# PRACTICAL POINTERS FOR PRIMARY CARE MEDICINE

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### Inversely Associated With Total And CVD Mortality, But Not Many Patients With DM Adhere To This Advice

### **10-1 PHYSICAL ACTIVITY AND MORTALITY IN INDIVIDUALS WITH DIABETES MELLITUS: Prospective Cohort Study**

Efforts to reduce the impact of diabetes (**DM**) complications have been predominantly aimed at controlling hyperglycemia, hypertension, and dyslipidemia.

Physical activity (**PA**) is a key factor for self-management of DM to prevent macrovascular complications and premature mortality.

This study of a large cohort of individuals with DM investigated whether PA is associated with cardiovascular disease (**CVD**) and total mortality

#### STUDY

- The EPIC study is an ongoing prospective study of 519 978 men and women age 35-70 from 10 European countries. Within EPIC, a cohort of patients with DM (n= 5859 was established at baseline between 1992 and 2000.
- 2. No information was available of the type of DM—DM-1 or DM-2.
- At baseline, participants received a lifestyle questionnaire asking about their PA: Occupational activity; and leisure time PA, including walking, cycling, gardening, sports, and doit-yourself activities during the past year.

Energy expenditure in leisure time activity was estimated by assigning metabolic equivalents (METs).

4. Total PA was determined using the Cambridge Physical Activity Index, which combines self-reported occupational activity with participation in cycling and sports.

Occupational activity was categorized into 4 groups: 1) sedentary, 2) standing manual, 3) manual, or 4) heavy manual.

Cycling and sports also categorized into 4 levels.

Based on this 4 X 4 matrix, participants were again divided into 4 categories:

- 1) Inactive (sedentary job and no recreational activity 2) Moderately inactive, 3) Moderately active, and 4) Active (heavy manual job, standing job with some recreational activity, or sedentary job with over 1 hour per day of recreational activity.
- 6. Energy expenditure was estimated by assigning metabolic equivalents (METs)

(One MET is the energy expended by a person while sitting quietly.)

#### RESULTS

 At baseline: mean age ~ 57; DM duration 4 to 5 years; BMI men 28 women 29; over 50% were hypertensive. Individuals who were more physically active were younger, more likely male, had a lower HbA1c, and shorter duration of DM.

2. Baseline characteristics (N = 5859)

	Inactive	Moderately Inactive	Moderately active	Active
A. Number	1897	1897	1171	998
B. Type of PA (MET h/wk)				
Cycling	0	3	9	23
Sports	0	0	0	6
Household	27	18	15	15
Walking	14	14	14	15

(The authors comment that Europeans are more physically active than Americans. Ed. )

C. Physical activity at wor	k %			
Sedentary	28	26	16	9
Standing	0	17	31	21
Manual	0	0	16	32
Heavy manual	0	0	0	12

- After a median follow-up of 9 years, 755 participants died (13%). Death due to CVD accounted for 28% of all deaths (n = 212)
- 4. Total PA was inversely associated with total and CVD mortality. The lowest HR was observed in persons categorized as moderately active. (The HR was 0.62 for total mortality.)
- 5. Leisure time PA was also inversely associated with a lower risk of CVD and total mortality.
- Participants who walked more than 2 hours per week had lower CVD mortality compared with those in the lowest activity group. (HR in those walking 2 to. 4.5 hours per week = 0.54) The relationship of walking with total mortality was less pronounced.
- Excluding participants with co-morbidities at baseline led to lower HRs; for total PA the HR for moderately active persons was 0.58 and 0.31 for CVD mortality.
- 8. Women had lower HRs across quartiles than men
- 9. Hazard ratios (HR) for associations:

	Total PA				
	Inactive	Moderately	Moderately	Active	
		Inactive	active		
Total mortality					
Cases per 1000/year	19	16	11	13	
Multivariate HR	1.00	0.69	0.62	0.74	
CVD mortality					
Cases per 1000/y	6	4	3	3	
Multivariate HR	1.00	0.65	0.51	0.62	
	Leisure time PA (MET h/wk)				
	<455	46-74	75-114	>113	
Total mortality					
Cases/ 1000/y	18	16	14	9	
Multivariate HR	1.00	0.85	0.80	0.73	
CVD mortality					
Cases/ 1000/y	5	6	4	2	
Multivariate HR	1.00	1.18	0.90	0.63	
	Walking h/wk				
	<2.0	2.0-4.5	4.6-9.0	>9.0	
Total mortality					
Cases/ 1000/y	17	14	13	13	
Multivariate HR	1.00	0.88	0.86	0.95	
CVD mortality					
Cases/ 1000/y	6	3	3	4	
Multivariate HR	1.00	0.54	0.50	0.64	

10. The association between total PA and mortality was slightly "J shaped". This could have been due to misclassification of activity levels. This result is in contrast to other studies.

#### DISCUSSION

1. In persons with and without DM, an increase in PA has previously been shown to improve insulin

sensitivity, and to have beneficial effects on inflammation, hypertension, dyslipidemia, endothelial function, and abdominal adiposity.

- 2. In this prospective analysis of individuals with diabetes, higher levels of total PA, leisure time PA, and walking were associated with lower risk of total and CVD mortality. People who reported being moderately physically active had lower mortality risk compared with those who reported being physically inactive.
- 3. Thus, patients with DM who are physically inactive have a higher risk of early death. Being moderately active may improve survival.
- 4. Walking may reduce the risk of CVD in people with DM by improving glycemic control and other risk factors. In the present study, people in the highest quartiles of walking duration had a lower risk of CVD mortality compared with those in the lowest quartile. In contrast, walking was not related to significant lowering of total mortality risk in this study.
- 5. The potential benefits of walking on mortality are well established in previous studies.

#### CONCLUSION

Evidence from the present study and from previous studies supports the widely held view that PA is beneficially associated with lower mortality in people with DM.

Although these findings highlight that persons with DM should engage in regular PA, they need to be confirmed a long-term randomized, controlled trial.

Because not many patients with DM adhere to this advice, future research should elucidate the determinants of physical inactivity and design successful strategies to promote active lifestyles.

Archives Internal Medicine September 24, 2012; 172: 1285-95 Original investigation by the European Prospective Investigation into Cancer and Nutrition (EPIC), first author Diewertje Sluik, German Institute of Human Nutrition, Potsdam, Germany

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The article also included a meta-analysis of 5 studies comparing highest PA with all-cause mortality and CVD mortality. The HR for highest vs lowest PA was 0.60.

*I abstracted this article, not because it revealed an unexpected outcome, but because it is an important application to primary care medicine.* 

The most important comment made by the author was that because not many patients with DM adhere to this advice, future research should elucidate the determinants of physical inactivity and

design successful strategies to promote active lifestyles. We must do better for our patients with DM (as well for all others). Asking about PA should be a routine part of every consultation.

### A Palliative Approach Should Be Taken Much Earlier 10-2 MULTIMORBIDITY: WHEN AND HOW TO TAKE A PALLIATIVE APPROACH TO CARE

Patients with multiple illnesses can experience chaotic care.

For these patients there has been a call for a paradigm shift from the disease-based models to one focused on palliative care. As patients with multimorbidity age, and healthcare providers face increasing problems with delivering complex care, doctors must consider when it is appropriate to broach the subject of scaling back or stopping treatments. They must then decide in what particular order to taper or eliminate treatments. This includes minimizing unnecessary and ineffective medications. (polypharmacy).

For patients who have borne a large burden of multiple drugs, frequent diagnostic tests, and numerous healthcare appointments, making this transition is often a relief.

How can clinicians and patients move through the change from disease modifying treatment to a palliative approach to care?

An approach to identifying patients who may benefit from scaling back treatments, assessing their needs and goals, and planning and coordinating care is outlined in the gold standard framework of palliative care for people nearing the end of life.

Taking a "palliative approach" to care for patients with multimorbidity begins much earlier than is usual when palliation is limited to palliation specialists and hospice programs.

Palliation generally aims to improve the quality of life for people with life-limiting illnesses by reducing suffering through early identification, assessment, and treatment of pain, cultural, psychosocial, and spiritual needs.

"We recommend that such a palliative approach be taken much earlier."

A key part of embarking on the palliative approach is communicating with other members of the health care team, so that unnecessary interventions do not go ahead as routine. Strong continuity of primary care in advanced disease has been shown to be associated with fewer emergency room visits and a greater chance of the patient's dying out of hospital.

Only a small proportion of people who may benefit from a palliative approach actually get it.

Once patients are identified as being suitable for a palliative approach, an active strategy to engage families in the process is needed.

Over past decades, doctors have become slaves to single disease guidelines and their costs. We must enable health care providers to move toward a palliative approach to care and support them to make such recommendations.

The transition to a palliative approach to care is not a transition from one care to another. Diagnosis, patient education, and chronic disease self-management are all phases through which we progress. The palliative approach is the last phase in the continuum of good care for patients with multi-morbidity in whom multiple active treatments are no longer appropriate. We must help patients to understand when it may be time to stop active treatment. We must know when to have a gentle, caring, supportive conversation to realize a new set of shared goals.

These conversations may be difficult. But they should not be avoided because palliative patientcentered care is the only sensible approach to caring for those with multiple chronic conditions who are approaching the end of life.

#### BMJ October 27, 2012; 345: 7 BMJ2012;345:e6324

Editorial, first author Fred Burg, Dalhousie University Halifax, Canada.

This is an important approach to treatment, which has long been neglected. All depends on the individual patient's goals and wishes. (Patient autonomy) If the patient lacks decision-making capacity, the problem is compounded.

There can be a change of mind any time.

I believe many patients would choose this path if they understood that it is acceptable and available. Several discussions in this regard may be appropriate.

When is it appropriate for a primary care clinician to broach this subject? The authors suggest at an estimated life-expectancy of one year. It may be easier to suggest palliative care when life is obviously limited. But, certainly, estimated life expectancy is not a limiting factor.

It is evident that many patients with multi-morbidity, as they approach the end of life, continue to receive drugs and interventions that are not only useless, but cause discomfort. We can relate many instances in which patients continue to receive ineffective medication and intrusive interventions up to the day of death.

Nurses who have continuing contact with the patient, including those who serve the patient at home, may have important influence on patient's decision making in this regard. There should be strict orders on the hospital and nursing hone chart: "Do not resuscitate". "Do not hospitalize"

### Patients Need Truthful Information In Order To Make Good Decisions. 10-3 TALKING TO PATIENTS ABOUT DEATH

Self deception is a valuable personal coping tool. It allows us to aspire to significance, strive for new knowledge, and yearn to make a lasting contribution to the world despite the certainty of our inevitable end.

Indeed, no arduous task would ever be undertaken if we were unable to exaggerate the benefits we expect from it, and underestimate the difficulties of its accomplishment.

This "planning fallacy" is the tendency to overestimate benefits and underestimate costs, and thus make foolish decisions and embark on risky pathways.

People have an optimistic bias. This helps us to cope with the inevitability of death—our "denial of death". If you ask dying persons what they believe will be the outcome of a treatment that they have already decided to take, what will they say?

A study in this issue of NEJM<sup>1</sup> asked nearly 1200 patients with metastatic cancer (lung and colorectal) whether they expect their treatment to cure them. The majority felt that the treatment was likely to "cure" them. Perhaps the problem here is the word "cure". To patients with advanced disease, it may mean something very different from the eradication of all disease without return. It may mean an end to pain and a hope for a better tomorrow with fewer incapacities.

If patients actually have unrealistic expectations of a cure from palliative treatment, we have a serious problem of miscommunication that we need to assess.

Were the patients in the study not actually told that their disease was incurable? Were they not told effectively? Did they choose not to believe? Did they fully understand?

Observational studies have shown that 2/3 of doctors tell patients when they have an incurable disease, but only 1/3 actually state the prognosis—at any time. It is not easy to tell patients that they are going to die. Most of us choose not to do so. This is why, 2 months before death, half of all patients with lung cancer have not heard any doctor use the word "hospice".

Patients also choose not to believe. When they are given their actual prognosis, 1/3 or more will not admit their treatment will not cure them.

However, this may not prevent them from making advanced directives and using hospice.

It is possible to tell patients more effectively that they have a terminal illness, and share information that would enable them to better plan their remaining life. But they need help. Nearly all patients want to know whether or not they can be cured, and the majority want to know their prognosis. An essential skill for physicians is to master the conversation known as "ask, tell, ask". This consists of asking the patients what they want to know about their prognosis, telling them what they want to know, and then asking "What do you now understand about your situation?"

Truthful conversations that acknowledge death help patients understand their curability, and do not squash hope or cause depression. We need help to break the news. This is not one hard conversation for which we can muster our courage, but a series of conversations over time. The author recommends stating the prognosis early, seeing that there is a discussion about advanced directives, and scheduling a visit for hospice information.

Palliative care increases knowledge of prognosis, helps alleviate symptoms, reduces stress on caregivers, may improve survival, and lowers costs. These are not trivial issues. Chemotherapy near the end of life is still common, does not improve survival, and is one reason why 25% of all Medicare funds are spent in the last year of life.

Patients need truthful information in order to make good decisions. If they are offered truthful information, they can choose wisely. Most people want to live as long as they can, with a good quality of life. And want a transition to a peaceful death outside the hospital. We have the tools to help them.

NEJM October 25, 2012; 367: 1651 -52 Editorial, first author Thomas J Smith, Johns Hopkins University School of Medicine, Baltimore MD

Primary care clinicians are very familiar with death, not only for patients with cancer, but with many other terminal conditions. It is important to hold discussions with these patients—to make sure they have had the opportunity to made all decisions related to the remainder of their life, and are comfortable about these decisions.

It may be difficult to start such a conversation. Every patient is different. Every clinician is different. Cultures differ markedly. Clinicians must develop their own approach. The challenge is to talk about death and choose the appropriate time.

The conversation may begin by asking the patient if he or she is "at peace", and proceed from there.

"What can I tell you about your illness? What are your preferences? I want you to be able to carefully plan your remaining life. All of us know that life is short. We must do the best we can with what time we have left".

How would we approach the subject of death when talking with a with 10-year old? I suspect female MDs are better at this than males.

"Patients' Expectations About Effects Of Chemotherapy for Advanced Cancer" NEJM October 25, 2012; 367: 1615-25 First author Jan C Weeks, Dana Farber Cancer Institute, Boston, Mass.

### 20% To 50% Of High-Tech Imaging Provided No Useful Information, And May Be Unnecessary. 10-4 THE OVERUSE OF DIAGNOSTIC IMAGING AND THE CHOOSING WISELY INITIATIVE

"Healthcare in America costs too much."

One important reason is the overuse of diagnostic tests—including, but not limited to, imaging studies.

A recent report indicated that between 2000 and 2007, imaging studies grew faster than any other physician service in the Medicare population. Another report from the American Health Insurance Plans claimed that 20% to 50% of high-tech imaging provided no useful information, and may be unnecessary.

Key federal agencies have taken steps to reduce reimbursement for imaging. However, a better approach might be to try to limit imaging studies and other tests and treatments that are inappropriate, unnecessary, wasteful, and redundant.

The American Board of Internal Medicine Foundation has worked with Consumer Reports to develop the Choosing Wisely initiative. Nine leading US medical organizations were brought into the campaign and developed a list of 45 services they believed were over used.

#### (www.choosingwisely.org)

Twenty four of 45 services were related to diagnostic imaging.

The authors of this article paraphrased some of the tests, combined others that were duplicative, and eliminated one, to yield a list of 16 overused imaging studies. They hope that all physicians who order imaging tests will reflect on this, choose wisely, and adjust their ordering patterns accordingly.

Why is imaging overused? Many physicians worry about malpractice liability and order too many tests for fear of overlooking anything that could conceivably contribute to a lawsuit. (Meaningful tort reform is needed.) Advanced imaging equipment is installed in physicians' offices, incentivising physicians to order imaging tests to generate revenue. (Self-referral leads to higher use.) Many patients demand advanced imaging after hearing about it from friends and the media, or even direct-to-consumer advertising.

In addition, even when the imaging is appropriate, sometimes unnecessary duplication occurs when the patient seeks a new physician. Or when the older studies are not readily available.

Radiologists themselves must acknowledge their own potential conflicts of interest.

Why is too much imaging a bad thing? Cost issues aside, inappropriate imaging unnecessarily exposes patients to excessive radiation, inconvenience, and harms that come from the cascade of diagnostic and therapeutic interventions that often follow identification of an incidentaloma.

How can we fix the problem? Radiologists can help by educating physicians as to the most appropriate imaging for a patient's clinical circumstances. Radiologists need to make some modifications to their daily routines and recommend testing only when indicated.

Primary care clinicians should be aware of these recommendations.

Appropriate criteria can be a valuable resource in the effort to reduce unnecessary imaging.

Specific imaging tests in the Choosing Wisely campaign that may be overused in primary care:

- 1) Imaging for headache in patients without risk factors for structural problems
- 2) Routine preoperative chest radiography in patients without cardio-respiratory symptoms
- 3) CT of sinuses in uncomplicated acute sinusitis
- 4) DEXA for suspected osteoporosis in women < age 65 and men < 75 in absence of risk factors
- 5) Stress cardiac imaging in patients without symptoms or high-risk markers
- 6) Stress cardiac imaging during pre-operative assessment for low-risk non-cardiac surgery with no immediate risk for CAD
- 7) Brain CT or MRI after simple syncope without neurological abnormalities
- Repeated CT in patients with abdominal pain who meet Rome III criteria for the functional abdominal pain syndrome and whose symptoms have not changed

Annals Internal Medicine October 16, 2012; 157: 574-6 "Ideas and Opinions", first author Vijay A Rao, Thomas Jefferson University, Philadelphia, PA

See Practical Pointers May 2012 [5-5] for an abstract of the original Choosing Wisely. .

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False positive results are a major adverse effect of screening. Ie, a report of a finding that would never impact the health of the patient adversely, but which leads to a cascade of additional tests and interventions.

The resultant increase in incidence of cancers due to excessive radiation is real. Harms may not appear for decades.

*I believe radiologists, who may not be fully satisfied by one imaging, add to the risks by advising additional or repeat examinations.* 

Regarding tort reform—would a reasonable defense be that the physician who ordered the test did so by strictly following guidelines based on the best evidence?

Some harassed physicians may immediately order a screening test rather than taking the time for a more complete history and physical. Additionally, some hospital administrators may urge the staff to use the newly installed (and expensive) machine to defray costs.

### *Iconoclastic; For Continued Debate* 10-5 NO PROVED BENEFIT IN DRUG TREATMENT FOR PATIENTS WITH MILD HYPERTENSION: COCHRANE REVIEW:

A Cochrane Review of studies conducted in the UK, USA, and Australia found that treating patients with stage 1 (mild) hypertension has no benefit in patients without pre-existing cardiovascular disease (**CVD**).

Data from 4 randomized, controlled trials involving 8912 asymptomatic patients with stage 1 hypertension (140-159/90-99; either or both) treated for 4 to 5 years found that drug therapy (vs placebo) did not reduce total mortality (risk ration = 0.85). coronary heart disease (RR = 1.12) or stroke (RR = 0.51).

Nine % of patients discontinued drugs because of adverse effects.

One reviewer said that he believes the analysis should lead to dramatic changes in the way clinicians treat mild hypertension. Instead of treating the BP, they should focus on more effective, evidence-based approaches such as smoking, exercise, and a healthy diet.

Until now, it had simply been assumed that treating mild hypertension, which most hypertensive patients have, is beneficial. Guideline writers have based their opinions on a combination of assumptions and data from clinical trials in which patients with mild hypertension were not analyzed separately.

The lack of benefit is perhaps even more significant because the review did not exclude patients with risk factors such as diabetes and probably included patients with target organ damage of a 10-year risk of CVD of 20% or more.

Joint National Committee-7 guidelines recommended lifestyle modification and drug treatment to achieve a BP below 140/90 for patients with stage 1 hypertension. The committee is currently reviewing BP treatment thresholds and goals.

The US National Heart, Lung, and Blood Institute plans to pass the Cochrane analysis along to the JNC-7 committee for consideration.

US and European guidelines are more aggressive than UK guidelines in recommending drug treatment for uncomplicated, mild hypertension. The UK recommends treatment only if the patient has additional risk factors.

A spokesperson for the American Hypertension Society commented that "We have long known that almost all benefit from treating severe hypertension comes from lowering BP just a little. Efforts to lower BP to 'normal' typically require multiple drugs, and are not only usually unsuccessful, but produce more harm than good. Drug treatment for mild hypertension, like intensive treatment for severe hypertension, may be of great value to drug makers, but it was almost predictable that it would provide little or no benefit for patients."

However, not all doctors are convinced that these results should change practice.

Some commentators have criticized the study because of the relatively few subjects for a short follow-up time.

A randomized trial to strengthen the evidence one way or another likely will not be conducted. It would take many subjects over many years of follow-up.

BMJ August 20, 2012; 345 BNJ2-12;35:e511. "News" by Jeanne Lenzer, New York. First author of the Cochrane Review – Diao O

JAMA October 3, 2012; 308:1305 "Clinicians Remain Reluctant to Allow Negative Findings to Influence Practice" "Medical News and Perspective' by Mike Mitka, JAMA Staff.

This study is iconoclastic. Should the term "hypertension" be redefined? But, "No proved benefit" does not mean there is no benefit.

Where did the cut-point 140/80 come from? Should the target BP be increased to 159/99? Has any large long term (longer than 4 to 5 years) study or meta-analysis of drug treatment of mild hypertension reported a beneficial effect? Is there any reason why a cut point of 159/99 eliminates risk?

I still believe that a systolic of 156 (and a diastolic of 96) is related to more adverse CVD events than a systolic of 136 (and a diastolic of 76). The absolute difference may be small, The benefit / harm-cost ratio may be small. Adverse effects of anti-hypertension dugs occur in about 10 patients. In addition to monetary costs, there are costs in bother, inconvenience, worry, and laboratory tests. May patients will discontinue treatment. Many patients with mild hypertension have associated risk factors. This would increase indications for BP treatment.

I doubt this report will change practice habits in the US. It is easier to treat than not to treat. How should primary care clinicians respond to this information? I believe most will continue to

treat mild hypertensions. If so, dose to an initial drug should start low and be titrated up to a modest dose. If systolic falls by 10 mm Hg, we should be satisfied with that.