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Performance of the Pulmonary Embolism Rule-out Criteria (the PERC rule) combined with low clinical probability in high prevalence population ☆

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ABSTRACT

Introduction: PERC rule was created to rule out pulmonary embolism (PE) without further exams, with residual PE risk<2%. Its safety is currently not confirmed in high PE prevalence populations even when combined with low clinical probability assessed by revised Geneva score (RGS). As PERC rule and RGS are 2 similar explicit rules with many redundant criteria, we hypothesized that the combination of PERC rule with gestalt clinical probability could resolve this limitation.
Methods: We collected prospectively documented clinical gestalt assessments and retrospectively calculated PERC rules and RGS from a prospective study of PE suspected patients. We analyzed performance of combinations of negative PERC with low clinical probability assessed by both methods in high overall PE prevalence population.
Results: Among the final study population (n = 959), the overall PE prevalence was 29.8%. Seventy-four patients (7.7%) were classified as PERC negative and among them, 4 patients (5.4%) had final diagnosis of PE. When negative PERC was combined with low pretest probability assessed by RGS or gestalt assessment, PE prevalence was respectively 6.2% and 0%. This last combination reaches threshold target of 2% and unnecessary exams could easily have been avoided in this subgroup (6%). However, it confidence interval was still wide (0%; CI 0–5).
Conclusions: PERC rule combined with low gestalt probability seems to identify a group of patients for whom PE could easily be ruled out without additional test.
A larger study is needed to confirm this result and to ensure safety.

Introduction

Because its clinical signs and symptoms are nonspecific and very common, acute pulmonary embolism (PE) is a real diagnostic challenge for clinicians. The fear of missing a potentially mortal diagnosis, associated with the wide availability and relatively low cost of the D-dimer test, has resulted in increasing testing for PE. However, the poor specificity of the D-dimer test leads to an elevated rate of false positive results. This could involve an overall increase of further exams negative for PE, with potentially harmful consequences for patients (radiation exposure, contrast iodine injection…), cost-effectiveness imbalance and increased patient length of stay in overcrowded emergency departments (ED) [1,2]. Moreover, unnecessary exams may lead to incidental findings which not only cause anxiety among patients but also prompt serial follow-up imaging studies [3].

In order to decrease the number of unnecessary exams, Kline et al. [4] derived and validated a PE exclusion rule (the PERC rule) (Table 1). If all 8 criteria are negative, patients are identified as PERC negative (PERC (−)) and should not require further testing, even D-dimer, because the residual PE risk in this group is lower than equipoise. Equipoise represents the threshold where the probability that the patient will be harmed by further exams exceeds the probability that the patient will benefit from further testing [5]. This threshold was estimated by Kline et al. at 2% [4,6], a similar rate to the one of thromboembolic event recurrences after negative angiogram (1.7%; 95% confidence interval (CI) 1–2.7) [7]. The PERC rule was subsequently evaluated in several studies [6,8–12]. Concordant results were obtained by most of them [6,9–11] but results were not conclusive when the PERC rule was applied to European populations with high overall PE prevalence (more than 20%). Righini et al. applied the PERC rule alone and found 6.7% of false negatives, suggesting that the PERC rule should be used in combination with

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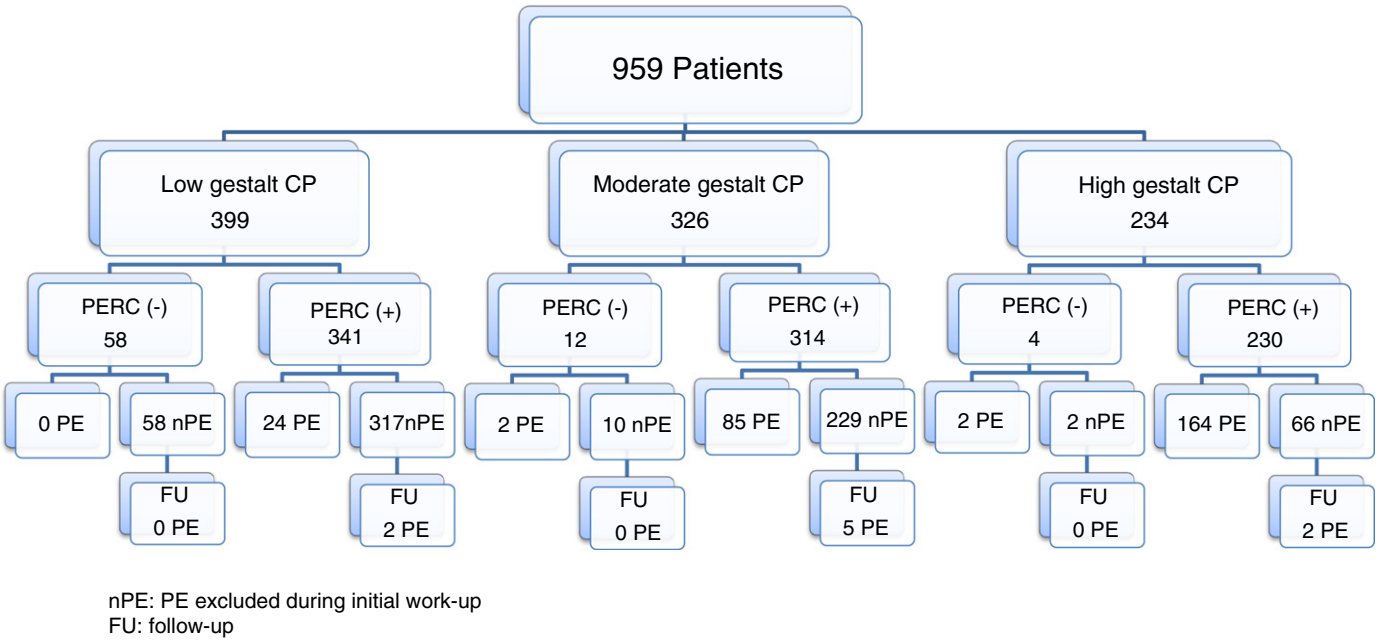

Fig. 1. Flow diagram for PE exclusion.

another clinical assessment rule in order to identify a very low risk PE population [8]. Hugli et al applied the PERC rule combined with low pretest probability using the revised Geneva score. In this selected population, they observed that prevalence of PE remained unacceptably high (6.4%) [12]. We hypothesized that this negative result may be due to the fact that the PERC rule and the revised Geneva score are two similar explicit rules with many redundant criteria, and that the combination of the PERC rule with an empirical assessment of clinical probability (clinician gestalt) could resolve this limitation. We therefore compared the PERC rule combined with low clinical probability assessed by the revised Geneva score or the clinician gestalt in a non-selected European population with high overall prevalence of PE.

Methods

We retrospectively analyzed a prospective cohort designed to measure the appropriateness of diagnostic criteria used in routine practice to rule in or rule out PE in 116 EDs in France and 1 in Belgium, which included 1529 consecutive patients suspected of PE [13]. Patients were managed by ED physicians; including (as in daily practice) young post-graduates having various levels of experience and confirmed emergency physicians. Physicians who examined the patients in the emergency department prospectively completed a standardized form to report patients' characteristics, diagnostic hypotheses, and prior to any diagnostic testing were invited to give their gestalt assessment of clinical probability of PE. This assessment was established as the answer to the question: "How do you estimate the pre-test clinical probability: low, moderate or high?". Physicians were free to manage patients as usual. How patients were handled as regards the exclusion or confirmation of PE was presented and discussed in the original study [13]. Patients, relatives or their general practitioner were interviewed at the end of a 3-month follow-up period about the possible occurrence of a venous thromboembolic event. Thromboembolic event was considered definite if the diagnosis was objectively documented according to accepted criteria [14,15]. Sudden deaths with no obvious cause were adjudicated as possibly related to PE. Patients were excluded if 1) the diagnosis of thromboembolic disease was documented before admission; 2) PE was suspected during a hospital stay of more than 2 days' duration; or 3) diagnostic testing was cancelled for ethical reasons, because of rapid death, or because the patient decided to leave the hospital against medical advice or declined testing.

Table 1
PERC rule.

Age < 50 years
Pulse < 100 bpm
Pulse oxymetry > 94%
No unilateral leg swelling
No hemoptysis
No surgery or trauma within 4 weeks
No prior deep vein thrombosis or pulmonary embolism
No oral hormone use

In the present study, we collected prospectively assessed clinical gestalt and retrospectively calculated the PERC rule and the revised Geneva score (RGS) by using the original data collection form. We analyzed the effectiveness of the combinations of PERC (−) with low clinical probability assessed by the revised Geneva score or the clinician gestalt. We considered as a final diagnosis of PE (and as a false negative of the exclusion rule): i) a PE diagnosis ruled in at the end of the initial diagnostic work-up; ii) a thromboembolic event (PE or deep vein thrombosis) occurring during follow-up among patients in whom the diagnosis of PE was initially ruled out or iii) death adjudicated as related or possibly related to PE.

We calculated 95% confidence interval (CI) by using the Mid-P exact value performed using OpenEpi, Version 2, Open source calculator–Proportion. All other statistical analyses were performed using SPSS 15.0 (SPSS Inc., Chicago, Il, USA). A chi2 test (for categorical variables) or Mann–Whitney *U*-test (for continuous variables) was used to compare characteristics between overall population and analyzed population. Characteristics for predicting PE (sensitivity, specificity, and negative predictive value) were calculated for PERC rule alone or combined with low clinical assessment (using revised Geneva score or gestalt).

Results

Over the total population (n = 1529), we excluded patients for whom the follow-up was not obtained (n = 55) and patients

Table 2
Baselines characteristics of population.

	Overall population N = 1529		Analyzed population N = 959		P value
	Data (missing/collected)	Mean or n (SD or %)*	Data (missing/collected)	Mean or n (SD or %)*	
Mean age, years	0/1529	64.2 (0.5)	0/959	63.9 (0.6)	0.72
Sex, female, (%)	0/1529	932 (61.0)	0/959	595 (62.0)	0.61
Mean heart rate, bmp	4/1425	91.2 (0.6)	0/959	91.4 (0.7)	0.90
Mean SBP, mmHg	46/1483	141.7 (0.7)	12/947	140.6 (0.8)	0.30
Mean DBP, mmHg	52/1472	78.8 (0.4)	16/943	78.9 (0.5)	0.84
Mean temperature, C°	128/1401	37.1 (0.02)	59/900	37.1 (0.003)	0.22
Mean respiratory rate, rpm	328/1201	22.1 (0.2)	167/792	22.2 (0.2)	0.66
Mean O2saturation, %	111/1418	94.0 (0.2)	0/959	93.7 (0.2)	0.43
Mean weight, kg	644/885	73.1 (0.5)	343/616	73.3 (0.6)	0.68
Chest pain, (%)	12/1517	863 (56.9)	6/953	552 (57.9)	0.64
Dyspnea, (%)	17/1512	1027 (67.9)	8/951	660 (69.4)	0.50
Syncope or dizziness, (%)	22/1507	332 (21.7)	10/949	228(24.0)	0.27
Hemoptysis, (%)	0/1529	77 (5.0)	0/959	52 (5.4)	0.74
Unilateral spontaneous calf pain, (%)	13/1516	266 (17.5)	3/956	157 (16.4)	0.50
Palpation pain and lower limb oedema, (%)	2/1527	204 (13.4)	0/959	122(12.7)	0.69
Chronic venous insufficiency, (%)	0/1529	207 (13.5)	0/959	131 (13.7)	0.98
Personal history VTE, (%)	0/1529	355 (23.2)	0/959	216 (22.5)	0.72
Familial history VTE, (%)	102/1427	119 (8.3)	58/901	80 (8.9)	0.71
Known congestive heart failure, (%)	15/1514	263 (17.4)	6/953	171 (17.9)	0.76
Chronic respiratory disease, (%)	0/1529	139 (9.1)	0/959	92 (9.6)	0.73
Stroke, (%)	9/1520	45 (2.9)	2/957	27 (2.8)	0.94
Cancer, (%)	0/1529	110 (7.2)	0/959	63(6.6)	0.60
Past surgery <1 month, (%)	0/1529	66 (4.3)	0/959	39 (4.1)	0.84
Fracture, (%)	0/1529	42 (2.7)	0/959	30 (3.1)	0.67
Travel, (%)	27/1502	52 (3.5)	12/947	34 (3.6)	0.95
Exogenous estrogen, (%)	0/1529	138 (9.0)	0/959	91 (9.5)	0.75
Current pregnancy, (%)	6/1523	13 (0.8)	1/958	6 (0.6)	0.69
Postpartum <4 weeks, (%)	7/1522	5 (0.3)	1/958	3 (0.3)	0.77
Current anticoagulant treatment, (%)	10/1519	109 (7.2)	2/957	60 (6.3)	0.43
Current anti-platelet treatment, (%)	31/1498	257 (17.2)	13/946	161 (16.8)	0.97
PE is the most likely diagnosis, (%)	2/1527	634 (41.5)	1/958	425 (44.3)	0.18
Final diagnosis of PE**	0/1529	443 (29.0)	0/959	286 (29.8)	0.68

*Mean and percentages are calculated on the collected data.
VTE: venous thromboembolism. SBP: systolic blood pressure. DBP: diastolic blood pressure.
**Final diagnosis of PE: PE during work-up, during follow-up and death related (or potentially related) to PE.

anticoagulated for an initial diagnosis of deep vein thrombosis without PE (n = 28). PERC, RGS and Gestalt assessments were available in 959 patients. Among this final study population, PE prevalence was 29.8%. Baseline characteristics of patients are presented in Table 2. Seventy-four patients (7.7%) were classified as PERC(−) and among them, 4 patients (5.4%) had a final diagnosis of PE. By using the revised Geneva score, 248 patients were classified as low, 621 as moderate and 90 as high probability. In each of these groups, PE prevalence was respectively 12.5%, 31.4% and 66.7%. By using the gestalt assessment, 399 patients were classified as low, 326 as moderate and 234 as high probability. In each of these groups, PE prevalence was respectively 6.5%, 28.2% and 71.8%. When PERC rule was combined with low pretest probability assessed by the revised Geneva score, the prevalence of PE was 6.2% (4/65). If we combined PERC (−) and low gestalt pretest probability, the condition was present in 58 patients (6% of the overall analyzed patients). None of them had a final diagnosis of PE (0%; CI: 0–5), resulting in 100% sensitivity and 100% negative predictive value for this combination. Table 3 shows the prevalence of PE and the performances of the rules in each of these cases. Figure 1 shows flow diagram for PE exclusion by using PERC(−) combined with gestalt clinical probability.

Discussion

We confirmed that the PERC rule alone or combined with low clinical probability assessed by using the RGS failed to identify a subgroup of patients with an acceptable risk of false negative rate (6.2%; CI:2–14.8) in a high PE prevalence population [8,12]. Conversely, our results showed that the combination of the PERC rule with low gestalt clinical probability could exclude the diagnosis of PE without recourse to any additional exams, with a false negative

Table 3
Performances of PERC- and combination of PERC- and low probability by using revised Geneva score or gestalt.

n	Overall PE prevalence % (95%CI)	Rule	N of patients meeting the rule (% overall)	FNR n (% ; 95%CI)	Sensibility % (95%CI)	Specificity % (95%CI)	LR- (95%CI)	NPV (95%CI)
959	29.8 (27.0-32.8)	PERC- alone	74 (7.7)	4 5.4(1.7-12.5)	98.6 (97.2-100)	10 (8–13)	0.13 (0.05-0.36)	94.6 (89.4-99.6)
959	29.8 (27.0-32.8)	PERC- with RGS low pretest probability	65 (6.7)	4 6.2 (2–14.8)	98.6 (97.2-100)	9 (7–11)	0.15 (0.06-0.42)	93.9 (88.0-98.9)
959	29.8 (27.0-32.8)	PERC- with low gestalt pretest probability	58 (6.0)	0 0 (0–5)	100 (99–100)	9 (6–11)	0 -	100 (95–100)

FNR: false negative rate.
LR-: negative likelihood ratio.
NPV: negative predictive value.
RGS: revised Geneva score.

rate of 0% (CI: 0-5%). This combination was present in 6% of the studied population.

Previous studies have shown that the PERC rule could safely be applied in low prevalence (<15%) populations (Table 4) [6,9–11]. Indeed, the PERC rule was derived and validated for low risk patients and is not designed to be used in patients in whom a negative D-dimer test will not allow exclusion of PE [6]. Both methods, clinical gestalt assessment and revised Geneva score, permit the definition of such sub-groups of patients [16,17]. However, when PERC (−) was combined with low RGS pretest probability in a population with high PE overall prevalence, the safety threshold target was not reached. In such a selected population, the prevalence of PE remained high: 6.4% in Hugli's study and 6.2% in our study. On the other hand, when PERC (−) was combined with low gestalt pretest probability , PE prevalence was 0%.

We supposed that the main reason for such discrepancy is the fact that the PERC rule and the RGS are based on the same explicit criteria (age, heart rate, leg swelling, hemoptysis, surgery or trauma, previous venous thromboembolism). Actually only the presence or not of a malignant condition in RGS completed the PERC rule, limiting the potential of the RGS to improve PERC performance. Conversely, when the clinical probability was assessed by gestalt judgment, the supplement of information appears much more comprehensive and not limited to a few objective criteria. That is in accordance with a previous work where we showed that the concordance between RGS and gestalt assessment was poor (kappa 0.21) i.e. the two rules do not identify not the same patients as having low PE probability [18]. Moreover, the prevalence of PE was higher in the low probability group assessed by the RGS than by the clinical gestalt assessment, respectively 12.5% and 6.5% and the proportion of patients classified as low probability was lower with RGS than with gestalt, 25.9% and 41.6%, respectively. These differences were statistically significant ($p = 0.01$) and suggests that gestalt assessment performed better in selecting low pretest probability patients.

In our high PE prevalence population, the combination of PERC (−) and low gestalt probability allowed us to determine a subgroup of patients among whom no further exams should have been necessary to rule out PE. However, the confidence interval is still wide (0%; CI 0–5) because of the modest number of patients selected by this combined tool and a larger study is needed to ensure safety.

Although this subgroup was a modest proportion (6% of the overall population), its determination could easily have contributed to avoid unnecessary exams and their adverse effects. Moreover, the proportion of concerned patients is probably higher in real life, since our study population did not include patients in whom a very low gestalt assessment was considered by the emergency physician as sufficient to excluding PE without asking for a D-dimer test. The PERC rule may be a useful tool to improve the relevance of this empirical decision and to limit the risk of undiagnosed PE [19] . Most of the time, these situations probably lead to further exams in the U.S. (due to fear of lawsuits) and may explain the good results obtained when PERC (−) was applied in North American. Of note, the PERC rule was initially proposed and evaluated for these patients with low gestalt probability for whom clinicians were in a rule out strategy [4].

Gestalt assessment has been criticized for its lack of standardization and the difficulty to teach it. However, several studies have confirmed the fair accuracy of gestalt assessment and clinical prediction rules do not yet appear to perform better [20–22]. Even though a majority of emergency clinicians declare they are familiar with a clinical decision rule for PE, only a minority of them use it frequently in daily practice, while the majority of emergency physicians indicate that they use gestalt assessment for suspected PE [23]. The specific work rhythm in ED with high patient turnover may explain this preference. Moreover, in another study Runyon et al. showed good accuracy for

Table 4
PERC validation studies.

Author	N of patients included	Overall PE Prevalence % (95%CI)	Rule tested	N of patients meeting the rule (% overall)	FNR % (95%CI)	Sensibility % (95%CI)	Specificity % (95%CI)	LR-(95%CI)	NPV (95%CI)
Kline et al 2004	1427	8 (6.6-9.5)	PERC- alone	362 (25)	1.4 (0.4-3.2)	96 (90–99)	27 (25–30)	0.16* (0.07-0.38)	98* (97–100)
	382	2.4 (1–4.4)	PERC- with another alternative diagnosis	57 (15)	0 (0–6)	100 (59–100)	15 (11–18)	-	100* (95–100)
Righini 2005	762	25.7 (23–29)	PERC- alone	89 (11.7)	6.7 (3–14)	97 (93–99)	15 (12–18)	0.2 (0.1-0.5)	93* (88–98)
Hogg 2005	425	5.3 (3.4-7.6)**	PERC- alone	216 (50.8)	1.39 (0.5-4)	86.4 (65.1-97.1)	53.9 (48.9-58.9)	0.25 (0.09-0.62)	98.6* (97.1-100)
Wolf et al 2007	134	12 (7.2-18.3)**	PERC- alone	19 (14)	0 (0-.14.6)*	100 (79–100)	16 (10–24)	-	100 (80–100)
	134	12 (7.2-18.3)**	PERC- with Wells low pretest probability	13 (9.7)	0 (0–20.6)*	100* (83–100)	11* (5–17)	-	100* (79–100)
Kline 2008	8138	6.9 (6.3-7.5)	PERC- alone	1952 (24)	1.3 (0.8-1.9)	95.7 (93.6-97.2)	25.4 (24.4-26.4)	0.17 (0.11-0.25)	98.7* (98.2-99.2)
	8138	6.9 (6.3-7.5)	PERC- with gestalt pretest probability <15%	1666 (20.5)	1 (0.6-1.6)	97.4 (95.8-98.5)	21.9 (21–22.9)	0.12 (0.07-0.19)	99* (98.6-99.5)
	8138	6.9 (6.3-7.5)	PERC- with another alternative diagnosis	1745 (21.4)	0.9 (0.5-1.5)	97.2* (95.8-98.5)	22.8* (21.9-23.8)	0.13* (0.08-0.20)	99.1* (98.6-99.5)
Dachs et al 2010	213	8.5 (5.2-13.2)	PERC- alone	48 (22.5)	0 (0–6.1)*	100 (78.1-100)	24.6 (18.9-31.4)	-	100 (90.8-100)
Hugli et al 2010	1675	21.3 (19.4-23.4)	PERC- alone	221 (13.2)	5.4 (3.1-9.3)	96.6 (94.2-98.1)	16 (14–17.9)	0.21* (0.12-0.37)	94.6 (90.8-96.9)
	1675	21.3 (19.4-23.4)	PERC- with RGS low pretest probability	188 (11.2)	6.4 (3.7-10.8)	96.6* (94.8-98.5)	13.4* (11.5-15.2)	0.25* (0.14-0.45)	93.6* (90.1-97.1)

*data calculated on the basis of the published data, considering the combination [PERC- and low probability] as one tool applied to the overall population.
**data calculated on the basis of the published data.
FNR: false negative rate LR-: negative likelihood ratio NPV: negative predictive value.
Wells: Wells score RGS: Revised Geneva score.

gestalt assessment independent of physician training level, with good interobserver agreement (kappa coefficient 0.60) [24].

In addition with the small number of patients with the negative combination, our study has some limitations. Firstly, it was a secondary analysis of a prospective study, which was not designed to evaluate the PERC rule. In the same way, RGS was retrospectively calculated. However, all the criteria needed were prospectively collected in a completed standardized form, allowing easy assessment of the PERC rule and the RGS. Moreover, our results were obtained from an unselected population issuing from a large number of emergency departments (117) and managed as in daily practice. Secondly, only 959 patients were analyzed due to the lack of information to calculate PERC rule or the unavailability of gestalt assessment. However the baseline characteristics of the overall population were statistically similar to the analyzed population (Table 2), decreasing the risk of a selection bias. Finally, 55 patients were excluded from analysis due to lack of 3 months follow-up. None of these patients had a final diagnosis of PE. We could not completely exclude the possibility of thromboembolic events or death related to PE during the follow-up period. However these patients were significantly younger and less sick than the analyzed population (data not shown), decreasing the risks of such a bias.

Conclusions

Our results confirm that the PERC rule can not be safely applied in high PE prevalence population even combined with low clinical probability assessed by revised Geneva score. However, the PERC rule combined with low gestalt probability seems to identify a group of patients in whom PE could easily be ruled out without any exams. Because of the potential of this combined tool in Emergency departments, a larger prospective study is needed to confirm this result.

Author contribution

Drs Penaloza and Roy had full access to all data study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and Design: Penaloza, Verschuren, Roy.

Acquisition of data: Verschuren, Roy.

Analysis and interpretation of data: Penaloza, Verschuren, Dambrine, Zech, Thys, Roy.

Drafting of the manuscript: Penaloza, Verschuren, Roy.

Critical revision of the manuscript for important intellectual content: Penaloza, Verschuren, Dambrine, Zech, Thys, Roy.

Statistical analysis: Penaloza, Zech, Vielle.

Study supervision: Penaloza, Verschuren, Dambrine, Zech, Thys, Roy.

Conflict of interest statement

None.

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