetes mellitus is associated with increased risk of acute kidney injury after transcatheter aortic valve replacement. Abbreviations: CI, confidence interval.

4 | DISCUSSION

The present study is a large meta-analysis evaluating the impact of DM on outcomes of patients undergoing TAVR. We included 64 studies with a total of 38 686 patients. The overall prevalence of DM was 29%. The main findings of our meta-analysis are (1) After TAVR, DM is associated with increased 1-year all-cause mortality. (2) Diabetic patients undergoing TAVR have higher risk of periprocedural AKI than nondiabetic patients. (3) After TAVR, DM has no impact on early mortality, CVA, major bleeding, or major vascular complications.

Currently, TAVR is a treatment modality for patients with severe aortic stenosis, especially those who are at prohibitive or high surgical risk.[16,17] A number of comorbid conditions have been associated with increased morbidity and mortality after TAVR.[18–21] However, there are contradicting data on the impact of DM on post-TAVR outcomes.

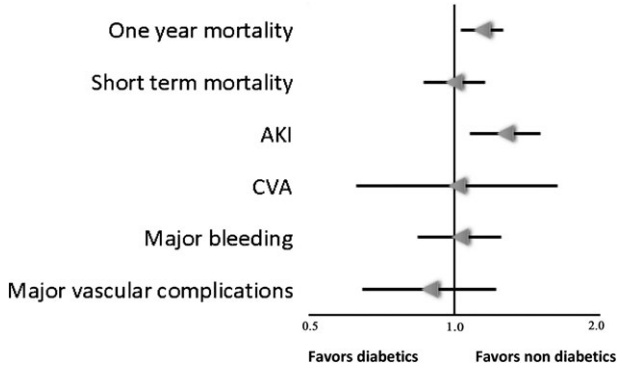

FIGURE 4 Forest plot showing impact of diabetes mellitus on all studied outcomes. Abbreviations: AKI, acute kidney injury; CVA, cerebrovascular accident.

Our meta-analysis showed that DM is associated with increased 1-year all-cause mortality after TAVR. In contrast to our findings, Lindman et al showed in a subgroup analysis of the PARTNER trial, that diabetic patients had lower mortality when compared to nondiabetics.[8] However, given that patients were not stratified based on DM status during randomization, Lindman et al suggested that differences in baseline characteristics between diabetics and nondiabetics might have confounded their results and led to this apparent diabetes paradox. In contrast, by multivariate analyses, Ludman et al and Tamburino et al showed that DM is associated with higher mortality after TAVR.[10,22] Our findings are in agreement with the latter studies' findings. However, given the retrospective nature of the studies included, a causality between DM and 1-year mortality following TAVR cannot be concluded based on the current study.

The present study also shows that diabetic patients have a higher risk of AKI after TAVR when compared to nondiabetics. AKI is a well-known complication after TAVR and has been attributed to multiple factors including contrast use, scraping of aortic atheromatous plaques leading to embolization, and transient hypotension episodes during the procedure.[23] Moreover, AKI development is an established predictor of increased short- and long-term mortality after TAVR.[23–27] Therefore, increased AKI rates after TAVR in diabetic patients can be partly contributing to the increased mortality seen in

those patients. A possible mechanism for increased long- term mortality in patients who develop AKI is progression to chronic kidney disease (CKD). However, CKD was not uniformly reported in the included studies, and hence, further studies are needed to test this hypothesis. Other short-term outcomes, including early mortality, CVA, major bleeding, and major vascular complications, were similar between diabetics and nondiabetics.

The results of the present meta-analysis are different from a meta-analysis conducted by Sun et al,[28] who showed that DM had no impact on any outcome after TAVR. However, Sun et al included 16 studies only, and therefore, our study is more comprehensive with a higher number of patients, which better reflects the impact of DM on different TAVR outcomes.

The role of insulin treatment on outcomes of diabetic patients undergoing TAVR have been evaluated by Abramowitz et al[9] and Conrotto et al,[29] who showed that only insulin-treated patients have an increased 2-year mortality after TAVR. Conversely, Berkovitch et al[30] showed that insulin treatment has no impact on mortality but is associated with higher tendency for AKI. However, the vast majority of studies included in our meta-analysis did not stratify patients based on insulin treatment.

Our meta-analysis shows that DM is a predictor of adverse outcomes after TAVR, and therefore, it should be included in risk stratifying patients prior to consideration for TAVR. Moreover, because DM is also a known predictor of poor outcomes after SAVR, randomized controlled trials are probably needed to evaluate the best treatment modality for diabetic patients with severe AS, especially those who are not at a prohibitive surgical risk.

A limitation of our meta-analysis is that it was based on nonrandomized data from retrospective or prospective studies. In addition, the majority of data collected were based on univariate analysis. Therefore, there might have been confounding factors that were not accounted for in our study, and accordingly, a definitive causal relationship between DM and poor outcomes after TAVR cannot be established based on the current study. Another limitation is that many of the included studies did not report all outcomes evaluated in our meta-analysis. A third limitation is the lack of data on the role of insulin treatment or hemoglobin A1C on outcomes evaluated in our meta-analysis. Hence, more studies are needed to evaluate the impact of insulin treatment and glycemic control on diabetic patients' outcomes.

5 | CONCLUSION

Our study suggests that diabetic patients have increased risk of 1-year mortality and periprocedural AKI after TAVR. Therefore, DM should be included in the process of risk stratification prior to consideration for TAVR.

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Conflicts of interest

The authors declare no potential conflicts of interest.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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