Using SEER-Medicare to Understand Patterns and Outcomes of Care for Elderly Patients with Cancer:

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Observational study Clinical trial

- Effectiveness
- Does it work?
- Real world condition
- Diverse population
- Lower cost
- Higher generalizability

SEER-Medicare Data include high proportion of patients age 65+ with cancer

- Efficacy
- Can it work?
- Ideal conditions
- Strictly defined population
- Higher cost
- Limited generalizability

RCT data underrepresent patients age 65 with cancer relative to the frequency at which they ocur

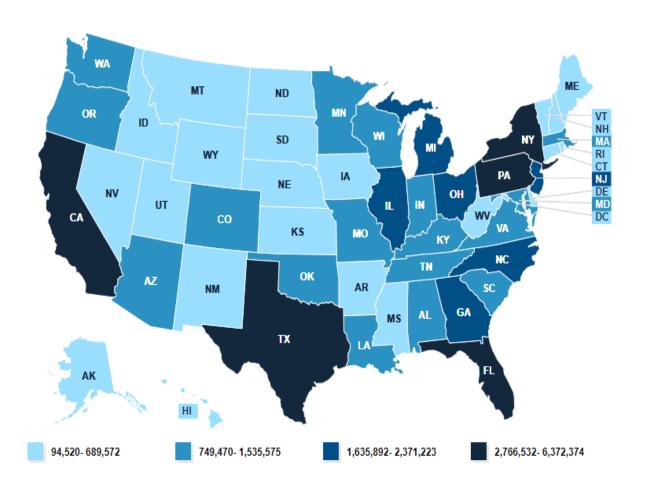
The NCI's SEER Registries



* Subcontract under New Mexico

** Three regions represent the state of California: Greater Bay, Los Angeles, and Greater California ***Research support registry only; not under contract to submit data

Medicare

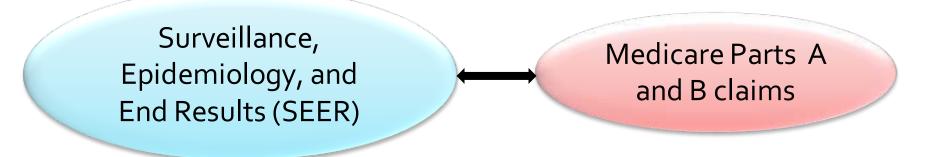


61.2 million Americans are insured by Medicare

37.8 million in Fee for service plan 23.4 million in Managed care plan

86% are eligible because they are >age 65 14% because they are disabled

SEER-Medicare Linked Data



- Cancer site, histology, stage, grade
- Dates of diagnosis and death
- Primary 1st course treatment
 - (radiation and surgery)
- Patient demographics
- Second primary cancers

- Chemotherapy
- Comorbidity
- MD visits
- Hospitalizations
- Pharmacy data
- Home health
- Nursing home and hospice

Who is included in the SEER-Medicare Linkage?

- 100% of cancer patients residing in the SEER region who are enrolled in Medicare
- 5% random sample of persons residing in the SEER areas who have not been diagnosed with cancer
 - "cancer free controls"
 - Allows evaluation of cancer screening tests (eg chest CTs, colonoscopies)
- Linkage to census data at the census tract and zip code level allow for ascertainment of social determinants of health

SEER-Medicare Data Availability and Use

- Data are available for the entire time a registry has participated in the SEER program; (some registries go back to 1973)
- Current release includes cancer cases reported to SEER registries through 2017
- Current release includes Medicare claims through 2018
- Data can be obtained from the NCI with an approved Data User's Agreement for a modest fee

The linked data can be used for analyses that span the course of cancer control activities Diagnosis/Tx \rightarrow Survivorship \rightarrow Second Occurrence \rightarrow Terminal Care

SEER-Medicare Linked Data Allow Rapid Inexpensive Ascertainment of Sizeable Cohorts of Patients age 65+

Cancer Site	Approximate Number of cases per year age 65+ (2015 estimates)		
Bladder	8881		
Breast	24432		
Colorectal	14754		
Kidney	5413		
Leukemias	4431		
Lung	24513		
Pancreatic	6096		
Prostate	24178		
Uterine	5339		

Health Care Services Used by Cancer Patients Enrolled in FFS Medicare in the year before CA, after CA and before death

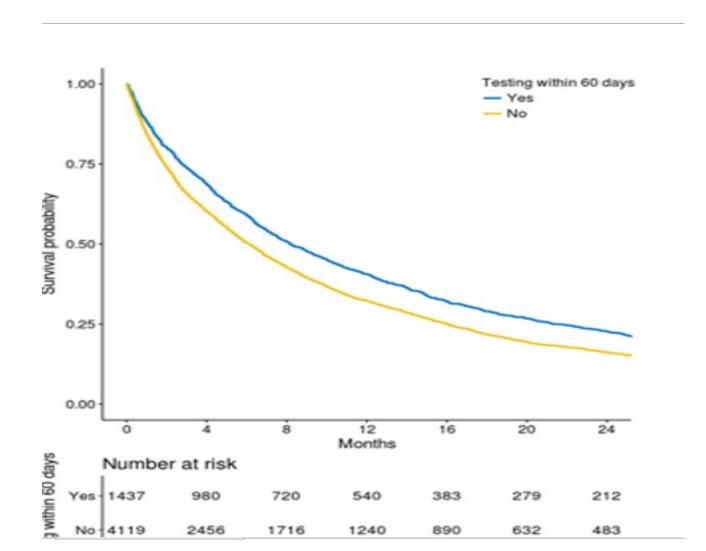
Claim type	% in Year before cancer	% in Year after cancer	% in Year before death
Any claim	96	94	98
Inpatient	21	44	78
Outpatient clinic	74	8 0	88
MD visits, labs	95	91	97
Hospice	1	17	58
Home health	10	21	38
Durable medical	30	39	52
Prescription drugs	59	59	65

Enewold JNCI 2020 From Table 4 based on estimates from 2015

Are patients age 65+ receiving a particular type of therapy?

Patterns of Care Questions

What % of Stage IV NSCLC patients undergo Genomic Profiling within 60 days of diagnosis?



25.9% of patients over age 65 had molecular testing within 60 days of stage IV NSCLC diagnosis manifest in Medicare claims

Those who have testing have better survival

Kehl JNCI 2019

Comparative Effectiveness Questions

Does treatment work?

What is the effectiveness of bevacizumab with chemotherapy compared to chemotherapy alone for patients with advanced NSCLC?

Does Bevacizumab Improve Survival for Elderly Cancer Patients Treated with Cytotoxic Chemotherapy?



- FDA approved for the treatment of colon (2004), NSCLC (2006) renal, brain, and other cancers
- A monoclonal antibody against vascular endothelial growth factor (VEGF)
- The first anti-angiogenesis inhibitor
- Adverse effects: hypertension, increased risk of bleeding
- Expensive

Older Patients were Under-represented in the Phase III Clinical trials that Established Efficacy of Bevacizumab

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

<40% of trial participants were < age 65

Paclitaxel–Carboplatin Alone or with Bevacizumab for Non–Small-Cell Lung Cancer

Alan Sandler, M.D., Robert Gray, Ph.D., Michael C. Perry, M.D., Julie Brahmer, M.D., Joan H. Schiller, M.D., Afshin Dowlati, M.D., Rogerio Lilenbaum, M.D., and David H. Johnson, M.D.

ABSTRACT

RESULTS

The median survival was 12.3 months in the group assigned to chemotherapy plus bevacizumab, as compared with 10.3 months in the chemotherapy-alone group (hazard ratio for death, 0.79; P=0.003). The median progression-free survival in the two groups was 6.2 and 4.5 months, respectively (hazard ratio for disease progression, 0.66; P<0.001), with corresponding response rates of 35% and 15% (P<0.001). Rates of clinically significant bleeding were 4.4% and 0.7%, respectively (P<0.001). There were 15 treatment-related deaths in the chemotherapy-plus-bevacizumab group, including 5 from pulmonary hemorrhage.

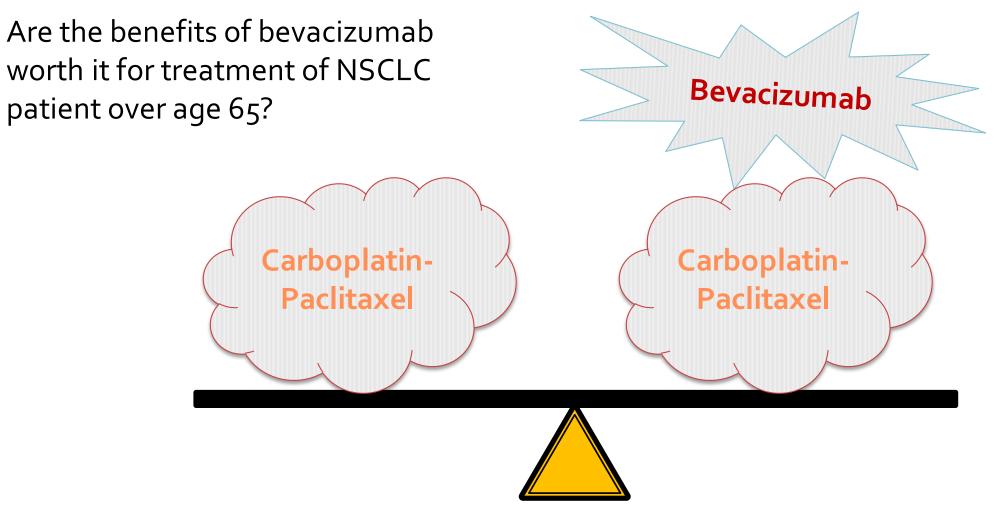
CONCLUSIONS

The addition of bevacizumab to paclitaxel plus carboplatin in the treatment of selected patients with non-small-cell lung cancer has a significant survival benefit with the risk of increased treatment-related deaths. (ClinicalTrials.gov number, NCT00021060.)

Subgroup	Hazard Ratio (95% CI)		
Weight loss			
<5%	0.77 (0.64-0.92)		
≥5%	0.85 (0.63-1.14)	_ _	_
Prior radiation thera	РУ		
No	0.80 (0.68-0.95)	j- 1	
Yes	0.60 (0.35-1.05)		
Disease stage			
IIIB	0.67 (0.40-1.10)		
IV	0.87 (0.73-1.04)	÷ -	
Recurrent	0.66 (0.38-1.14)		-
Measurable disease			
Yes	0.81 (0.69-0.96)		
No	0.55 (0.29-1.04)		
Sex			
Male	0.70 (0.57-0.87)		
Female	0.98 (0.77-1.25)		
Age		1	
<65 yr	0.71 (0.58-0.88)		
≥65 yr	0.89 (0.70-1.14)	÷	-
Race			
White	0.83 (0.70-0.98)		
Black	0.46 (0.21-1.03)		
Other	1.92 (0.37-9.97)		
ECOG performance	status		
0	0.75 (0.57-0.98)		
1	0.83 (0.68-1.01)	- -	
No. of sites of cance	r	_	
0-2	0.74 (0.58-0.94)		
>2	0.85 (0.69-1.05)	+	
Site			
Pleura	0.86 (0.63-1.18)		_
Liver	0.68 (0.49-0.96)		
Bone	0.81 (0.62-1.07)	÷	
Adrenal	0.97 (0.65-1.46)		
Overall survival	0.79 (0.67–0.92)	0.5 1.0	PC Better

Study Objective:

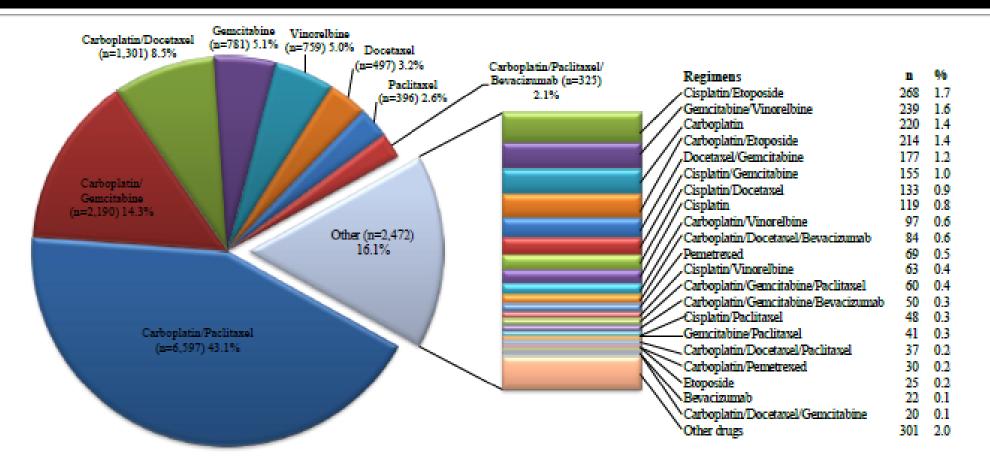
What is the effectiveness of adding Bevacizumab to chemo in the advanced NSCLC Medicare population?



Cohort Assembly: Inclusion Criteria

- From SEER records
 - Non-small cell lung cancer
 - Stage IIIB or IV
 - Non-squamous histology
 - Diagnosis pathologically confirmed
 - Age at diagnosis <u>></u>65 y
 - First and only cancer
- From Medicare enrollment and claims records
 - Continuously eligible for Medicare Parts A & B from diagnosis to death or 6-mo follow-up
 - Not enrolled in Medicare managed care from diagnosis to death or 6-mo follow-up
 - Survival

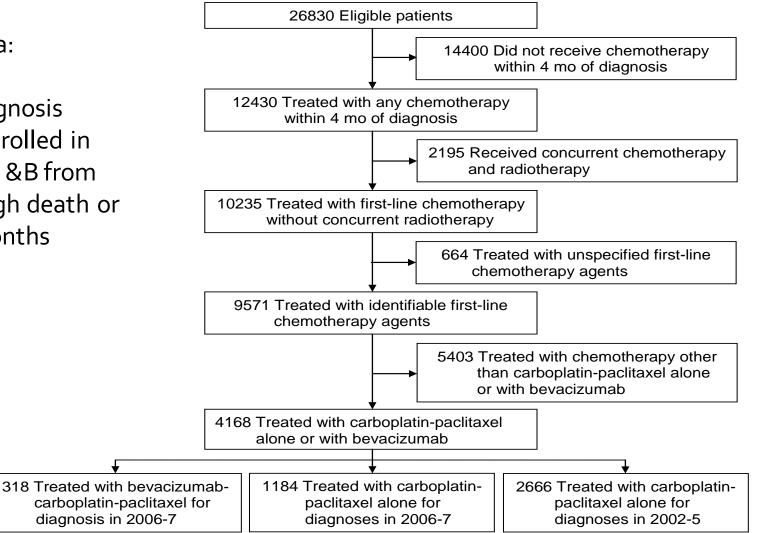
First-Line Chemotherapy in Elderly Patients with Non-Small Cell Lung Cancer



Data: Surveillance, Epidemiology, and End Results (SEER)-Medicare

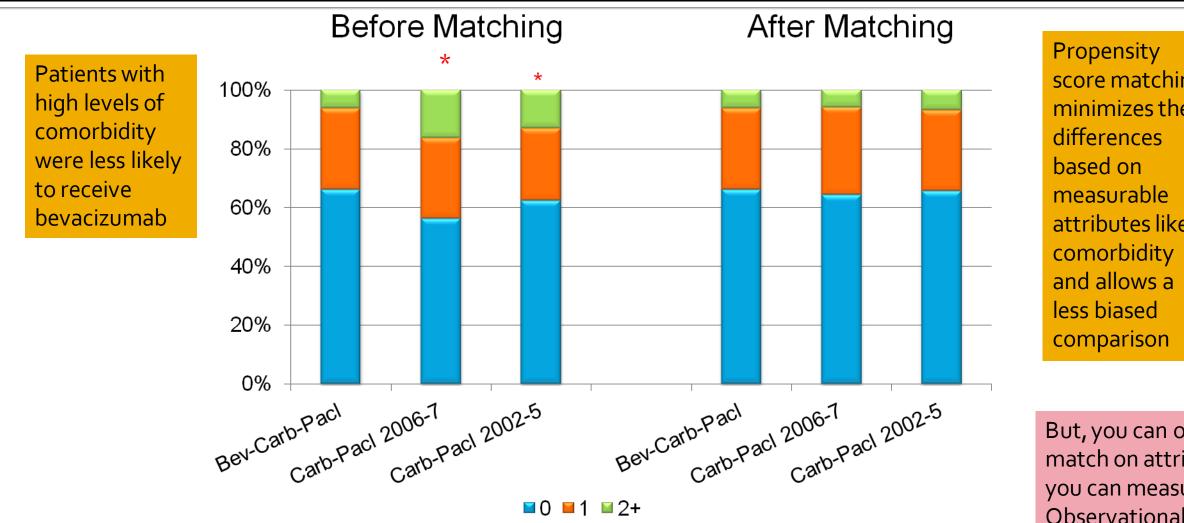
Patterns of Care for Elderly Patients with NSCLC in SEER-Medicare

Inclusion Criteria: Stage IV NSCLC Age >=65 at diagnosis Continuously enrolled in Medicare part A &B from diagnosis through death or for at least 6 months



Comorbidity Score

(modified Charlson-Deyo)



* Statistically significant difference in distribution of the characteristic compared with Bev-Carb-Pacl

score matching minimizes the attributes like

But, you can only match on attributes you can measure Observational data are not RCT data

How did survival outcomes with and without bevacizumab compare?

	Carboplatin- Paclitaxel Alone	Carboplatin- Paclitaxel with Bevacizumab	Adjusted Hazard Ratio (95% CI)
Median Survival (IQR) All patients age 65+	8.9 (3.5-19.3)	9.7 (4.4-18.6)	1.01 (0.88-1.15)
Median Survival in patients age 75-79	6.8 (3.2-18.5)	8.5 (3.6-16.7)	1.10 (0.95-1.27)

• Adding bevacizumab to carboplatin-paclitaxel chemotherapy was not associated with a statistically significant improvement in survival among FFS Medicare beneficiaries aged 65 and older

Zhu JAMA 2012

Limitations of the SEER-Medicare Data

- Although observational research methods can minimize bias, they cannot eliminate it
- Lag in data availability
- Reasons treatments are or are not administered cannot be determined
- Test results cannot be ascertained

Summary Thoughts About Using

SEER-Medicare Data to Assess Cancer Care in Geriatric Populations

- SEER-Medicare are a critically important resource characterizing cancer care in the US population age 65+
- Because most people over 65 in the US are insured by Medicare it is "almost" population based and representative
- Outstanding resource for measuring patterns of care
- Excellent resource for measuring quality of care
- Good resource for measuring effectiveness of care
- Extremely useful for generating hypotheses and prioritizing studies that rely on more detailed data sources (EHR data) or data obtained directly from patients.
- NCI has worked hard on enhancements and timeliness of the data
- Investing in tumor registries and modernizing them with molecular and treatment data is a priority

More Details on the SEER-Medicare data

SEER-Medicare WEB site:

https://healthcaredelivery.cancer.gov/seermedicare/obtain/current.html