

ORIGINAL CONTRIBUTION

Alex Plus Versus Xience Drug-Eluting Stents for Percutaneous Coronary Intervention in Routine Clinical Practice: A Propensity Score-Matched Analysis

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Keywords

[Alex Plus Stent](#)
[Drug-Eluting Stent](#)
[Percutaneous Coronary Intervention](#)
[Xience](#)

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Abstract

Background. The next iteration of drug-eluting stents (DESs) for percutaneous coronary intervention (PCI) has focused on bioresorbable polymers and thin struts. The Alex Plus DES is a new-generation sirolimus-eluting device with 70 µm cobalt chromium struts, a 5 µm bioresorbable polymer and a very small profile. Despite such favorable features, limited data are available to estimate the risk-benefit profile of Alex Plus. We aimed at comparing the effectiveness of Alex Plus in real-world practice. **Methods.** Retrospective clinical data on patients treated with Alex Plus at our institutions were collected and clinical outcome data over follow-up were obtained, comparing them with those of subjects receiving Xience, a leading DES with permanent polymer. **Results.** A total of 100 patients (126 lesions) treated with Alex Plus and 753 subjects (1020 lesions) receiving Xience were included. Baseline and procedural features were largely similar in the 2 groups, with the notable exception of age, sex, and left circumflex coronary artery as the target vessel. Clinical follow-up showed that patients with Alex Plus had a significantly higher risk of major adverse clinical event (MACE), mainly driven by an excess in repeat PCI (hazard ratio, 4.81; 95% confidence interval, 2.83-8.20; *P*<.001). Even after propensity-score matching, Alex Plus was associated with an increased risk of MACE (*P*<.001). **Conclusions.** Our clinical experience to date with Alex Plus has been disappointing, despite the favorable promises. Further improvements are likely needed in the Alex Plus DES, most likely in drug delivery, before this device is considered for routine clinical use in complex patients or lesions.

Key words: Alex Plus stent, drug-eluting stent, percutaneous coronary intervention, Xience

The burden of cardiovascular disease continues to be substantial in terms of morbidity and mortality, even if ongoing developments have occurred in management strategies, including cardiovascular devices.¹ Indeed, despite recent refinements in drug-eluting stent (DES) devices for percutaneous coronary intervention (PCI) in patients with acute coronary syndromes (ACS) or stable ischemic heart disease (SIHD), there is still uncertainty regarding the best platform/drug-polymer combo.² In particular, thinner struts, open cells, -limus drugs and biodegradable polymers have been suggested as optimal ingredients for the best DES recipe, but it is also evident that selected and well-refined DES devices with permanent polymers (eg, Onyx zotarolimus-eluting stent [Medtronic] or Xience everolimus-eluting stent [Abbott Vascular]) can be very effective and safe, as demonstrated by many reports exploiting real-world datasets as well as randomized controlled trials.^{3,4}

Alex Plus (Balton) is a novel DES characterized by a very small profile (possibly the smallest at 0.034"), cobalt chromium platform, thin (70-µm) struts, sirolimus coating with release controlled by a biodegradable polymer coating (5 µm, lasting 2 months), and available in a large range of sizes (2.0-4.5 mm in diameter, 8-40 mm in length).⁵⁻⁸ Several reports have highlighted its potential role in PCI, with observational evidence suggesting that Alex Plus can be considered as safe and as effective as other workhorse DES devices with established risk-benefit profile.⁵⁻⁹ However, all such reports originated from a limited number of institutions and thus the external validity of their results is not conclusive yet.

Our institutional practice has been to use consistently few DES devices in a homogenous fashion, including workhorse devices such as Xience, and to follow treated patients systematically to adjudicate clinical events and ensure adherence to prescribed guideline-directed medical therapies. Recently, we have been using Alex Plus stents in most of our cases, ranging from ST-segment-elevation myocardial infarction (STEMI) to chronic coronary artery disease presenting as chronic total occlusions (CTOs), with apparently satisfactory results.

We thus aimed to compare the risk-benefit profile of Alex Plus vs Xience, considered to be the reference standard, in our 2-center routine clinical practice.

Methods

Study design. This was a retrospective, observational, comparative-effectiveness study conducted at 2 Italian tertiary cardiovascular-care centers, where the same interventional cardiology team (including nurses and technicians) operates, using the same cardiovascular devices and electronic health records. All patients provided written informed consent for data collection and analysis in anonymized form, and ethical approval was provided for the retrospective study. For the Alex Plus group, patients were included if PCI with Alex Plus had been attempted, without any other selection criterion. The decision to implant each DES was liberal and at the operator's discretion. For the Xience group, we relied on an established patient cohort whose details have been provided in the past.¹⁰

DES / Feature	Alex Plus (n=100)	Xience (n=753)	P value
Age (years)	68.1 ± 11.2	65.3 ± 12.1	.001
Male (%)	88	88	—
Female (%)	12	12	—
MI (%)	100	100	—
MI type (%)			
STEMI	100	100	—
NSTEMI	0	0	—
Unstable angina	0	0	—
Other	0	0	—
MI to PCI interval (days)	1.2 ± 0.8	1.1 ± 0.7	.85
MI to PCI interval (hours)	12.5 ± 15.2	11.8 ± 14.5	.85
MI to PCI interval (minutes)	100 ± 120	95 ± 115	.85
MI to PCI interval (seconds)	6000 ± 7000	5700 ± 6500	.85
MI to PCI interval (milliseconds)	360000 ± 420000	342000 ± 390000	.85
MI to PCI interval (microseconds)	21600000 ± 25200000	20520000 ± 23400000	.85
MI to PCI interval (nanoseconds)	1296000000 ± 1512000000	1231200000 ± 1404000000	.85
MI to PCI interval (picoseconds)	77760000000 ± 90720000000	73932000000 ± 81240000000	.85
MI to PCI interval (femtoseconds)	489600000000 ± 564000000000	461880000000 ± 507600000000	.85
MI to PCI interval (attoseconds)	29376000000000 ± 33840000000000	27711600000000 ± 29856000000000	.85
MI to PCI interval (zeptoseconds)	1762560000000000 ± 2030400000000000	1663296000000000 ± 1791360000000000	.85
MI to PCI interval (yoctoseconds)	109920000000000000 ± 127944000000000000	103968000000000000 ± 111432000000000000	.85
MI to PCI interval (rattoseconds)	6744000000000000000 ± 7934400000000000000	6372960000000000000 ± 6964560000000000000	.85
MI to PCI interval (s)	421500000000000000000 ± 495900000000000000000	398280000000000000000 ± 422784000000000000000	.85
MI to PCI interval (ms)	4215000000000000000000 ± 49590000000000000000000	39828000000000000000000 ± 42278400000000000000000	.85
MI to PCI interval (µs)	421500000000000000000000 ± 4959000000000000000000000	3982800000000000000000000 ± 4227840000000000000000000	.85
MI to PCI interval (ns)	42150000000000000000000000 ± 495900000000000000000000000	398280000000000000000000000 ± 422784000000000000000000000	.85
MI to PCI interval (ps)	4215000000000000000000000000 ± 49590000000000000000000000000	398280000000000000000000000000 ± 422784000000000000000000000000	.85
MI to PCI interval (fs)	421500000000000000000000000000 ± 4959000000000000000000000000000	39828000000000000000000000000000 ± 42278400000000000000000000000000	.85
MI to PCI interval (as)	42150000000000000000000000000000 ± 495900000000000000000000000000000	3982800000000000000000000000000000 ± 4227840000000000000000000000000000	.85
MI to PCI interval (zs)	4215000000000000000000000000000000 ± 49590000000000000000000000000000000	398280000000000000000000000000000000 ± 422784000000000000000000000000000000	.85
MI to PCI interval (ys)	421500000000000000000000000000000000 ± 4959000000000000000000000000000000000	39828000000000000000000000000000000000 ± 422784000000000000000000000000000000000	.85

Procedures and endpoints. Procedures were performed as per standard practice with default radial access. Direct stenting was performed whenever feasible, and postdilatation with non-compliant balloons was performed if postimplantation angiography disclosed a suboptimal result. Medical therapy included pretreatment or front-loading with aspirin and a P2Y₁₂ inhibitor, intravenous weight-adjusted heparin, and routine periprocedural intravenous glycoprotein IIb/IIIa inhibitors. Clinical follow-up was based on predischarge visit, and then periodic phone contacts followed by in-person visits. Endpoints of interest were death, myocardial infarction, repeat revascularization, the composite of death or myocardial infarction (DMI), and the composite of

Table 1. Baseline features.

TABLE 2. Procedural features.			
Characteristics	Alex Plus Stent	Xience Stent	P-Value
Patients (n)	100	753	—
Lesions (n)	126	1020	—
Diseased vessels	1.3 ± 0.5	1.3 ± 0.6	.40
Target vessel			
Left main	1 (0.8%)	24 (2.4%)	.52
Left anterior descending	51 (40.5%)	354 (34.7%)	.20
Left circumflex	21 (16.7%)	284 (27.8%)	<.01
Right coronary artery	53 (42.1%)	359 (35.2%)	.14
Total occlusion	14 (11.1%)	100 (9.8%)	.64
Stent per lesion	1.87 ± 0.31	1.80 ± 0.32	.82
Minimum stent diameter (mm)	2.77 ± 0.42	2.77 ± 0.48	>.99
Total stent length (mm)	29.34 ± 4.89	29.31 ± 5.01	.96
Hospital stay (days)	5.4 ± 3.1	3.4 ± 2.0	<.001
Antithrombotic therapy at discharge			<.001
Clopidogrel and novel oral anticoagulant	2 (2.0%)	5 (0.7%)	
Aspirin and clopidogrel	53 (53.0%)	593 (79.0%)	
Aspirin and prasugrel	1 (1.0%)	1 (0.4%)	
Aspirin and ticagrelor	44 (44.0%)	150 (20.1%)	

Data presented as mean ± standard deviation or number (%).

Table 2. Procedural features.

Table 2 content is identical to Table 1 above.

was more prevalent (27.0% vs 20.2%; $P < .001$), and left circumflex was more prevalent as the target vessel (16.7% vs 27.8%; $P < .01$).

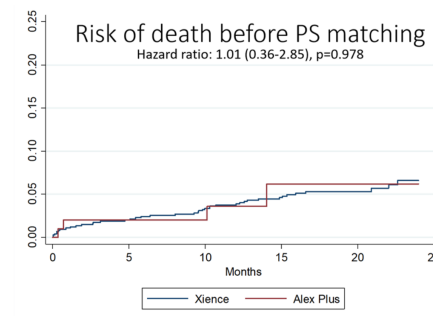


Figure 2. Failure analysis for all-cause death before propensity-score (PS) matching (hazard ratios >1 favor Xience, <1 favor Alex Plus).

TABLE 3. Clinical outcomes.			
Outcome	Alex Plus	Xience	P-Value
Patients (n)	100	753	—
Lesions (n)	126	1020	—
Follow-up (months)	12.3 ± 5.4	20.2 ± 8.0	<.001
Death			
1 month	2 (2.0%)	8 (1.1%)	.33
6 months	2 (2.0%)	18 (2.4%)	>.99
12 months	3 (3.0%)	29 (3.9%)	>.99
Cumulative	4 (4.0%)	46 (6.1%)	.50
Myocardial infarction			
1 month	2 (2.0%)	1 (0.1%)	.04
6 months	2 (2.0%)	2 (0.3%)	.07
12 months	2 (2.0%)	5 (0.7%)	.19
Cumulative	2 (2.0%)	7 (0.9%)	.28
Repeat revascularization			
1 month	1 (1.0%)	0 (0.0%)	.12
6 months	6 (6.0%)	1 (0.1%)	<.001
12 months	13 (13.0%)	4 (0.5%)	<.001
Cumulative	16 (16.0%)	7 (0.9%)	<.001
Surgical revascularization			
1 month	0 (0.0%)	0 (0.0%)	>.99
6 months	0 (0.0%)	0 (0.0%)	>.99
12 months	1 (1.0%)	1 (0.1%)	.22
Cumulative	1 (1.0%)	1 (0.1%)	.22
Definite stent thrombosis			
1 month	1 (1.0%)	0 (0.0%)	.12
6 months	1 (1.0%)	0 (0.0%)	.12
12 months	1 (1.0%)	0 (0.0%)	.12
Cumulative	1 (1.0%)	0 (0.0%)	.12
Major adverse cardiac events			
1 month	3 (3.0%)	8 (1.1%)	.13
6 months	8 (8.0%)	18 (2.4%)	<.01
12 months	15 (15.0%)	32 (4.3%)	<.001
Cumulative	20 (20.0%)	53 (7.0%)	<.001

Data presented as mean ± standard deviation or number (%).

Table 3. Clinical outcomes.

DES selection. The choice of DES for PCI remains a challenge. While evidently most available DES devices from leading vendors have achieved a remarkable safety and efficacy profile, some unmet challenges remain.^{11,12} First, some DESs have approved labels for 1-month dual-antiplatelet therapy only, but others do not.¹³⁻¹⁵ Moreover, optimal strut thickness continues to be questioned. In particular, small vessels may benefit from thinner-strut DES devices such as the Orsiro stent (Biotronik), but relatively thicker-strut DES options may be more appropriate in larger coronary vessels.¹⁶ Similarly, open cells are crucial for side-branch protection and access.¹⁷ Finally, the outstanding question rests on the purported superiority of bioresorbable polymers, given the underlying premise that durable/permanent polymers may lead to persistent smoldering inflammation and eventual late restenosis or atherothrombosis. Accordingly, Alex Plus theoretically seems to be a very appealing device, given its low profile, thin struts, bioresorbable polymer, and wide range of sizes. Yet, clinical evidence to date on this device is quite limited. In particular,

death, myocardial infarction, or repeat revascularization (major adverse cardiac event; MACE).

Statistical analysis. Continuous variables are reported as mean ± standard deviation, categorical variables as number (%), and censored variables according to Kaplan and Meier. For unadjusted analysis, continuous variables were compared with unpaired Student's *t* test, categorical variables with Fisher's exact test, and censored variables with Cox proportional hazard analysis. Propensity-score matching was performed to take into account potential confounders, with a 1:1 matching approach, specifying a 0.1 propensity-score caliper, without replacement. After propensity matching, we repeated the same hypothesis tests stated above (ie, unpaired Student's *t* test, Fisher's exact test, and Cox proportional hazard analysis). Statistical significance for hypothesis testing was set at the 2-tailed .05 level, without multiplicity adjustment. Computations were performed with Stata 13 (StataCorp).

Results

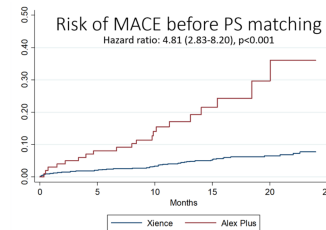


Figure 1. Failure analysis for major adverse cardiac events (MACE) before propensity-score (PS) matching (hazard ratios >1 favor Xience, <1 favor Alex Plus).

Baseline and procedural features. We included 100 patients (126 lesions) treated with Alex Plus between 2018 and 2019, comparing them with 753 subjects (1020 lesions) receiving Xience between 2015 and 2017. Baseline features are reported in Table 1. In particular, age was lower in the Alex Plus group (68.2 ± 11.7 years vs 70.6 ± 10.4 years; $P = .03$), female sex

Clinical follow-up. Follow-up reaching 12 months or more was available in all patients receiving Alex Plus and in 711 patients (94.4%) receiving Xience, with average durations of 12.3 ± 5.4 months vs 20.2 ± 8.0 months ($P < .001$) (Table 2). Clinical follow-up highlighted similar rates of death in the 2 groups (Table 1), with cumulative rates of all-cause death in 4 patients (4.0%) vs 46 patients (6.1%), respectively ($P = .50$). Notably, cardiac death occurred in 3 patients (3.0%) in the Alex Plus group, and 24 patients (3.2%) in the Xience group ($P > .99$). Myocardial infarction was infrequent in both groups, despite apparently higher rates with Alex Plus, especially in the short term. Revascularization was significantly more common with Alex Plus, with differences already reaching significance at 6 months, and maintained at 12 months as well as subsequently. Notably, MACE rates were also significantly different in the 2 groups, with a significantly higher risk of MACE in patients treated with Alex Plus at 6 months (8 [8.0%] vs 18 [2.4%]; $P < .01$), as well as at 12 months (15 [15.0%] vs 32 [4.3%]; $P < .001$) and cumulatively (20 [20.0%] vs 53 [7.0%]; $P < .001$). Survival analysis confirmed the significantly higher MACE rate with Alex Plus vs Xience (hazard ratio, 4.81; 95% confidence interval, 2.83-8.20; $P < .001$) (Figure 1), whereas mortality appeared similar in the 2 groups (hazard ratio, 1.01; 95% confidence interval, 0.36-2.85; $P = .98$) (Figure 2).

Propensity score-matched analysis. Propensity-score matching yielded a total of 180 cases for the patient-level analysis, and 206 cases for the lesion-level analysis (Table 4), with good overlap of propensity scores. Whereas rates of mortality, myocardial infarction, surgical revascularization, and stent thrombosis were similar in the Alex Plus and Xience groups, MACE rates in the propensity-matched groups were significantly higher with Alex Plus at 12 months (14 [15.6%] vs 3 [3.3%]; $P < .01$) and cumulatively (18 [20.0%] vs 7 [7.8%]; $P = .03$), mainly driven by differences in revascularization. Survival analysis confirmed the significantly increased risk of MACE with Alex Plus even after propensity-score matching (hazard ratio, 6.50; 95% confidence interval, 2.29-18.47; $P < .001$) (Figure 3), whereas the risk of death remained similar (Figure 4).

Discussion

The present retrospective, observational study, focusing on the short- and mid-term clinical performance of the new-generation Alex Plus DES, and exploiting a large cohort of patients receiving as comparator DES a device with established effectiveness (the Xience stent), has several implications. First, Alex Plus appears as a user-friendly device that can be used in real-world procedures. This holds even truer as our practice does not include adjunct devices such as atherectomy or intravascular lithotripsy. Second, in comparison with patients receiving Xience, albeit earlier on, subjects treated with Alex Plus had similar clinical and procedural features, despite younger age, higher prevalence of female sex, and treatment in the left circumflex. Third, however, mid-term follow-up showed that Alex Plus was associated with a significantly higher risk of repeat revascularization and, accordingly, higher MACE rate, with risk estimates suggesting a 4- to 5-fold higher risk in comparison with Xience. Accordingly, further studies are recommended in order to more precisely appraise the risk-benefit balance of Alex Plus in patients undergoing PCI. Ideally, results of a pivotal randomized controlled trial should be provided before any claims of clinical effectiveness are made for this new-generation DES.

Outcome	Alex Plus	Xience	P Value
Patients (n)	90	90	—
Losses (n)	200	200	—
Follow-up (months)	12.4 ± 5.4	21.1 ± 9.1	<.001
Death			
1 month	2 (2.2%)	0 (0.0%)	.50
6 months	2 (2.2%)	2 (2.2%)	>.99
12 months	3 (3.3%)	3 (3.3%)	>.99
Cardiac	1 (1.1%)	0 (0.0%)	.50
Myocardial infarction			
1 month	2 (2.2%)	0 (0.0%)	.50
6 months	2 (2.2%)	0 (0.0%)	.50
12 months	3 (3.3%)	0 (0.0%)	.50
Cardiac	2 (2.2%)	0 (0.0%)	.50
Repeat revascularization			
1 month	0 (0.0%)	0 (0.0%)	>.99
6 months	5 (5.6%)	0 (0.0%)	.26
12 months	10 (11.1%)	0 (0.0%)	<.01
Cardiac	9 (10.0%)	0 (0.0%)	<.01
Surgical revascularization			
1 month	0 (0.0%)	0 (0.0%)	>.99
6 months	0 (0.0%)	0 (0.0%)	>.99
12 months	1 (1.1%)	0 (0.0%)	>.99
Cardiac	1 (1.1%)	0 (0.0%)	>.99
Stent thrombosis			
1 month	1 (1.1%)	0 (0.0%)	>.99
6 months	1 (1.1%)	0 (0.0%)	>.99
12 months	1 (1.1%)	0 (0.0%)	>.99
Cardiac	1 (1.1%)	0 (0.0%)	>.99
Major adverse cardiac event			
1 month	3 (3.3%)	0 (0.0%)	.25
6 months	7 (7.8%)	2 (2.2%)	.27
12 months	14 (15.6%)	2 (2.2%)	<.01
Cardiac	14 (15.6%)	2 (2.2%)	<.01

Table 4. Clinical outcomes after propensity matching.

Buszman et al provided preliminary support to the favorable features of Alex Plus in a porcine study involving 17 animals, including detailed angiographic, optical coherence tomography, and pathologic analyses.⁸ Subsequent reports, including an observational study by Gąsior et al,⁹ also provided corroborating results. Indeed, this study included almost 2000 patients with acute coronary syndrome treated at 4 Polish centers, and provided risk-effect estimates before and after propensity-score matching when comparing Alex Plus vs Xience. Despite many baseline differences initially favoring Alex Plus (eg, prevalence of prior myocardial infarction), matching yielded groups with apparently similar features. Clinical events at 1 month, 6 months, and 12 months were similar in both groups, with 12-month estimates of 8.5% vs 8.5% for death ($P>.99$), 8.3% vs 8.0% for myocardial infarction ($P=.84$), and 7.1% vs 5.2% for revascularization ($P=.14$).

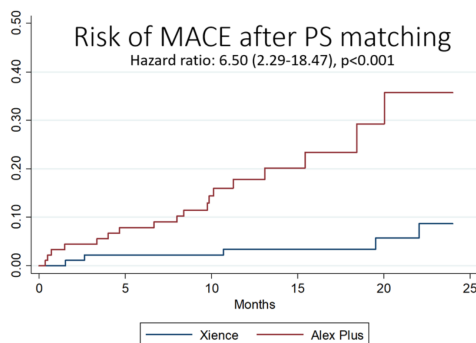


Figure 3. Failure analysis for major adverse cardiac event (MACE) rate after propensity-score (PS) matching (hazard ratios >1 favor Xience, <1 favor Alex Plus).

Alex Plus in clinical practice. Our present work, expanding the hitherto limited evidence base on Alex Plus, provides lukewarm results on this device. In particular, the increased risk of revascularization and MACE during follow-up may suggest that the elution kinetics are not perfectly tuned to inhibit neointimal hyperplasia, being possibly too fast, thereby resulting in an overall performance similar to bare-metal stents, rather than an actual DES. Of course, these findings are mainly hypothesis generating and

exploratory, especially in light of the apparent discrepancy with the study by Gąsior et al, and call for additional studies on this topic.⁹ In particular, upcoming pivotal randomized trials on Alex Plus should be able to provide accurate and precise effect estimates for safety, efficacy, and effectiveness of Alex Plus. In the meantime, we suggest a cautious approach to this device, thus leading to a limited and very selective use, whenever other DES options with more established safety and efficacy cannot be used.¹⁸

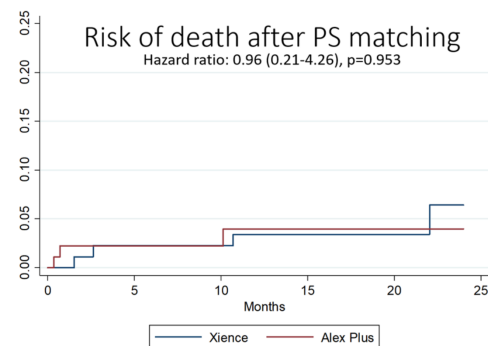


Figure 4. Failure analysis for all-cause death after propensity-score (PS) matching (hazard ratios >1 favor Xience, <1 favor Alex Plus).

Study limitations. This work has many drawbacks, which must be borne in mind when considering its results. First, it is a retrospective study exploiting a historically distinct cohort of patients. Second, device type and sizing, medical therapy, and subsequent management were all at operator's discretion.^{19,20} Third, no formal procedure for angiographic follow-up was enforced, thus inhibiting the computation of restenosis rates and ancillary detailed analyses. Finally, the sample of patients receiving Alex Plus was limited in size, leading to large confidence intervals for effect estimates at both unadjusted and adjusted analyses. As previously stated, further studies are thus needed to confirm or disprove the present findings.

Conclusion

Our clinical experience to date with Alex Plus has been disappointing, despite the favorable premises. Indeed, despite lower patient and lesion complexity, as well as shorter follow-up, Alex Plus proved significantly inferior to Xience. In particular, Alex Plus was associated with a significant increase in repeat revascularizations, as well as in MACE, defined as the composite of death, myocardial infarction, and revascularization. Further improvements in Alex Plus are likely needed, most likely in drug delivery, before this device is considered for routine clinical use in complex patients or lesions.

Affiliations and Disclosures

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