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**Full Title:** Television Viewing, physical activity and Venous Thromboembolism Risk: the REasons for Geographic and Racial Differences in Stroke (REGARDS) Study

**Short Title:** Television Viewing, physical activity and VTE

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**Conflict of Interest Statement**

All the authors listed above have no conflict of interests in the subject discussed in this manuscript including financial, intellectual, or otherwise.

**Essentials**

- Television (TV) viewing is a common form of inactivity
- TV viewing has previously been linked to venous thromboembolism (VTE) risk factors and increased VTE risk
- In this study, TV viewing wasn't associated with VTE risk accounting for VTE risk factors
- These data suggest TV viewing may not be a major contributor to VTE risk

**Abstract**

**Introduction**

Television (TV) viewing may be associated with increased venous thromboembolism (VTE) risk independent of VTE risk factors including physical activity. This association was assessed in a large biracial United States cohort of Black and White adults.

### **Methods**

Between 2003-2007 The REasons for Geographic and Racial Differences in Stroke (REGARDS) recruited 30,239 participants aged  $\geq 45$  years, who were surveyed for baseline TV viewing and followed for VTE events. TV viewing was categorized as  $< 2$  hours (light), 2 to 4 hours (moderate), and  $\geq 4$  hours (heavy) per day. Physical activity was classified as poor, intermediate, or ideal based on reported weekly activity. Hazard ratios of TV viewing and physical activity were calculated adjusting for VTE risk factors. Multiple imputation for missingness was used as a sensitivity analysis.

### **Results**

Over 96,813 person-years (median: 5.06 years) of follow up there were 214 VTE events. Heavy TV viewing was not associated with VTE risk in the unadjusted and fully adjusted model (aHR: 0.92 [95%CI: 0.62, 1.36]). Ideal physical activity trended towards a reduced VTE risk (HR: 0.71 [95%CI: 0.51, 1.01]). There was no evidence of an interaction between TV viewing, physical activity and risk of VTE.

### **Conclusions**

In this contemporary racially and geographically diverse United States cohort, there was no association between TV viewing and VTE risk, before and after accounting for physical activity. The high burden of traditional VTE risk factors in REGARDS may mask any association of TV viewing with VTE, or TV viewing may have only a modest association with VTE risk.

### **Keywords:**

Cardiovascular diseases, venous thromboembolism, television, physical activity, risk factors, epidemiology

## **Introduction**

Prolonged sedentary behavior is a risk factor for venous thromboembolism (VTE) [1-5] and TV viewing represents one of the most prevalent contributors to sedentary behavior worldwide [6]. Prior studies reported a positive association between time viewing TV and VTE risk factors including BMI at the population level [7]. Comparatively, physical activity reduces VTE risk, even after adjusting for BMI and other VTE risk factors [8]. To the best of our knowledge, TV viewing and VTE risk has only been evaluated in two studies. Both found a positive association between TV viewing and increased risk of VTE [2, 9], and in one study this association was partially moderated by BMI but not physical activity [9]. Because TV viewing and physical activity are potentially modifiable, further study in contemporary, and geographically and racially diverse populations is needed to further characterize a possible interaction between TV viewing and physical activity, and to inform research and public awareness campaigns.

We assessed the association of TV viewing with VTE risk accounting for physical activity and other VTE risk factors in the Reasons for Geographic and Racial Differences in Stroke Study (REGARDS). The REGARDS cohort is a contemporary sample of self-identified White and Black adults aged  $\geq 45$  years living in the contiguous United States and recruited in their homes. The goals of this analysis were to: 1) determine the association of TV viewing with incident VTE, and 2) assess whether the TV viewing-VTE relationship is confounded or modified by physical activity. We hypothesized that greater TV viewing would be associated with greater risk of VTE and that physical activity would attenuate the association between TV viewing and incident VTE.

## **Methods**

### **Population**

REGARDS cohort study recruited 30,239 Black and White participants from the contiguous United States between 2003-2007 [10]. REGARDS was designed to evaluate regional and racial differences in stroke and cognitive impairment in the United States. Participants were identified from a

commercially available list and initially sent a mailer introducing them to the goals of the study followed by a telephone interview. After verbal informed consent, a structured computer assisted telephone interview was performed to assess eligibility and willingness to participate as well as basic risk factor information. The telephone interview was followed by an in-person assessment which obtained written informed consent and included measurement of anthropomorphic variables and obtained fasting blood work (Examination Management Systems Inc, Irving, TX) using standard protocols [10]. The telephone response rate was 33% and overall cooperation rate was 45%, similar to other cohort studies including the Cardiovascular Health Study and Atherosclerosis Risk in Communities (ARIC) Study [11, 12]. At enrollment, participants were aged 45 years and older, 55% female, 42% Black, and 55% from the stroke belt states in the southeastern United States (Alabama, Arkansas, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee). We excluded participants with self-reported VTE prior to baseline, lack of baseline data, or lack of follow-up in REGARDS.

### **TV Viewing and covariates**

At the baseline in-home interview, the Block 98 Food Frequency Questionnaire (FFQ) survey was left with participants for self-administration with a stamped and addressed envelope. [13] The questionnaire included questions on TV viewing behavior with possible responses: “None”, “1-6 hours a week”, “1 hour a day”, “2 hours a day”, “3 hours a day”, or “4 or more hours a day”. Categories of TV viewing per day were defined and analyzed as <2 hours a day (light), 2-4 hours a day (moderate), and  $\geq 4$  hours a day (heavy), consistent with prior publications in REGARDS and elsewhere [2, 4, 6].

Physical activity was classified as the number of times in a typical week that participants reported activity sufficient to work up a sweat and was categorized by the American Heart Association Life’s Simple 7 criteria as poor (0 times), intermediate (1-3 times), and ideal (4 or more times). [14] Race was self-identified as ‘Black/African American’ or ‘White’. Region of residence was classified as either the “Southeast” and “Rest of Country”. “Southeast” included residents of Alabama, Arkansas, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee [15, 16]. Body mass index (BMI) was calculated as  $\text{kg/m}^2$  and coded as a categorical variable into underweight and normal weight (<25), overweight (25 to <30), and obese ( $\geq 30$ ). C-reactive protein (CRP) was measured using

a high-sensitivity immunonephelometric assay. Estimated glomerular filtration rate (eGFR) was calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation [17] as mL/min/1.73 m<sup>2</sup> and categorized as  $\geq 60$  mL/min/1.73 m<sup>2</sup>, 30-60 mL/min/1.73 m<sup>2</sup>, <30 mL/min/1.73 m<sup>2</sup>. Income information was self-reported as “less than \$20k”, “\$20k-\$34k”, “\$35k-\$74k”, “\$75k and above”, and “Missing/Refused”. Education was self-reported as “less than high school”, “high school graduate”, “some college”, “college graduate and above” and “Missing/Refused”.

### **Event ascertainment**

Methods for capturing VTE endpoints in REGARDS have been previously published [18]. Briefly, patients were contacted via telephone and asked about VTE events, reasons for hospitalization were reviewed to ascertain VTE events, and potential VTE events discovered during other endpoint review or death adjudication were assessed. All inpatient and outpatient medical records and imaging were retrieved spanning up to one year before and after the suspected event to further characterize the VTE event. Up to three attempts were made to retrieve records from hospitals, imaging centers, and primary care providers. Suspected events were initially reviewed by a research nurse and if deemed a non-event confirmed by a single physician (N.A.Z.). Potential VTE events were independently reviewed by 2 physicians. Major disagreements regarding the presence of a VTE event, or whether it was provoked or un-provoked were adjudicated by a third blinded physician. If all reviewers had significant disagreement, the three physician reviewers resolved the disagreements via telephone conference.

### **Statistical Analyses**

In individuals free of prior VTE at baseline, we used standard descriptive statistics to compare baseline characteristics by TV viewing habits (light, moderate, and heavy). Crude incidence rates were calculated as the sum VTE events divided by the person-years and 95% confidence intervals (CI) estimated using Poisson distribution. We used Cox proportional hazard models to calculate hazard ratios of incident VTE for moderate and heavy daily TV viewing, compared to light daily TV viewing, controlling for age, sex, race, region of residence, BMI, physical activity, eGFR, and CRP. Models were constructed by sequential addition of demographic risk factors and VTE risk factors. A

race-region interaction term was included in all models due to a known race-region interaction in REGARDS[19]. Type 2 tests for analysis of covariance were used to test for risk factor interaction. CRP was natural-log transformed due to known non-normal distribution[20]. Schoenfeld residuals were estimated to confirm that the proportional hazard assumption was not violated.

Sensitivity analysis was performed to account for all missing data by using multiple imputation with chained equations with 100 iterations to create 5 imputed datasets followed by pooled regression to calculate hazard ratios with 95% CI.

All analyses were performed using R version 3.4.4 (The R Project for Statistical Computing). We considered an alpha of 0.05 to indicate statistical significance. All participants provided informed consent, REGARDS and this study have Institutional Review Board Approval at all performance sites and conformed with the precepts of the Declaration of Helsinki.

## Results

Among the 30,239 participants, n=56 were missing consent forms and excluded from analyses. Additionally n=2,378 were excluded due to prior VTE at baseline or lack of follow-up in REGARDS, leaving 27,805 individuals. TV viewing data were missing in n=5,791 individuals, and n=1,692 were missing other covariates, leaving 20,322 individuals for the main analysis (complete case) and 27,805 for the sensitivity analysis using multiple imputation (**Figure 1**). Characteristics of those individuals with complete versus incomplete data are presented in **Supplementary Table 1**. Participants who answered the TV viewing survey had higher levels of education and income, were older (65.0 vs. 63.6 years), less commonly Black (35.5%, 7,215/20,322 vs. 60.9%, 3,524/5,791), less obese (36.0%, 7,325/20,322 vs. 43.6%, 2,525/5,791), and reported more ideal levels of physical activity (30.8%, 6,250/20,322 vs. 26.6%, 1,542/5,791).

Nearly half (49.5%, 10,059/20,322) of participants reported moderate daily TV viewing and 30.0% (6,100/20,322) reported heavy daily TV viewing. In comparison to light TV viewing, those who reported heavy TV viewing were slightly older (65.3 vs 63.7 years), more likely female than male (59.9%, 3,654/6,100 vs. 54.5%, 2,268/4,163) and more often self-identified as Black than White (50.3%, 3,069/6,100 vs. 30.1%, 1,251/4,163). Heavy TV watchers were also more obese (44.1%,

2,688/6,100 vs. 28.9%, 1,204/4,163) and reported lower levels of ideal physical activity (25.2%, 1,536/6,100 vs. 35.4%, 1,473/4,163).

The follow-up time and incidence of VTE by TV viewing category is presented in **Table 1**. Among the 20,322 participants there were 214 VTE events over 96,813 person years of follow-up. The overall median follow-up was 5.06 (IQR: 2.53) years, and this was similar across TV viewing levels. The crude VTE incident rate (IR) was 2.22 events per 1,000 person-years (95%CI: 1.93, 2.51), and this was similar among light (IR: 2.16 [95%CI: 1.57, 2.87]) and moderate TV watchers, (IR: 2.07 [95%CI: 1.69, 2.50]), and slightly higher in heavy TV watchers, (IR, 2.49 [95%CI: 1.96, 3.12]).

As shown in **Table 2**, in the complete case analysis in both the demographic adjusted (base) model and the final model adjusting for age, sex, race, region, physical activity, BMI, CRP, and eGFR, compared to light TV viewing there was no association between moderate (HR: 0.82 [95%CI: 0.57, 1.17]) or heavy (HR: 0.92 [95%CI: 0.62, 1.36]) daily TV viewing with VTE risk (p for trend=0.35). Ideal versus poor physical activity trended towards a reduced risk of VTE (HR: 0.71 [95%CI: 0.51,1.01]) in the fully adjusted (final) model.

In the fully adjusted model, when stratified by physical activity, there remained no association of TV viewing with VTE (p-interaction = 0.07). Among those with ideal physical activity, the HR for VTE for heavy versus light TV viewing was 0.48 (95%CI: 0.21, 1.09), and for moderate versus light TV viewing the HR was 0.81 (95%CI: 0.45, 1.48). These findings were similar after the sensitivity analysis using multiple imputation (**supplementary table 2**).

## Discussion

In the current analysis of the REGARDS cohort, almost a third of the cohort reported TV viewing  $\geq 4$  hours a day (heavy TV viewing), similar to estimates of TV viewing by United States adults [6]. At baseline, heavy TV viewers had higher baseline levels of VTE risk factors such as obesity, poor physical activity, and CRP. However, we found no association between reported hours of TV viewing and risk of incident VTE, and there was also no difference in association when stratified by physical activity level.

A null or weak association between TV viewing and VTE risk is generally supported by studies of occupational and travel-associated inactivity. A large longitudinal cohort found no association of exposure to occupational inactivity and VTE [21]. Two case-control studies reported weakly elevated odds ratios associated with inactivity for increased VTE risk among patients with high levels of VTE risk factors such as personal or family history of VTE, or recent surgery [22, 23], while two other case-control studies found that occupational-associated inactivity was not associated with an increased VTE risk [24, 25]. Among individuals with VTE risk factors, air travel over 10 hours confers slightly elevated risk of thrombosis [5, 26-28]. In sum, most prior studies of occupational and travel-associated inactivity would suggest that prolonged occupational inactivity, at best, is a weak risk factor for VTE.

Our findings of no association of TV viewing with VTE risk stand in contrast with two large prospective cohort studies, the Japanese Collaborative Cohort (JACC) and ARIC study [2, 9]. In JACC, each additional 2-hour increment of TV viewing increased the associated risk of mortality from PE (HR, 1.4 95%CI [1.0–1.8]), but an association between TV viewing and incident VTE was not presented [2]. In ARIC, there was an increased risk of VTE among participants who viewed TV “Very often” (HR, 1.53 95%CI [1.13–2.08]) [9]. Differences in participants among these 3 cohorts (JACC, ARIC, and REGARDS) may help explain the different findings of TV viewing and VTE risk. Participants in ARIC had a much lower burden of VTE risk factors at baseline than in REGARDS, with only 18.4% of ARIC participants obese compared to 36.3% in REGARDS. [29]. The higher burden of baseline VTE risk factors in REGARDS may attenuate the effect of TV viewing, which presumably is associated with a much smaller overall contribution to risk associated with VTE than traditional VTE risk factors such as age, sex, and BMI. Another major difference is that JACC and ARIC enrolled participants in the 1980s and 1990s when TV viewing behaviors were likely different when compared to the REGARDS enrollment period (2002-2007).

In the current analysis, a possible true association of TV viewing and VTE risk may have been statistically insignificant for several reasons. TV viewing was only assessed by survey at baseline, with the possibility of inaccurate classification or change in viewing habits over time. However, in REGARDS physical activity was also assessed at baseline and has been associated with other health outcomes, including incident atrial fibrillation [30] and stroke [31], suggesting physical activity is a

clinically meaningful risk factor and that our ascertainment of baseline exposures is valid. TV viewing behavior was ascertained in categories instead of as a continuous response, which may have reduced the power to detect differences. Additionally, the absolute number of VTE events in the sensitivity analysis was relatively low (n=267), despite a sample of 27,805 participants followed for a median of 5.05 years. However, the strengths of our analysis include a contemporary cohort, racially and geographically diverse participants, a vigorously validated VTE outcome, and a confirmatory sensitivity analysis using multiple imputation. Results argue that TV viewing behavior is not a strong risk factor for VTE.

### **Conclusion**

In this contemporary cohort, TV viewing was not associated with incident VTE without or after accounting for VTE risk factors and with no differential association by physical activity level. These findings are largely consistent with the literature that sedentary behavior contributes to a relatively minor increased VTE risk in the general population.

### **Authorship Addendum**

#### ***Listed in Order of Authorship with Significant Contributions:***

Jordan A. Munger, BS\*: Concept and design, analysis and interpretation of data, critical writing, revising intellectual content, and final approval

Insu Koh, PhD†: Concept and design, analysis of data, revising intellectual content, and final approval

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**Table 1: Baseline characteristics by categories of T.V. viewing duration**

	Light	Moderate	Heavy	Overall
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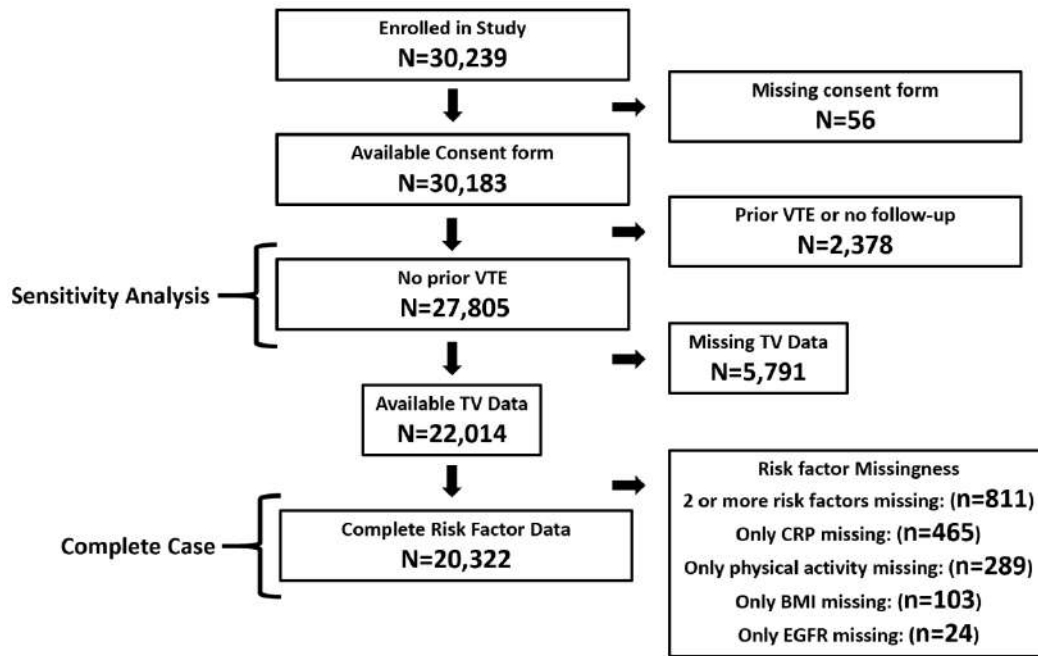
	(N=4163)	(N=10059)	(N=6100)	(N=20322)
<b>Age, mean (SD)</b>	63.7 (9.51)	65.3 (9.31)	65.3 (9.13)	65.0 (9.32)
<b>Female, n (%)</b>	2268 (54.5%)	5105 (50.8%)	3654 (59.9%)	11027 (54.3%)
<b>Black, n (%)</b>	1251 (30.1%)	2895 (28.8%)	3069 (50.3%)	7215 (35.5%)
<b>Southeast Region, n (%)</b>	2302 (55.3%)	3428 (56.2%)	5713 (56.8%)	11443 (56.3%)
<b>Body Mass Index (kg/m<sup>2</sup>), n (%)</b>				
<b>Normal/Underweight (&lt;25)</b>	1391 (33.4%)	2556 (25.4%)	1317 (21.6%)	5264 (25.9%)
<b>Overweight (25 to &lt;30)</b>	1568 (37.7%)	4070 (40.5%)	2095 (34.3%)	7733 (38.1%)
<b>Obese (≥30)</b>	1204 (28.9%)	3433 (34.1%)	2688 (44.1%)	7325 (36.0%)
<b>Physical Activity, n (%)</b>				
<b>Poor</b>	1069 (25.7%)	2893 (28.8%)	2583 (42.3%)	6545 (32.2%)
<b>Intermediate</b>	1621 (38.9%)	3925 (39.0%)	1981 (32.5%)	7527 (37.0%)
<b>Ideal</b>	1473 (35.4%)	3241 (32.2%)	1536 (25.2%)	6250 (30.8%)
<b>InCrp (mg/L), mean (SD)</b>	0.56 (1.18)	0.70 (1.15)	0.99 (1.18)	0.76 (1.17)
<b>eGFR (mL/min/1.73 m<sup>2</sup>), n (%)</b>				
<b>≥60</b>	3825 (91.9%)	5297 (86.8%)	9041 (89.9%)	18163 (89.4%)
<b>≥30 to &lt;60</b>	309 (7.4%)	713 (11.7%)	929 (9.2%)	1951 (9.6%)
<b>&lt;30</b>	29 (0.7%)	89 (0.9%)	90 (1.5%)	208 (1.0%)
<b>VTE Events, n</b>	43 (1.0%)	100 (1.0%)	71 (1.2%)	214 (1.1%)
<b>Person-Years</b>				
<b>Median (IQR)</b>	5.06 (2.52)	5.06 (2.51)	5.05 (2.53)	5.06 (2.53)
<b>Sum</b>	19,952	483,634	28,497	96,813
<b>VTE Incident Rate per 1,000 (95%CI)</b>	2.16 (1.57, 2.87)	2.07 (1.69, 2.50)	2.49 (1.96, 3.12)	2.22 (1.93, 2.51)

Physical activity was classified as the number of times in a typical week that participants reported activity sufficient to work up a sweat and was categorized by the American Heart Association Simple 7 criteria as poor (0 times), intermediate (1-3 times), and ideal (4 or more times).

**Table 2: Hazard Ratios of Main and Sensitivity Analyses**

	<b>Complete Case</b>		<b>Sensitivity (Multiple Imputation)</b>	
	<b>Base Model</b>	<b>Final Model</b>	<b>Base Model</b>	<b>Final Model</b>

	HR (95% CI)	HR (95% CI)	HR (95% CI)	HR (95% CI)
<b>TV Viewing</b>				
<b>Light</b>	ref	ref	ref	ref
<b>Moderate</b>	0.89 (0.62, 1.28)	0.82 (0.57, 1.17)	0.95 (0.67, 1.33)	0.88 (0.62, 1.23)
<b>Heavy</b>	1.13 (0.77, 1.65)	0.92 (0.62, 1.36)	1.19 (0.82, 1.72)	0.99 (0.68, 1.45)
<b>Age, per 10 years</b>	1.55 (1.34, 1.80)	1.58 (1.34, 1.85)	1.55 (1.36, 1.77)	1.60 (1.39, 1.85)
<b>Male Sex</b>	1.35 (1.02, 1.78)	1.53 (1.15, 2.04)	1.46 (1.14, 1.87)	1.66 (1.28, 2.14)
<b>Race-Region Interaction</b>				
<b>Black race in Southeast vs. rest of country (ref)</b>	1.51 (0.94, 2.42)	1.47 (0.92, 2.37)	1.49 (1.00, 2.2)	1.46 (0.98, 2.16)
<b>White race in Southeast vs. rest of country (ref)</b>	0.82 (0.59, 1.14)	0.82 (0.59, 1.13)	0.83 (0.61, 1.13)	0.83 (0.62, 1.13)
<b>Physical Activity</b>				
<b>Poor</b>	ref	ref	ref	ref
<b>Intermediate</b>	-	0.73 (0.53, 1.01)	-	0.79 (0.59, 1.05)
<b>Ideal</b>	-	0.71 (0.51, 1.01)	-	0.72 (0.53, 0.99)
<b>Body Mass Index (kg/m<sup>2</sup>)</b>				
<b>Normal/Underweight (&lt;25)</b>	ref	ref	ref	ref
<b>Overweight (25-29.9)</b>	-	1.53 (1.03, 2.28)	-	1.41 (0.98, 2.03)
<b>Obese (≥30)</b>	-	2.05 (1.36, 3.07)	-	1.97 (1.36, 2.85)
<b>Ln C-Reactive Protein/SD (mg/L)</b>	-	1.28 (1.11, 1.48)	-	1.25 (1.09, 1.43)
<b>eGFR (ml/min/1.73 m<sup>2</sup>)</b>				
<b>≥60</b>	ref	ref	ref	ref
<b>30 to &lt;60</b>	-	1.23 (0.83, 1.81)	-	1.08 (0.73, 1.58)
<b>&lt;30</b>	-	2.04 (0.83, 5.02)	-	2.06 (0.95, 4.46)



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