CardioOncology: Advancing the Cardiovascular Care of the Oncology Patient

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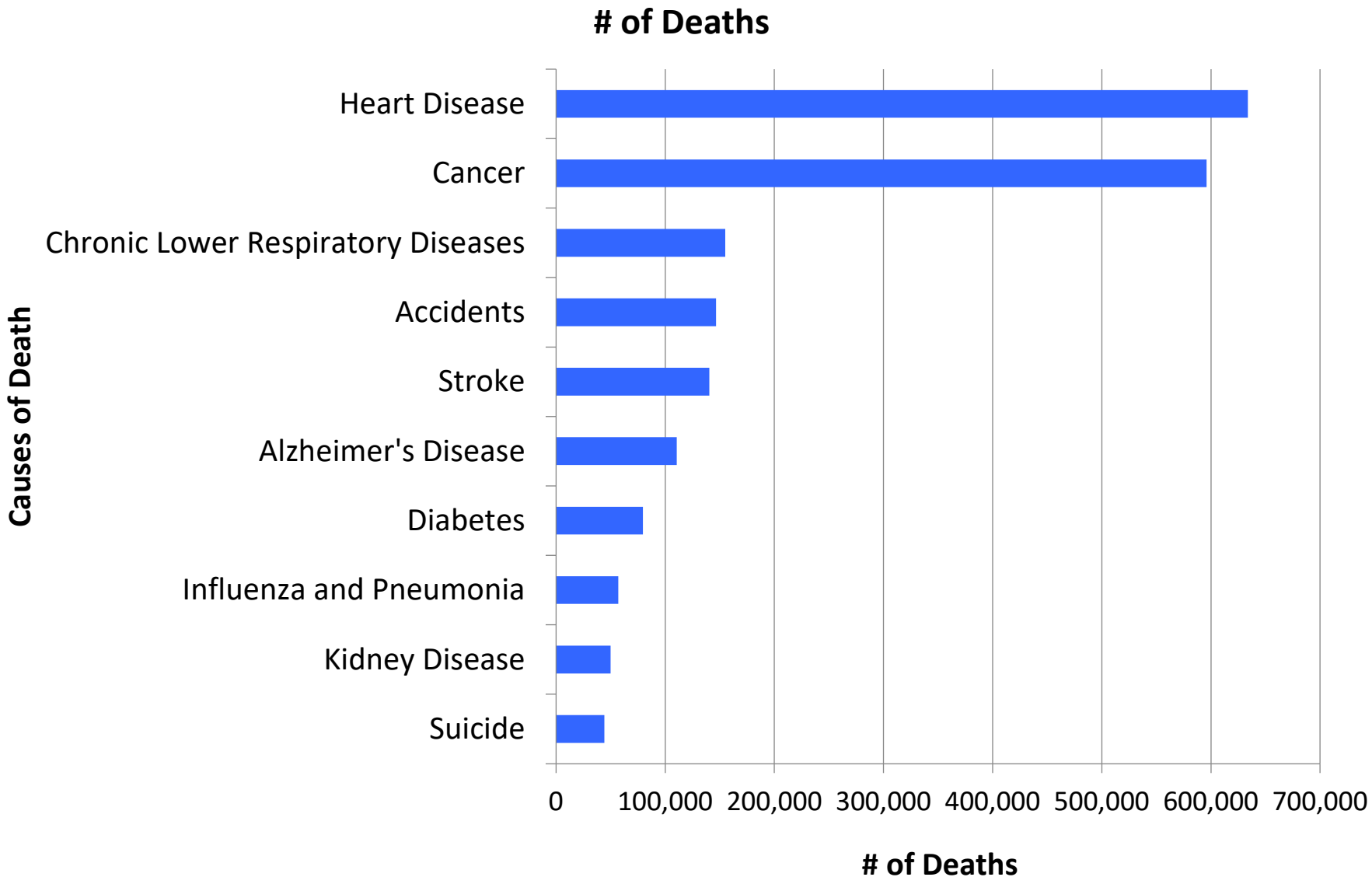
Why a new subspecialty of Medicine?

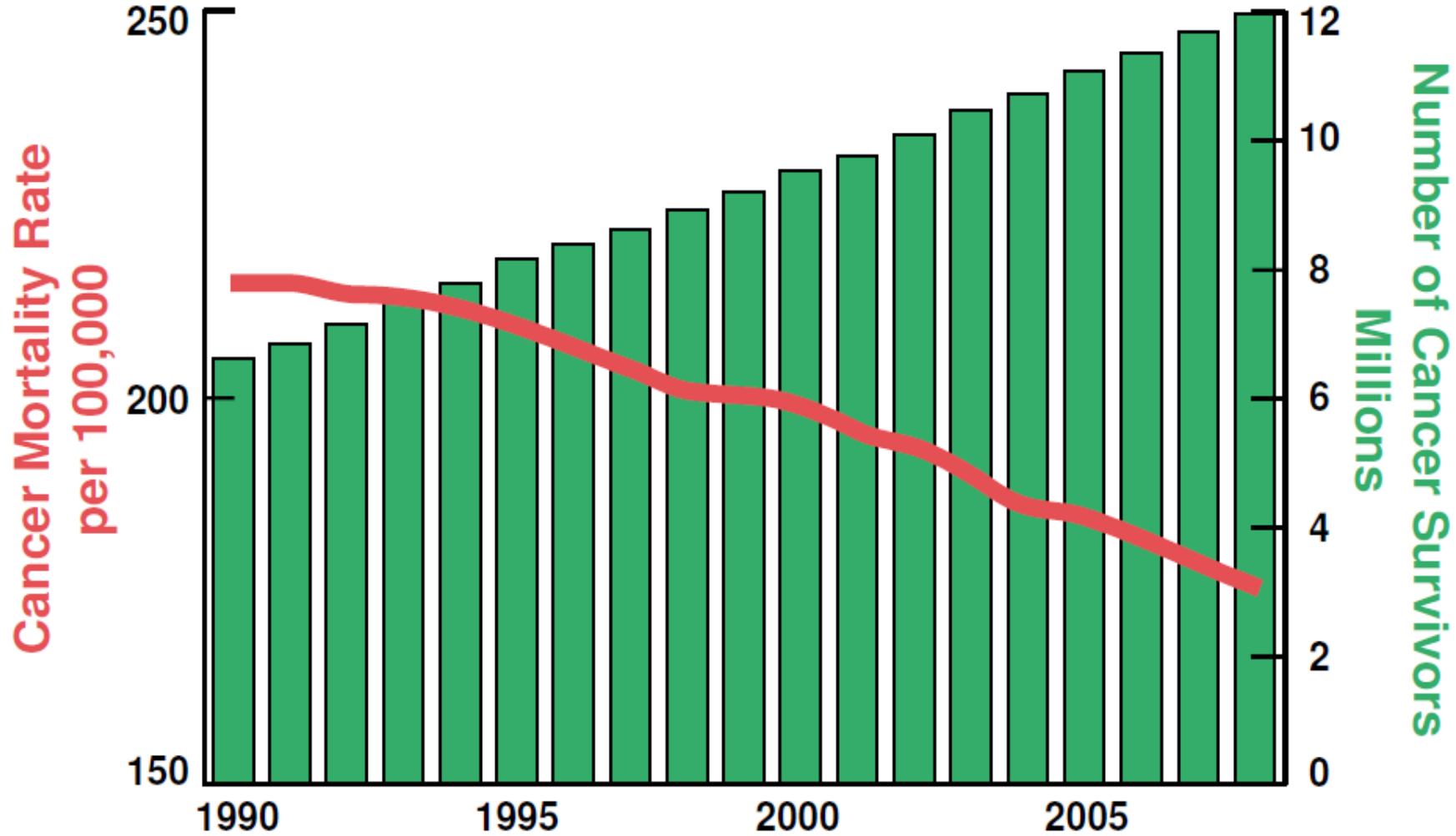
"Rapidly growing market of novel and emerging cancer therapies and rising number of patients living with and surviving cancer, often in the setting of new or pre-existing cardiovascular disease and risk factors, have created a need for specialty cardiovascular care. "

Anna Barac, MD, PhD, Section Lead ACC CardioOncology

2015 CDC US Mortality Data



Cancer in the United States, 1990-2008
Surviving Rising, Mortality Decreasing



Data from the National Cancer Institute on estimated number of cancer survivors and age-adjusted cancer deaths per 100,000 people

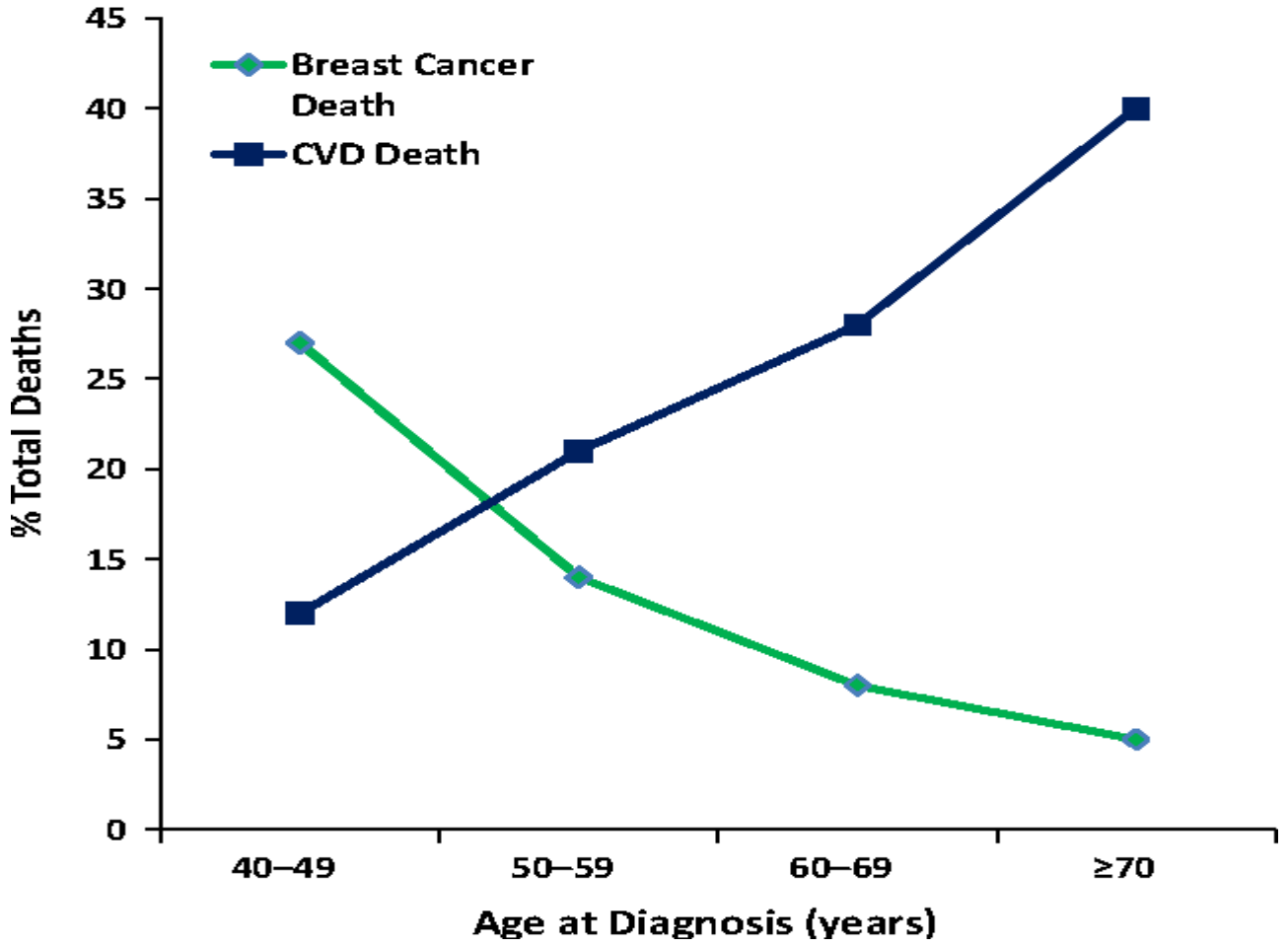


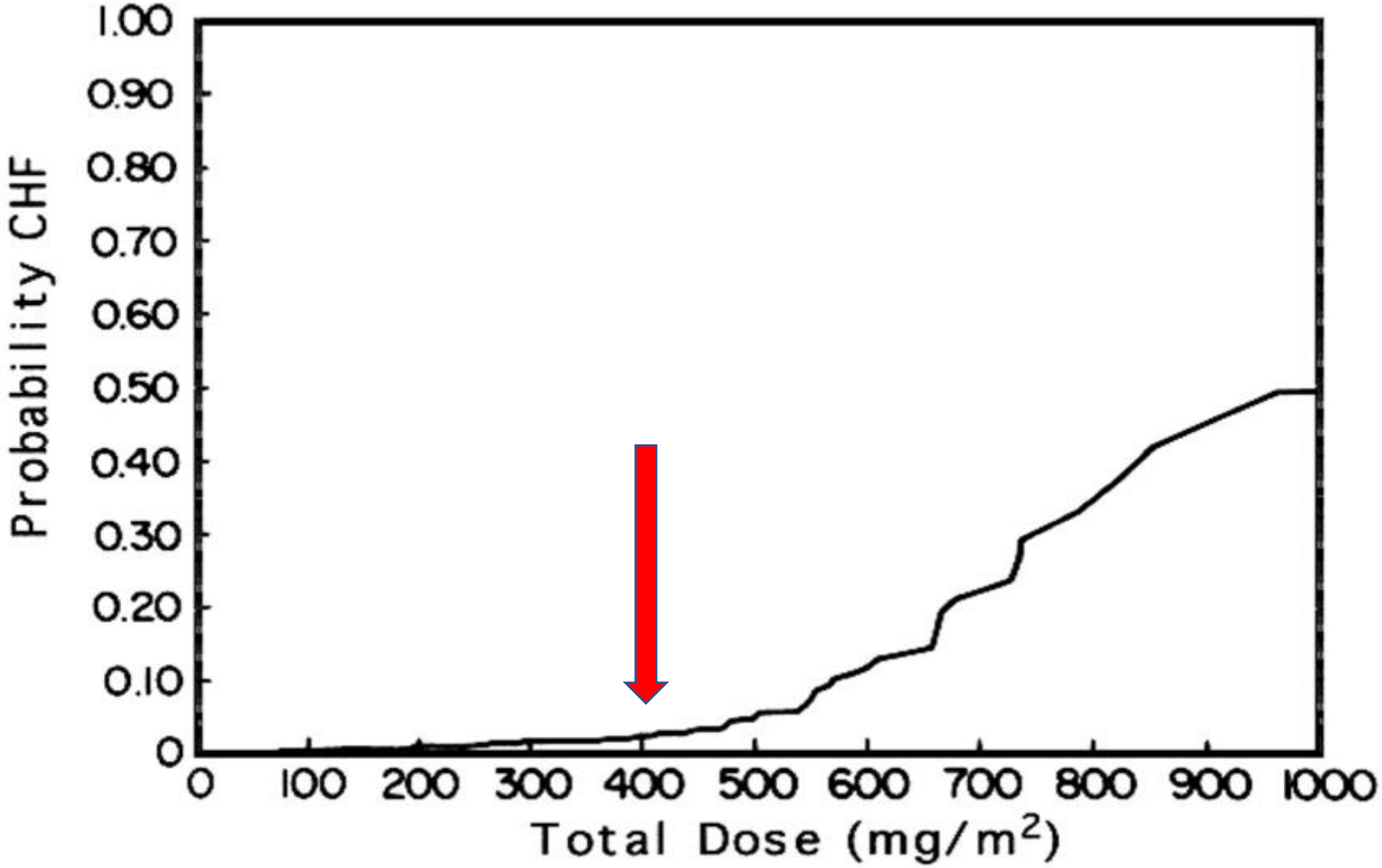
Fig. 1 Percentage of total cardiovascular deaths versus breast cancer deaths by age of ductal carcinoma in situ (DCIS) diagnosis

Berkman et al. Breast Cancer Research and Treatment 2014
DOI:10.1007/s10549-014-3168-3

Anthracyclines

- In the 1950s, daunorubicin, a compound isolated from the soil bacterium *Streptomyces peucetius*, was found effective against tumors in mice, and eventually, acute leukemia and lymphoma.
- Among the most effective anticancer treatments ever developed and are effective against more types of cancer than any other class of chemotherapeutic agents (R-CHOP)
- MOA: intercalates between DNA/RNA, affects topoisomerase II, free radial generation
  - Associated with troubling side-effect: cardiotoxicity (in some cases: irreversible), many of whom went to require heart transplant

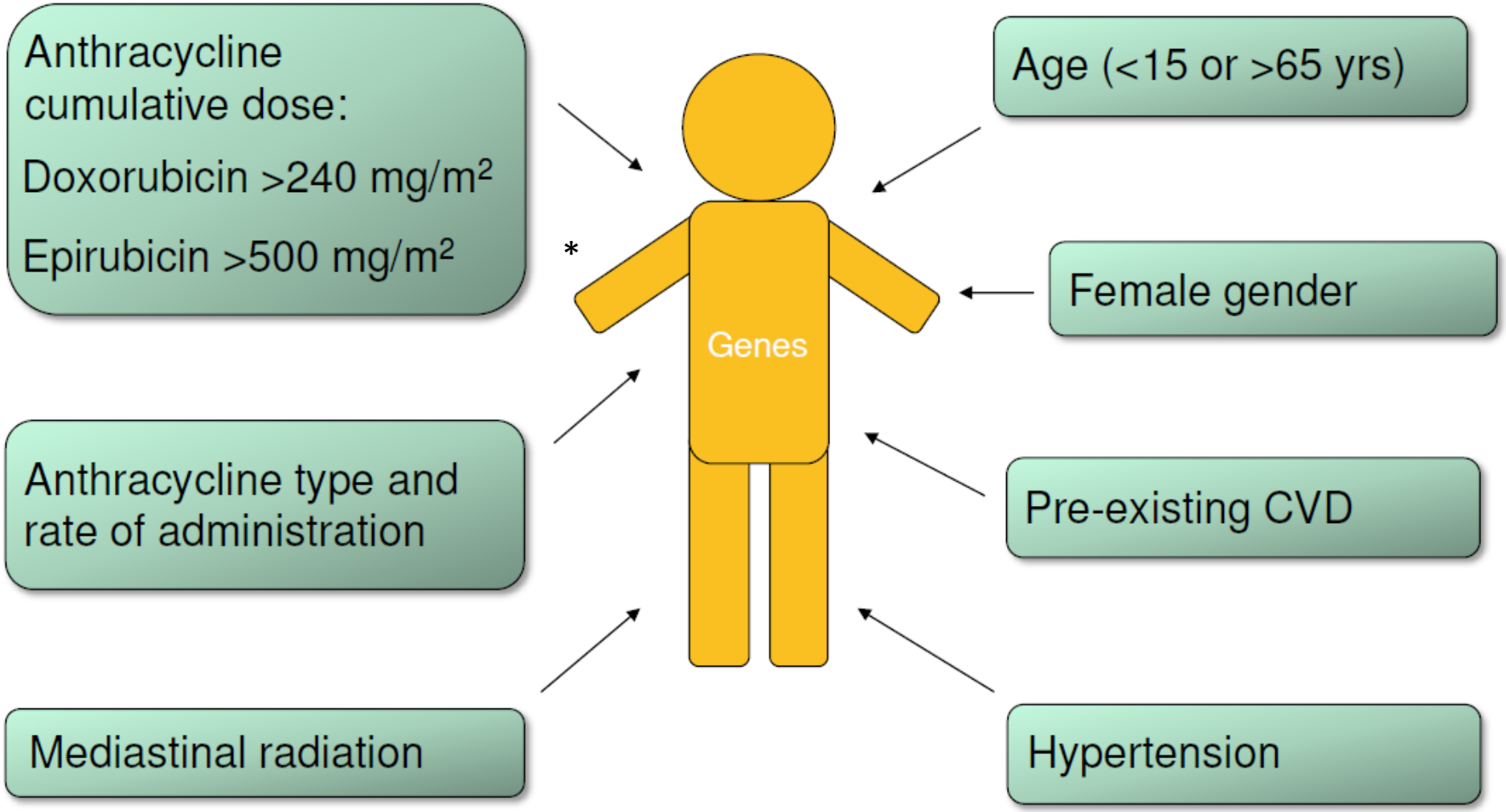
Anthracycline Dose Cardiac Toxicity



Shan et al. *Ann Intern Med.* 1996;125(1):47-58.

Anthracycline Cardiotoxicity

Predictors



* Van Dallen EC Cochrane Review 2010

Ewer MS and Ewer SM. Nat. Rev. Cardiol. 2010; 7,564–75

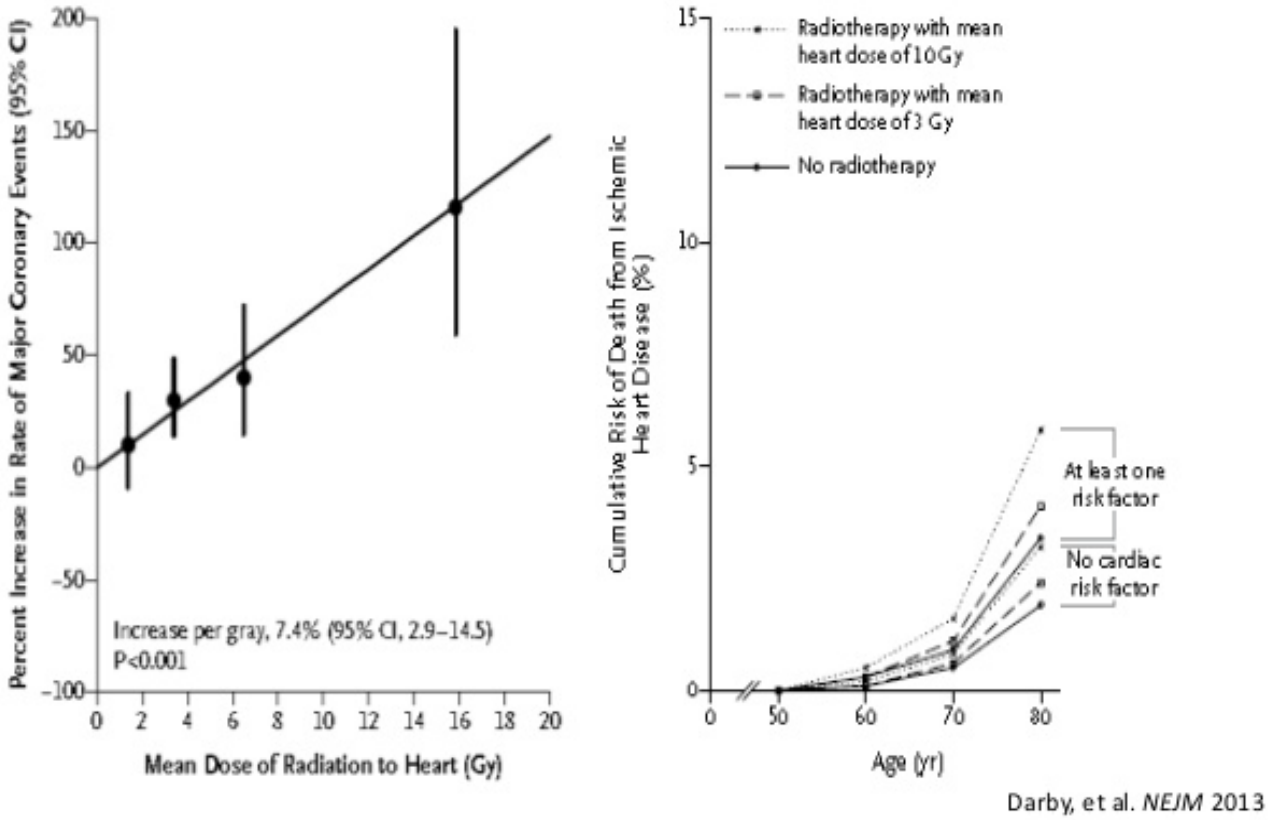
"One of the goals of cardio-oncology is to PREVENT the cancer survivor of today from becoming the heart failure patient of tomorrow."

Radiation Therapy and CV disease

- XRT: curative vs palliative intent
- Mantle Cell Lymphoma, Adjuvant therapy in breast cancer, Hodgkin's lymphoma, lung cancer
- Cardiac complications when dose is greater than 30 Gy
- Shrinking problem: breath holding technique, shielding, smaller fractions, PET scans

Coronary Events in Breast Cancer

Radiation Therapy



Darby, et al. *NEJM* 2013

Incidental exposure of the heart to radiotherapy for breast cancer increased the rate of major coronary events by 7.4% per gray, with no apparent threshold. The percentage increase per unit increase in the mean dose of radiation to the heart was similar for women with and women without preexisting cardiac risk factors

Radiation Induced Cardiotoxicity

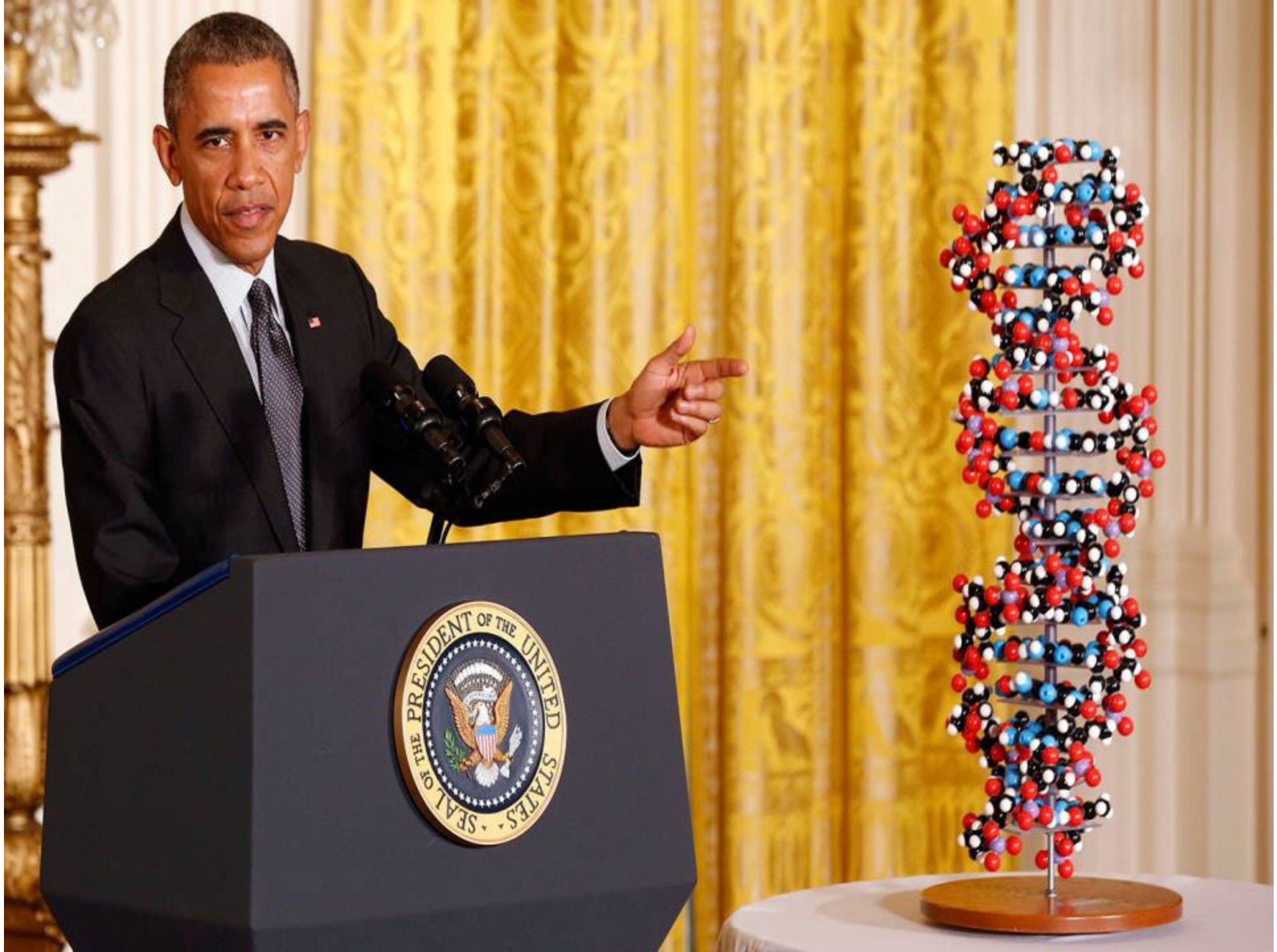
Valve disease

Atherosclerosis
(Symptomatic or asymptomatic)

Pericardial disease
(Acute pericarditis; chronic pericarditis; pericardial effusion; constrictive pericarditis)

Myocardial and endocardial disease
(Pancarditis, cardiomyopathy)

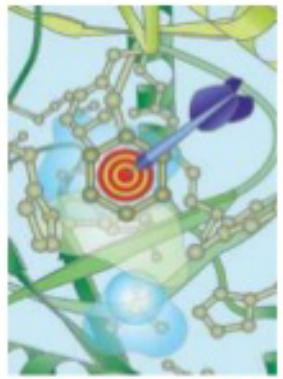
Conduction disturbances
(Right bundle branch block, atrioventricular block)


SEAL OF THE PRESIDENT OF THE UNITED STATES

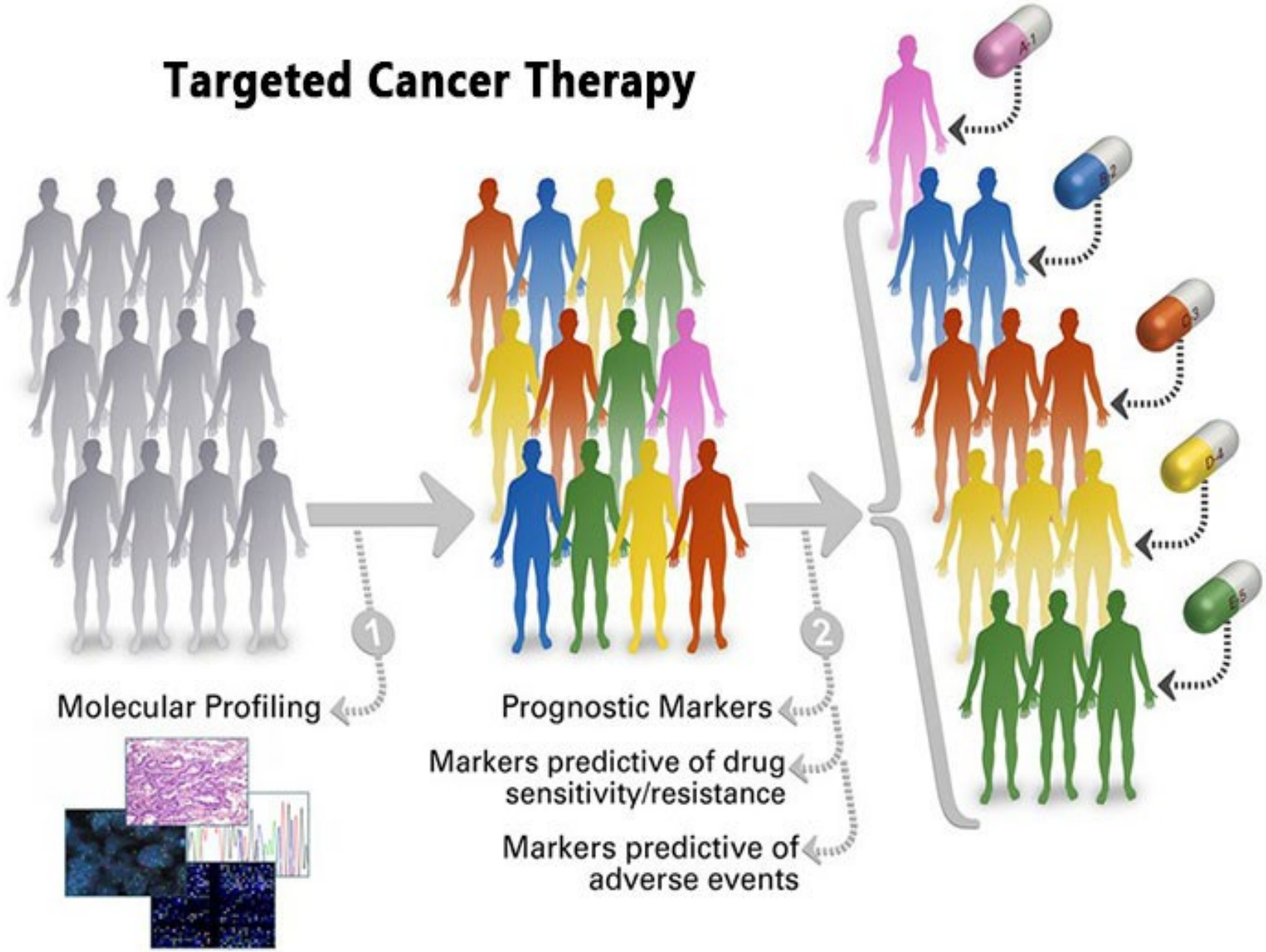
Chemotherapy vs Targeted Therapy

- **Chemotherapy:**
  - Drugs that effect cells that are doubling
  - Not very specific
  - Mostly intravenous, some oral agents
  - Cytotoxic

- **Targeted therapy:**
  - Drugs that inhibit a more specific target in cells
  - Many are oral agents
  - Mixture of cytostatic and cytotoxic

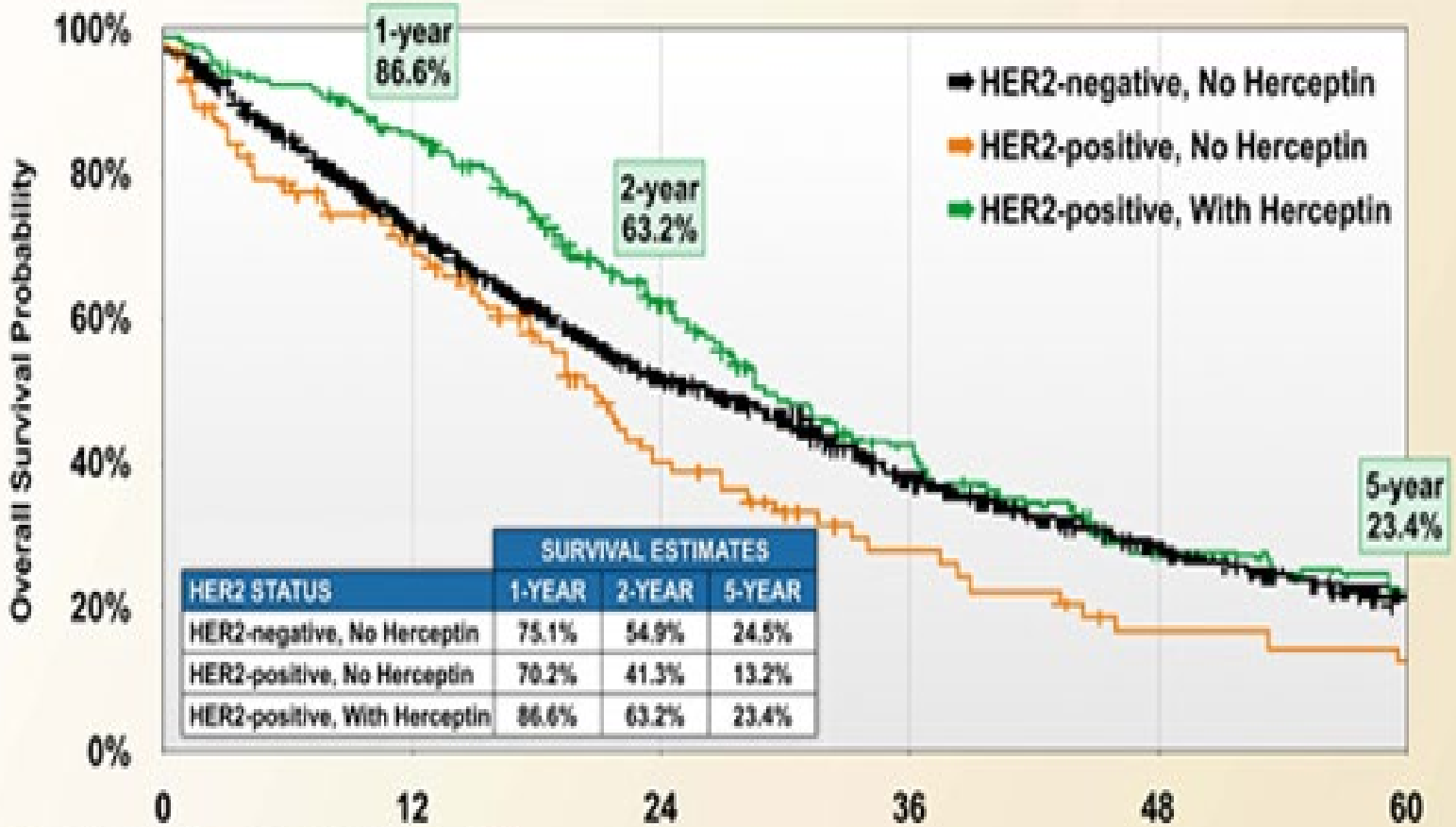


Targeted Cancer Therapy



Herceptin Has Altered The Natural History of HER2+ Breast Cancer

STAGE IV BREAST CANCER – OVERALL SURVIVAL



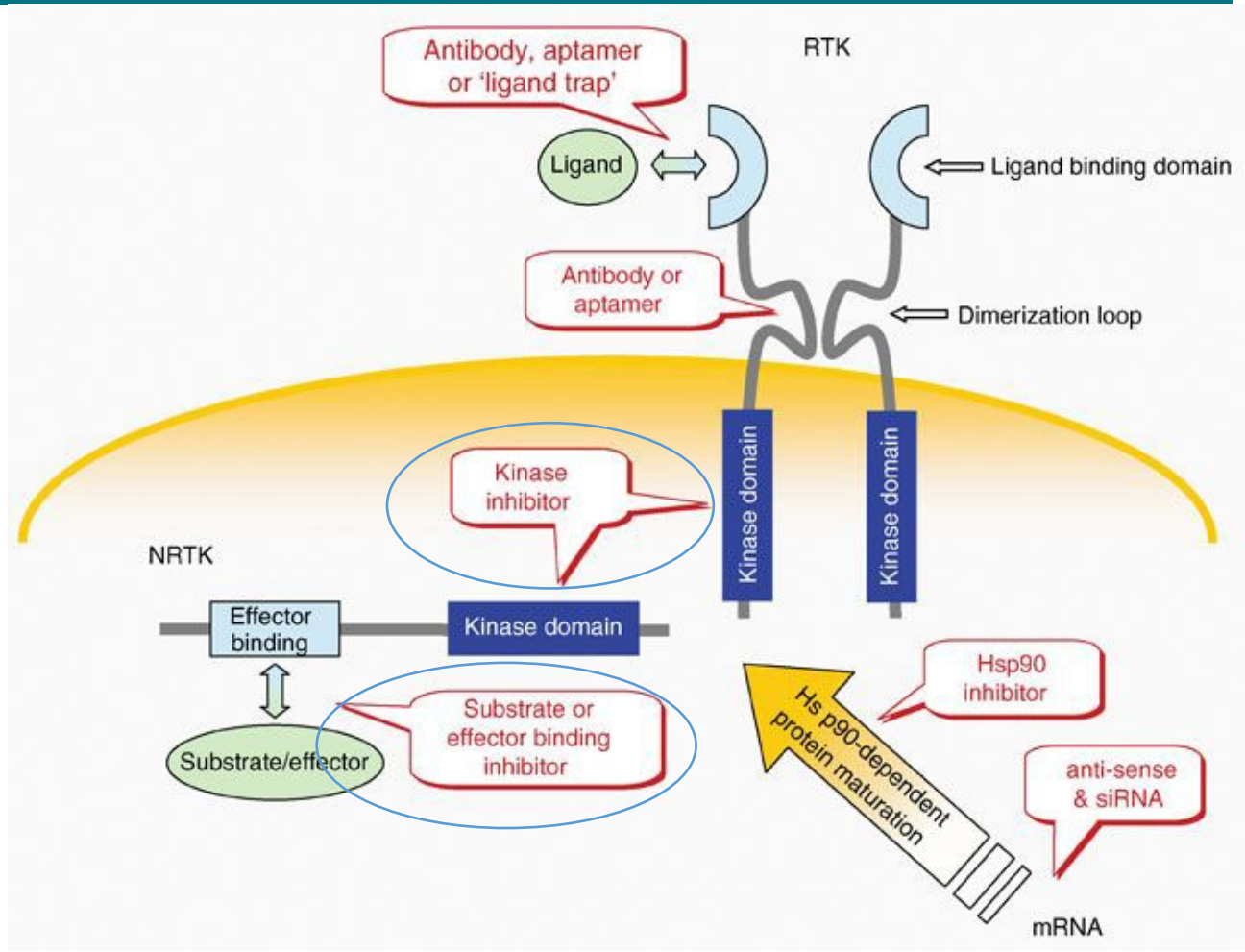
	SURVIVAL ESTIMATES		
HER2 STATUS	1-YEAR	2-YEAR	5-YEAR
HER2-negative, No Herceptin	75.1%	54.9%	24.5%
HER2-positive, No Herceptin	70.2%	41.3%	13.2%
HER2-positive, With Herceptin	86.6%	63.2%	23.4%

Dawood S *et al*, American Society of Clinical Oncology, June 2008

Oral Targeted Therapies

- Block the process/signals that helps cancer cells multiply and spread

- ExampleTargets: ALK, BCR-Abl, BRAF, BTK, CSF1R, CKD 4/6, EGFR, FLT 3, FGFR, HER2, JAK2, KIT, MEK, PI3K, TRK, VEGFR, etc.



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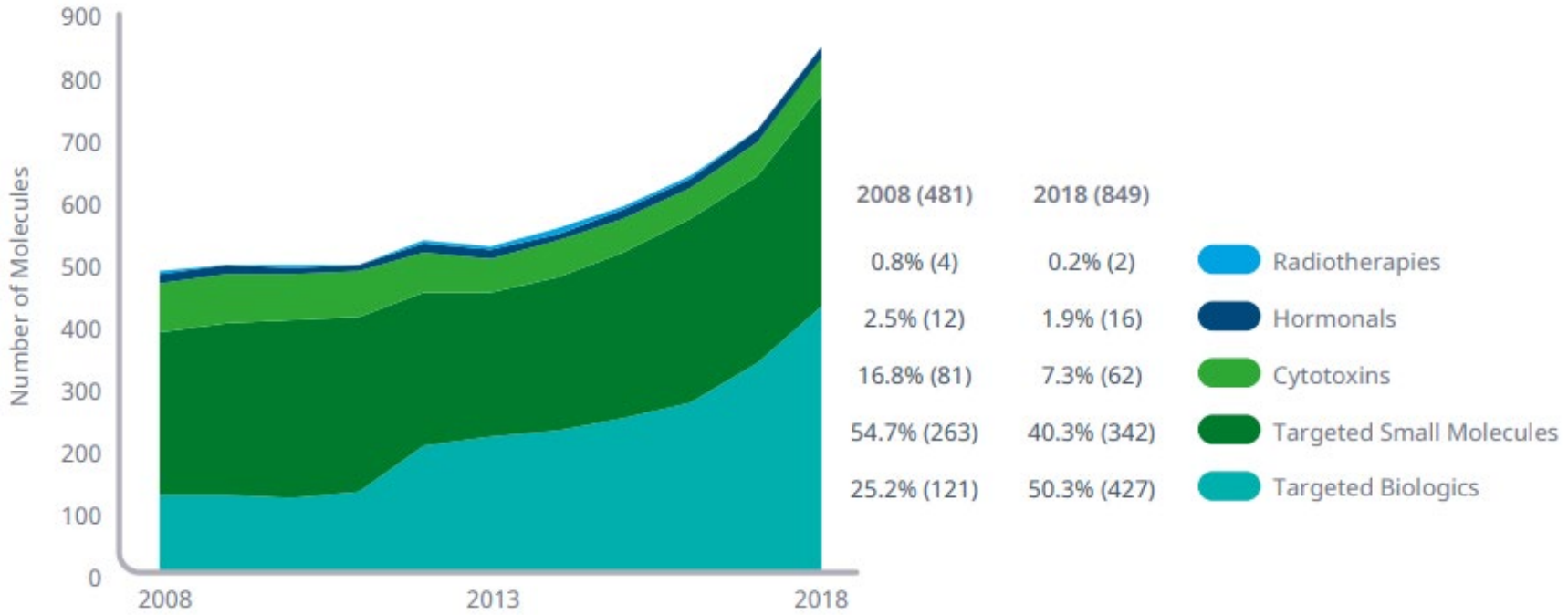
Transition from cytotoxic drugs to targeted therapies…

The late-stage oncology pipeline included 849 molecules in 2018, up 77% since 2008, due to the increasing number of targeted therapies

Exhibit 9: The Pipeline of Late Phase Oncology Molecules, 2008–2018



Source: IQVIA Pipeline Intelligence, Dec 2018; IQVIA Institute, May 2019

A Revolution in the Treatment of Multiple Malignancies

>50 approved by the FDA	May avoid chemotherapy	Treat at home

Example: Advanced Renal Cell Carcinoma

PRINCIPLES OF SYSTEMIC THERAPY FOR RELAPSE OR STAGE IV DISEASE

FIRST-LINE THERAPY FOR CLEAR CELL HISTOLOGY

Risk	Preferred Regimens	Other Recommended Regimens	Useful in Certain Circumstances
Favorable[a]	• Axitinib + pembrolizumab[b] (category 1) • Cabozantinib + nivolumab[b] (category 1) • Lenvatinib + pembrolizumab[b] (category 1)	• Axitinib + avelumab[b] • Cabozantinib (category 2B) • Ipilimumab + nivolumab[b] • Pazopanib • Sunitinib	• Active surveillance[c] • Axitinib (category 2B) • High-dose IL-2[d] (category 2B)
Poor/ intermediate[a]	• Axitinib + pembrolizumab[b] (category 1) • Cabozantinib + nivolumab[b] (category 1) • Ipilimumab + nivolumab[b] (category 1) • Lenvatinib + pembrolizumab[b] (category 1) • Cabozantinib	• Axitinib + avelumab[b] • Pazopanib • Sunitinib	• Axitinib (category 2B) • High-dose IL-2[d] (category 3) • Temsirolimus[e] (category 3)

SUBSEQUENT THERAPY FOR CLEAR CELL HISTOLOGY

Preferred Regimens	Other Recommended Regimens	Useful in Certain Circumstances
• Cabozantinib (category 1) • Lenvatinib + everolimus (category 1) • Nivolumab[b] (category 1)	• Axitinib (category 1) • Axitinib + pembrolizumab[b] • Cabozantinib + nivolumab[b] • Ipilimumab + nivolumab[b] • Lenvatinib + pembrolizumab[b] • Pazopanib • Sunitinib • Tivozanib[g] • Axitinib + avelumab[b] (category 3)	• Everolimus • Bevacizumab[f] (category 2B) • High-dose IL-2 for selected patients[d] (category 2B) • Sorafenib (category 3) • Temsirolimus[e] (category 2B)

NCCN Guidelines Kidney Cancer, Version 4.2022
https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf

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The Downside of Oral Targeted Therapy

Adherence	Delays in starting therapy	Drug-Drug Interactions
Monitoring	Tolerability and Supportive Care	$$$Cost$$$

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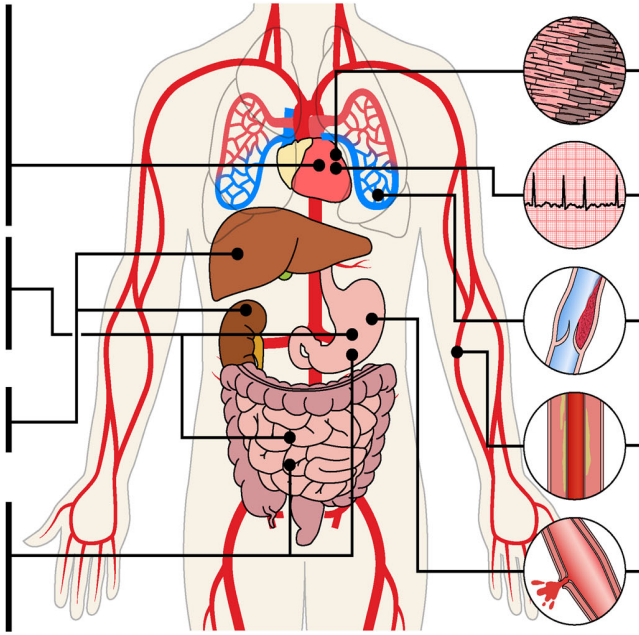
Drug-Drug Interactions

Pharmacokinetic Drug Interactions

Metabolism
- CYP1A2 (e.g., vemurafenib + carvedilol, verapamil + erlotinib)
- CYP2C9 (e.g., ibrutinib + warfarin, select ARBs + imatinib)
- CYP2C19 (e.g., clopidogrel + enzalutamide)
- CYP2D6 (e.g., tamoxifen + dronedarone)
- UGT (e.g. dapagliflozin + sorafenib)
- CYP3A4 (e.g. select TKIs + DOACs, atorvastatin + idelalisib, diltiazem + bosutinib)
- P-gp (e.g,. ANT + digoxin, select TKIs + DOACs, select beta-blockers + imatinib)

Elimination
(e.g., vinblastine + amiodarone)

Absorption
- CYP3A4 (e.g. select TKIs + DOACs, atorvastatin + idelalisib, diltiazem + bosutinib)
- P-gp (e.g,. ANT + digoxin, select TKIs + DOACs, select beta-blockers + imatinib)



Pharmacodynamic Drug Interactions

Cardiomyopathy
(e.g., ANTs + HER2i)

Myocarditis
(e.g., ICIs + BRAFi)

QT Prolongation
(e.g., arsenic, SERMs, select TKIs)

Prothrombotic Events – Pulmonary embolism, Deep vein thrombosis
(e.g., IMiDs + dexamethasone, pegaspargase + ANTs)

Hypertension
(e.g., select VEGF inhibitors)

Bleeding – GI bleed, Hemorrhagic stroke
(e.g., ibrutinib + LMWH/DOACs)

Circulation. 2022;145:e811-e838

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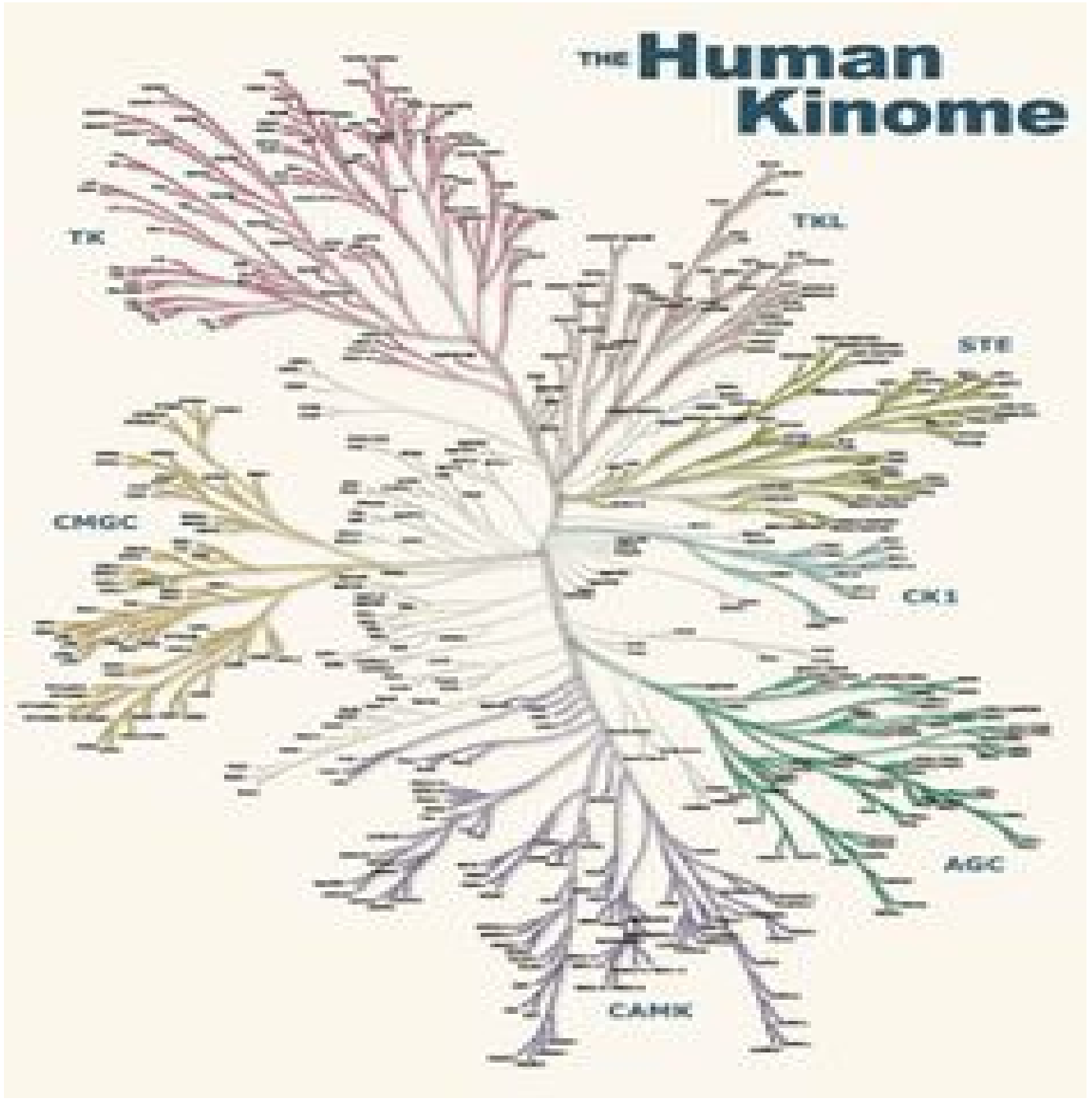
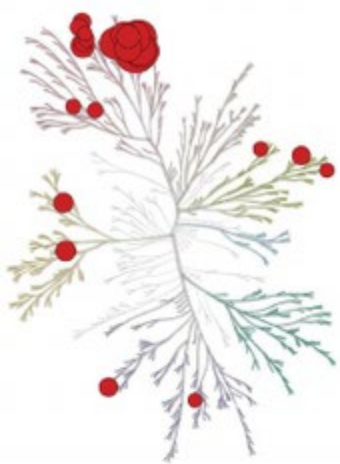
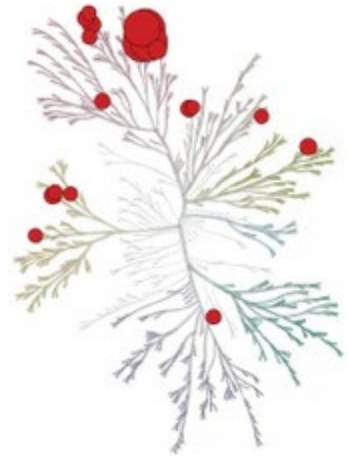
Steve Breen SAN DIEGO UNION-TRIBUNE


THE Human Kinome
TK
TKL
STE
CMGC
CK1
AGC
CAMK

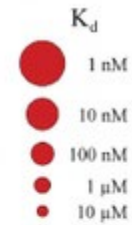


AC220

CEP-701



MLN-518



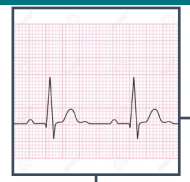
PKC-412

CGP-52421

Sorafenib

Sunitinib

Cardiac Impact of Oral Targeted Therapy

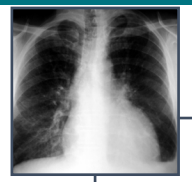


QT Prolongation

- Bosutinib
- Ceritinib
- Crizotinib
- Dabrafenib
- Dasatinib
- Encorafenib
- Entrectinib
- Gilteritinib
- Glasdegib
- Ivosidenib
- Lapatinib
- Lenvatinib
- Midostaurin
- Nilotinib
- Osimertinib
- Panobinostat
- Pazopanib
- Ribociclib
- Sorafenib
- Sunitinib
- Vandetanib
- Vemurafenib
- Vorinostat

Hypertension

- Abiraterone
- Axitinib
- Brigatinib
- Cabozantinib
- Everolimus
- Lenvatinib
- Niraparib
- Pazopanib
- Regorafenib
- Sorafenib
- Sunitinib



Heart Failure

- Binimetinib
- Cobimetinib
- Dabrafenib
- Entrectinib
- Fedratinib
- Lapatinib
- Lenalidomide
- Lenvatinib
- Osimertinib
- Pazopanib
- Pomalidomide
- Ponatinib
- Sunitinib
- Thalidomide
- Trametinib

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Oral Antineoplastic Agent Monitoring Recommendations

- FDA labels, July 2020 (56/85 = 66%) recommend some form of cardiac monitoring
- Synthesis of FDA labels and phase III trials = reasonable monitoring recommendations
- Balance risk of over-testing which may lead to inappropriate withholding of life-saving anti-neoplastic therapy with missing identification of CV toxicity which may impact outcome for patients with malignancy

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THE PRESENT AND FUTURE

JACC STATE-OF-THE-ART REVIEW

Clinical Approach to Cardiovascular Toxicity of Oral Antineoplastic Agents

JACC State-of-the-Art Review

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ABSTRACT

Precision medicine has ushered in a new era of targeted treatments for numerous malignancies, leading to improvements in overall survival. Unlike traditional chemotherapy, many molecular targeted antineoplastic agents are available in oral formulation, leading to enhanced patient convenience and a perception of reduced risk of adverse effects. Although oral antineoplastic agents are generally well-tolerated, cardiovascular toxicities are being reported with increasing frequency in part due to U.S. Food and Drug Administration and manufacturer recommended cardiac monitoring. Monitoring strategies have focused on left ventricular dysfunction, hypertension, and QT prolongation/arrhythmias. Given the rapid pace of development and availability of new oral antineoplastic agents, the purpose of this review is to provide clinicians with an up-to-date practical approach to monitoring and management of cardiovascular toxicities with the aim of improving overall outcomes for patients with cancer. (J Am Coll Cardiol 2021;77:2693–716) © 2021 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Historically, the first chemotherapeutic agents demonstrating serious cardiovascular (CV) side effects were anthracyclines. Left ventricular (LV) dysfunction and heart failure (HF) were observed in a dose–response relationship (1). The introduction of trastuzumab for the treatment of breast cancer, although a paradigm shift in cancer care, was associated with LV dysfunction and HF, particularly in patients treated with concomitant anthracyclines (2). As a result, oncologists modified chemotherapy regimens and expanded care for patients by establishing CV monitoring algorithms to prevent cardiotoxicity. The current landscape of oncological care has been revolutionized with the ability to routinely perform tumor typing, thus identifying key cellular signaling pathways responsible for oncological transformation. Drugs specifically targeting these pathways, such as tyrosine kinase inhibitors (TKIs), have dramatically improved overall cancer survival rates. However, these same pathways are vital for normal physiological function of many organs, including the cardiovascular system.

Despite increased recognition of CV side effects from cancer therapy, clinical care for patients remains

Listen to this manuscript's audio summary by Editor-in-Chief Dr. Valentin Fuster on JACC.org.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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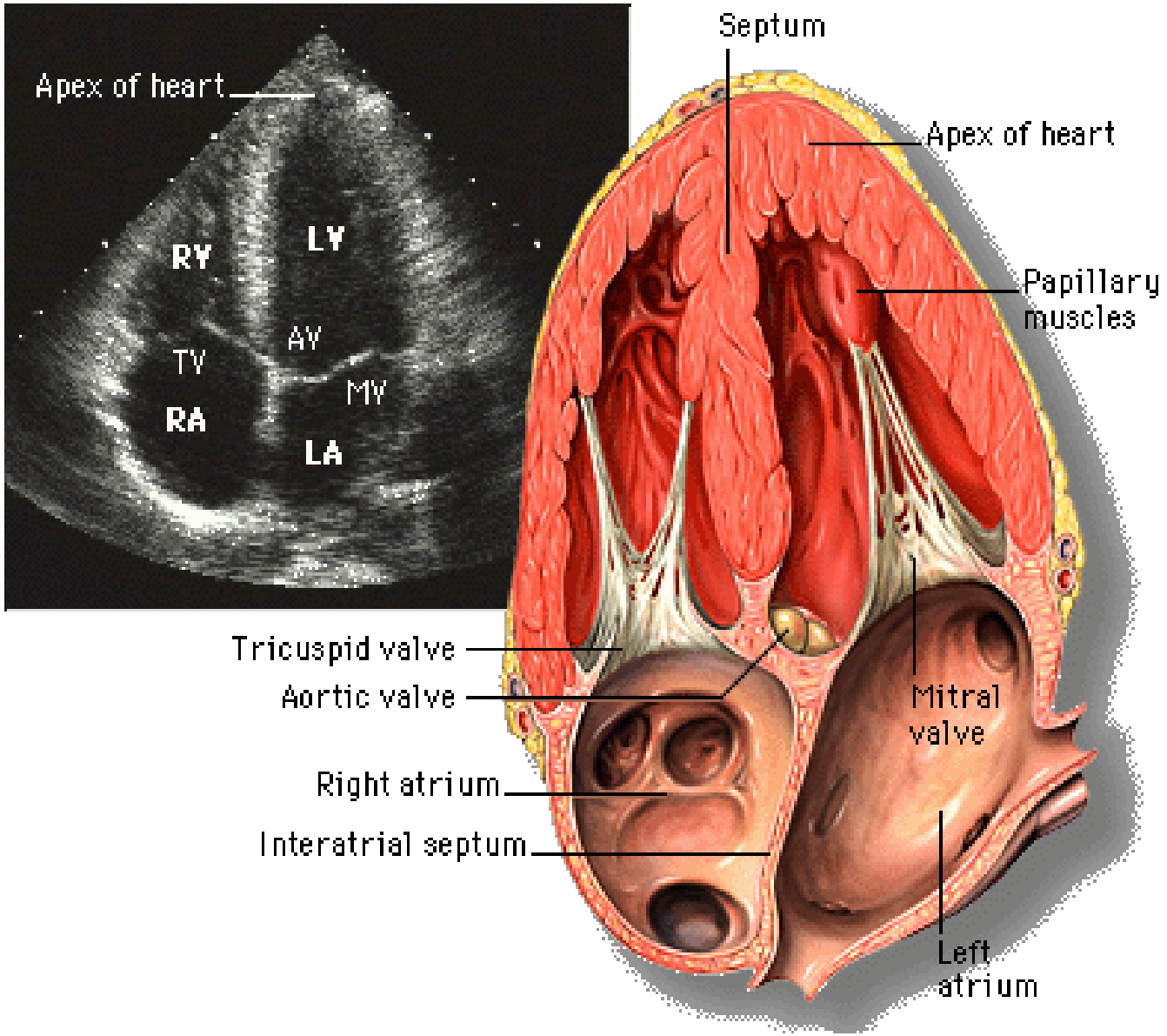
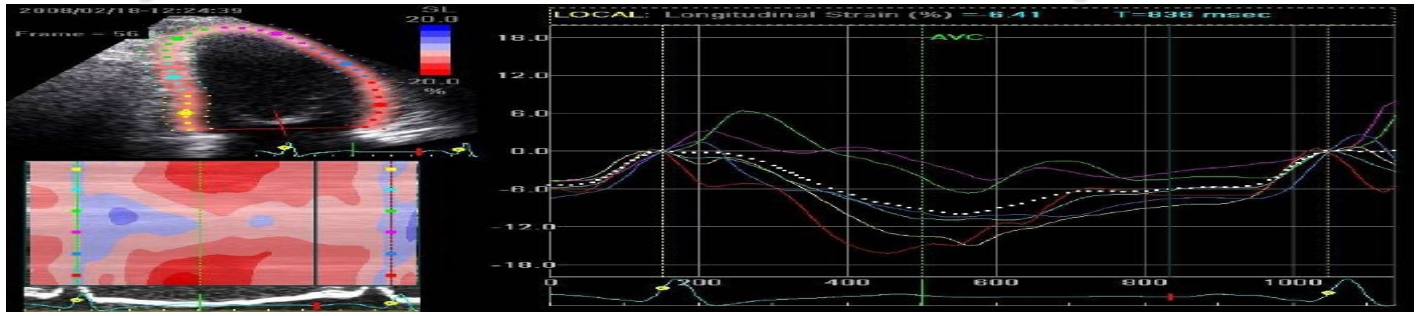
Echocardiography

CTRCD: Cancer Therapy-Related Cardiac Dysfunction

- Decline in LVEF of >10% and/or value of <53%
- IV Contrast to enhance endocardial border definition



Myocardial strain analysis



- 10-15% drop in GLS by STE predicts future drop in EF for both anthracycline and trastuzumab chemotherapy [Thavendiranathan et al JACC 2014 volume (63):2751]
- GLS provided incremental prognostic information in cancer patients when combined with clinic variables [Rhea et al JASE 2015 28 (6) 667]
- SUCCOUR study: international randomized trial GLS vs echo guided strategy to prevent cardiotoxicity (mostly anthracyclines and Herceptin), did not meet primary endpoint of change in LVEF at 1 year; a few secondary endpoints were positive (*J Am Coll Cardiol* 2021;77:392-401)

Cardiac MRI

- 3-Dimensional: not limited by geometric assumptions; gold standard for LVEF
- If considering stopping anti-neoplastic agent due to LVEF drop, cMRI recommended

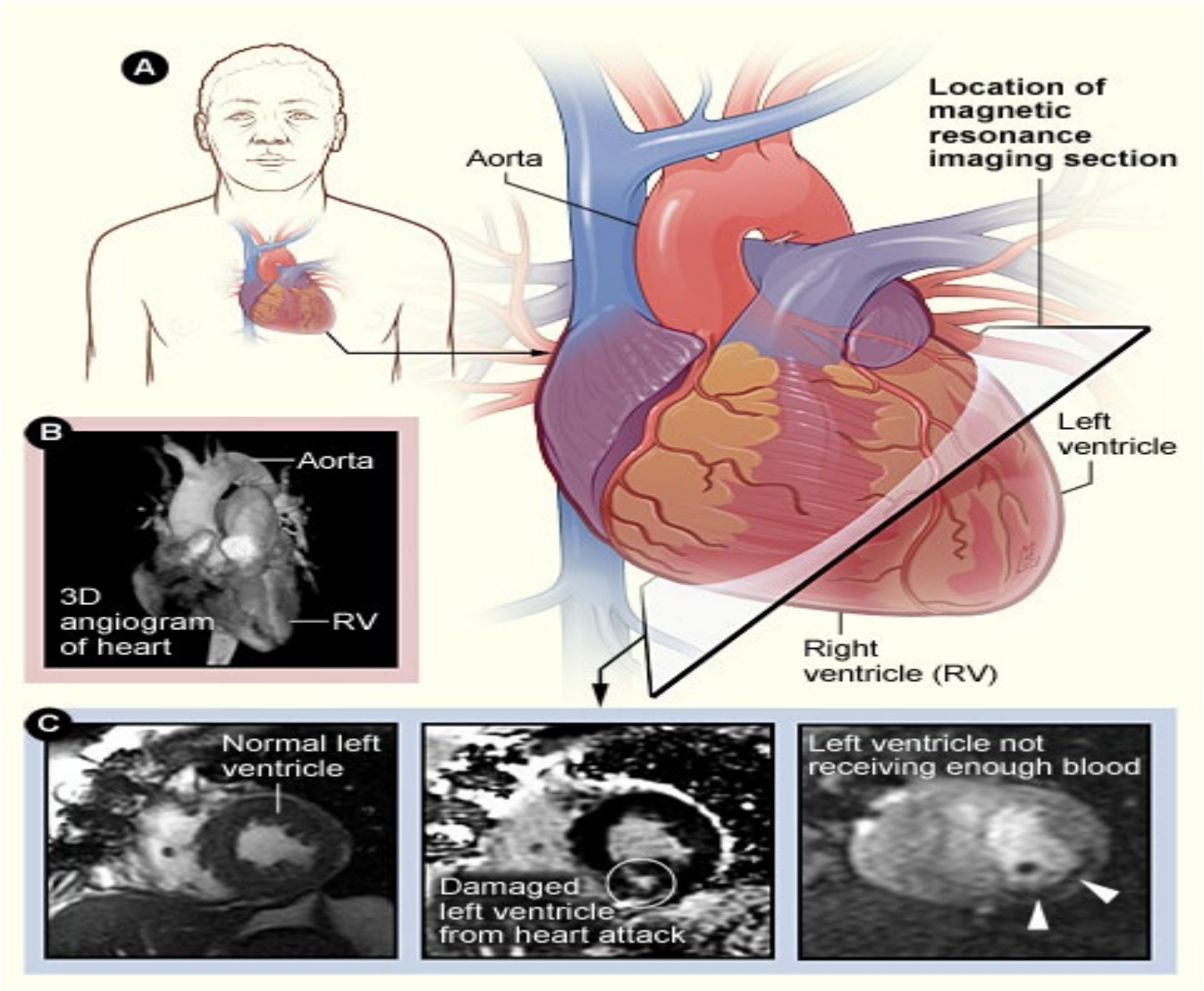


TABLE 4 Drugs to Avoid (if Possible) in Patients Taking Oral Antineoplastic Agents With QT-Prolonging Potential

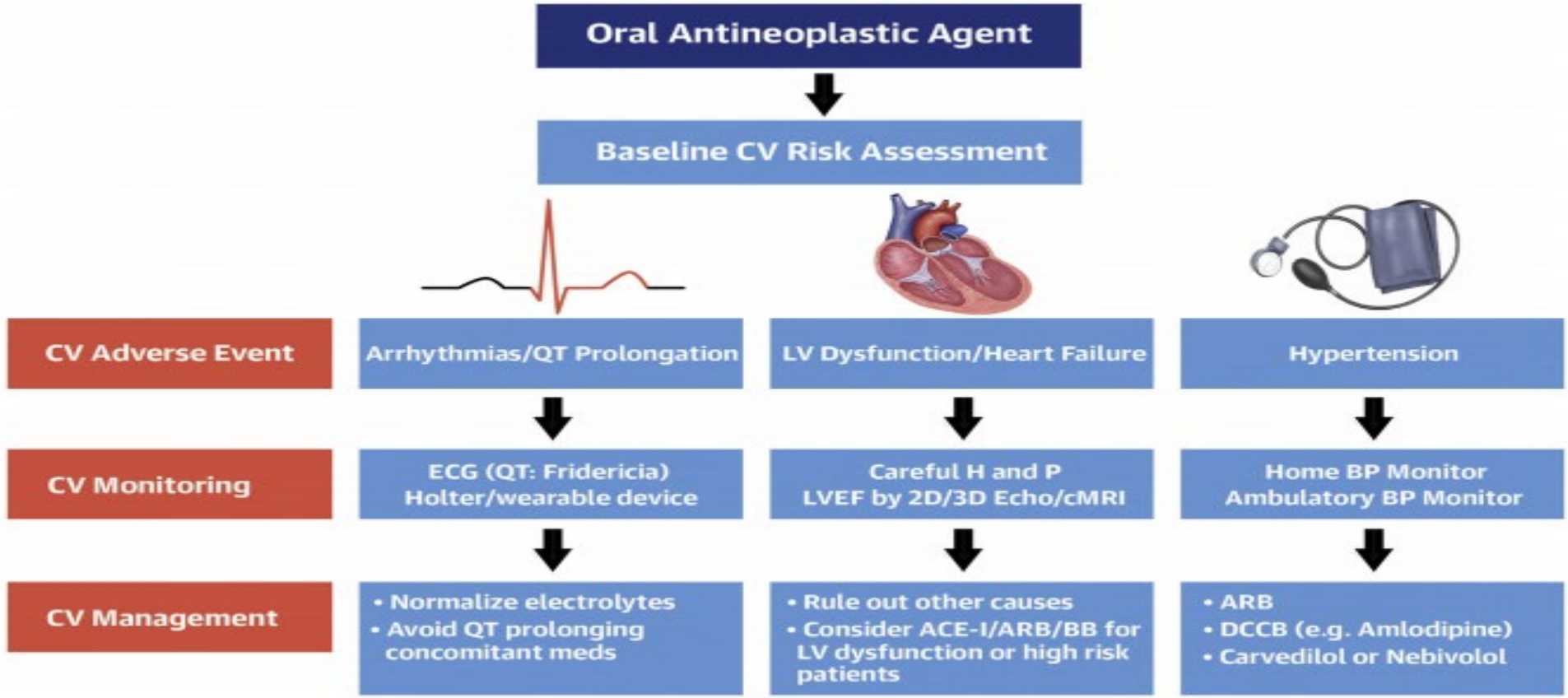
Anti-Infective Agents	Antiemetics	Antidepressants	Antipsychotic Agents	Antiarrhythmic Agents	Other
Fluoroquinolones	Domperidone	SSRIs	Clozapine	Amiodarone	Fosphenytoin
Ciprofloxacin	Droperidol	Citalopram	Thioridazine	Disopyramide	Methadone
Levofloxacin	Ondansetron	Escitalopram	Haloperidol	Dofetilide	Methylphenidate
Moxifloxacin		Fluoxetine	Quetiapine	Dronedarone	Phenytoin
Macrolide antibiotics		Paroxetine	Risperidone	Ibutilide	
Azithromycin		Sertraline	Ziprasidone	Procainamide	
Clarithromycin		Trazodone		Quinidine	
Erythromycin		SNRIs		Sotalol	
Azole antifungals		Venlafaxine			
Fluconazole		TCAs			
Itraconazole		Amitriptyline			
Ketoconazole		Clomipramine			
Voriconazole		Desipramine			
Antimalarials		Doxepin			
Chloroquine		Imipramine			
Hydroxychloroquine		Nortriptyline			
Mefloquine					

SNRI = serotonin norepinephrine reuptake inhibitor; SSRI = selective serotonin reuptake inhibitor; TCA = tricyclic antidepressant.

TABLE 6 Clinical Pearls: Hypertension Due to Oral Antineoplastic Agents

Hypertension is a common adverse effect of oral antineoplastic agents owing to common molecular pathways.
The rates of white coat hypertension may be higher in the cancer population, and hence, greater attention must be placed on at-home blood pressure measurements.
Identification of secondary causes of hypertension should be addressed, including untreated obstructive sleep apnea, which may be under-recognized in this population.
The use of lower-dose, antihypertensive combination therapy may have inherent advantages including greater efficacy with lower side-effect profile.

CENTRAL ILLUSTRATION Oral Targeted Antineoplastic Agent Cardiovascular Toxicity, Monitoring, and Management Strategies



Rao, V.U. et al. J Am Coll Cardiol. 2021;77(21):2693-716.

Graphical illustration of how to monitor and manage LV dysfunction, arrhythmia/QT prolongation, and HTN due to oral antineoplastic agents. 2D/3D = 2-dimensional/3-dimensional; ACEi = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; BB = beta-blocker; BP = blood pressure; cMRI = cardiac magnetic resonance imaging; CV = cardiovascular; DCCB = dihydropyridine calcium-channel blocker; ECG = electrocardiogram; H and P = history and physical; LV = left ventricular; LVEF = left ventricular ejection fraction.

How to implement CV monitoring strategies

- CardioOncologists work with Oncologists to identify agreed upon monitoring strategy for oral agents
  - Again goal is not to stop chemotherapy but to continue safely!
- Engage the oncology pharmacist to include cardiac testing in order set for drug initiation
  - Home monitoring of bp using wireless technology integrated into EMR (setting up guideposts for bp that trigger nursing communication), HTN education for patients (lower salt diet, exercise, address sleep apnea)
  - Baseline ECGs, drug-drug interactions (Qtc prolonging meds)
  - Work with your cardiologists to utilize best imaging modality for assessment of LV function at your institution (if using GLS, perform inter-intra observer variability testing; software now harmonized between vendors 2022)
- Track Data: CV events, % patients coming off drug due to CV side effects

How to Build a CardioOncology Program

- Identify Cardiology and Oncology Champions (attend ACC CardioOncology course in Feb annually in DC)
- Obtain administration buy-in (better overall outcomes for patients, revenue generation from appropriate imaging/testing, distinguish your cancer center/hospital)
- Hire a nurse navigator to serve as liaison between oncologists and cardiologists
- Consider using a cardiotoxicity risk score (incorporating oncology drug and pre-existing CV risk factors) to identify high risk patients who can be referred to cardio-oncology team
- International CardioOncology Society (IC-OS) has terrific website with many resources; eventually apply for Center of Excellence

Cardio-oncology Risk Calculator

Cardiac monitoring: Baseline echo/troponin and then per risk score recommendations

Cardiac Risk Score (CRS)

> 7: Very high **6-7:** High **4-5:** Intermediate

Medication-related risk	Score
High (risk score of 4)	
Anthracyclines, cyclophosphamide (>150mg/kg, > 1.5 gm2/daily), Ifosfamide, Clofarabine, Herceptin	
Intermediate (risk score of 2)	
Docetaxel, Pertuzumab, Sunitinib, Sorafinib	
Low (risk score of 1)	
Bevacizumab, Dasatinib, Imatinib, Lapatinib	
Rare (risk score of 0)	
Etoposide, rituximab, thalidomide	
Medication Risk Score	

Patient-related risk factors (1 point per risk)	Score
Heart failure	
CAD or equivalent (include PAD)	
HTN	
Diabetes mellitus	
Prior or current use of anthracycline	
Prior or current chest radiation	
Smoking	
Atrial fibrillation	
Hyperlipidemia	
BMI >30	
OSA	
Female	
Age <15 or >60	
Patient Risk Score	

TOTAL RISK SCORE:

Monitor Recommendations

Baseline 2D TTE w strain and troponin for all that require monitoring

Very High: 2D TTE w strain and troponin – Q other cycle; completion; one year post infusion

High: 2D TTE w strain and troponin – Q 3 cycles; completion; and one year post infusion

Intermediate: 2D TTE w troponin – midterm; completion

Low and Very Low: no routine testing unless cardiovascular symptoms develop

Baseline echo/troponin results:

Baseline 2D TTE with strain and troponin/BNP for all who require monitoring

Anthracyclines: baseline; at cumulative dose of 240-300 mg/m2; at cumulative dose of 400-450 mg/m2; prior to each additional 50 mg/m2; completion and 1 year

Herceptin/Perjeta: Q 3 months, completion and then every 6 months X 2 years (neoadjuvant with both drugs echo surveillance is recommended Q 6 weeks)

CRS _____ cardiac monitor recommendation_____

Cycle's dates/results

_____ _____ _____ _____

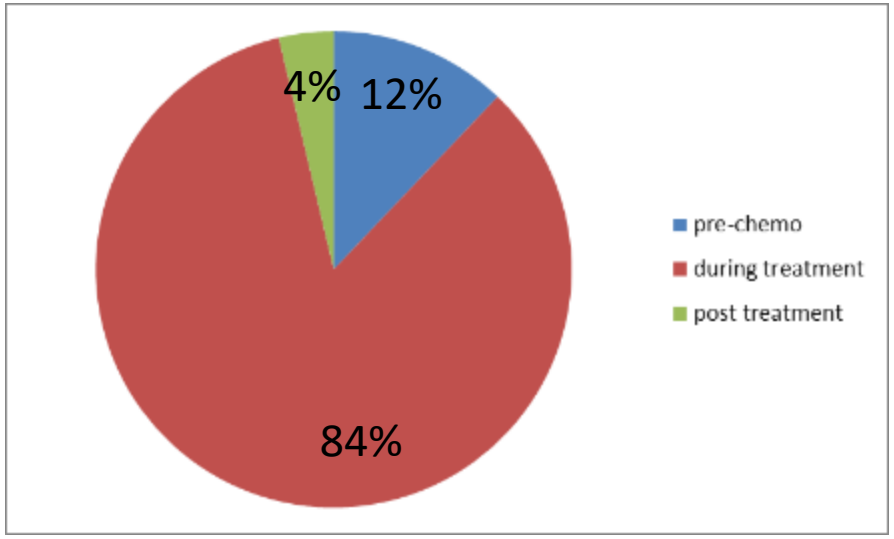
_____ _____ _____ _____

Deferral reasons_____

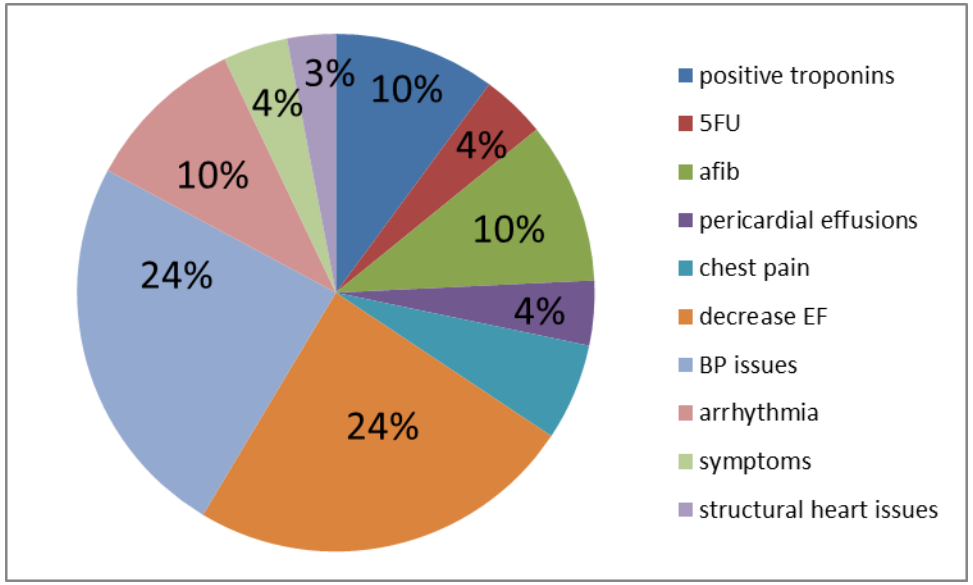
CV risk: ___HF/cardiomyopathy ___CAD/abn EKG ___HTN ___arrhythmia/syncope ___QT prolongation

CV complication: ___<EF ___Heart Failure ___pericardial effusion ___>biomarkers ___myocardial ischemia/CP ___QT > ___arrhythmia/syncope ___hypotension ___uncontrolled HTN

Referral Patterns for Cardio-oncology patients at Franciscan Indianapolis
January 2017-November 2018



Breakdown of referral during treatment



58% arrhythmia, HTN, decreased LVEF

Indiana CardioOncology Network (ICON) in conjunction with the Indiana Chapter of the American College of Cardiology, CardioOncology subsection

- Biannual CardioOncology Case Conference (4 years running)
  - Cardiology, Oncology, pharmacy, nursing, BMT
  - Virtual option available
  - Send an email to Rachel.Zirchelbach@franciscanalliance.org to be added to the email invitation list

Franciscan CardioOncology: Oncologist Perspectives

- “Helps to provide better and more appropriate treatment plans”
- “The collaborative clinic makes care for our patients a priority”
- “They have helped to modify treatment plans with cardiovascular disease so that the patient has better tolerance and treatment progression”
- “Assist with volume condensing which has made huge difference with our CHF patients management”
- With the increased attention to our patient’s cardiac status we can move through our patient’s treatment plans with more ease and confidence.”
- “The follow up is amazing and our patient’s satisfaction with them is wonderful; they keep everyone connected.”
- “I don’t know how we did it without them.”

Franciscan Health, Indianapolis International CardioOncology Center of Excellence: GOLD

- Cardiology
  - Dr. Vijay Rao (Director)
  - Dr. Atul Chugh
  - Dr. Ryan Daly
  - Dr. Angela Brittsan
  - Dr. George Lolay
- Oncology
  - Dr. Peter Garrett (Director, Cancer Center)
  - Dr. Meghana Raghavendra (Oncology Lead)
  - Dr. David Reeves (Oncology pharmacist)
- CardioOncology Nurse Navigators
  - Holly Page (oral therapies)
  - Tammy Ditto (radiation)
  - Christie Abernathy (IV therapies)

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