“When can I drive again?”: Crash risks in the first few months after ICD implantation

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Objectives

- Describe our studies on crash risks in the first few months after ICD implantation
- Consider several study designs that can be used to study cardiac incapacitation and crash risk

I acknowledge with gratitude that I live and work on the traditional and unceded territories of the xʷməθkʷəy̓əm (Musqueam), Skwxwú7mesh Úxwumixw (Squamish), and səl̓ílwətaʔɬ (Tsleil-Waututh) First Nations.

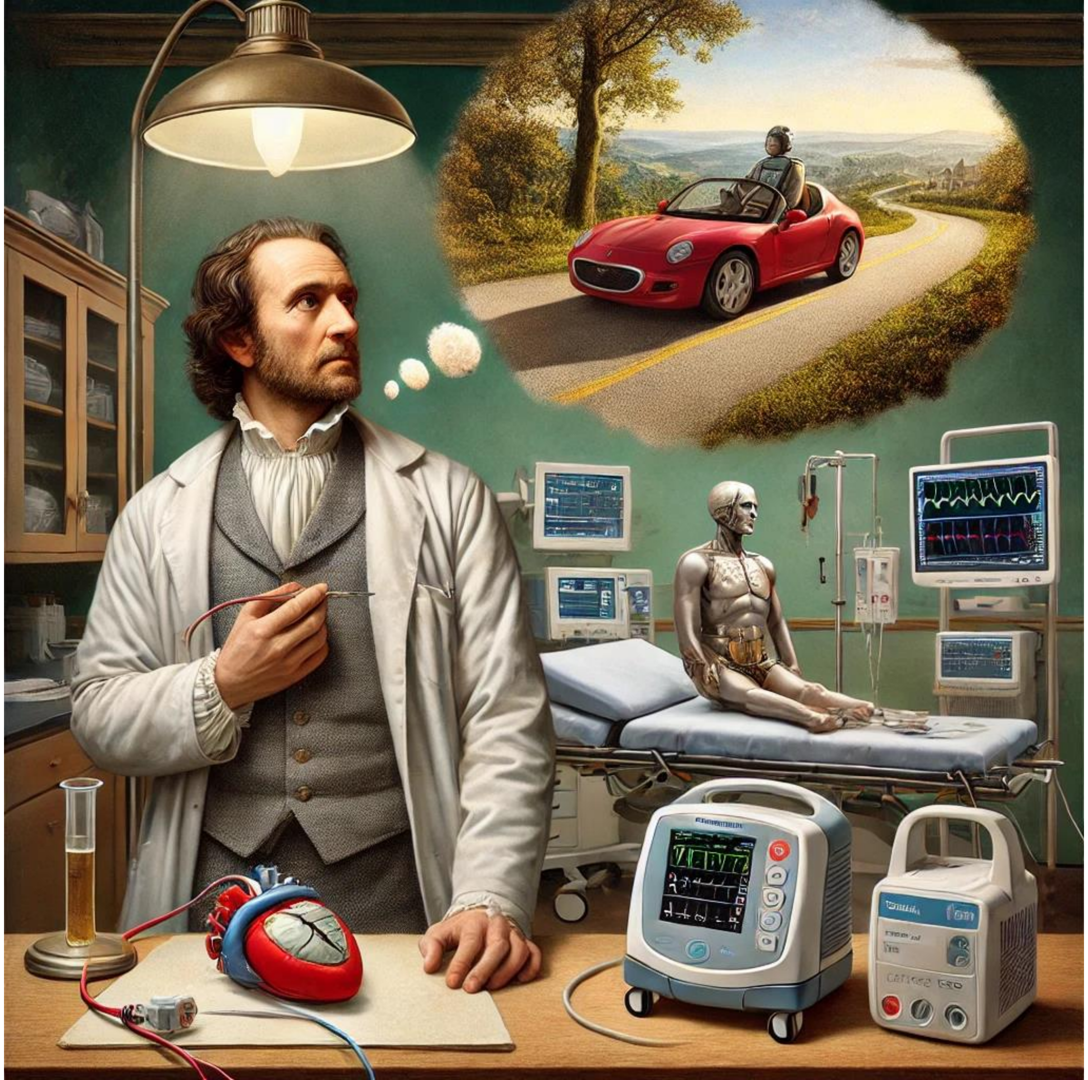
Conflicts of interest

- None

Disclaimer

- All inferences, opinions, and conclusions drawn in this presentation are those of the authors, and do not reflect the opinions or policies of the Data Stewards or funders of the cited research.

Background



Dall-E 2024

JOURNAL OF FORENSIC SCIENCES

Case History

In February 2018, just before 8:00 a.m., in good weather, on a straight stretch of a two lane road, an accident took place during which the driver of an SUV drifted onto the opposite lane and crashed into a lorry (front/side impact). As a result, the 69-year-old male driver of the SUV died on the spot.

The lorry driver participating in the accident reported that when several dozen meters away, the SUV approaching from the opposite direction started to gently and steadily drift to the opposite lane toward the lorry in a swerving movement. The witness reported that it looked as if the driver "had fallen asleep at the wheel."

Discussion

On the basis of the analysis of the victim's entire documentation, including his medical files, documentation from the scene of the accident and intracardiac records from the ICD explanted during the autopsy, it was established that immediately before the accident, the driver of the SUV suffered from ventricular fibrillation (VF), which resulted in his fainting, loss of control of the car, and, in consequence, a road traffic accident, and the driver's death.

VF, VT and shocks might be more common in the first few months after ICD implantation.

Kaliszan J Forensic Sci 2019

Driving restrictions after ICD implantation

Procedure	Canada (pre 2023)	USA	Europe
ICD, primary prevention	1 month (post 2023: 1 week)	≥1 week	1 month
ICD, secondary prevention (no impaired LoC)	≥1 week; 1 month from VT if LVEF≧30; 3 months from VT if LVEF<30. (post 2023: 1 week)	6 months	3 months
ICD, secondary prevention (impaired LoC)	6 months after last episode of sustained symptomatic VT or syncope likely due to VT or cardiac arrest. (post 2023: 3 months)	6 months	3 months

Guerra Can J Cardiol 2024

Driving restrictions are burdensome

- “Patients and their spouses stated that the imposed driving ban was the hardest part of having the ICD implant.”
- Threatens employment
- Reduces social activity
- Reduces QoL
- Associated with depression

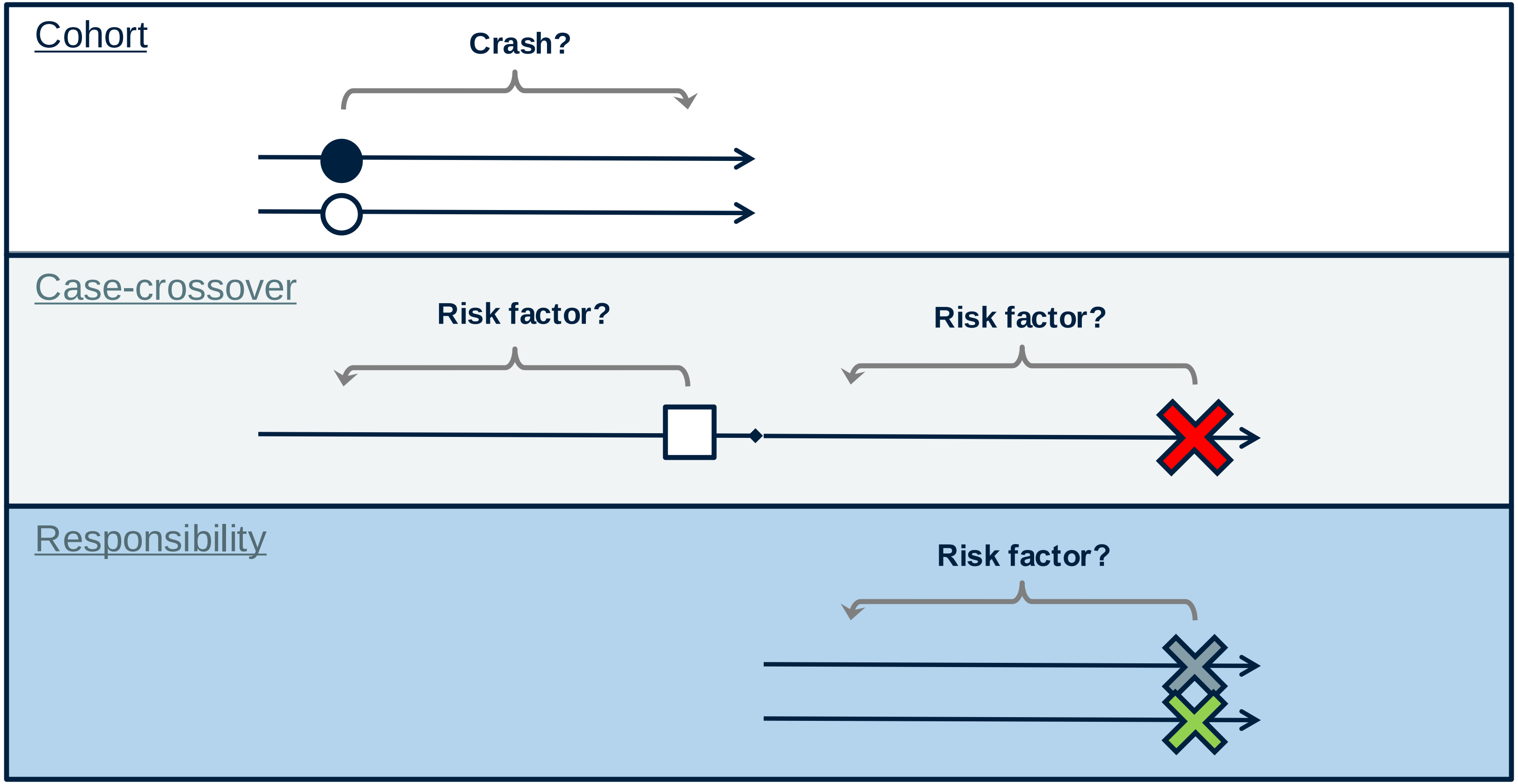
Task force members EuroPace 2009

Driving restrictions are based on limited evidence

- Few studies
- Vast majority have no controls
- Underpowered
- Self-reporting of driving and crashes
- Extrapolation from baseline risks
- Rely on theoretical calculations
- Underrepresentation of marginalized groups

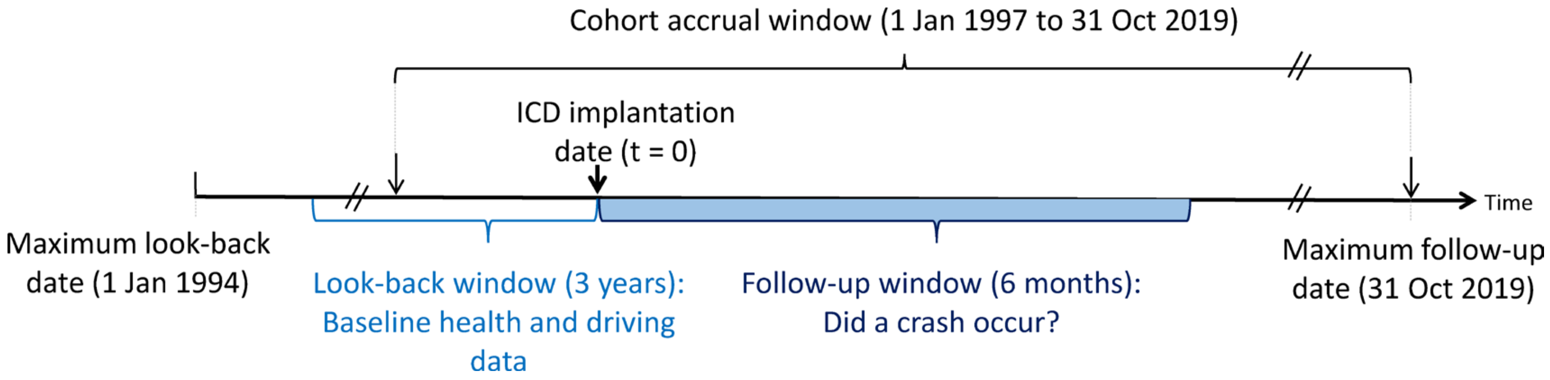
New evidence

Study designs



Cohort study

- 9373 drivers with a first ICD implantation between 1997 and 2019 (22 years)
- 28,119 age- and sex-matched controls (3:1 matching)
- Primary outcome: Involvement as a driver in a crash in the first 6 months after ICD implantation that was attended by police or resulted in an insurance claim
- Right censoring (e.g. death, license expiry)



Staples Heart 2024

Table 1 Baseline characteristics (selected variables only)

Description	Individuals with ICD implantation, count (%) n=9373	Controls, count (%) n=28 119	P value	Effect size
Demographics				
Female sex	1808 (19.3)	5424 (19.3)	1.00	<0.01
Median age (Q1, Q3), years	66 (56, 73)	66 (56, 73)	0.98	<0.01
Comorbidities				
Myocardial infarction	3227 (34.4)	547 (1.9)	<0.001	0.47
Congestive heart failure	7096 (75.7)	939 (3.3)	<0.001	0.76
Renal disease	1304 (13.9)	774 (2.8)	<0.001	0.21
Syncope	1076 (11.5)	237 (0.8)	<0.001	0.25
Alcohol misuse	387 (4.1)	379 (1.3)	<0.001	0.09
LVEF				
<35%	1519 (16.2)	–	–	
≥35%	1044 (11.1)	–	–	
Missing	6810 (72.7)	28 119 (100)	–	
Active prescriptions at baseline				
Loop diuretics	2910 (31)	607 (2.2)	<0.001	0.43
ACEi or ARB	5301 (56.6)	6167 (21.9)	<0.001	0.33
MRA	2320 (24.8)	221 (0.8)	<0.001	0.41
Beta blockers	5334 (56.9)	2917 (10.4)	<0.001	0.49
Active licence	7924 (84.5)	22 690 (80.7)	<0.001	0.04
Active insurance policy	6772 (72.3)	19 285 (68.6)	<0.001	0.03
≥1 crash in the past 3 years	2344 (25)	5688 (20.2)	<0.001	0.05
Any contravention	696 (18.1)	4406 (15.7)	<0.001	0.03

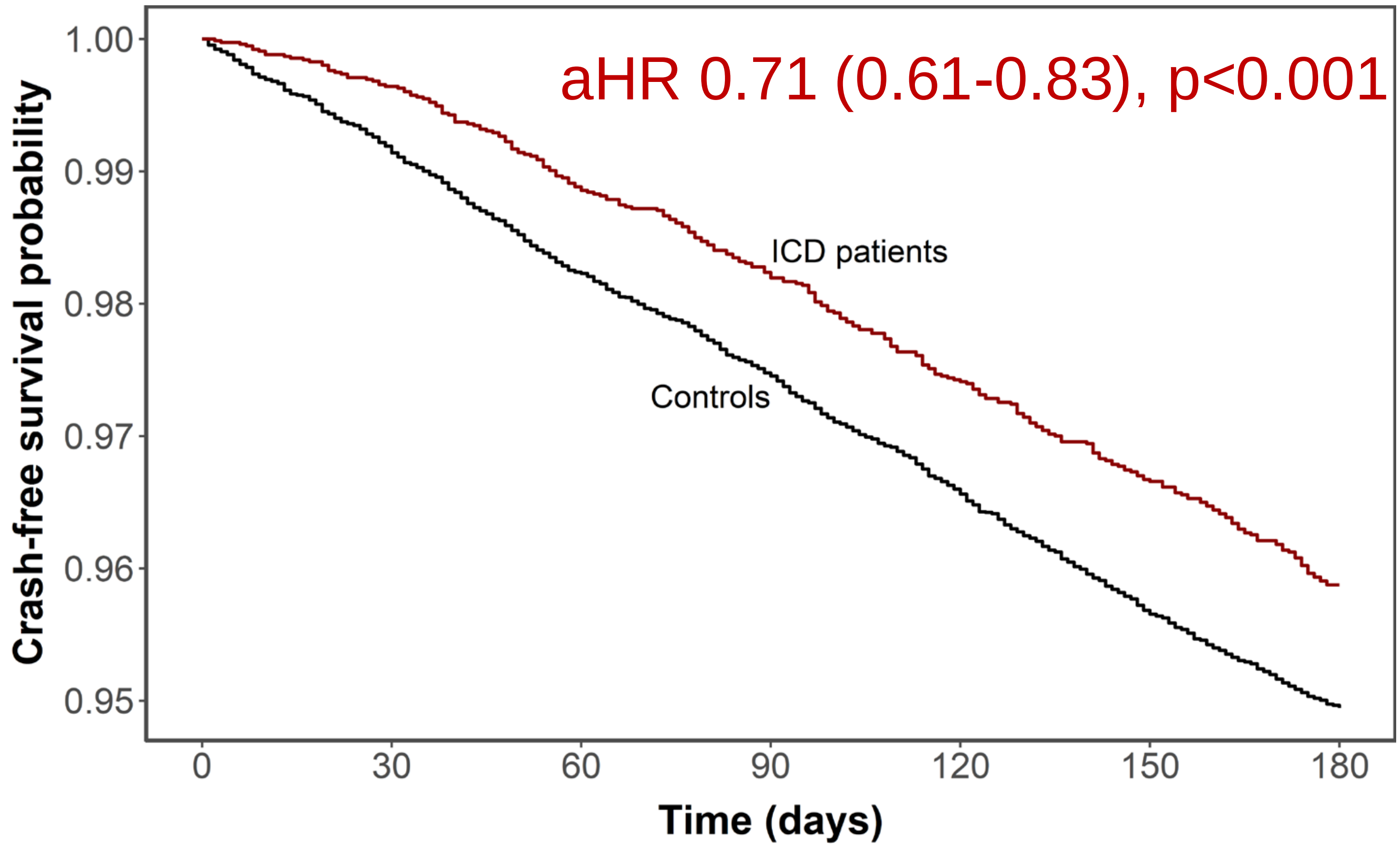
Indication:

1^{o} prevention: 39%

2^{o} prevention: 36%

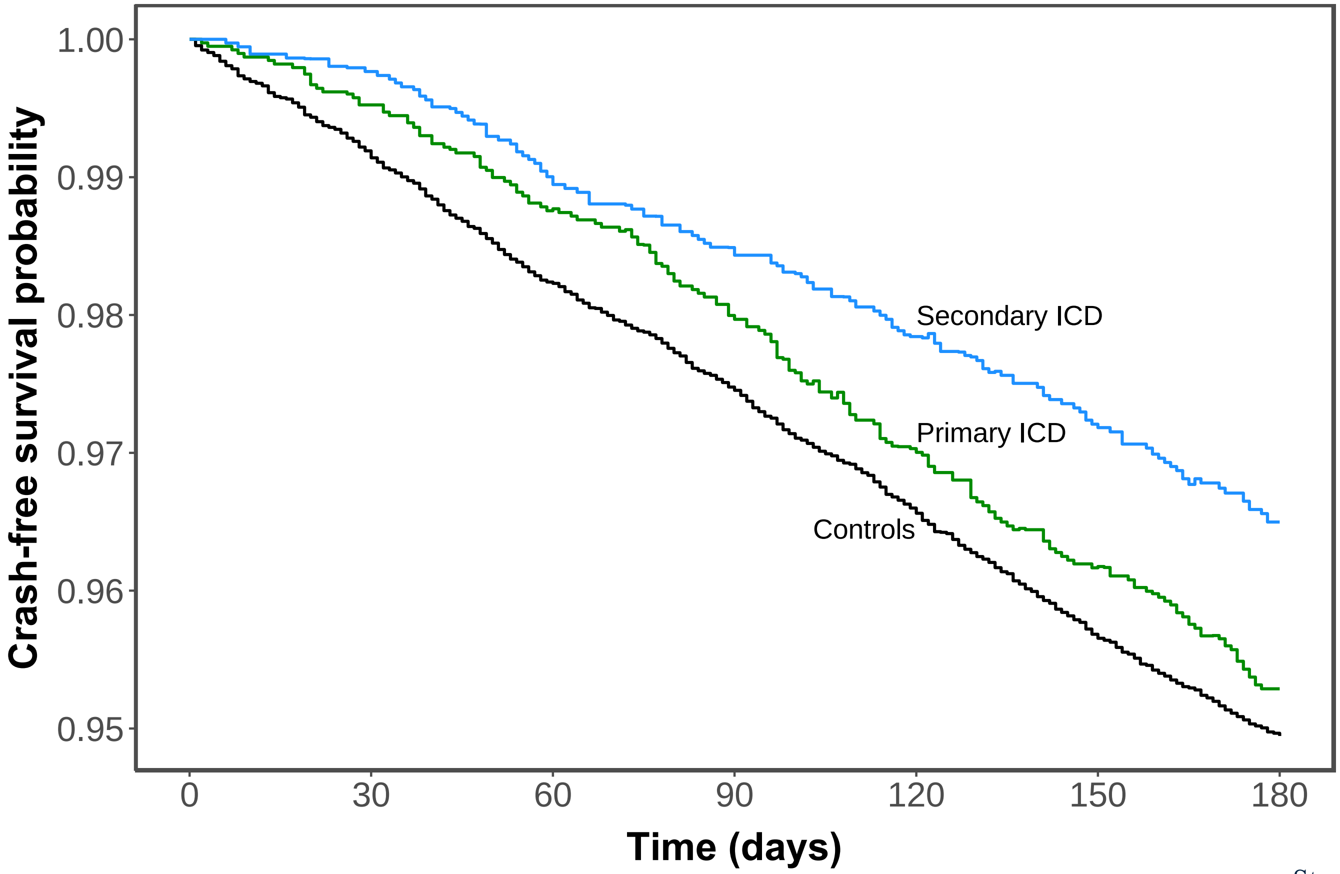
Unknown: 26% → imputed using validated algorithm

Staples Heart 2024; Robinson Can J Cardiol 2024

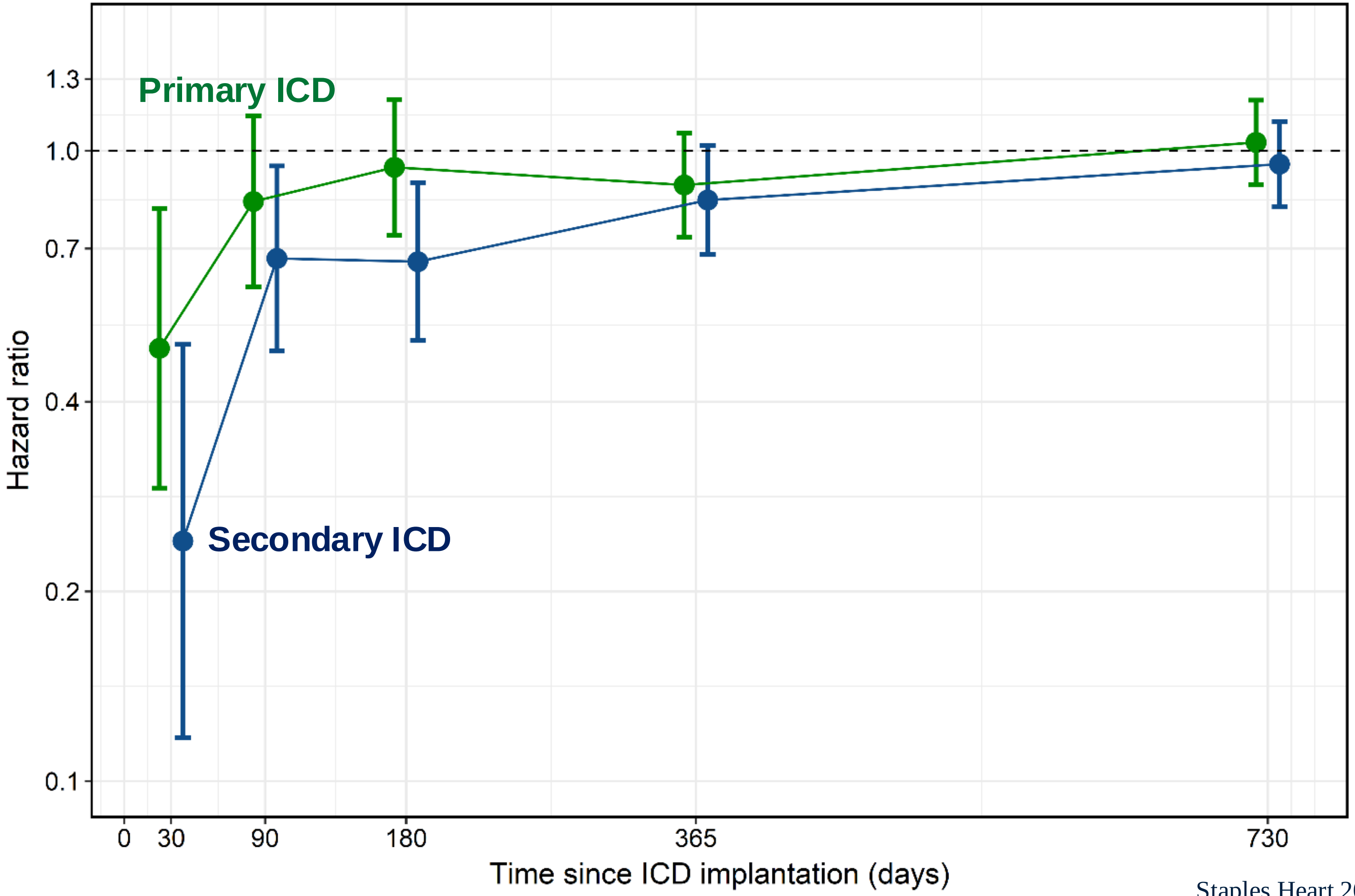


Crash prior to a censoring event for 296 of 9373 ICD recipients vs 1077 of 28,119 controls (crude incidence rate, 8.5 vs 10.5 crashes per 100 person-years)

Staples Heart 2024

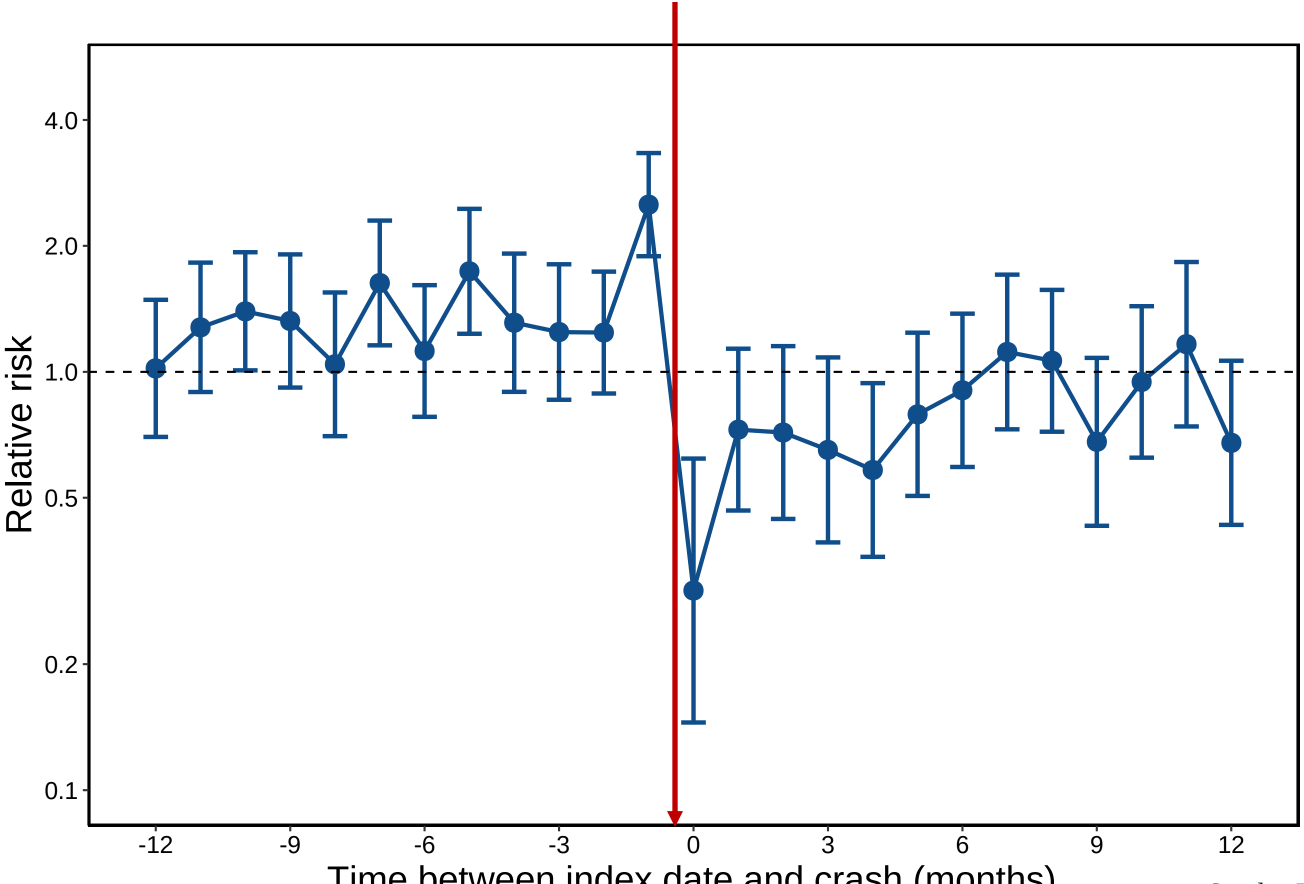


Staples Heart 2024



Staples Heart 2024

2^o ICD implantation



Staples Heart 2024

Main limitation is lack of data on road exposure

- Road exposure: Hours or kilometers of driving per month
- Relationship between ‘crash risk per month’ and ‘crash risk per hour of driving’ depends on road exposure
  - e.g. Among 100 controls, 10 crashes in a year
    Among 100 ICD recipients, 7 crashes in a year (but 90 stopped driving)
    RR (ignoring road exposure) = 7% / 10% = 0.70
    RR (accounting for road exposure) = 70% / 10% = 7.0

- Also, note no commercial drivers

Adjusting for road exposure

Driving restrictions after ICD implantation

Procedure	Canada (pre 2023)	USA	Europe
ICD, primary prophylaxis	1 month (post 2023: 1 week)	≥1 week	1 month
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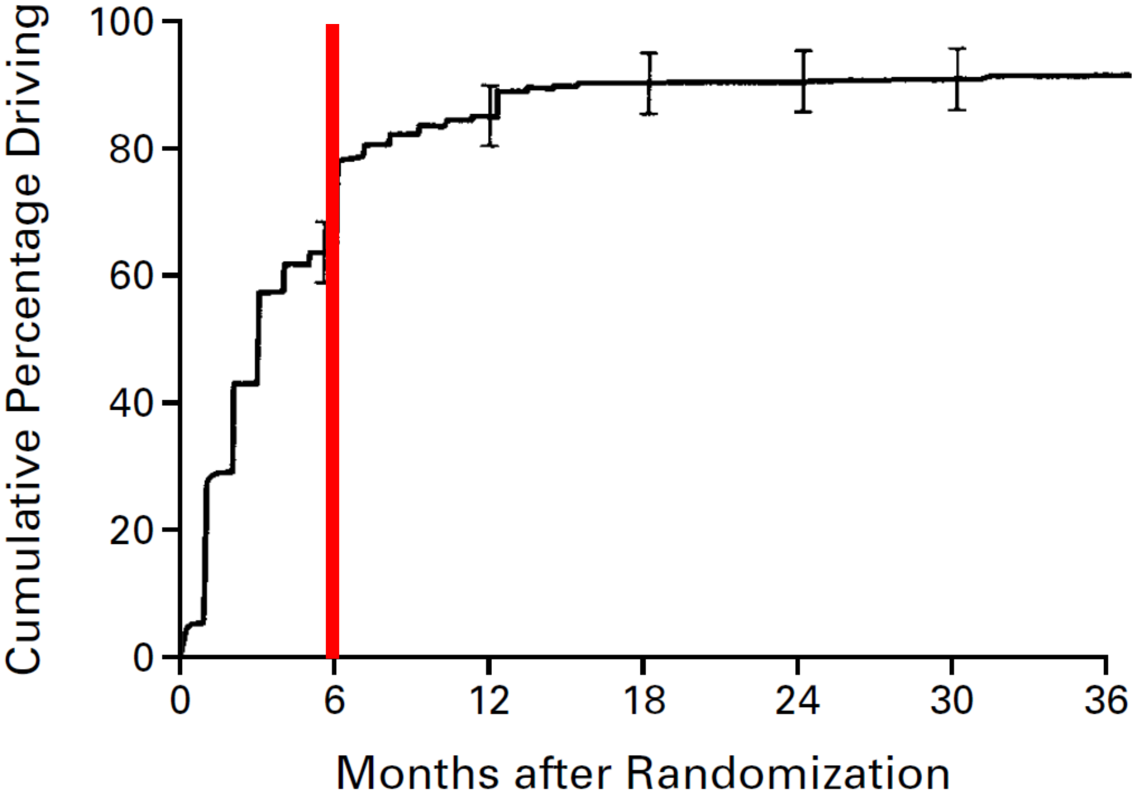
Guerra Can J Cardiol 2024

Adherence to medical driving restrictions is imperfect

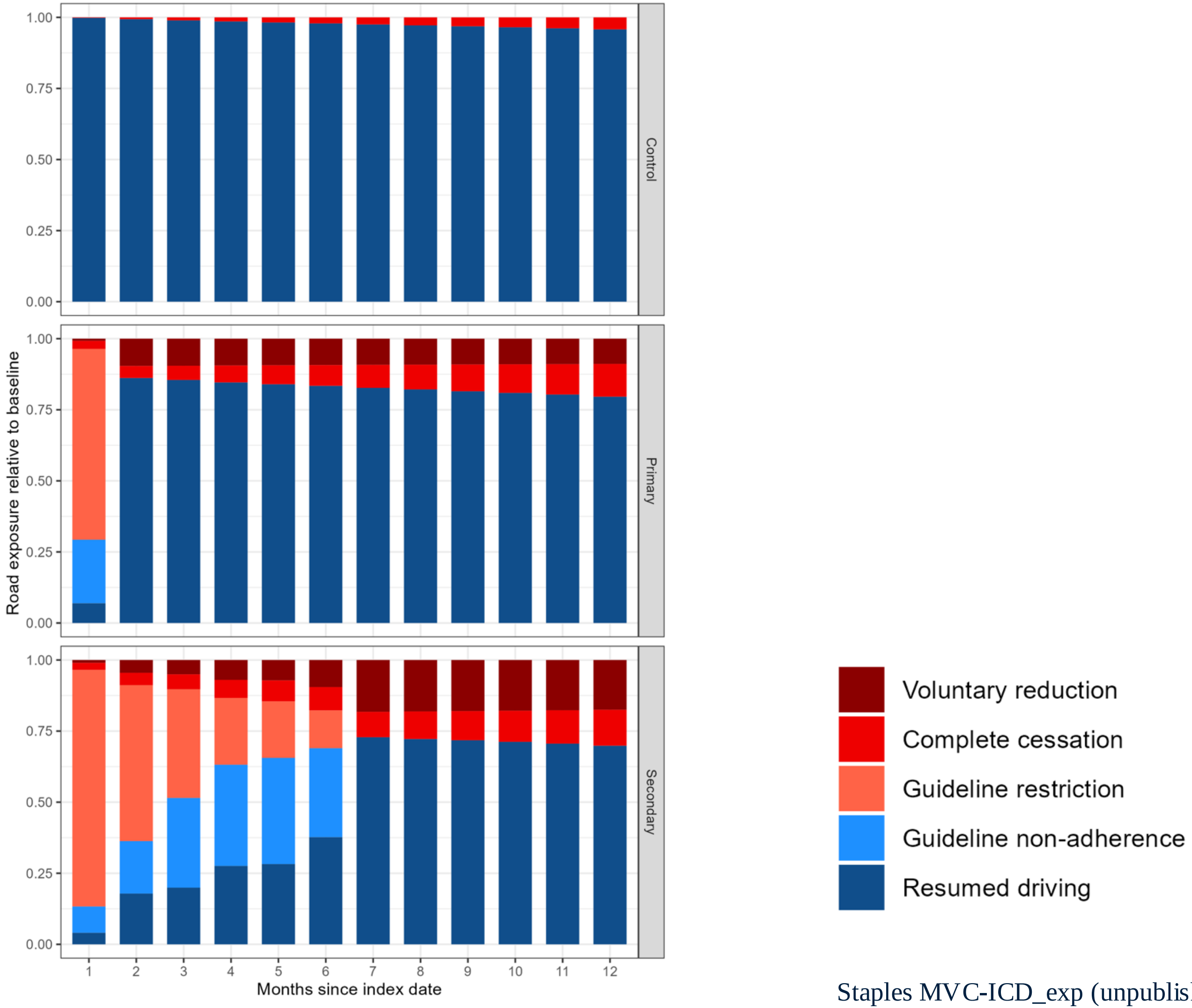


Akiyam NEJM 2001

Accounting for road exposure by adjusting cohort study results by modeled road exposure

- Estimated 'road exposure relative to baseline' for 3454 1^{o} prev + 3070 2^{o} prev ICD recipients plus their matched controls
- Accounted for the **likely duration of individual driving restrictions** using clinical data
- Accounted for **incomplete adherence** (i.e., early resumption of driving) using rates reported in prior studies
- Accounted for **voluntary reduction in driving in the post-restriction period** using rates reported in prior studies (0.90 and 0.80 of baseline for primary prevention and secondary prevention ICD cohorts, respectively)
- Accounted for **permanent cessation of driving** using license expiry or suspension
- Estimated cohort-level road exposure relative to baseline by month since ICD implantation

Staples MVC-ICD_exp (unpublished)



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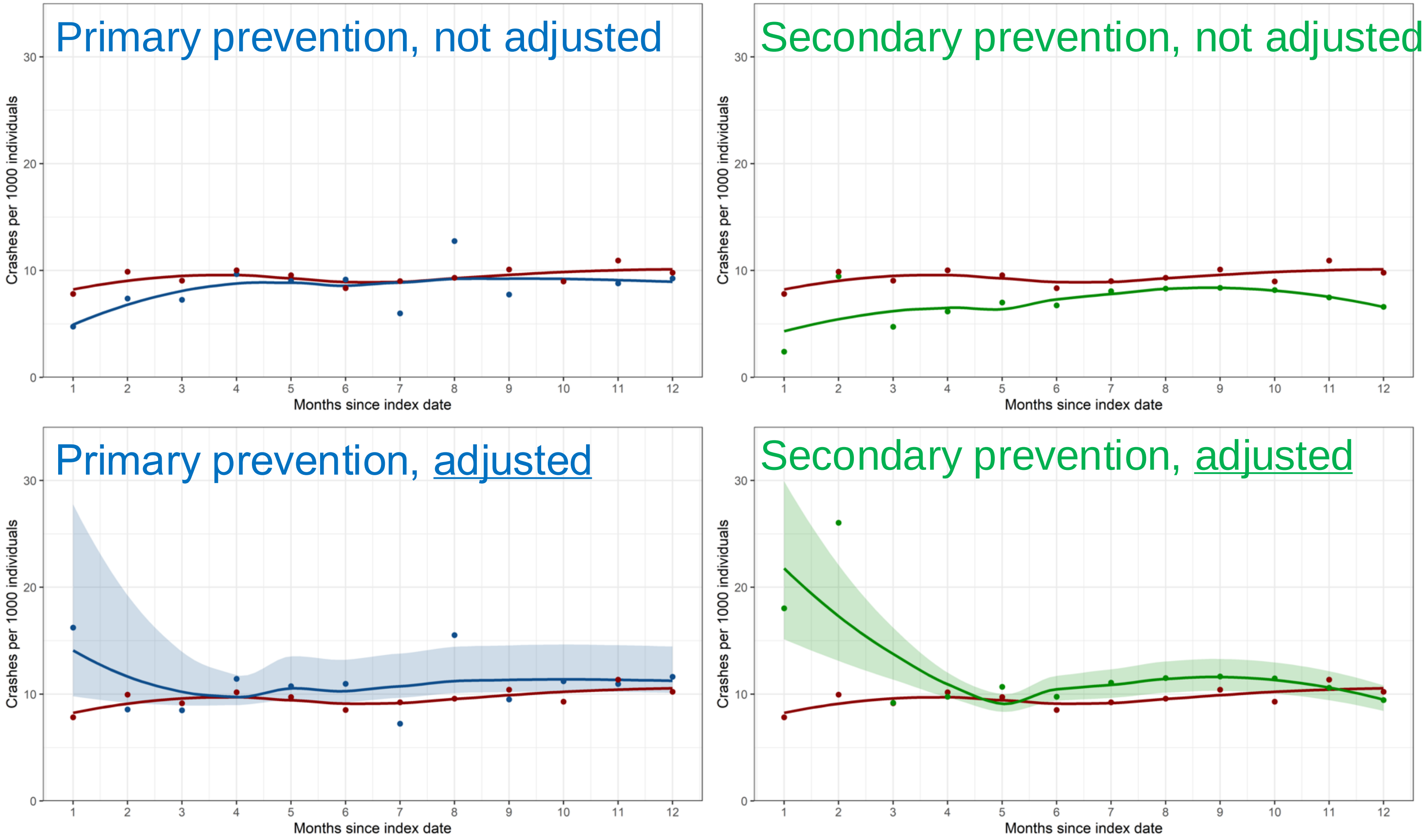


Staples MVC-ICD_exp (unpublished)

Accounting for road exposure: Responsibility analysis

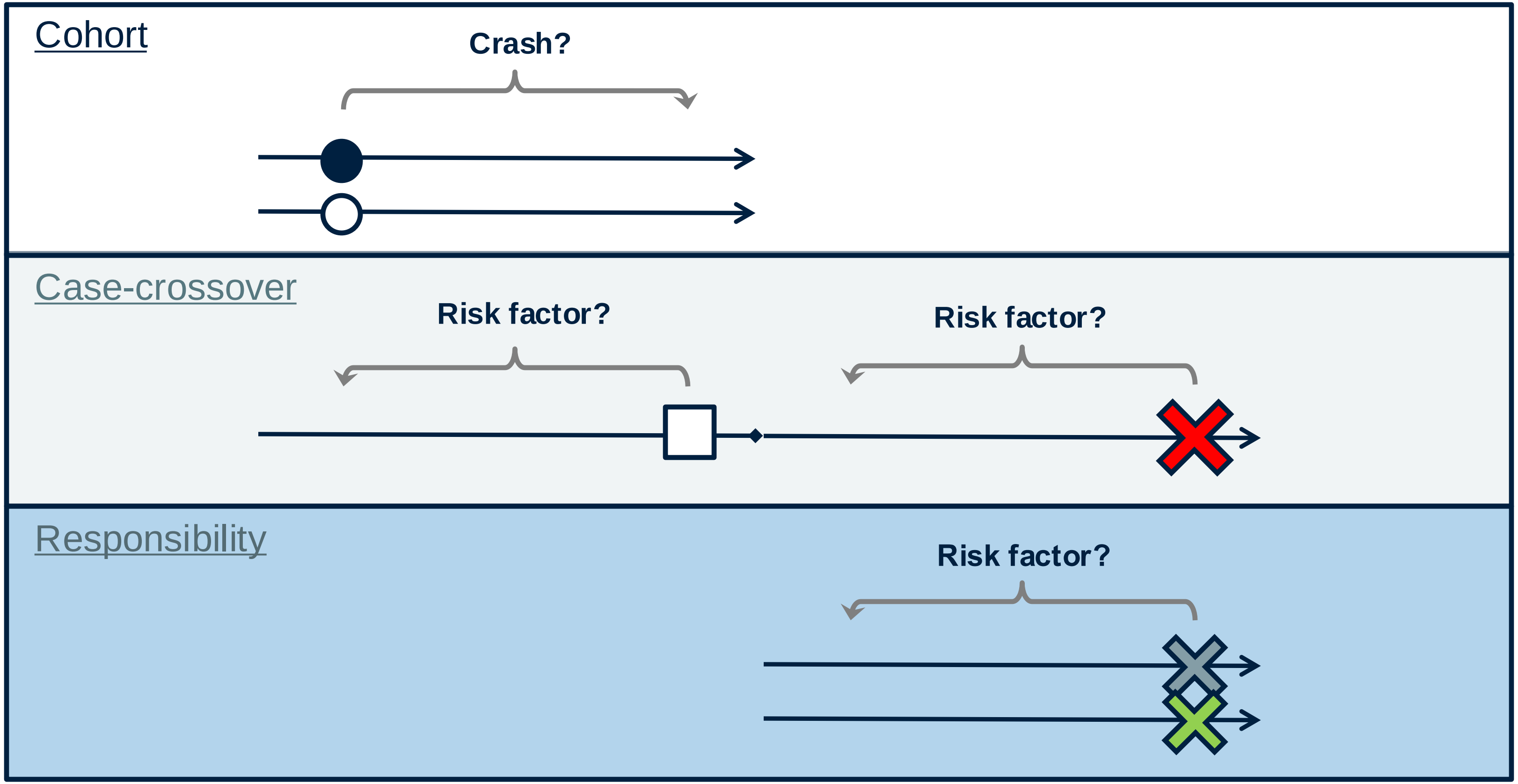
Responsibility analysis

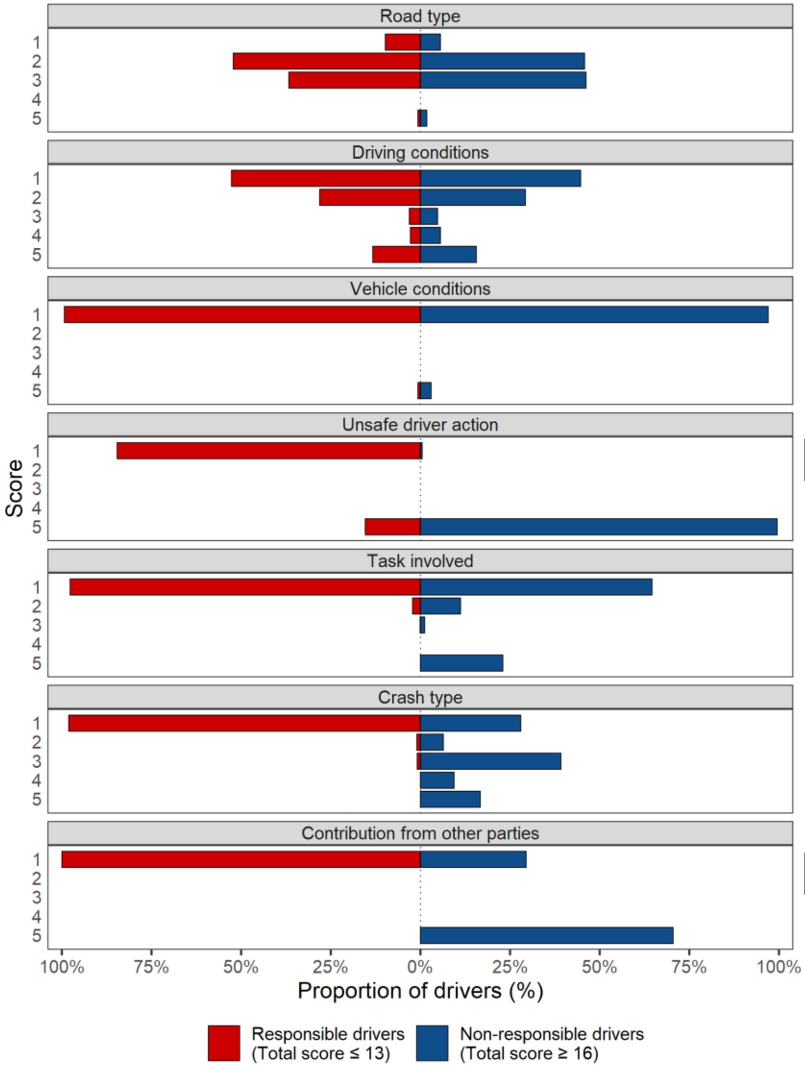
- In the cohort study, there was evidence of reduced road exposure:
  - Primary prevention ICD: In the first month after implantation, crashes declined by 69% and contraventions by 73%
  - Secondary prevention ICD: In the first 6 months after implantation, crashes declined by 59% and contraventions by 41%

- Responsibility analysis might account for changes in road exposure

Staples Heart 2024

Study designs





Unsafe driving = Responsible for crash

No-one else contributing = Responsible for crash

Staples JACC: Clin Electrop 2024

Responsibility analysis

- 1,191,210 drivers in a police-attended crash in BC between 1997 and 2019 (23 y)
- Only 0.002% had ICD implantation in prior 6 months
- 64% of recent ICD recipients vs 51% of controls deemed responsible for their crash

aOR 2.20 (0.94-5.30), p=0.08

Staples JACC Clin Electrophys 2024

Accounting for confounders: Case-crossover study

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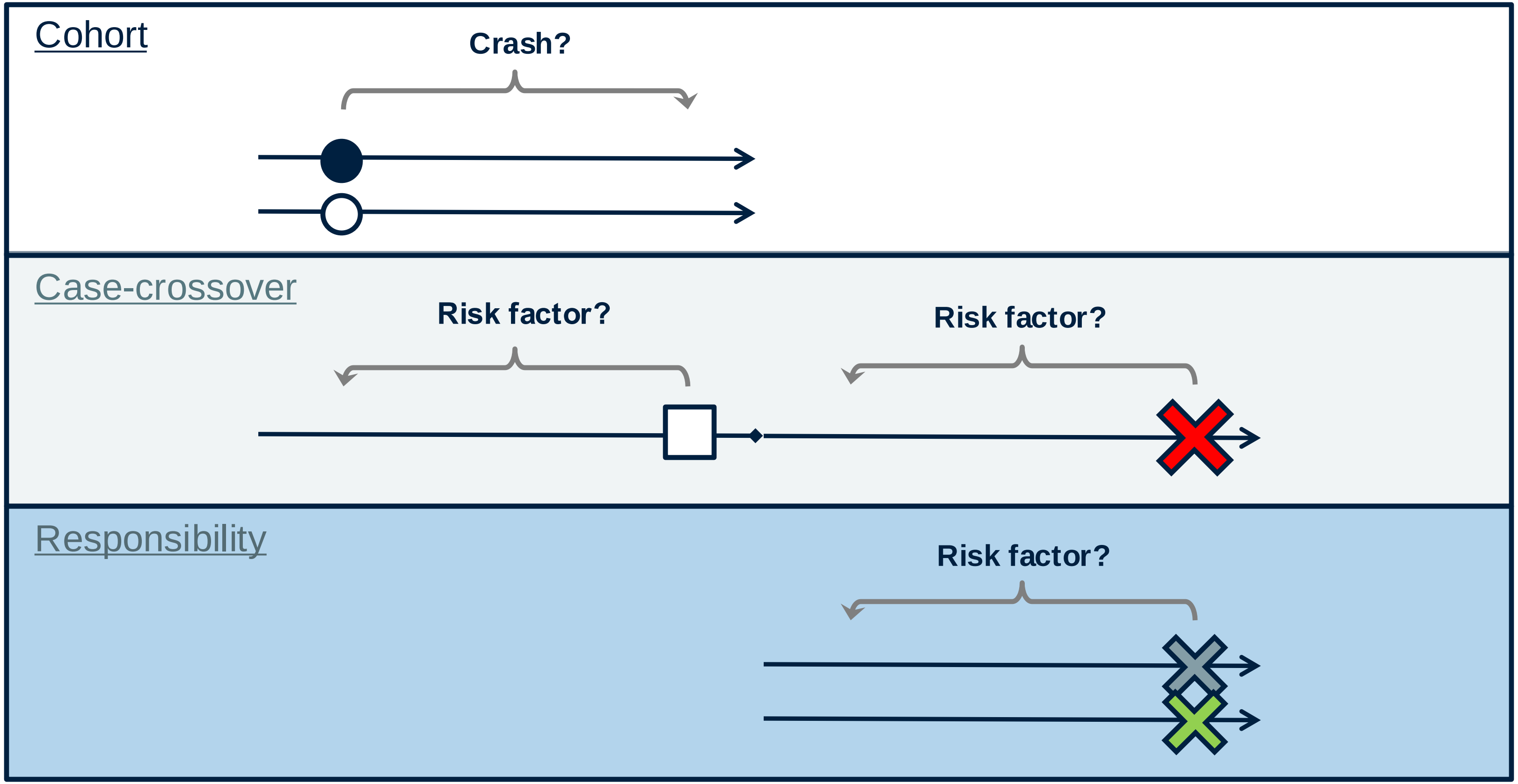
ICD recipients differ from controls.

How can we deal with residual confounding from unmeasured baseline characteristics?

Staples Heart 2024; Robinson Can J Cardiol 2024

Study designs



Case-crossover study

- 3299 individuals with an ICD implantation and a subsequent police-reported crash, both between 1997 and 2019
- 6-month exposure lookback intervals, ending 1y and 2y prior to crash
- Adjusted for time-varying covariates
- Inherently accounts for relatively fixed covariates (whether measured or unmeasured): Genetics, personality, driving experience, daily travel routines, etc.

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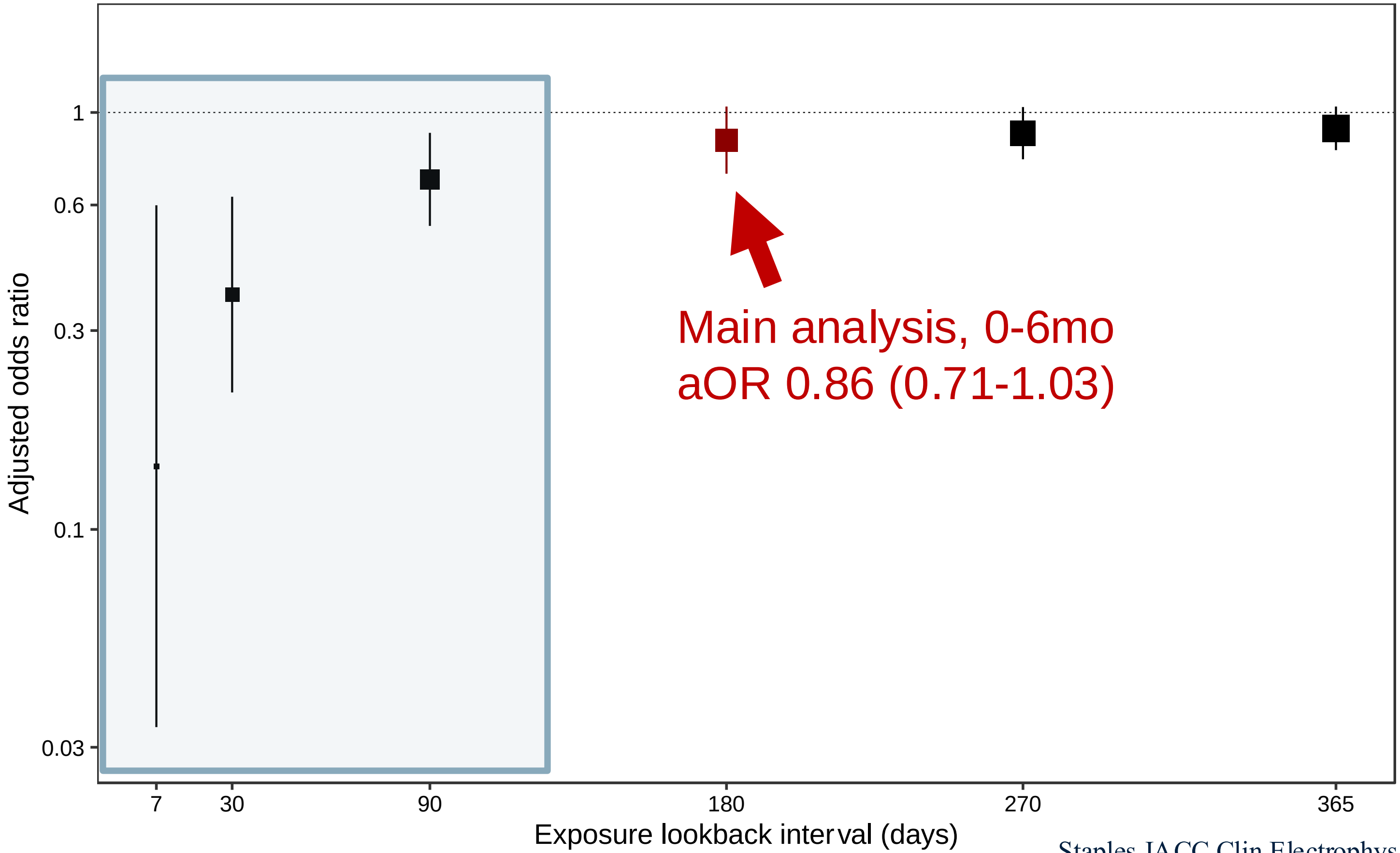
Sensitivity analysis of different exposure intervals

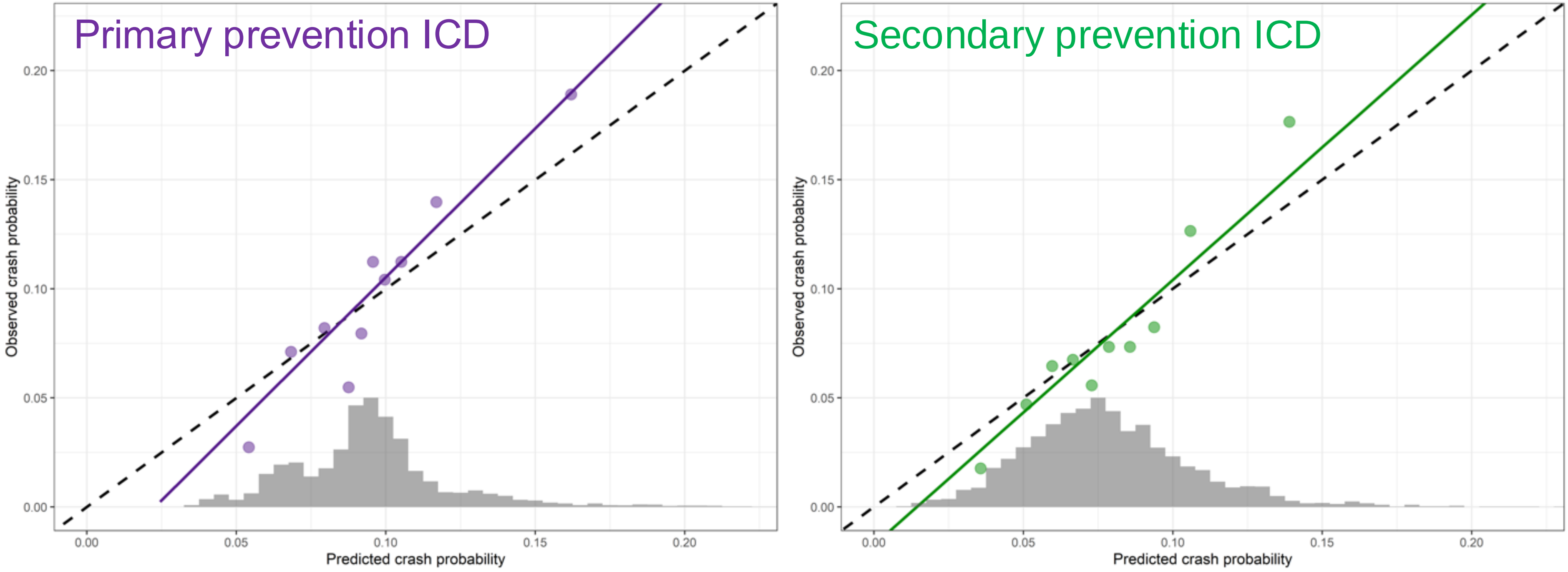


Can we identify drivers who are more likely to crash after ICD implantation?

Can we predict crash risk?

- Stratified by ICD indication (primary vs secondary prevention of sudden cardiac death) then used baseline health and driving data to estimate 1-year crash risk using regression techniques
- Calculated optimism-corrected discrimination and calibration of the final model using 200 bootstrapped samples
- 352 crashes among 3652 primary prevention ICD recipients and 270 crashes among 3408 secondary prevention ICD recipients

Staples MVC-ICD_pred (unpublished)



Staples MVC-ICD_pred (unpublished)

Can we predict crash risk?

- Crash prediction models exhibited good calibration but poor discrimination (c-statistics 0.60 and 0.61, respectively).
- The strongest predictors of crash among primary prevention ICD recipients were male sex, active vehicle insurance in the past year, and the number of crashes in the past year. The strongest predictors of crash among secondary prevention ICD recipients were male sex, no history of seizure, an active prescription for opioids, and active vehicle insurance in the past year.
- Conclusions: Crash prediction models based on health and driving data had a limited ability to distinguish individuals who subsequently crashed from individuals who did not. Observed crash risks are likely to be strongly influenced by unobserved changes in road exposure (the hours or miles driven per week), limiting the application of these risk scores by clinicians and policymakers.

Staples MVC-ICD_pred (unpublished)

Online risk calculator: https://stapleslab.shinyapps.io/mvc-icd-risk-shiny-app/

https://stapleslab.shinyapps.io/mvc-icd-risk-shiny-app/ 67%

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Predicted risk of motor vehicle crash in the first year after ICD implantation

This risk estimation tool aims to use health and driving data available at the time of cardioverter-defibrillator implantation to estimate the probability of involvement as a driver in a motor vehicle crash in the following year. These risk estimates are based on 622 crashes occurring among 7060 implantable cardioverter-defibrillator (ICD) recipients. All 622 crashes were attended by police and/or resulted in an insurance claim. Internal validation suggests the risk estimation tool exhibits good calibration (i.e., for a large group of patients, the predicted crash risk is similar to the observed crash risk) but poor discrimination (i.e., it has a limited ability to distinguish individuals who subsequently crashed from individuals who did not, with c-statistics of 0.60 for primary-prevention ICD recipients and 0.61 for secondary-prevention ICD recipients). A full description of the derivation and validation of the risk estimation tool can be found in the accompanying paper: Staples JA, Daly-Grafstein D, Khan M, Erdelyi S, Hawkins NM, Chan H, Steinberg CS, Krahn AD, Brubacher JR. Predicting the risk of motor vehicle crash in the first year after cardioverter-defibrillator implantation. [manuscript in preparation].

Indication for ICD

Secondary prevention of sudden cardiac death

Select model covariates

Age (years) 18 – 65 – 99 (18, 27, 36, 45, 54, 63, 72, 81, 90, 99)

Sex ○ Female ◉ Male

Comorbidities at ICD implantation
☑ Cardiac arrest ☐ Ventricular tachycardia or fibrillation ☐ Heart failure ☐ Chronic ischemic heart disease ☐ Diabetes
☑ Alcohol or other substance misuse ☐ Seizure ☐ Obstructive sleep apnea

Hospitalization for myocardial infarction in past 6 weeks ○ Yes ◉ No

Left ventricular ejection fraction <35% ○ Yes ◉ No

NYHA class 3 or 4 heart failure symptoms ○ Yes ◉ No

Overnight hospital stays in past year 0 – 3 – 30 (0, 3, 6, 9, 12, 15, 18, 21, 24, 27, 30)

Charlson Comorbidity Index >= 2 ◉ Yes ○ No

Active prescription medications at ICD implantation 0 – 30 (0, 3, 6, 9, 12, 15, 18, 21, 24, 27, 30)

Active prescriptions at ICD implantation ☐ Opioids ☐ Benzodiazepines ☐ Antipsychotics

Urgent/emergency ICD implantation ◉ Yes ○ No

Overnight hospital stay at implantation ◉ Yes ○ No

Driver license type at ICD implantation ◉ Full license ○ Learner or Novice license

Held active motor vehicle insurance at some point in the past year ◉ Yes ○ No

Impairment-related traffic contraventions in the past year (eg. impaired driving) 0 – 5 (0, 1, 2, 3, 4, 5)

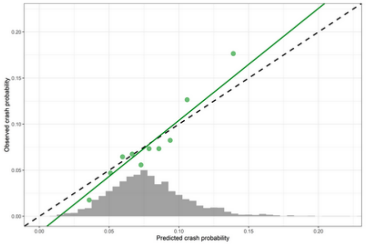
Non-impairment-related traffic contraventions in the past year (eg. speeding, distracted driving)" 0 – 20 (0, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20)

Crashes in past year 0 – 10 (0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10)

Dual-chamber ICD or cardiac resynchronization device ◉ Yes ○ No

Year of ICD implantation 1998 – 2019 (1998, 2001, 2004, 2007, 2010, 2013, 2016, 2019)

Probability of crash within 1 year (95% prediction interval):
10.8% (6.1%, 22.2%)



Legend: The horizontal axis represents predicted crash probabilities. The grey histogram represents the distribution of predicted probabilities. Circular data points reflect the predicted and observed crash probabilities for predicted probability deciles. The solid (dashed) line reflects the optimism-corrected (perfect) calibration slope.

Disclaimer:
All inferences, opinions, and conclusions drawn are those of the authors and do not reflect the opinions or policies of the Data Stewards. The risk estimation tool is intended for use by healthcare professionals. Results should be used for informational purposes only. Results and other information on this website do not constitute professional advice. Physicians and other healthcare professionals using this risk estimation tool to inform clinical discussions with patients should consult a variety of sources and should exercise their own clinical judgment about the information they provide. Individuals who are not healthcare professionals using this risk estimation tool do so at their own risk. We advise individuals to seek out professional medical advice to guide their driving decisions. Your reliance upon information and content obtained by you at or through this site is solely at your own risk. We do not assume any liability or responsibility for damage or injury (including death) to you, other persons, or property arising from any use of any information, idea, or instruction provided on this site. Recommended citation: Daly-Grafstein D, Khan M, Erdelyi S, Hawkins NM, Chan H, Steinberg CS, Krahn AD, Brubacher JR, Staples JA. Predicted risk of motor vehicle crash in the first year after ICD implantation [Internet]. Vancouver (Canada): University of British Columbia; 2024 November 18. Available from: https://stapleslab.shinyapps.io/mvc-icd-risk-shiny-app/

Putting it all together

Design	Details	Results	Strengths	Limitations
Cohort	9373 ICD recipients 28,119 controls	aHR 0.7 (0.6-0.8), p<0.001	- Easier to interpret - Gives absolute and relative risks - Can account for competing risks and censoring	- Bias from selection of controls - Does not account for road exposure
Cohort, adjusted for likely road exposure	3454 1^{o} prev ICDs 3070 2^{o} prev ICDs (+ matched cntls)	aHR 1.1 (0.8-1.4), p=0.53 aHR 1.2 (0.9-1.5), p=0.29	- Uses empirical data to account for road exposure - Gives absolute and relative risks - Can account for competing risks and censoring	- Road exposure estimates requires many assumptions
Case-crossover	3299 crashes	aOR 0.9 (0.7-1.0), p=0.11	- Accounts for fixed individual characteristics - Efficient for rare outcomes	- Only examines transient risks - Complicated to explain
Responsibility	>1M driver-crash combinations	aOR 2.2 (0.9-5.3), p=0.08	- Accounts for road exposure	- Many assumptions - Complicated to explain

Conclusions

- The messy mixture of driving restrictions, non-adherence to driving restrictions, and voluntary reductions in driving seems to adequately mitigate any large increase in crash risk after ICD implantation.
- Whether the less stringent restrictions proposed in the 2023 CCS guidelines will result in a greater number of crashes remains uncertain, and monitoring would be prudent.
- **Better data will be required** (eg. ICD recordings, crash records from smartphones, driver-facing cameras etc) to address issues of road exposure and adherence and to address uncertainties about causality.
- **Large (population-wide?), registry-based, adaptive randomized trials** (e.g. driving restriction A vs driving restriction B) are very promising but politically challenging.

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  - VCHRI
  - CIHR
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  - 2017 Mentored Clinician Scientist Award, Vancouver Coastal Health Research Institute
  - 2020 Health Professional-Investigator Award, Michael Smith Foundation for Health Research

Vancouver CoastalHealth Research Institute

MICHAEL SMITH FOUNDATION FOR HEALTH RESEARCH
BC's health research funding agency

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Co-chairs:; Guerra PG, Simpson CS, Van Spall HGC; Writing Panel:; Asgar AW, Billia P, Cadrin-Tourigny J, Chakrabarti S, Cheung CC, Dore A, Fordyce CB, Gouda P, Hassan A, Krahn A, Luc JGY, Mak S, McMurtry S, Norris C, Philippon F, Sapp J, Sheldon R, Silversides C, Steinberg C, Wood DA. Canadian Cardiovascular Society 2023 Guidelines on the Fitness to Drive. Can J Cardiol. 2024 Apr;40(4):500-523. doi: 10.1016/j.cjca.2023.09.033. Epub 2023 Oct 10. Erratum in: Can J Cardiol. 2024 Sep 10:S0828-282X(24)00942-5. doi: 10.1016/j.cjca.2024.07.032. PMID: 37820870.

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Staples JA, Daly-Grafstein D, Khan M, Brubacher JR. Modeling road exposure in the first year after cardioverter-defibrillator implantation. [manuscript in preparation].

Staples JA, Daly-Grafstein D, Khan M, Brubacher JR. Predicting the risk of motor vehicle crash in the first year after cardioverter-defibrillator implantation. [manuscript in preparation].

See my other work on syncope and crash risks, as well as schizophrenia/psychosis and crash risks.

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