Dynamic Treatment Choices and Selection into RCTs: Evidence from Prostate Cancer

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Motivation

- Randomized Controlled Trials (RCTs) are the gold standard research design for estimating treatment effects. Medicine, social sciences, etc.
- RCT identifies an average treatment effect (`ATE`) among *volunteers* or `VATE`, which has:
  - Internal validity because of randomization
  - External validity issues because of selection into RCT participation
- RCT does NOT identify the full patient population `ATE`.
- We study selection's impact on Comparative Effectiveness RCTs.
  - Treatments available to individuals outside of the RCT
  - Examples: Off-label Rx, behavioral interventions, fast vs. slow Tx.

Motivation

- Comparative effectiveness RCTs often include two treatment strategies that vary in their effectiveness and side effects:
  - Treatment A: more effectiveness + more side effects
  - Treatment B (including monitoring): less effective + fewer side effects
- Dynamics can matter: patients may first try option B and retain the option to treat later with A if necessary.
- Key question: What are the additional health risks of (starting on) B? RCT goal is to estimate $\texttt{ATE} = E[Y_{Bi} - Y_{Ai}]$.
- Our contribution: Structural model allows us to calculate a population ATE using a combination of RCT and observational data.
- Our application: Prostate cancer treatment.

Prostate Cancer

- Prostate cancer: Slow-moving disease with options:
  - Treat now (A). Surgery, radiation, hormone therapy. **Side effects**
  - Wait (B). Active surveillance with option to treat later.
- Impact of active surveillance depends on willingness to switch when/if disease progresses. Also, effectiveness of A may vary across patients.
- Prostate cancer RCTs have attempted to estimate the mortality impact of immediate treatment vs. waiting.
- **BUT** RCT recruitment warns:

  "Men should not undergo randomisation unless they are able to view all treatments as reasonably equivalent"

Literature

- Heckman (1992) and Heckman and Smith (1995): non-random selection into RCTs by non-representative samples of the population.
- Malani (2008) studies "single-shot" RCTs for new medical treatments. Selection on Roy gains.
- Combining RCTs with structural models: Todd and Wolpin (2022); Galiani, Murphy, and Pantano (2015).
- Structural models of dynamic treatment choice: Hamilton, Jungheim, McManus, and Pantano (2018).
- Combining RCT and non-experimental data: Athey, Chetty, and Imbens (2020); Gechter (2022).

Dynamic Model of Treatment Choice & RCT Enrollment I

Setup and Notation

- Men can be diagnosed at any time between ages $\underline{a}$ and $\bar{a}$. Model begins at diagnosis (a_0) and focuses on treatment choice.
- A patient's disease state (severity) is ω.
- Treatment choice at a is $d_a \in \{A, B\}$
- New patients drawn from distribution $f(a_0, \omega_{a_0}, \alpha, \varphi)$, with:
  - a_0 is the age at diagnosis
  - ω_{a_0} disease state at time of diagnosis
  - α is importance attached to side effects
  - φ match value for treatment A
- Finite horizon with uncertain survival to $\bar{a}$.
- Patients diagnosed at age a_0 can die at any age between $a_0 + 1$ and $\bar{a}$, whether from the disease of interest or from other causes.

Dynamic Model of Treatment Choice & RCT Enrollment II

Setup and Notation

- Time unit is 3 months.
- State vector $\chi_a = \{a, \omega_a, d_{a-1}, a_A, \omega_{a_A}, H_a\}$ at age a includes:
  - a: age of the patients.
  - ω_a: disease biomarker. Higher = worse; grows weakly over time.
  - d_{a-1}: previous choice tracks who is still on treatment strategy B. Initialize $d_{a_0-1} = B$.
  - a_A: age at which active treatment (A) was taken for those who ever took active treatment.
  - ω_{a_A}: disease severity biomarker at time active treatment A.
  - H_a: survival indicator for dead (0) or alive (1). Death possible from cancer and non-cancer.

Dynamic Model of Treatment Choice & RCT Enrollment

Timing and Choices

- At any time, including at diagnosis, patients **outside of RCT** can choose to take the monitoring strategy (B) or active treatment (A).
- At age a_0, the patient makes the initial treatment choice d_{a_0}.
- Patient stops making choices after choosing active treatment.
  Optimal stopping problem: if and when to take A.
- At any age $a > a_0$, patient chooses between B and A as long as he is still alive ($H_a = 1$) and on active monitoring ($d_{a-1} = B$).

Dynamic Model of Treatment Choice & RCT Enrollment I

Optimal treatment choice outside the RCT

- Newly diagnosed patients who **do not** enroll in the RCT maximize

$$\max_{\{d_a(\chi_a)\}_{a=a_0}^{a=\bar{a}}} \left\{ E\left[\sum_{a=a_0}^{\bar{a}} \delta^{a-a_0} u(d_a, \chi_a, \alpha) \middle| \chi_{a_0} \right] \right\}$$

  where

- $u(\cdot)$ period-specific flow utility
- $E[\cdot]$ is expectation with respect to the transitions in the state variables, including the survival transition.
- If choose A at a, make no additional decisions in later periods.

Dynamic Model of Treatment Choice & RCT Enrollment II

Optimal treatment choice outside the RCT

- Recursive representation outside the RCT:

$$V(\chi_a, \texttt{free}) = \max_d \left\{ u(d, \chi_a, \alpha) + \delta E[V(\chi_{a+1}, \texttt{free}) | \chi_a, \omega_a, d_a = d] \right\}$$

- The alternative-specific value functions for $d \in \{A, B\}$:

$$V_d(\chi_a, \texttt{free}) = u(d, \chi_a, \alpha) + \delta E[V(\chi_{a+1}, \texttt{free}) | \chi_a, \omega_a, d_a = d]$$

- The value function:

$$V(\chi_a, \texttt{free}) = \max_d \left\{ V_d(\chi_a, \texttt{free}) \right\}$$

Dynamic Model of Treatment Choice & RCT Enrollment I

Optimal treatment choice in the RCT

- Given d_{a_0} is experimentally assigned, newly diagnosed patients who volunteer into the RCT start making choices at age $a_0 + 1$.
- To make B meaningful, patients assigned to B cannot switch to A immediately.
- Formalization of RCT protocol: Patient's disease state ω must exceed a threshold $\underline{\omega}$ to consider A.
- Patients maximize:

$$\max_{\{d_a(\chi_a)\}_{a=a_0+1}^{a=\bar{a}}} \left\{ E\left[\sum_{a=a_0+1}^{\bar{a}} \delta^{a-a_0} u(d_a, \chi_a, \alpha) \middle| \chi_{a_0+1}, d_{a_0} \right] \right\}$$

subject to the constraint that $d_a(\chi_a) = B$ if $\omega_a < \underline{\omega}$ and $d_{a_0} = B$

Dynamic Model of Treatment Choice & RCT Enrollment II

Optimal treatment choice in the RCT

- Value of active treatment (A) same inside and outside RCT:

$$V_A(\chi_{a_0}, \texttt{rct}) = V_A(\chi_{a_0}, \texttt{free}) = V_A(\chi_{a_0}) \tag{1}$$

- At age a, the value of continuing in the monitoring arm of the RCT (either by choice or by protocol) is:

$$\begin{aligned} V_B(\chi_a, \texttt{rct}) = u(B, \chi_a, \alpha) \\ + \delta \Big\{ \bar{p}_\omega E[\max_d \{V_d(\chi_{a+1}, \texttt{rct})\} | \chi_a, \omega_a, d_a = B, \omega_{a+1} \geq \underline{\omega}] \\ + (1 - \bar{p}_\omega) E[V_B(\chi_{a+1}, \texttt{rct}) | \chi_a, \omega_a, d_a = B, \omega_{a+1} < \underline{\omega}] \Big\} \end{aligned}$$

- $\bar{p}_\omega = \Pr(\omega_{a+1} \geq \underline{\omega} | \omega_a)$ is the probability that the ω evolves between a and $a+1$ to allow unconstrained choice in the RCT.

Dynamic Model of Treatment Choice & RCT Enrollment I

RCT Enrollment Decision

- Newly diagnosed patients are screened and offered a place in RCT.
- RCT patients randomized to A with probability p_A and to monitoring protocol B with probability $p_B = 1 - p_A$.
- The value of enrolling in the RCT is:

$$V(\chi_{a_0}, \texttt{rct}) = p_A V_A(\chi_{a_0}, \texttt{rct}) + p_B V_B(\chi_{a_0}, \texttt{rct}) + \boxed{\varepsilon}$$

- The value of declining the RCT offer, $V(\chi_{a_0}, \texttt{free})$

$$V(\chi_{a_0}, \texttt{free}) = \max \left\{ V_A(\chi_{a_0}, \texttt{free}); V_B(\chi_{a_0}, \texttt{free}) \right\}$$

- Enroll in RCT $\iff$ $V(\chi_{a_0}, \texttt{rct}) \geq V(\chi_{a_0}, \texttt{free})$

The Setting and Data

- ProtecT UK prostate cancer study. Screened and enrolled newly diagnosed prostate cancer patients from 1999-2009.
- All patients screened on:
  - Age: between 50 and 70
  - PSA score (ω): between 3 and 19.9
  - Other severity and comorbidity measures
- Patients who passed screening could:
  - Enroll in RCT and agree to randomization ($N = 1643$)
  - Decline randomization but continue in study ($N = 958$)
- We use published statistics on patient characteristics and outcomes from both populations (`rct` and `free`) to estimate our model.

The Setting and Data

- We simplify approach to treatment arms:
  - A: Surgery OR Radiotherapy
  - B: Active surveillance
- We add metastasis to our framework
  - In ProtecT: A cancer outcome indicating disease progression
  - In our model, cancer must metastasize before patient experiences risk of cancer death.

The Setting and Data

The NEW ENGLAND JOURNAL of MEDICINE

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10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer

F.C. Hamdy, J.L. Donovan, J.A. Lane, M. Mason, C. Metcalfe, P. Holding, M. Davis, T.J. Peters, E.L. Turner, R.M. Martin, J. Oxley, M. Robinson, J. Staffurth, E. Walsh, P. Bollina, J. Catto, A. Doble, A. Doherty, D. Gillatt, R. Kockelbergh, H. Kynaston, A. Paul, P. Powell, S. Prescott, D.J. Rosario, E. Rowe, and D.E. Neal, for the ProtecT Study Group*

European Association of Urology

Platinum Priority – Prostate Cancer

Editorial by Vidit Sharma and R. Jeffrey Karnes on pp. 331–332 of this issue

Ten-year Mortality, Disease Progression, and Treatment-related Side Effects in Men with Localised Prostate Cancer from the ProtecT Randomised Controlled Trial According to Treatment Received

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The Setting and Data

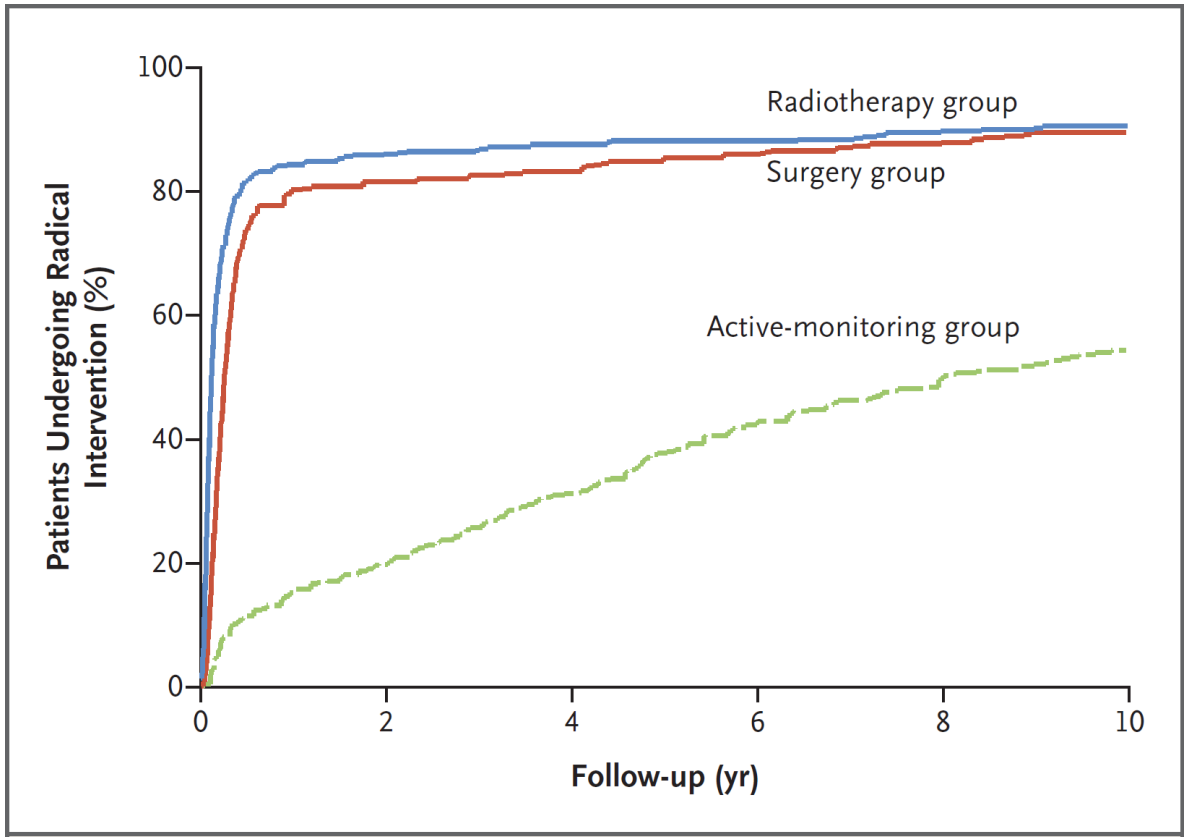
Hamdy et al. (2016):

Table 1. Prostate-Cancer Mortality, Incidence of Clinical Progression and Metastatic Disease, and All-Cause Mortality, According to Randomized Treatment Group.

Variable	Active Monitoring (N = 545)	Surgery (N = 553)	Radiotherapy (N = 545)	P Value*
Prostate-cancer mortality				
Total person-yr in follow-up	5393	5422	5339	
No. of deaths due to prostate cancer†	8	5	4	
Prostate-cancer–specific survival — % (95% CI)†				
At 5 yr	99.4 (98.3–99.8)	100	100	
At 10 yr	98.8 (97.4–99.5)	99.0 (97.2–99.6)	99.6 (98.4–99.9)	
Prostate-cancer deaths per 1000 person-yr (95% CI)†	1.5 (0.7–3.0)	0.9 (0.4–2.2)	0.7 (0.3–2.0)	0.48
Incidence of clinical progression‡				
Person-yr of follow-up free of clinical progression	4893	5174	5138	
No. of men with clinical progression	112	46	46	
Clinical progression per 1000 person-yr (95% CI)	22.9 (19.0–27.5)	8.9 (6.7–11.9)	9.0 (6.7–12.0)	<0.001
Incidence of metastatic disease				
Person-yr of follow-up free of metastatic disease	5268	5377	5286	
No. of men with metastatic disease	33	13	16	
Metastatic disease per 1000 person-yr (95% CI)	6.3 (4.5–8.8)	2.4 (1.4–4.2)	3.0 (1.9–4.9)	0.004
All-cause mortality				
Total person-yr in follow-up	5393	5422	5339	
No. of deaths due to any cause	59	55	55	
All-cause deaths per 1000 person-yr (95% CI)	10.9 (8.5–14.1)	10.1 (7.8–13.2)	10.3 (7.9–13.4)	0.87

The Setting and Data

Hamdy et al. (2016):



The Setting and Data

Neal et al. (2020):

	Treatment group as defined in the first column Events/*N* (rate/1000 person years)		
	Active monitoring	Surgery	Radiotherapy
Prostate cancer death—randomised cohort			
Randomised groups	8/545 (1.5)	5/553 (0.92)	4/545 (0.75)
Treatment received[b]	11/628 (1.8)	2/488 (0.43)	4/491 (0.85)
Prostate cancer death—treatment choice cohort			
Treatment received	10/507 (2.2)	3/262 (1.2)	1/189 (0.57)
Metastatic disease or prostate cancer death—randomised cohort			
Randomised groups	33/545 (6.1)	13/553 (2.4)	16/545 (3.0)
Treatment received	36/628 (6.0)	10/488 (2.2)	15/491 (3.2)
Metastatic disease or prostate cancer death—treatment choice cohort			
Treatment received	28/507 (6.1)	8/262 (3.3)	3/189 (1.7)
Disease progression—randomised cohort			
Randomised groups	112/545 (20)	46/553 (8.5)	46/545 (8.6)
Treatment received	142/628 (24)	26/488 (5.6)	30/491 (6.3)
Disease progression—treatment choice cohort			
Treatment received	79/507 (17)	18/262 (7.5)	15/189 (8.5)
Hormone treatment—randomised cohort			
Randomised groups	47/545 (8.7)	26/553 (4.8)	30/545 (5.6)
Treatment received	53/628 (8.8)	22/488 (4.8)	25/491 (5.3)
Hormone treatment—treatment choice cohort			
Treatment received	30/507 (6.5)	11/262 (4.6)	11/189 (6.2)
All death—randomised cohort			
Randomised groups	59/545 (11)	55/553 (10)	55/545 (10)
Treatment received	64/628 (11)	45/488 (9.7)	55/491 (12)
All death—treatment choice cohort			
Treatment received	54/507 (12)	23/262 (9.6)	17/189 (9.6)

The Setting and Data

Neal et al. (2020) – Closeup:

	Active monitoring	Surgery
Prostate cancer death—randomised cohort		
Randomised groups	8/545 (1.5)	5/553 (0.92)
Treatment received[b]	11/628 (1.8)	2/488 (0.43)
Prostate cancer death—treatment choice cohort		
Treatment received	10/507 (2.2)	3/262 (1.2)
Metastatic disease or prostate cancer death—randomised cohort		
Randomised groups	33/545 (6.1)	13/553 (2.4)
Treatment received	36/628 (6.0)	10/488 (2.2)
Metastatic disease or prostate cancer death—treatment choice cohort		
Treatment received	28/507 (6.1)	8/262 (3.3)

Moments to match

- We use **aggregate** outcomes from `rct` and `free` cohorts on transitions by month t since a_0 in:
  - Transitions to treatment (B to A)
  - Transition to metastasis by month
  - Death by prostate cancer by month
  - Death by other cause
- Example: Share who transition from B to A by month $t \in \{24, 48, 72, 96, 120\}$.
- Additional data: NC ProCESS provides information on patient concern level about side effects (low, medium, or high).

Empirical implementation

- Parametric assumptions on payoffs, probabilities, & distributions.
- Per-period utility:
  - If dead: $u(\cdot, H_a = 0, \cdot) = 0$.
  - If alive and no side effects: $u(B, H_a = 1, \cdot) = Q(a) \in (0, 1)$
  - If alive and side effects after A: $u(B, H_a = 1, \cdot) = Q(a) \times [1 - \Phi(\alpha_i)]$
- $\omega \in \{3, 4, ..., 30\}$ and takes discrete steps of random size $\Delta(\omega)$.
- So many logit probabilities. Example on metastasis:

$$\pi^m(\chi_a, d_a = B) = \Lambda\left[\lambda_1^m + \lambda_2^m \omega_a\right]$$

- Similar parameterized expressions for metastasis after A, death by cancer, death by non-cancer.

Estimation

- Strategy: for guess at Θ, simulate histories for patients with different $(a_0, \omega_0, \alpha, \varphi)$.
- Calculate moments from simulated histories.
- Match predicted moments to:
  - Characteristics of patients who participate vs don't in RCT
  - Empirical moments on behavior in `rct` population
  - Empirical moments on behavior in `free` population

Estimates: Empirical & Predicted Moments

Moments Regarding Enrollment			
ID	**Moment**	**Data**	**Model**
M_PRTCT	Pr(Enrolls in RCT |Eligible)	0.620	0.669
Moments from RCT Volunteers under RCT Restrictions			
M_RCT_1	Pr(Assigned to A at a_0 | Volunteer into RCT)	0.609	0.610
M_RCT_2	Pr(switched to A by 24 months after a_0)	0.178	0.072
M_RCT_3	Pr(switched to A by 48 months after a_0)	0.270	0.182
M_RCT_4	Pr(switched to A by 72 months after a_0)	0.352	0.316
M_RCT_5	Pr(switched to A by 96 months after a_0)	0.404	0.428
M_RCT_6	Pr(switched to A by 120 months after a_0)	0.432	0.501

Estimates: Empirical & Predicted Moments

Moments from RCT Volunteers under RCT Restrictions

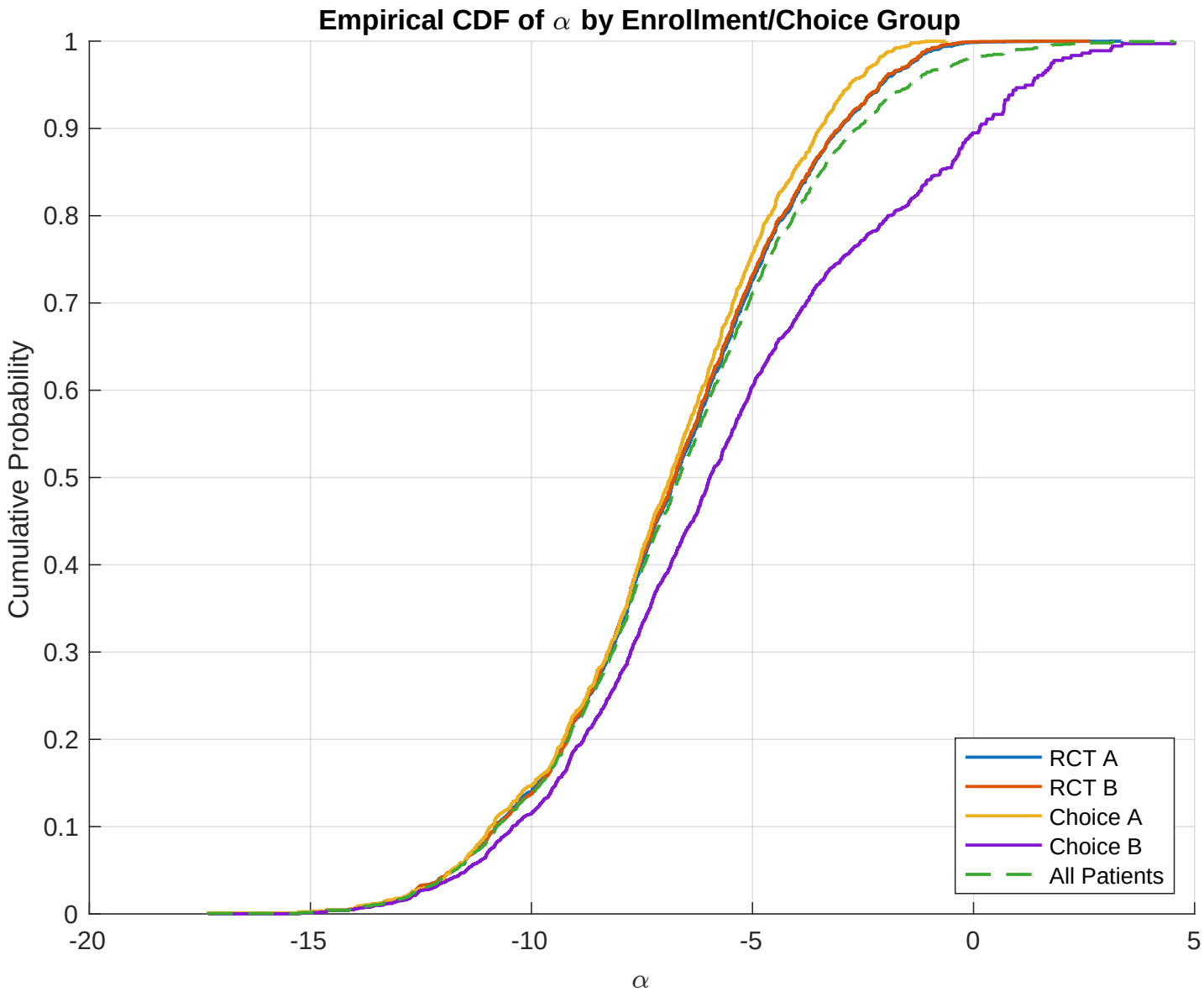
ID	Moment	Data	Model
M_RCT_7	Pr(metastasis by $t = 120$ mo $\mid d_{a_0} = B$)	0.061	0.269
M_RCT_8	Pr(metastasis by $t = 120$ mo $\mid d_{a_0} = A$)	0.026	0.096
M_RCT_9	Pr(survived cancer at 60 mo $\mid d_{a_0} = B$)	0.994	0.999
M_RCT_10	Pr(survived cancer at 120 mo $\mid d_{a_0} = B$)	0.985	0.984
M_RCT_11	Pr(survived cancer at 60 mo $\mid d_{a_0} = A$)	1.000	0.999
M_RCT_12	Pr(survived cancer at 120 mo $\mid d_{a_0} = A$)	0.992	0.991
M_RCT_13	Pr(dead non-cancer by 120 mo $\mid d_{a_0} = B$)	0.094	0.097
M_RCT_14	Pr(dead non-cancer by 120 mo $\mid d_{a_0} = A$)	0.092	0.091

Estimates: Empirical & Predicted Moments

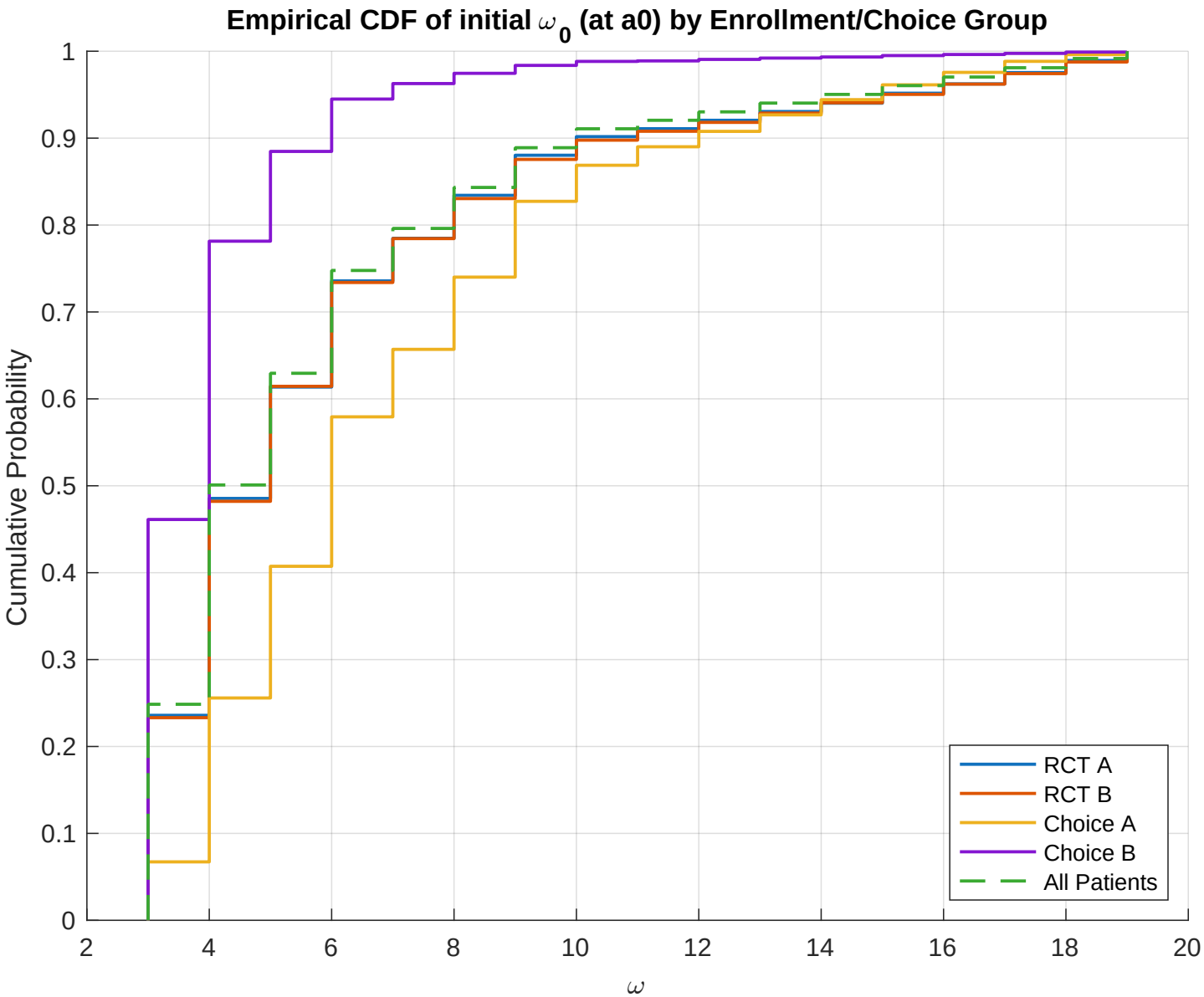
Moments from RCT Decliners (Choice Cohort)

ID	Moment	Data	Model
M_CHOICE_1	$\Pr(d_{a_0} = A \mid a_0 \in 50\text{–}69)$	0.471	0.468
M_CHOICE_2	Pr(switched to A by 24 months after a_0)	0.136	0.166
M_CHOICE_3	Pr(switched to A by 48 months after a_0)	0.256	0.282
M_CHOICE_4	Pr(switched to A by 72 months after a_0)	0.343	0.365
M_CHOICE_5	Pr(switched to A by 96 months after a_0)	0.381	0.420
M_CHOICE_6	Pr(switched to A by 120 months after a_0)	0.400	0.457
M_CHOICE_7	$\Pr(\text{metastasis by } t = 120 \text{ mo} \mid d_{a_0} = B)$	0.036	0.169
M_CHOICE_8	$\Pr(\text{metastasis by } t = 120 \text{ mo} \mid d_{a_0} = A)$	0.016	0.120
M_CHOICE_9	$\Pr(\text{survived cancer at 120 mo} \mid d_{a_0} = B)$	0.980	0.988
M_CHOICE_10	$\Pr(\text{survived cancer at 120 mo} \mid d_{a_0} = A)$	0.991	0.987
M_CHOICE_11	$\Pr(\text{dead non-cancer by 120 mo} \mid d_{a_0} = B)$	0.087	0.095
M_CHOICE_12	$\Pr(\text{dead non-cancer by 120 mo} \mid d_{a_0} = A)$	0.080	0.015

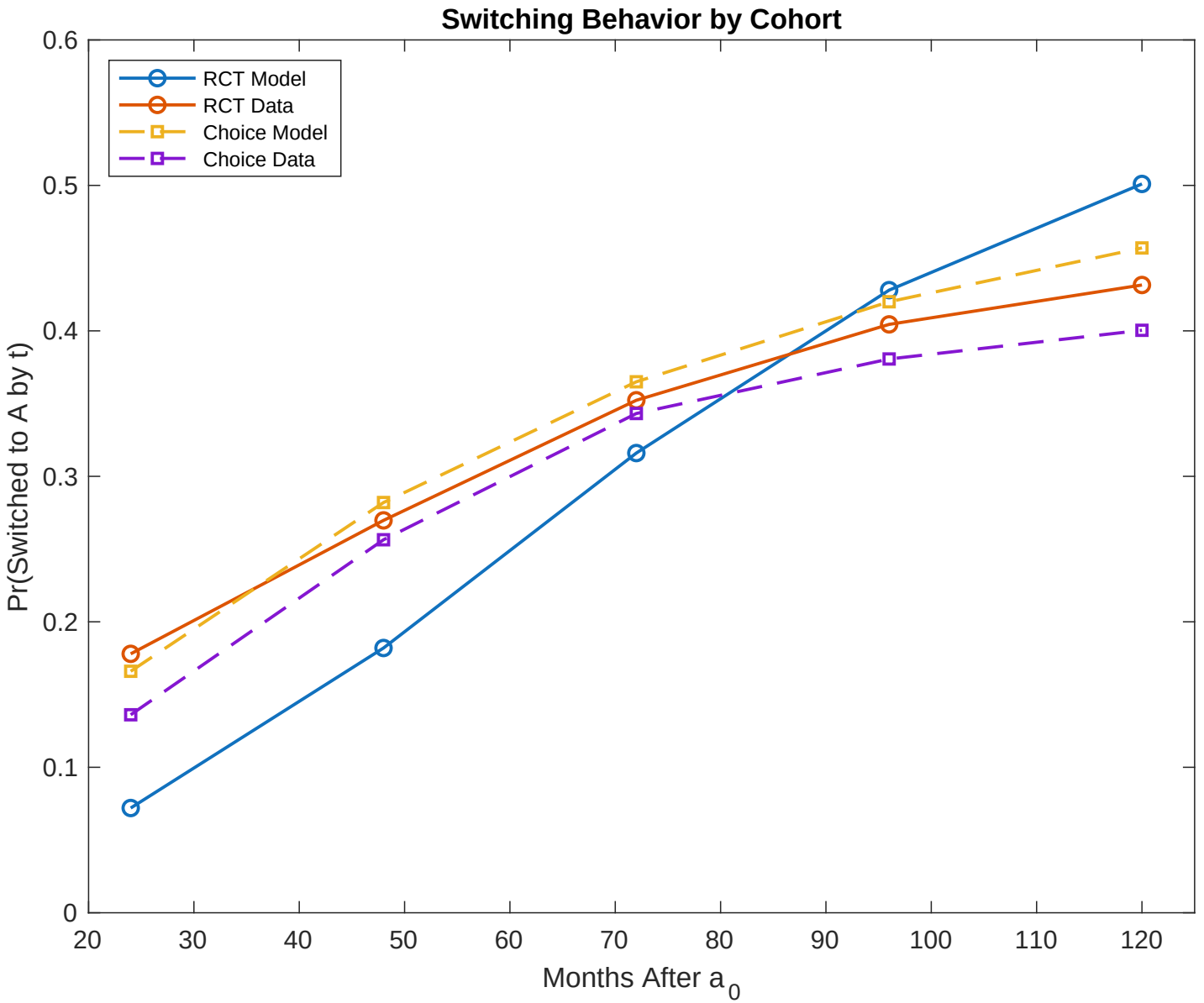
Estimates: Separation by distaste for side effects (α)



Estimates: Separation by initial disease severity (ω_{a_0})



Estimates: Switching behavior



From VATE to ATE in 10-year mortality

- The ProtecT RCT reports: $VATE = [0.015 - 0.008] = 0.007$
- Our model predicts: $VATE = [0.01616 - 0.00920] = 0.00696$
- If we compare A and B for the full diagnosed population under the $\underline{\omega} = 20$ protocol, we get:

$$ATE = [0.01653 - 0.00944] = 0.00709$$

- Essentially identical to VATE.
- **Caveat:** the parameter estimates are preliminary and will change.
- Additional result: When $\underline{\omega} = 4$,

$$ATE = [0.01172 - 0.00944] = 0.00227$$

Conclusions

- We combined RCT data and a structural model of treatment effects
- Combine experimental + non-experimental data
- Computed `ATE` under RCT protocol and with alternative guidance.

Thank You!

Appendix

- We study selection's impact on Comparative Effectiveness RCTs.
  - Treatments available to individuals outside of the RCT
  - Examples: Off-label Rx, behavioral interventions, fast vs. slow Tx.
  - Patients' preferences and treatment match affect participation choice, actions taken within RCT.
- Our application: Prostate cancer treatment.
- Our contribution: Structural model allows us to calculate a population ATE using a combination of RCT and observational data.
  - Selection on indifference across treatment arms
  - Decisions reflect preferences and expected outcomes
  - Forward-looking behavior by individuals
  - Model provides mapping from theory to empirics

Empirical Application – Assumptions I

Parameterization: Disease Progression

- The disease severity biomarker ω_a takes integer values from 3 to 30.
- Between periods, it grows by $\Delta_a^\omega \in \{0, 1, 2, ..., J\}$ steps.
- Δ_a^ω is drawn from a discrete approximation to the exponential distribution, as in Rust (1996).
- The density function approximates

$$f(\Delta_a^\omega | \omega_a) = \lambda_a^\omega \exp\Big(- \lambda_a^\omega \Delta_a^\omega \Big),$$

where $\lambda_a^\omega = \lambda_1^\omega + \lambda_2^\omega \omega_a$.

Empirical Application – Assumptions I

Parameterization: Metastasis Transition

- Probability of transitioning to metastasis between age a and $a+1$ conditional on choosing B at a is:

$$\pi^m(\chi_a, d_a = B) = \Lambda\left[\lambda_1^m + \lambda_2^m \omega_a\right]$$

- Match values on Treatment Success: $\varphi \sim N(\mu_\varphi, \sigma_\varphi)$
- When treatment is successful (with probability $\Phi(\varphi)$)

$$\pi^m(a, a_A, \omega_{a_A}, d_a = A, o = \text{success}) = \Lambda\left[\lambda_1^m + \lambda_2^m\left(\frac{\omega_{a_A}}{1 + a - a_A}\right)\right]$$

- If treatment is unsuccessful (with probability $[1 - \Phi(\varphi)]$), the patient retains the metastasis transition risk associated with his ω_{a_A}:

$$\pi^m(\omega_{a_A}, d_a = A, o = \text{failure}) = \Lambda\left[\lambda_1^m + \lambda_2^m \omega_{a_A}\right]$$

Empirical Application – Assumptions I

Parameterization: Survival

- Survival from a to $a+1$ two-step process. First, the patient needs to avoid death from other causes.
- The probability of dying from other, non-cancer sources of mortality from a to $a+1$, $\Pr\left(D_{a+1}^{nc}=1|a\right)$ depends on age and it is given by

$$\pi_{a+1}^{nc}=\Lambda\left(\lambda_1^{nc}+\lambda_2^{nc}a\right)$$

  where $\Lambda(\cdot)$ is the logistic CDF.
- For patients with metastatic disease, the probability of a cancer-related death is:

$$\pi^{c}(\chi_a)=\Lambda\left[\lambda_1^{c}+\lambda_2^{c}(a-a_M)\right],$$

  where a_M is the age at metastasis.

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