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Discontinuation of secondary prevention medication after myocardial infarction – the role of general practitioners and patients

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Summary

BACKGROUND: Despite the significant benefits of secondary prevention (SP) medication after acute myocardial infarction (MI), evidence suggests that these medications are neither consistently prescribed nor appropriately adhered to by patients. The aim of this study was to investigate the role of general practitioners (GPs) and patients regarding discontinuation of SP medication after MI and reasons for discontinuation.

METHODS: In this observational study, GPs of patients who had suffered acute MI provided information on discontinuation of SP medication 6 and 12 months after hospital discharge. A questionnaire-based approach was used (a) to assess the consistent use of SP medication after MI, (b) to determine reasons for stopping SP medication, (c) to quantify the involvement of GPs and patients regarding discontinuation, and (d) to analyse potential factors that are associated with discontinuation of medication.

RESULTS: Of 204 subjects 6 and 12 months after hospital discharge 83% and 75% patients, respectively, were still on recommended SP medication. Overall, one or more SP medications were stopped (53 medications) or modified (15 medications) in 52 (25%) patients. Adverse side effects were the main reason for stopping medication (63%). GPs reported being responsible for initiating discontinuation or modification more frequently than patients (62% vs 38%, p = 0.065).

CONCLUSION: The consistent use of evidence-based pharmacotherapy 6 and 12 months after myocardial infarction was adequate. Three out of four patients were still on recommended SP medication after 1 year of follow-up. Two-thirds of medication discontinuations were initiated by GPs, predominantly because of side effects.

Key words: *secondary prevention; acute myocardial infarction; evidence based medicine; primary health care*

Introduction

Coronary artery disease (CAD) is one of the leading causes of death in developed countries. For example, in 2008 an estimated 17.3 million of people died from CAD, representing 30% of all global deaths [1]. In Switzerland an estimated 150,000 patients suffer from CAD [2] causing a considerable volume of costs [3]. The use of evidence-based secondary prevention (SP) medication after acute coronary syndrome (ACS) episode is efficacious in reducing the risk of death, reinfarction or recurrent coronary ischaemia [4–6]. According to current guidelines [7] aspirin should be used indefinitely in all patients with myocardial infarction (MI). Dual antiplatelet therapy, combining aspirin and an adenosine diphosphate (ADP) receptor blocker (clopidogrel, prasugrel or ticagrelor), is recommended in patients with MI who are undergoing primary percutaneous coronary intervention (for up to 12 months). The benefit of long-term treatment with beta-blockers after MI is well established. The benefits of statins in secondary prevention have been unequivocally demonstrated and specific trials have demonstrated the benefit of early and intensive statin therapy. It is well established that angiotensin-converting enzyme (ACE) inhibitors should be given to patients with an impaired ejection fraction (<40%) or who have experienced heart failure in the early phase. Opinions still differ as to whether to give ACE inhibitors to all patients or to high risk patients only. Patients who do not tolerate an ACE inhibitor should be given an angiotensin receptor blocker (ARB). Despite the significant benefits of SP medication, several studies clearly suggest that these medications are neither consistently prescribed nor appropriately adhered to by patients [8–12]. However, few studies have assessed the role of the healthcare provider and of the patient in cases of discontinuation [13]. In primary care the various reasons for discontinuing SP medication by general practitioners (GPs) or for insufficient adherence to medication by patients have scarcely been investigated.

The aim of the present study was to determine GP-reported persistence with evidence-based secondary prevention medication 6 and 12 months after MI. Of particular interest was whether discontinuation of medication was initiated by the GP or the patient and to identify potential predictive factors in stopping medication.

Patients and methods

Recruiting of patients and inclusion criteria

The study used an observational design. In order to optimise the methodological procedure we preceded according to the STROBE (strengthening the reporting of observational studies in epidemiology) guidelines [14]. In collaboration with the Department of Cardiology at the University Hospital of Basel, Switzerland, we identified all patients treated for MI in 2008. We restricted our study sample to patients who had a discharge diagnosis of MI; patients with unstable angina were excluded. All patients with MI [15] for whom hospital discharge documents were available were eligible for the study. MI was defined by the presence of biomarkers and/or electrocardiographic findings in a setting in which signs and symptoms were consistent with acute ischaemia and outlined by standard diagnostic criteria [16]. A questionnaire was sent to all GPs caring for patients who had been hospitalised for MI in 2008 and who had given their written consent to use their health data.

The questionnaire consisted of four parts: (1.) medication used at 6 and 12 months after hospital discharge, (2.) medication stopped or modified (giving an alternative drug, e.g. due to side effects) during the 1 year observation period after hospital discharge, (3.) GP and/or patient role regarding discontinuation or modification of medication, (4.) reasons for stopping one or more SP medications. Closed questions were used and no possibility of free text was offered.

The study was approved by the local ethics committee and written informed consent was obtained from all patients.

Outcome measures

Two primary outcome measures were assessed. Firstly, the number of discontinuations or modifications of evidence-based SP medication for acute MI 6 and 12 months after hospital discharge. We expected consistent use of beta-blockers [6, 7, 17], aspirin, statins, ACE inhibitors / ARBs [4, 7] at least for the observed time spam during the study. According to current guidelines, we expected clopidogrel treatment for all patients treated with a drug-eluted stent of 12 months duration and a strict minimum of 1 month for patients who had received a bare-metal stent [7]. Secondly, the person primarily initiating the discontinuation or modification of the medication (GP or patient) was recorded. We are aware of the fact that in specific clinical situations (e.g. cough caused by an ACE inhibitor) discontinuation is based on a shared decision-making process initiated equally by the GP and the patient. When designing the study we decided that GPs had to determine who was primarily responsible for discontinuation of medication. Demographic data of the study sample such as age, sex, number of cardiovascular risk factors and classification of MI (ST-elevation or non-ST-elevation MI) was collected by analysing the hospital discharge report.

Statistical analysis

The results are presented as descriptive statistics: proportions, means, and standard deviations (SDs), unless otherwise specified. Categorical data are given as absolute numbers and percentages of the study population. For continuous paired-traits, Mann-Whitney U-statistics were calculated. Analysis of categorical data was performed by chi-square tests. To calculate relations between two variables (e.g. age and discontinuation of therapy) a Spearman's rank correlation test was used. A p-value of <0.05 was considered to be statistically significant. All data were calculated using the Stata statistical package, version 11.2 (Stata Incorporation, College Station, TX, USA)

Results

Initially, we received a list of all patients treated for ACS in 2008 from the Department of Cardiology at the University Hospital of Basel, including discharge reports with information on the medication at hospital discharge (n = 708). Of these, 64 (9%) patients did not fulfil the criteria of MI according to current guidelines or were hospitalised for unstable angina without rise and/or fall of cardiac biomarkers (troponin and/or creatine kinase) [16]. The local ethics committee requested written informed consent from the remaining 644 patients prior to sending a questionnaire to their treating GP. Of the 644 patients to whom an informed consent form was sent, ten patients explicitly refused to take part in the study by sending back the unsigned informed consent, 30 patients died during the hospital stay or within 1 year after hospital discharge and in 23 cases the letter of invitation was not deliverable owing to incorrect contact details. A total of 249 patients did not send back the informed consent form despite reminding letters and for 35 patients, who agreed to participate, contact details of the GP could not be traced. Eventually, this excluded 347 (49%) patients before sending out the questionnaire to their GPs.

The GPs of the remaining 297 patients (42%) who agreed to participate received a questionnaire. Despite written reminders by post, email and personal telephone calls, GPs did not send back the questionnaires of 93 patients. Eventually, data of 204 (29%) patients were analysed.

Demographic characteristics are given in table 1. Half of the patients (51%) had been treated by the same GP for more than ten years. The frequency of consultations per year during the observation period was less than two in 39 (19%) patients, three to ten consultations in 128 (63%), and more than ten consultations in 37 (18%) patients. At

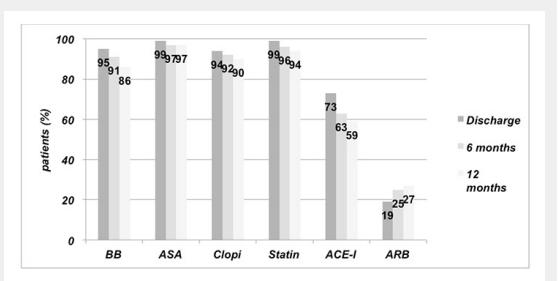

Figure 1

Secondary prevention medication after myocardial infarction (n = 204) at hospital discharge, and 6 and 12 months after discharge. ACE-I = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; ASA = acetylsalicylic acid; BB = beta-blocker; clopi = clopidogrel

hospital discharge 194 (95%) patients were treated with evidence-based SP medication. Six and 12 months after hospital discharge 169 (83%) patients and 153 (75%) patients respectively, were still on evidence-based SP medication. A detailed overview is given in figure 1.

Discontinuation or modification of evidence-based medication [4, 6] was observed in 52 (25.5%) of all patients over the course of 12 months. In total, 53 medications were discontinued (contrary to evidence) and 15 medications were modified (mainly replacement of an ACE inhibitor by an ARB due to cough), 63% between hospital discharge and 6 months, and 37% between 6 and 12 months after hospital discharge (table 2). GPs reported being responsible for discontinuation or modification more frequently than patients (42 [62%] vs 26 [38%], p = 0.065).

Discontinuation or modification of ACE inhibitors to an ARB was initiated more often by GPs (21 vs 8 discontinuations, p = 0.031), whereas discontinuation of statins was initiated more frequently by patients (8 vs 2 discontinuations, p = 0.034). ARBs were never stopped during the observational period. No difference between GP and patient was found regarding discontinuation of beta-blockers, clopidogrel and acetylsalicylic acid (p >0.05). The main reason (in 63% of cases) for discontinuation or modification of medication was the occurrence of adverse side effects of pharmacological treatment. The most prevalent side effect was a cough in patients taking ACE-inhibitors (22%). In all these patients an ARB instead of an ACE-inhibitor was prescribed alternatively (modification of the treatment).

In one-third of cases (32%) the patient was unwilling to take the medication as a long term treatment. In 15% the GP considered that further administration of this drug was not indicated.

An overview of reasons for discontinuing/modifying medication is given in table 3.

We found no differences in terms of sex, single cardiovascular risk factors, total number of cardiovascular risk factors, duration of doctor-patient-relationship or number of consultations per year between patients taking SP medicine during the observation period and patients in whom recommended treatment was stopped (p-values >0.05). Age was related to discontinuation of medication (p = 0.049).

Discussion

Maintaining persistence with SP medications in patients with CAD is a challenging task in primary care. Patients after MI who discontinue taking evidence-based medications are at increased mortality risk [11, 17]. A prior study found that stopping SP medications was associated with approximately 50%–80% increased risk of mortality and 10%–40% increased risk of hospitalisations for cardiovascular conditions [18]. Although there have been some reported improvements in adherence rates to cardiac medication over time [19], discontinuation of evidence-based medication after MI remains a significant issue in general practice and becomes relevant early after hospital discharge [8, 20].

The main focus of our study was to evaluate who predominantly initiated the discontinuation of evidence-based medication. We found that in a majority of cases GPs were primarily responsible for stopping medication. This finding might be unexpected since patients generally seem to be

Table 1: Baseline characteristics of the study population (n = 204).

Characteristic	Description
Median age (years) (SD, range)	64.5 (11.3, 38–88)
Male gender, n	158 (78%)
Diabetes, n	34 (17%)
Dyslipidaemia, n	90 (44%)
Smoking cigarettes, n	65 (32%)
Hypertension, n	118 (60%)
Type of MI, n	
Non-ST-segment elevation MI	114 (56%)
ST-segment elevation MI	90 (44%)

MI = myocardial infarction; SD = standard deviation

Table 2: Discontinuation and modification of evidence-based secondary preventive medication by general practitioners and patients. Overall, 53 medications were discontinued and 15 were modified in 52 of 204 patients.

	6 months n (%*)	12 months n (%*)
Discontinuation by GP	18 (26.5)	13 (19.1)
Modification by GP	9 (13.2)	2 (2.9)
Discontinuation by patient	13 (19.1)	9 (13.2)
Modification by patient	3 (4.4)	1 (1.5%)

* Percentages refer to the proportion of all discontinued or modified medications (n = 68)

Table 3: Reasons for discontinuation/modification of secondary prevention medication after myocardial infarction (n = 68) 6 and 12 months after discharge.

	BB	ASA	Clopi	Statin	ACE-I	ARB
Cough	–	–	–	–	15[5]	–
Bradycardia, hypotension	6	–	–	–	4	–
Increased bleeding risk	–	–	5	–	–	–
Myopathy[1], hepatopathy[2]	–	–		4	–	–
Major bleeding[3]	–	–	2	–	–	–
Erectile dysfunction	2	–	–	–	–	–
Asthma	2	–	–	–	–	–
Severe heart failure	1	–	–	–	–	–
Renal failure[4]	–	–	–	–	1	–
Hives of urticaria	–	–	–	–	1	–
Not indicated as stated by the GP	4	–	–	–	4	–
Patient refused drugs	4	2	1	6	4	–

ACE-I = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; ASA = acetylsalicylic acid; BB = beta-blocker; clopi = clopidogrel
[1] with or without increasing creatin kinase; [2] > threefold elevation of transaminases from baseline; [3] need for transfusion; [4] rise in serum creatinine level >30% from baseline; [5] in all these patients ACE-I were replaced by ARB

concerned about the necessity of their prescribed medication and are also interested in information about the benefits of this medication as compared to the potential adverse effects of taking it [21]. In a recent study, Melloni and colleagues assessed potential reasons for early discontinuation of evidence-based medication after ACS [13]. As in the present study all discharge medications were obtained from hospital charts and patients were interviewed by telephone 3 months after discharge to determine if evidence-based medication prescribed at discharge was continued. In contrast to our results the authors report that a majority of patients self-discontinued SP medication and only 38% of patients discontinued therapy following the advice of their GPs.

This divergent finding might be due to the fact that in the study by Melloni – in contrast to our investigation – patients were asked whether they still took the cardiovascular medication while patient's treating physician did not know about the study. Furthermore, Melloni studied a population without mandatory health insurance coverage, suggesting that some patients possibly could not have afforded the recommended medication (in fact, this was also documented in the study) [13]. It is important to note that in Switzerland health insurance coverage is regulated by law and is mandatory for all residents.

In the present study a large majority of patients was still on recommended therapy 6 months after hospital discharge (86%) and at 1 year of follow-up 75% were still prescribed complete SP medication. This adherence to recommended pharmacotherapy seems to be higher than reported previously. A study of primary care in Iceland found that among patients after MI only 52% were on beta-blocker-treatment and 25% of patients were prescribed lipid lowering therapy [22]. Lee and colleagues reported that at 3 months following hospitalisation for ACS, a minority of patients (42%) were still receiving the evidence-based therapy [10]. One explanation for the comparably high and persistent adherence in our study might be that in the study by Lee a majority of patients included (74.5%) had an intermediate coronary syndrome and only 24.5% of patients fulfilled diagnostic criteria for acute MI as defined in our study (rise and/or fall of cardiac biomarkers). Evidence suggests that discontinuation of SP medication in patients with intermediate coronary syndrome is more common than in patients with acute MI [23]. It is also noteworthy that adherence to SP medication has improved over the last decade [8].

Several publications suggest that elderly patients (>65 years) are less likely to be prescribed (long-term) SP medications than patients <65 years of age [10, 24]. Our results are in line with these findings. Age seems to be a risk factor for discontinuing SP therapy. Elderly patients are at increased risk for comorbid conditions. Patients with comorbidity have been reported to discontinue cardiovascular medication more frequently than patients with fewer comorbid conditions [25]. Elderly patients are also more prone to adverse side effects of cardiac medication. Our results suggest that adverse side effects were the main reason for discontinuing secondary prevention medication. Generally, for elderly patients adverse side effects have more serious consequences than for younger patients and may result in more frequent hospitalisations [26]. Side effects of cardiac medication after MI cannot be completely eliminated, however there is still a potential for education and motivation of patients to improve use of evidence-based medication after hospital discharge. Griffo and colleagues assessed the impact of a cardiac rehabilitation program on lifestyle, risk factors and medication modifications. The intervention showed that patients after MI participating in a cardiac rehabilitation program not only benefited in terms of life style modifications but also regarding adherence to and persistence of secondary prevention medication [27].

Some limitations of this study should be considered. Information concerning whether primarily the GP or the patient initiated the discontinuation of medications was provided by the GP. This could have resulted in an over-reporting of patient involvement in treatment discontinuation because GPs may be reluctant to report stopping evidence-based medication. However, our data show that GPs reported themselves as being mainly responsible for the discontinuation of medication. This may indicate that the information given by GPs was accurate. Medication use at 6 and 12 months was also GP-reported and this may be a unilateral reflection of adherence and persistence of medication. However, the objective of the present study was not to evaluate patients' adherence to medication, but to determine who primarily is responsible for discontinuation of medication. Therefore, it seems appropriate to use GP-reported data for studying treatment quality. Of course, we are aware of the fact that the study was single centred that may limit the generalisability of the results. Finally, the number of patients eventually analysed (n = 204 of 704 discharged with ACS from hospital) was comparably low. The main reason for this was that patients did not send back the written informed consent form despite reminding letters (n = 249).

Conclusions

In summary, the consistent use of evidence-based pharmacotherapy after myocardial infarction among Swiss patients from primary care was comparably high. Three out of four patients were still on recommended secondary prevention medication after 1 year of follow-up. Discontinuation or modification of at least one medication after MI was observed in 25% of patients within the first year after hospital discharge. There was a trend that the GPs mainly initiated the discontinuation of medication, predominantly due to adverse side effects.

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Figures (large format)

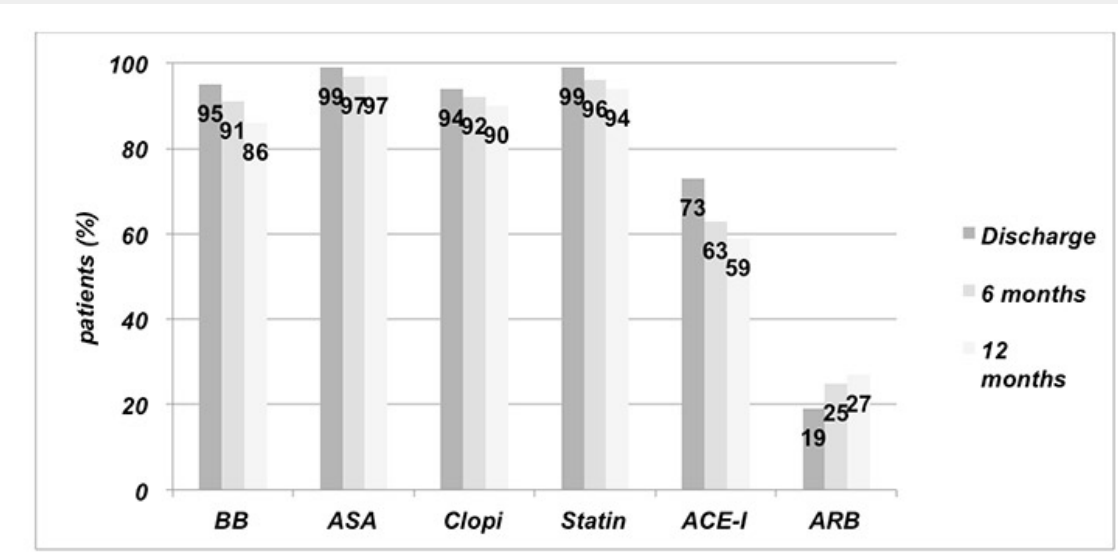

Figure 1

Secondary prevention medication after myocardial infarction (n = 204) at hospital discharge, and 6 and 12 months after discharge.
ACE-I = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; ASA = acetylsalicylic acid; BB = beta-blocker; clopi = clopidogrel