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Acceptance of a Polypill Approach to Prevent Cardiovascular Disease Among a Sample of U.S. Physicians

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Abstract

Objective—To examine US physicians' self-reported knowledge about the Polypill, factors considered in deciding whether to prescribe it, and acceptance of prescribing it for cardiovascular disease (CVD) prevention.

Methods—Numerical scales of 0 (lowest) to 5 (highest) were used to assess self-reported knowledge and importance of factors relevant to making a decision to prescribe a Polypill. Characteristics of physicians indicating they would prescribe a Polypill were compared.

Results—Among 952 physicians surveyed February through March 2010, mean self-rated knowledge about the Polypill was 2.0±1.5. Importance of degree of CVD event reduction, cost, and side effects were rated with means of 4.4, 4.3, and 4.3, respectively. 83% of respondents indicated they would “definitely” or “probably” prescribe it for high-risk patients; 62% would do so for moderate risk patients. Physicians with self-rated knowledge at ≥75th percentile were more likely to indicate they would prescribe a Polypill for moderate risk (adjusted OR 2.16; 95% CI 1.60–2.93) and high-risk (adjusted OR 1.57; 95% CI 1.07–2.32) patients.

Conclusion—Among this sample of physicians, there is relatively high acceptance of prescribing a Polypill for CVD prevention despite relatively modest knowledge about it.

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CONFLICT OF INTEREST STATEMENT

The authors declare that there are no conflicts of interest.

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INTRODUCTION

Cardiovascular disease (CVD) accounts for 1 of every 3 deaths in the United States (US), (Lloyd-Jones et al, 2009). Prevention of CVD therefore remains a high public health priority, and the high-rate of initial CVD events that are fatal or disabling makes primary prevention paramount. The conventional clinical approach to primary prevention of CVD relies on identification and treatment of individual threshold-based risk factors such as hyperlipidemia and hypertension. However, a sizeable proportion of CVD events occur among people with average levels of blood pressure (BP) and cholesterol(Law et al, 2004; Rose 1985 ; Wald and Law 2003). This “prevention paradox” occurs because there are many more people in the middle of the distribution of these risk factors(Rose 1985) .

An approach of only offering preventive pharmacotherapy to people with elevated risk factors based on the upper tail of the distribution does not take into full account the consistent increase in relative risk of CVD as BP or cholesterol increases, the combined effects of risk factors, or the fact that the strongest risk factor is age(Hingorani and Psaty, 2009; Lewington et al, 2002; Lewington et al, 2007; Rose 1985). An exclusive risk factor level approach therefore does little to help reduce the risk in the large portion of the population whose overall CVD risk is elevated but whose individual risk factors are only mildly elevated or “normal” (Hingorani and Psaty, 2009; Law et al, 2004; Persell et al, 2006).

In 2003 Wald and Law proposed a strategy to address this significant limitation of the clinical approach to CVD prevention(Wald and Law, 2003) . They calculated that if a combination pill containing three half-standard doses of BP-lowering drugs, a statin (standard dose), low-dose aspirin, and folic acid was given to all adults 55 years and older(regardless of risk factor levels), the potential impact would be substantial, with reductions in coronary heart disease and stroke events of 80% and 88%, respectively . However, the actual efficacy of a population-level Polypill approach in reducing CVD events is unknown. Calculations based on data observed in The Indian Polycap Study (TIPS) suggest a risk reduction closer to 60%—still a tremendous potential impact (The Indian Polycap Study, 2009).

With the publication of TIPS, ongoing initial research in several countries, and at least three Indian pharmaceutical companies currently producing versions of a Polypill, it appears that the Polypill-type approach may become a viable option for CVD prevention, but additional studies are needed(Combination Pharmacotherapy and Public Health Research Working Group, 2005; Hingorani and Psaty, 2009; Wald and Wald, 2010). Currently, however, there are no Polypill trials in the US, and physician acceptance of a population-level Polypill approach may be limited by concerns such as potential side effects, cost, and inability to individualize therapy. A clinical-level approach, whereby people could be counseled about the potential risks and benefits of taking a Polypill and could be monitored, might be more acceptable to physicians than the population-level approach. The goal of this study was to examine US physicians’ knowledge and attitudes regarding a Polypill approach with particular focus on whether physicians would prescribe a Polypill for primary prevention to patients at varying levels of increased cardiovascular risk.

METHODS

Overall Design

This study was a web-based survey of a national sample of family physicians, general internists, and cardiologists. The survey was designed by the investigators and revised after pretesting among a convenience sample of family physicians, general internists, and

cardiologists. Some items were modified from a questionnaire used in a Polypill study in Sri Lanka (Soliman EZ et al, Wake Forest University, unpublished study, 2010). This study was approved by the Institutional Review Board of the University of North Carolina at Chapel Hill.

Study Sample and Invitations to Participate

Personalized invitation letters were mailed to 8623 physicians randomly selected from databases of members of the American Academy of Family Physicians and the American College of Physicians. These letters described that the survey would ask about new ideas in CVD prevention and provided instructions for accessing it online. An individualized identification code allowed tracking of non-respondents. At two and four weeks after the initial invitation, non-respondents were mailed reminder letters. As an incentive to participate, physicians could have their name entered into a drawing for one of two \$500 gift cards.

A total of 1238 physicians participated in the survey. Respondents who indicated they do not see patients in the office setting (n=251) or whose specialty was not family medicine, general internal medicine, or cardiology (n=55) were excluded. Seventy-four letters were returned as undeliverable, including 8 because the intended recipient was deceased, and 3 because of delivery refusal. The adjusted response rate was 15%. The final sample consisted of 390 family physicians, 272 general internists, and 290 cardiologists.

Variables

Data obtained included self-rated knowledge about the Polypill, factors considered important to the decision to prescribe a Polypill, and level of agreement with the idea that CVD risk factors would not need monitoring in patients receiving the Polypill. The numerical scale for items ranged from 0 to 5, with 0 being lowest level (of knowledge, agreement or importance) and 5 being the highest. For reporting associations with acceptance, self-rated Polypill knowledge and ratings of perceptions of problems with adherence to CVD prevention medications were dichotomized at $\geq 75^{\text{th}}$ percentile of the sample. In order to assess acceptance of a clinical approach to using a Polypill, respondents were asked whether they would be likely to prescribe a Polypill for primary prevention to patients at moderate CVD risk and high CVD risk (not otherwise defined). For these items, respondents were told to assume that the Polypill halved the risk of CVD events. Information on specialty type, amount of patient care time, year in practice, type of practice setting, and region of the country was also collected.

Analysis

Responses to each of the items were tabulated and differences were compared by respondent characteristics. Testing for significant differences was performed using analysis of variance for numerically-scaled outcomes and chi-square for categorical outcomes. Because of multiple comparisons, statistically significant differences were defined as a p-value < 0.01 . Characteristics of physicians who indicated they would “definitely” or “probably” prescribe a Polypill for primary prevention were compared in unadjusted analyses and then by logistic regression to adjust for specialty, years in practice, region of country, self-rated knowledge and perceptions of patients’ adherence to risk-reducing medications. All analyses were performed using Stata 10.1 software (StataCorp, College Station, TX).

RESULTS

Characteristics of Respondents

Most respondents were male (74%), in practice ≥ 10 years (78%), and spent $>50\%$ time in office-based patient care (71%) (Table 1). The most common practice type was small group practice (2 to 9 clinicians). Family physicians and general internists spent more time in office-based care than cardiologists. Cardiologists were more likely to be in practice for a longer time frame.

Knowledge and Attitudes about Polypill

Self-rated knowledge about the Polypill ranged from 0 (lowest) to 5 (highest) with a mean of 2.0. Cardiologists' self-rated knowledge (2.7) was higher than that reported by family physicians (1.5) and general internists (1.9) ($p < 0.0001$) (Table 2). In terms of factors important in the decision to prescribe a Polypill, respondents rated cost, degree of CVD event risk reduction, and side effects nearly equally important with means of 4.3, 4.4, and 4.3, respectively. Importance of patient's likely adherence and ability to modify doses were rated slightly less important. Among respondents of all three specialties there was low agreement (mean 1.0) with the idea to forgo routine monitoring of CVD risk factors in patients receiving the Polypill.

Acceptance of Prescribing Polypill

Assuming the Polypill halved the risk of cardiovascular events, 41.1% (95% CI 37.9%–44.2%) of respondents would “definitely” prescribe it and 41.4% (95% CI 38.2%–44.5%) would “probably” prescribe it for high-risk patients (Table 3). There was greater uncertainty among respondents about whether they would prescribe the Polypill for moderate risk patients. Still, 50.1% (95% CI 46.9%–53.3%) indicated that they “probably” would prescribe the Polypill to moderate risk patients, and 12.3% (95% CI 10.1%–14.4%) indicated they would “definitely” prescribe it to moderate risk patients. When asked whether the Polypill should be available without a prescription assuming that a well-done large clinical trial showed that it halved the risk of CVD events and it was approved for use in the US, 89.2% of respondents indicated “no.”

Characteristics of Physicians who would Prescribe Polypill

Physicians who indicated that they would “definitely” or “probably” prescribe the Polypill to high risk patients as primary prevention were somewhat more likely to be in practice 10 to 19 years, live in the South, and believe that adherence to risk reducing medications was a problem in their practice (Table 4). Cardiologists were somewhat more likely than general internists and family physicians to be willing to prescribe Polypill for moderate risk patients (68.7% vs 61.7% vs 58.3%, $p = 0.02$). Physicians with higher self-rated Polypill knowledge were more likely to be willing to prescribe it for moderate risk patients (73.2% vs 54.7%, $p < 0.001$). Other characteristics of physicians who would prescribe Polypill for moderate risk patients were similar to characteristics of those who would prescribe to high risk patients.

In adjusted models (Table 5), the factors associated with physicians' acceptance of prescribing a Polypill were self-rated knowledge about the Polypill and region of country. Physicians with self-rated knowledge about the Polypill at $\geq 75^{\text{th}}$ percentile were more likely to indicate they would prescribe it as primary prevention for moderate risk (OR 2.16; 95% CI 1.60–2.93) and high-risk (OR 1.57; 95% CI 1.07–2.32) patients. Physicians practicing in the South were also more likely to indicate that they would prescribe the Polypill.

DISCUSSION

This study is the first to the authors' knowledge to examine acceptance of a Polypill approach among a sample of US physicians. The findings can be summarized as follows: (1) based on risk/benefit tradeoff there is a high level of acceptance for prescribing a Polypill for primary prevention to high risk patients and a moderate level of acceptance for prescribing it to moderate risk patients, (2) physicians consider multiple relevant factors equally important when deciding on whether they would prescribe a Polypill, (3) self-rated knowledge about the Polypill is low, and higher knowledge is associated with greater acceptance, (4) perceptions of problems with adherence to CVD risk-reducing medications do not appear to be associated with greater acceptance, (5) physicians would prefer some ability to modify doses of a Polypill, and (6) physicians do not favor forgoing risk factor monitoring in patients taking a Polypill.

As initially proposed, the Polypill would be a population level strategy rather than a clinical one (Wald and Law, 2003). That is, it would be taken by all adults using some non-clinical criterion such as age (e.g., ≥ 55 years) without any known CVD (and who had no contraindication to its components) (Wald and Law, 2003; Wald and Wald, 2010). The clinical monitoring of risk factor levels and routine assessments for side effects (including laboratory parameters) would be major barriers to using such a strategy as would the need to see a physician to obtain a prescription for the Polypill. In other words, requiring the person interested in taking the Polypill to be a "patient" may limit its population-level potential (Wald and Wald, 2010). However, US physicians currently have very low agreement with the idea that CVD risk factors would not need routine monitoring in those taking the Polypill. Additionally, US physicians did not feel that the Polypill should be available without a prescription. Physicians were not asked to rate their level of agreement with the possibility of having the Polypill available by other means (e.g., pharmacists who could dispense the Polypill after an appropriate screening) (Wald and Wald, 2010). Nevertheless, the physicians sampled seemed generally unwilling to endorse a population-based approach to cardiovascular prevention, but could envision the implementation of a more clinical one.

The clinical type of Polypill approach that physicians in this sample find acceptable still would offer many advantages. While patients at high risk usually have their risk addressed because of their inherently higher level of risk factors, many people at moderate risk are not receiving appropriate risk-reducing therapies, particularly in combination (Persell et al, 2006). It is for this group, estimated to be about 13% of the US adult population, that the Polypill could be targeted clinically (Ajani et al, 2006). The use of global CVD risk (e.g., Framingham-based) assessments could facilitate such an approach. Global risk takes into account the combined contributions of the major risk factors (including age), and can be used by clinicians to guide preventive pharmacotherapy without reliance on threshold BP and cholesterol levels (Pearson et al, 2002). As such, it would be important that the Polypill not be viewed as a pill for "treatment" of risk factors. Rather, its indication should be for "prevention" of CVD.

This study showed that physicians with higher self-rated knowledge about the Polypill have greater acceptance of prescribing a Polypill, particularly to patients at moderate CVD risk. Specific knowledge questions were not included in this study, however. Thus, it is not known what particular understandings about the Polypill approach influenced the physicians' acceptance. Respondents practicing in the South were somewhat more likely to indicate that they would "probably" or "definitely" prescribe the Polypill for primary prevention. This association may be related to the greater burden of CVD seen in the South (e.g., the "Stroke Belt") (Lanska and Kuller, 1995).

Limitations

The most important limitation of this study is the low response rate. If attitudes and acceptance as reported by physicians who responded are different from responses that would be reported by physicians who did not respond, then our results will be biased. If physicians who chose to respond to the survey were more passionate about CVD prevention, they might also be more accepting of a Polypill. In such a case our results will overestimate the acceptance of a Polypill. It is also possible that those especially opposed to the Polypill idea participated more than physicians whose opinions were in favor of or neutral towards the idea. In such an instance, our findings would underestimate the level of acceptance.

Whether or not the Polypill would contain aspirin was not specified. In the original Polypill description, aspirin was included as a component (Wald and Law, 2003). However, the efficacy of aspirin in primary prevention of CVD has been called into question (AT T, 2009; Fowkes et al, 2010; Ogawa et al, 2008). Further, the use of aspirin for CVD prevention needs to be weighed against the risk of gastrointestinal bleeding (Wolff et al, 2009). It is not known whether respondents considered such issues in formulating their answers, or whether respondents' acceptance would differ between a Polypill containing aspirin and one that did not.

CONCLUSIONS

US physicians' acceptance of a clinical approach to using Polypill for CVD prevention appears fairly high, but our findings suggest that US physicians are not ready to support a true population level Polypill approach. A clinical strategy using a Polypill for primary prevention of CVD in the US has tremendous potential and is worthy of study.

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Table 1

Characteristics of Respondents(N=952)

	All		Family physicians (n=390)		General internists (n=272)		Cardiologists (n=290)		p-value
	%	%	%	%	%	%	%	%	
% male	73.5	57.8	74.6	94.3					<0.001
Years in practice									<0.001
≥ 20	61.4	37.8	68.7	86.6					
10–19	17.0	21.8	19.1	8.7					
<10	21.6	40.4	12.2	4.7					
Region of country									0.018
Northeast	23.9	18.3	25.7	29.3					
South	33.2	34.3	33.6	31.4					
Midwest	24.2	24.5	24.2	23.9					
West	18.8	22.9	16.6	15.4					
Time spent in office-based patient care									<0.001
≥ 75%	56.6	71.0	63.5	30.3					
51 to 74%	14.6	9.5	11.1	25.1					
50%	8.5	5.6	6.6	14.3					
25 to 49%	10.2	9.0	6.6	15.3					
<25%	10.0	4.9	12.2	15.0					
Practice setting									<0.001
Solo practice	12.5	9.7	14.8	14.1					
Small group (2–9 clinicians)	32.0	36.7	32.6	25.2					
Large single specialty group (10+ clinicians)	11.8	9.7	4.8	21.0					
Large multi-specialty group (10+ clinicians)	14.0	13.9	18.5	9.7					
Academic group	20.6	21.8	17.0	22.4					
Other	9.1	8.2	12.2	7.6					

Physicians were surveyed in the United States from February to March 2010

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Table 2

Physician Self-rated Knowledge and Attitudes about Polypill, Rated 0 to 5*

	All	Family physicians	General internists	Cardiologists	p-value
Self-rated knowledge about the Polypill	2.0	1.5	1.9	2.7	<0.0001
Importance of patient's likely adherence on decision to prescribe Polypill	4.0	4.0	3.8	4.0	0.13
Importance of ability to modify doses on decision to prescribe Polypill	3.9	3.9	3.8	4.1	0.04
Importance of cost of pill on decision to prescribe Polypill	4.3	4.4	4.2	4.4	0.12
Importance of degree of CVD event risk reduction on decision to prescribe Polypill	4.4	4.4	4.3	4.4	0.11
Importance of side effects on decision to prescribe Polypill	4.3	4.3	4.3	4.4	0.64
Agreement with idea that CVD risk factors would not need routine monitoring in patients receiving Polypill	1.0	1.0	1.0	1.0	0.80

* "0" is lowest level or lowest importance, and "5" is highest level or highest importance Physicians were surveyed in the United States from February to March 2010

Table 3
 U.S. Physicians Acceptance of Prescribing Polypill as Primary Prevention Assuming it Halved Risk of Cardiovascular Events

	All respondents, % (95% CI)	Family physicians, % (95% CI)	General internists, % (95% CI)	Cardiologists, % (95% CI)	p-value
Moderate risk patients for primary prevention					
Yes, definitely	12.3 (10.1–14.4)	9.6 (6.6–12.5)	13.2 (9.1–17.2)	15.3 (11.0–19.6)	0.04
Yes, probably	50.1 (46.9–53.3)	48.7 (43.7–53.7)	48.5 (42.5–54.5)	53.5 (47.5–59.4)	
Uncertain	17.9 (15.4–20.3)	21.8 (17.7–25.9)	16.2 (11.7–20.6)	13.8 (9.7–17.9)	
No	19.8 (17.2–22.4)	20.0 (15.9–24.0)	22.2 (17.2–27.2)	17.5 (12.9–22.0)	
High-risk patients for primary prevention					
Yes, definitely	41.1 (37.9–44.2)	38.4 (33.5–43.3)	42.1 (36.1–48.1)	43.5 (37.6–49.4)	0.02
Yes, probably	41.4 (38.2–44.5)	45.6 (40.6–50.6)	40.6 (34.7–46.5)	36.6 (30.9–42.3)	
Uncertain	9.2 (7.4–11.1)	10.8 (7.7–13.9)	8.3 (4.9–11.6)	8.0 (4.8–11.2)	
No	8.4 (6.6–10.1)	5.2 (2.9–7.4)	9.0 (5.6–12.5)	12.0 (8.1–15.8)	

Physicians were surveyed in the United States from February to March 2010

Table 4

Characteristics of Physicians who would “Definitely” or “Probably” Prescribe Polypill for Primary Prevention of Cardiovascular Disease

	Moderate risk patients	p-value	High risk patients	p-value
	%		%	
Specialty		0.02		0.42
Family medicine	58.3		84.0	
General internal medicine	61.7		82.7	
Cardiology	68.7		80.1	
Sex		0.43		0.63
Male	62.9		82.7	
Female	60.0		81.3	
Years in practice		0.04		0.05
≥ 20	64.2		80.8	
10–19	66.9		89.1	
<10	55.3		83.4	
Region of country		0.02		0.04
Northeast	61.3		82.8	
South	68.3		86.4	
Midwest	61.4		81.3	
West	53.7		76.1	
Time spent in office-based patient care		0.33		0.62
≥ 75%	61.8		83.3	
Between 50% & 75%	68.7		82.1	
50%	58.2		83.8	
Between 25% & 50%	64.9		82.5	
<25%	56.2		76.4	
Practice setting		0.89		0.06
Solo practice	66.4		83.6	
Small group (2–9 clinicians)	61.4		87.3	
Large single specialty group (10+ clinicians)	64.6		79.1	
Large multi-specialty group (10+ clinicians)	59.2		76.3	
Academic group	61.8		82.3	
Other	62.3		77.1	
Self-rated Polypill knowledge ≥75 th percentile		<0.001		0.06

	Moderate risk patients	p-value	High risk patients	p-value
	%		%	
Yes	73.2		85.3	
No	54.7		80.4	
Adherence to BP medications a problem in practice *		0.07		<0.001
Yes	65.7		87.9	
No	59.7		78.5	
Adherence to lipid lowering medications a problem in practice *		0.05		0.001
Yes	65.4		86.9	
No	59.1		78.3	
Adherence to aspirin a problem in practice *		0.02		0.01
Yes	66.6		86.0	
No	58.9		79.7	

* Based on being at or above 75th percentile of sample in response to question, "On a scale from 0 to 5, where 0 indicates not a problem at all and 5 indicates an extremely big problem, how big of a problem is nonadherence to [the medication] in your practice?" Physicians were surveyed in the United States from February to March 2010

Table 5

Independent Associations* of Characteristics of Physicians who would “Definitely” or “Probably” Prescribe Polypill for Primary Prevention of Cardiovascular Disease

	Moderate risk patients		High risk patients	
	OR	95% CI	OR	95% CI
Specialty				
Family medicine	ref		ref	
General internal medicine	1.04	0.73–1.48	0.91	0.57–1.45
Cardiology	1.22	0.83–1.80	0.69	0.43–1.12
Years in practice				
≥ 20	1.18	0.81–1.72	0.89	0.55–1.46
10–19	1.48	0.94–2.34	1.54	0.81–2.94
<10	ref		ref	
Region of country				
Northeast	1.36	0.89–2.07	1.75	1.05–2.94
South	1.98	1.33–2.96	2.20	1.34–3.62
Midwest	1.52	1.00–2.31	1.57	0.95–2.60
West	ref		ref	
Self-rated Polypill knowledge ≥ 75th percentile				
Yes	2.16	1.60–2.93	1.57	1.07–2.32
No	ref		ref	
Adherence to BP medications a problem in practice**				
Yes	1.03	0.72–1.48	1.48	0.93–2.36
No	ref		ref	
Adherence to lipid lowering medications a problem in practice**				
Yes	1.09	0.77–1.54	1.29	0.83–2.00
No	ref		ref	
Adherence to aspirin a problem in practice**				
Yes	1.31	0.95–1.81	1.13	0.74–1.71
No	ref		ref	

* Adjusted for all characteristics in table

** Based on being at or above 75th percentile of sample in response to question, “On a scale from 0 to 5, where 0 indicates not a problem at all and 5 indicates an extremely big problem, how big of a problem is nonadherence to [the medication] in your practice?” Physicians were surveyed in the United States from February to March 2010.