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Communicating risk using absolute risk reduction or prolongation of life formats:

cluster-randomised trial in general practice

Abstract

Background
It is important that patients are well-informed about risks and benefits of therapies to help them decide whether to accept medical therapy. Different numerical formats can be used in risk communication but It remains unclear how the different formats affect decisions made by real-life patients.

Aim
To compare the impact of using Prolongation Of Life (POL) and Absolute Risk Reduction (ARR) information formats to express effectiveness of cholesterol-lowering therapy on patients' redemptions of statin prescriptions, and on patients' confidence in their decision and satisfaction with the risk communication.

Design and setting
Cluster-randomised clinical trial in general practices. Thirty-four Danish GPs from 23 practices participated in a primary care-based clinical trial concerning use of quantitative effectiveness formats for risk communication in health prevention consultations.

Method
GPs were cluster-randomised (treating practices as clusters) to inform patients about cardiovascular mortality risk and the effectiveness of statin treatment using either POL or ARR formats. Patients' redemptions of statin prescriptions were obtained from a regional prescription database. The COMRADE questionnaire was used to measure patients' confidence in their decision and satisfaction with the risk communication.

Results
Of the 240 patients included for analyses, 112 were allocated to POL information and 128 to ARR. Patients redeeming a statin prescription totalled six (5.4%) when informed using POL, and 32 (25.0%) when using ARR. The level of confidence in decision and satisfaction with risk communication did not differ between the risk formats.

Conclusion
Patients redeemed statin prescriptions less often when their GP communicated treatment effectiveness using POL compared with ARR.

Keywords
cardiovascular disease; decision making; general practice; patient participation; risk assessment; risk communication.

INTRODUCTION

Considerable research has been carried out regarding GPs engaging in risk communication and shared decision-making with their patients concerning risk of chronic diseases and benefits of risk-reducing interventions.[1–3]

Existing evidence, mainly based on literature on adherence, indicates that patients' decisions concerning medication depend on a variety of factors, including sex, age, the nature of their illness, earlier experiences with the illness, either personally or in the family, patients' perceived control of health, their degree of aversion to risk, financial considerations, personal values, and cultures and traditions.[4] This includes information given by the GP on disease risks and effectiveness of therapies, and the patient's understanding of the information given.[5,6]

GPs may have different preferences for risk communication regarding the kind of information to provide.[7,8] One way of communicating risk is by means of numerical information.[9–11] Despite considerable research, uncertainty remains as to how the numerical formats influence patients' decisions to redeem prescriptions as well as the impact of the formats on patients' confidence in their decisions or experiences of the communication with their GP.[12–14]

Absolute Risk Reduction (ARR) is recommended as the most appropriate way of presenting medication effectiveness,[1,2,15] and is used in clinical guidelines on cardiovascular disease (CVD) when communicating risk and preventive therapies.[16] However, recent research suggests that people may comprehend information on risk and effectiveness better when effectiveness is communicated using Prolongation Of Life (POL) rather than ARR format.[15,17–19] Most research so far has involved hypothetical scenarios,[13,17–23] and it is unclear how closely these hypothetical scenarios correspond to the decisions of real patients. The present study involves real decisions in a real-life setting.

The aim of the study was to compare ARR with POL used in communication about statin effectiveness in reducing CVD risk, examining the effects on patients' redemption of prescriptions, confidence in the decision regarding initiation of therapy, and satisfaction with the risk communication in the consultation.

Based on previous research,[10,15,17,18] it was hypothesised that patients presented

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How this fits in

Much research in risk communication and shared decision-making concerns the way patients are optimally informed to enable them to make decisions that are in line with their own best interests, values and judgements, and which they will adhere to. However, there is still uncertainty though regarding how to communicate the risk and benefits of preventive therapy. So far most research has been conducted in hypothetical scenarios. This study was conducted with real-life patients in general practices and compares the impact of two different numerical effectiveness formats on actual patients faced with real-life decisions concerning their own cholesterol-lowering medication. Patients were less likely to choose medication if informed by means of Prolongation Of Life format compared with Absolute Risk Reduction.

with effectiveness information in POL format are less likely to accept cholesterol-lowering medication compared with patients presented with ARR information, as most people have more experience with assessing differences in time than probabilities, and find the gain in life expectancy insufficient to warrant lifelong therapy.

METHOD

Design and setting

This prospective, cluster-randomised trial was performed in general practices in the Region of Southern Denmark between October 2009 and March 2011. The study protocol has been published elsewhere.[24]

GP recruitment

GPs in the Region of Southern Denmark were invited to participate in a clinical trial concerning use of numerical formats in risk communication in health prevention consultations. Each GP agreeing to participate subsequently participated in either an external information session or received an office visit from the study coordinator with thorough instructions and information about the allocated risk format.[24]

As POL is a format only recently implemented in risk communication, many GPs may be unaccustomed to this format compared with ARR. Although the design of the study did not include assessing how well the formats were communicated, the information material and instruction programmes for each of the formats was specifically developed to be suitable for GPs in practice.[24] Furthermore, throughout the study period the participating GPs could contact the project group when in doubt about any issue involved in the risk communication or the formats used.

Participating GPs completed a questionnaire before they started recruiting patients. The questionnaire comprised seven items concerning the GPs' prior preferences and experiences with quantitative formats when discussing preventive therapies with their patients, and six items concerning characteristics of the GPs' practices and workload.

Randomisation

To minimise contamination between groups, a cluster-randomised design was chosen, randomising at the level of general practices and allocating the practices to one of two different ways of presenting the effectiveness of cholesterol-lowering therapy: ARR versus POL. At the external information session, with GPs from several practices gathered, randomisation was based on grouping of doctors into pairs using geographical location as first criterion, then type of practice (single-handed or partnership). In each pair one GP was allocated to ARR and the other to POL based on a random-number computer-generated table prepared before recruiting general practices. When visiting individual single-handed practices during working hours, practices were allocated using a concealed random-number computer-generated table with block randomisation of the two formats in groups of four, and an alternative list was used for partnership practices.[24]

Patient recruitment

Patients were eligible for the study if attending in general practice for a consultation during which, among other things, cholesterol levels had been measured and were now being reviewed. Patients were to be aged 40 to 69 years with a total-cholesterol level above 4 mmol/l (155 mg/dl), corresponding to the lower limit in Danish cardiovascular prevention guidelines.[25]

Patients were excluded if during the previous year they had already been confronted with decision-making concerning initiation of cholesterol-lowering medication, or if they had diabetes or established CVD (cerebrovascular disease or coronary heart disease), which would render them at high risk of further events and prompt a different approach concerning intervention.

Finally, patients were excluded if they were not sufficiently fluent in the Danish language.

Interventions

Each group of GPs (ARR and POL) received specially designed risk information sheets which were to serve as tools in the health prevention consultations.[24] The sheets featured information on personalised prognosis (10-year mortality risk or life expectancy) and statin effectiveness (ARR or POL, respectively) based on the individual patient's sex, age, systolic blood pressure, smoking status, and total-cholesterol. Thus, the total-cholesterol level was not considered to be a single risk factor but included in a multifactorial risk assessment. Calculations of the prognosis and effectiveness estimates were derived from a modification of the SCORE model.[16,26]

ARR-GPs informed patients of the estimated absolute risk (in percentages) of dying from any cause within the following 10 years when not using cholesterol-lowering medication. This was followed by information on the effectiveness of statin therapy on mortality by means of ARR. Likewise, POL-GPs informed patients of their life expectancy (in years) if not starting cholesterol-lowering medication, followed by information on the effectiveness of medication by means of POL (in months) (Box 1).

Patients were informed about the study after the individual risk information had been provided. Those giving informed consent to participate then received a questionnaire concerning their confidence in the decision-making and satisfaction with the risk communication, as well as questions about socioeconomic background, marital status, personal experience with CVD and/or CVD in the family, and self-rated health. The patients were encouraged by their GPs and by a project pamphlet to complete the questionnaire immediately after the consultation, which the majority of the patients did. The aim was to minimise the risk of recall bias by following up non-responders with up to two telephone calls within 2 weeks of the consultation.

Based on each patient's civil registration number, Odense Pharmaco-Epidemiological Database (OPED),[27] covering all individuals in the Region of Southern Denmark, provided information on redemption of statin prescriptions in the 3 months after consultation.

Endpoints

The primary endpoint was redemption of statin prescriptions during the first 3 months after inclusion.[27] The 3 months accounted for undertaking lifestyle intervention before initiating cholesterol-lowering medication, in accordance with Danish guidelines on primary prevention of CVD.[25]

Secondary endpoints were patients' confidence in the decision and satisfaction with risk communication using the Combined Outcome Measure for Risk Communication And Treatment Decision Making Effectiveness (COMRADE).[28] Each of the 20 items in COMRADE has a 5-point Likert response scale (strongly agree to strongly disagree). Ten of the items constitute the subscale 'confidence in decision' and the remaining items constitute the 'satisfaction with communication' subscale, which concerns exchange and content of information as seen from the patient's perspective.

The COMRADE instrument was translated from English into Danish and back-translated into English, and was tested for content validity.[29,30]

Statistical analyses

The sample size calculation was based on expected redemptions of statin prescriptions in the two groups. With an expected 80% redemption in the ARR-group and redemption of 60% in the POL-group, 91 patients would be needed in each of the two groups to obtain an 80% power at 95% significance level in a non-clustered study. Because of clustering, and assuming an intra-cluster correlation (ICC) of 0.1,[31] a need for a total of 346 patients was estimated. Some buffer was included for possible dropouts, and thus a total of 380 patients was required to be recruited by approximately 40 practices.

The primary outcome was analysed using multilevel logistic regression, and the secondary outcomes were analysed using multilevel linear regression, accounting for possible clustering effects at GP and practice level. Tests were made for

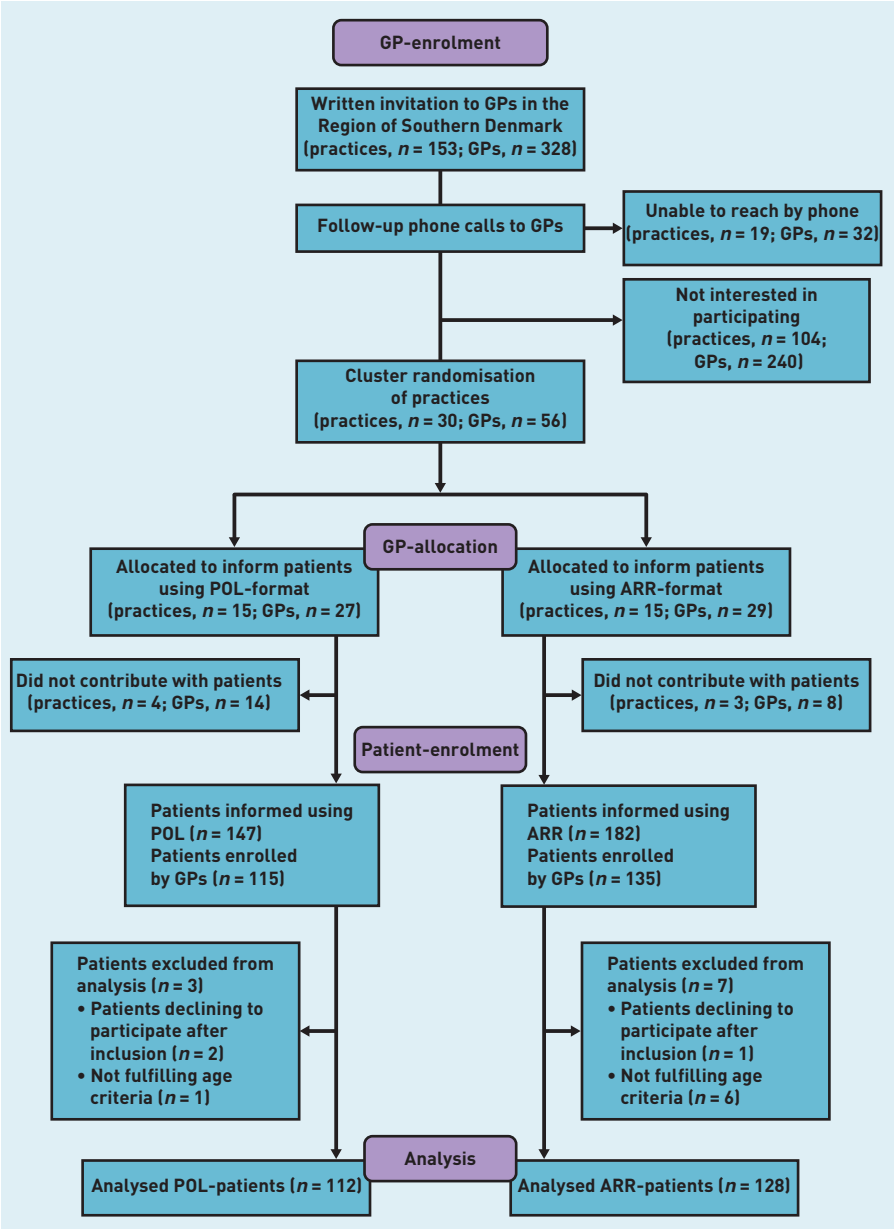
Box 1. An everyday life example to illustrate ways to inform about risk and benefits of cholesterol-lowering therapy by means of either POL or ARR

Case:	John Smith presents to his GP for a health check; 65 years old, non-smoker, no predispositions, no symptoms, no medication, normal weight, blood pressure 120/80 mmHg, total-cholesterol = 8 mmol/l
ARR:	*'If people with a cholesterol level like yours do not take the medicine, on average 6.6%, or approximately 7 out of 100 persons, will die within the next 10 years.* *However, if people take the medicine, on average 5.7%, or approximately 6 out of 100, will die over the next 10 years. That means that on average one person fewer out of 100 will die over the next 10 years.'*
POL:	*'If people with a cholesterol level like yours keep on living the way they do, they will on average live 16 years from now.* *If they take cholesterol-lowering medication for the rest of their lives, they will on average live 4 months longer than if they do not take medicine.'*

differences between the POL and the ARR allocation in patients' redemptions and the two COMRADE outcomes: patients' confidence in the decision and satisfaction with communication.

Although the randomised design should balance possible confounders, the study was reluctant to rely on the randomisation because of the high dropout rate. Adjustments were made, therefore, for possible confounders. As the size of the study population did not allow inclusion of all potential confounders in one single model, different models were used, adjusting for different groups of potential confounders. Thus, for each outcome regression analyses were analysed using five different models. Model 1 estimated the unadjusted effect of the effectiveness format on redemption and patients' confidence in the decision and satisfaction with communication, respectively. Model 2 was adjusted for possible patient-related confounders. For the primary outcome these consisted of baseline risk, patient's history of angina, impaired circulation or hypertension, and marital status. The secondary outcomes were adjusted for sex and age. In Models 3 to 5 the analyses were adjusted for possible GP-related confounders for all outcomes: Model 3 was adjusted for the GP's professional experience (number of years in general practice), and allocation to 'familiar' information type. Model 4 was additionally adjusted for the effect of an affiliation between patient and GP of more than 5 years. Finally, Model 5 additionally adjusted for the GP's self-estimated workload. Workload was a dichotomisation of a 4-point Likert scale (ranging from '1' = high to '4' = low), and coded a score of 1–2 as 'High workload' and a score of 3–4 as 'Low workload'. All potential confounders were identified *a priori*. All analyses were performed in STATA (version 11).

Figure 1. Participation flowchart.



RESULTS

Fifty-six GPs from 30 practices agreed to participate in the study. Twenty-seven GPs were allocated to inform using POL and 29 to inform using ARR. Of the 56 GPs, 22 did not enrol any patients and were excluded from further analyses (Figure 1).

A total of 329 patient information forms was returned by the GPs, whereas 250 patients returned the COMRADE questionnaire (ARR *n* = 135, POL *n* = 115). Three POL patients and seven ARR patients were excluded from further analysis because they did not fulfil the inclusion criteria (Figure 1). Of the 240 questionnaires left for further analyses, 224 (93%) had complete data for COMRADE items.

Baseline characteristics of GPs and patients were acceptably balanced in the two allocations (Table 1).

Among the 240 responding patients, 38 (15%) redeemed a prescription for a statin during the first 3 months after inclusion. The proportion was 25.0% among ARR patients and 5.4% among POL patients (Table 2). A significantly positive effect of the ARR format was found on patients' redemptions of statin prescriptions compared with the POL format, with a crude OR of 8.3 (95% CI = 2.0 to 34.6; ICC at GP level<0.001) (Table 2). This effect was augmented when adjusted for patient characteristics and GP characteristics, while additional adjustment for GPs' 'self-estimated work-load' slightly

Table 1. Descriptive statistics of participating patients and GPs

Patient characteristics	Total *n* = 240	'POL-patients' *n* = 112	'ARR-patients' *n* = 128
Mean age, years	56.4	56.9	56
Median (IDR)	57 (46–66)	58.5 (45–65)	55.5 (46–67)
Female (%)	126 (53)	66 (59)	60 (47)
Highest attained educational level (%)			
Basic school/high school	45 (19)	17 (15)	28 (23)
Vocational training	97 (40)	47 (42)	50 (39)
Higher education	98 (41)	48 (43)	50 (39)
Married/cohabiting	201 (84)	99 (88)	102 (80)
Smoker (%)	46 (20)	21 (20)	25 (21)
History of angina, impaired circulation or hypertension (%)	117 (49)	50 (45)	67 (52)
Mean total-cholesterol, mmol/l	6.2	6.2	6.2
median (IDR)	6.2 (5.0–7.4)	6.2 (5.0–7.7)	6.2 (5.1–7.4)
>5 years' affiliation to GP	157 (68)	85 (79)	72 (58)
GP characteristics	**Total *N* = 34**	**'POL-GPs' *n* = 13**	**'ARR-GPs' *n* = 21**
Female (%)	12 (35)	5 (39)	7 (33)
Mean years working as GP	16	18	15
Range, (IDR)	35 (2–34)	27 (10–25)	34 (1–34)
Use of quantitative formats in risk communication			
To a lesser extent (%)	23 (70)	8 (67)	15 (71)
To a greater extent (%)	10 (20)	4 (33)	6 (29)
Preference for quantitative format			
ARR (%)	8 (24)	3 (23)	5 (24)
POL (%)	3 (8.8)	2 (15)	1 (4.8)
Other formats or a combination (%)	16 (47)	5 (38)	11 (52)
Never used quantitative formats (%)	7 (21)	3 (23)	4 (19)
Self-rated workload			
High (%)	23 (72)	7 (58)	16 (80)
Low (%)	9 (28)	5 (42)	4 (20)

IDR = interdecile range.

reduced the positive effect of the ARR format (Table 2).

The mean scores of patients' confidence in the decision on a scale from 1 to 5 were 4.17 (95% CI = 4.00 to 4.34) for POL patients and 4.05 (95% CI = 3.89 to 4.22) for ARR patients (Table 3). The mean scores for satisfaction with the communication in the consultation were 4.41 (95% CI = 4.27 to 4.55) and 4.23 (95% CI = 4.09 to 4.39), respectively. The analyses on the COMRADE mean scores revealed no significant effect of effectiveness format (Table 3). Adjustments for patient and GP

Table 2. Multilevel logistic regression of patients' acceptance of cholesterol-lowering treatment related to format allocation (*n* = 240)

Format	Redemption, *n* (% of allocation)	Model 1 (crude analysis) Crude OR (95%CI)	Model 2[a] OR (95% CI)	Model 3[b] OR (95% CI)	Model 4[c] OR (95% CI)	Model 5[d] OR (95% CI)
POL	6 (5.4)	ref	ref	ref	ref	ref
ARR	32 (25.0)	8.30 (1.99 to 34.60)	9.07 (1.95 to 42.11)	9.16 (2.23 to 37.69)	9.07 (2.27 to 36.23)	7.89 (2.04 to 30.56)

ref = reference. [a] Adjusted for four patient-related variables. [b]Adjusted for two GP-related variables. [c]Adjusted for three GP-related variables. [d]Adjusted for four GP-related variables. ICC at GP level<0.001 (see Statistical analyses for further details on the models).

Table 3. Multilevel linear regression of patients' scores of the COMRADE 'confidence' and 'communication' subscales related to format allocation (*n* = 240)

	Mean	Difference between ARR and POL				
		Model 1 (95% CI)	Model 2[a] (95% CI)	Model 3[b] (95% CI)	Model 4[c] (95% CI)	Model 5[d] (95% CI)
Patients' rating of confidence in decision						
POL	4.17 (4.00 to 4.34)	ref	ref	ref	ref	ref
ARR	4.05 (3.89 to 4.22)	−0.04 (−0.36 to 0.28)	−0.02 (−0.32 to 0.28)	−0.03 (−0.35 to 0.29)	−0.08 (−0.39 to 0.24)	−0.11 (−0.40 to 0.18)
Patients' rating of satisfaction with communication						
POL	4.41 (4.27 to 4.55)	ref	ref	ref	ref	ref
ARR	4.23 (4.09 to 4.39)	−0.15 (−0.40 to 0.11)	−0.13 (−0.38 to 0.11)	−0.14 (−0.35 to 0.08)	−0.16 (−0.38 to 0.06)	−0.16 (−0.38 to 0.06)

ref = reference. [a]Adjusted for two patient-related variables. [b]Adjusted for two GP-related variables. [c]Adjusted for three GP-related variables. [d]Adjusted for four GP-related variables (see Statistical analyses for further details on the models).

characteristics did not influence the format effect.

DISCUSSION

Summary

A significantly higher proportion of patients redeemed a statin prescription, if they were informed using ARR rather than using POL. There was no difference between the two groups regarding patients' confidence in their own decisions or satisfaction with communication with GPs.

Strengths and limitations

Unlike most trials in the field of risk communication, this trial studied real-life patients rather than hypothetical scenarios. The study subjects responded to an actual risk to their own health, based on an individual risk profile and treatment effectiveness assessment. The real-life approach is of importance when examining risk communication and the effects of manipulation, that is framing, of information on attitudes, perceptions, and choices. A number of studies and reviews[32–34] have shown different effects of framing variations in clinical versus laboratory settings, predominantly due to the influences of contextual factors like stressors, previous personal experiences, and different ways that the risk information may be used or shared, and have called for further studies conducted in real practice.

The definition of the patient population was clear, inclusion and exclusion criteria being well-defined, and the recruitment task in the hands of the GPs straightforward. However, as a consequence of GPs conducting the patient recruitment process, and the prospective inclusion of patients after randomisation of the GPs, there may have been for some selection bias through the recruitment of certain types of patients by the respective GPs, such as those considered particularly suitable for the allocated information format.

The trial used real-life consultations in routine practice. The study does not have information on exactly how the consultations proceeded, nor on whether the effectiveness format was presented as intended. It could have been informative to supplement data collection with audio or video recordings to assess what actually happened in the consultations and the dynamics of the health prevention talk between GPs and their patients. Although approaches such as audio or video recordings might have provided information on intervention fidelity and these dynamics of health prevention talks between GPs and patients, such approaches would require considerable resources.[35] Moreover, such monitoring may have affected the dynamics and potentially also influenced patients' decisions or satisfaction outcomes. In this study, to reduce the risk of intervention infidelity, a detailed protocol was implemented, including a thorough instruction programme for the participating GPs on numerical risk communication and how to use the prognosis and effectiveness information sheets in health prevention consultations with patients concerning CVD risk and effectiveness of cholesterol-lowering medication. It is impossible to know the GPs' preferred learning styles to which educational methods might be tailored to achieve optimal understanding of risk, effectiveness formats, and skills

in communication. This study aimed at pitching the teaching at an appropriate level, in that academic GPs and social scientists in the project group developed the instruction programme based on experiences and knowledge from other trials within the field.[11,36–38] Although a degree of performance bias cannot be ruled out, it is the study's belief that overall intervention fidelity is likely to have been good, as the GPs only had access to the specific information sheets corresponding to their respective allocations. The sheets held information not published elsewhere at the time of the trial, thus GPs could not readily compute the alternative information format from resources available elsewhere. Some selection or attrition bias at the GP level cannot be ruled out: the high dropout rate may have disturbed the randomisation resulting in attrition bias. Furthermore, the GPs choosing to participate in the trial might represent those already well versed in risk communication (selection bias). This might partly explain the relatively high scores on the COMRADE subscales.

Nevertheless, the cluster-randomisation of practices was successful in creating groups of equal sizes, and with an acceptably balanced allocation of patients in the two groups, although the total number of included GPs was modest. Data on characteristics of the participating GPs were sparse, but the study population resembled the background GP population with regard to sex (35% women in the study population and 39% in the background population) and age (mean age of participating GPs 53.9 years, corresponding to the background GP population in 2009 [39,40]). The study GP population differed slightly from the background GP population with regard to type of practice, in that 22% of the participating practices were single-handed compared with 28% in the background population. Workload may be higher in single-handed than partnership practices, and hence trial participation may have lower priority. Of the 30 practices (56 GPs) initially enrolling for the study, seven practices (22 GPs) did not contribute to recruiting patients. These seven were four POL-allocated practices (14 GPs) and three ARR-allocated practices (eight GPs). The dropouts were characterised by being from partnership practices (86%, $n = 19$), were equally distributed among male and female GPs, and were not associated with the randomised allocation. Overall, the study feels that the risks of selection and attrition bias were low, but there was some risk of performance bias which is not unusual in an effectiveness study of a skill or competency applied in routine practice.

Corresponding to the study's hypothesis, the results indicated a greater willingness to redeem statins among ARR patients compared with POL patients, albeit with a broad 95% confidence interval. As a patient's individual risk (for example, cholesterol level) may likely influence the decision-making, analyses were conducted adjusting for patients' baseline risk (which included the cholesterol level). This augmented the difference in redemption propensity.

The overall redemption rate regardless of information format was much lower than expected in the power calculation. However, the reliability of the results is supported by the fact that the study had power to detect a statistically significant difference in the primary outcome. While it would not be informative to conduct a post-hoc power analysis, the knowledge gained from the discrepancy between the initial expectations and the experienced redemption rates may be useful in planning future studies in this field.

Lack of statistical power may be a contributing reason for not finding significant results regarding the secondary outcomes, the COMRADE subscales.

Comparison with existing literature

The tendency to reject medication when presented with POL information could be explained by the ease of evaluating the information.[41] Most people are used to evaluating numeric differences in time, but not in risks or probability. Consequently, they may find it easier to understand the level of effectiveness when presented with POL, and then find the gain too small to justify redemption of a prescription.

Studies on laypersons and hypothetical scenarios have shown sensitivity to information presented by POL and ability to evaluate POL data.[17,18] The hypothesis that patients might require a considerable POL to accept therapy corresponds to findings from Trewby *et al*,[14] where most participants, presented with a hypothetical scenario, required a considerable POL of at least 18 months before being willing to take a hypothetical preventive cholesterol-lowering drug. However, few medical interventions postpone death by more than 1 year.[42] Inconsistent sensitivity to levels of effectiveness of a hypothetical cholesterol-lowering drug regardless of effectiveness format used, has been indicated in another Danish study.[15] Literature on the impact of these formats on real-life patients' decision-making is sparse. To the study's knowledge,

no research to date has compared ARR and POL used in real-life risk communication between GPs and their patients.

Implications for research and practice

Although the results of this study revealed a clear difference in redemptions of prescriptions between patients informed by means of ARR and POL, and showed that patients in general seemed confident with their decision and satisfied with the risk communication regardless of format used, it is noteworthy that the redemption of prescriptions was very much lower than expected for both trial groups. This suggests that in the decision-making process about whether to accept a preventive therapy, patients faced with information about their own risk of CVD are indeed sensitive to effectiveness formats. This indicates that with informed decision-making, many patients are not impressed with the reported benefits of proposed therapies, or that the level of effectiveness is not the only determinant of patients' decision-making concerning therapy. This is consistent with the tension between public health, guidelines, and informed decision-making found in previous studies.[37,43–45] It is important that GPs are aware of this tension when talking about health prevention and potential medication with their patients, and that in the decision-making process they handle numerical information on effectiveness with care.

It would be important for future research to assess real-life patients' perceptions of risk, in general and concerning their own risk when informed about prognosis of disease, and how these perceptions may influence decisions concerning choice of therapy and adherence to chosen therapy. Assessing GPs' perception of risk would also be important in future research. Knowledge of how patients and their GPs interpret and understand risk information to make decisions to which they adhere, could increase cost-effectiveness of therapies and improve compliance with guideline recommendations.

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Trial Registration:

NCT01414751 (ClinicalTrials.gov).

Ethical approval

The trial was conducted in accordance with Danish legislation and was approved by the Research Ethics Committee of the Region of Southern Denmark (project identification number S-20090034) and reported to the Danish Data Protection Agency (file number 2009-41-3208). Informed patient consent was obtained before enrolment in the trial.

Provenance

Freely submitted; externally peer reviewed.

Competing interests

The authors have declared no competing interests.

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