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Self-management program improves anticoagulation control and quality of life: a prospective randomized study

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Abstract

Objective: Previous retrospective studies suggest that patients' self management of oral anticoagulants leads to improved control. In this prospective randomized study, we investigated the effects of self management on the control of anticoagulant therapy and quality of life. Comparison with the conventional management through the Dutch Thrombosis Service is addressed. **Methods:** Between January 2005 and June 2007, 62 consecutive patients who underwent elective mechanical aortic valve replacement were included in this study. Patients were randomized into two groups: (1) conventional group controlled by the Local Thrombosis Service, and (2) self management group using CoaguChek®. Primary endpoints were the total number of international normalized ratio (INR) values within the target range as well as the quality of life measurements (SF-36v2)® one year postoperatively. **Results:** The number of INR values within the target range (2.5–4.5) was significantly higher in the self management group (mean = 72.9 ± 11%) than in the conventional group (53.9 ± 14%; $p = 0.01$). Both groups showed an improvement in the quality of life scores one year postoperatively. However, postoperative improvement was statistically significant in the self management group regarding the physical component summary only ($p = 0.001$). **Conclusion:** Despite the well-organized INR control by the Thrombosis Service in The Netherlands, self management program after adequate training improves the INR control. Postoperative improvement in the quality of life scores was significant in the self management group with regards to the physical component summary only. Further studies are needed to describe whether self management program will reduce the risk of bleeding and/or thrombo-embolism.

Keywords: Prosthetic heart valve; Oral anticoagulation therapy; Self management; International normalized ratio

1. Introduction

The risk of bleeding and thrombo-embolism still accounts for most of the complications after mechanical heart valve replacement, with an incidence of 0.9–3.6% per patient year [1]. These complications occur most frequently during the first six months after surgery. Later on, the risk decreases and remains constant for years [2]. The risk of anticoagulant-related events increases when the long-term INR variance is higher. When bleeding or thrombo-embolism occurs, as much as 60% of the INR values were observed to lie outside the therapeutic range [3].

In the Netherlands, control of oral anticoagulant therapy is regulated through a network of anticoagulation clinics called 'The National Thrombosis Service'. This has led to a decrease in thrombo-embolic and bleeding complications [4]. Frequent long-term monitoring of the INR values can lead to a better control, but it has physical, psychological, social and financial consequences for both patients and health care system [5].

With the development of portable INR measurement devices, it was possible for many patients to control their own anticoagulation therapy. After sufficient training, the patient can adjust the intensity of anticoagulation and eventually change the dose if needed [6,7].

Recent studies [8,9] have demonstrated that INR self management can lead to better anticoagulation control and this can lead to less complications. This study was prospectively designed to evaluate the safety and efficacy of INR self management in comparison with the National Thrombosis Service in the Netherlands in patients undergoing elective mechanical aortic valve replacement.

2. Materials and methods

Between January 2005 and June 2007, 62 consecutive patients were prospectively included and randomized in this study. This study was approved by the medical ethics review

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committee. All patients who were accepted for an elective mechanical aortic valve replacement operation were screened for the study.

Inclusion criteria:

1. Elective mechanical aortic valve replacement.
2. Informed consent.
3. Enough knowledge of computers and use of Internet.

Exclusion criteria:

1. Patients already using anticoagulants before the operation.
2. Patients with chronic bleeding diathesis.
3. Patients with chronic liver disease.
4. Chronic alcoholism.
5. Neurological deficits which interfere with the self measurement method; e.g. tremors, amnesia, etc.
6. Severe operative or postoperative complications that can prolong the hospital stay or any other complications that, according to the investigator, can influence the postoperative course.

After signing the informed consent, patients were randomly divided into two groups:

1. Conventional management group, which follows the Dutch Thrombosis Service.
2. Self management using CoaguChek® devices (Roche Diagnostics GmbH, Manheim Germany).

Three weeks preoperatively, patients of group 2 received a special information session. During this session, the patient received CoaguChek® and all the disposables needed. This was followed by registration of the patient in a special website (www.Heartspoint.nl). After sufficient training for at least one week under supervision of the Thrombosis Service, the patient had to pass an exam of self measurement. One day preoperatively, patients were asked to complete the SF-36v2® questionnaire.

The postoperative procedures started in the hospital with adjustment of oral anticoagulants. An INR target range of 3—4 was accepted for both groups in consultation with the 'Thrombosis Service' of Eindhoven. During data analysis the range was extended to 2.5—4.5 to discard small deviations in readings.

Patients of the self management group had to measure the INR themselves under supervision of the ward physician. After discharge, these patients measured the INR at home and notified the anticoagulant dose on the website. During the first four weeks, the patient's suggestions were revised and corrected, if needed, by the Thrombosis Service. The patient had then to pass the exam of anticoagulant dosage on the website. Afterwards, all patients were re-evaluated by the Thrombosis Service once every three months.

One year postoperatively, all patients were clinically evaluated by the research physician. They had to complete the SF-36v2® questionnaire again.

2.1. Data analysis

All the INR values were collected in a special data base. With the use of a spread sheet (Microsoft® Excel) the total number of INR values within the target range was compared in the two groups. The SF-36v2® scores are transformed into eight components (four physical and four mental). The mean score for every component is 50 ± 10 (mean US population 1998). The questionnaire has been used in numerous public health studies [10]. Analysis of discrete variables was accomplished by a two-tailed Fisher's exact test. Comparison of means for continuous variables was conducted using an unpaired Student's *t*-test. A *p*-value of <0.05 was considered significant.

3. Results

Between January 2005 and June 2007, all patients who were scheduled for an elective mechanical aortic valve replacement ($n = 481$) were screened for the study. Only 132 patients (27.5%) were possible candidates of the study. Sixty-two patients (47%) have signed the informed consent. Four patients were excluded from the study: one patient has got a biological valve, one patient was operated as an emergency, one patient has got a percutaneous coronary intervention (PCI) and one patient died preoperatively.

The number of patients who completed the one-year follow up was 58 (29 in each group). The mean age was 55.7 ± 9.3 years in group 1 and 56.3 ± 8.6 years in group 2 without statistically significant difference.

The total number of INR values differs significantly between the two groups. In group 1 (conventional management), this number was 666 values (mean = 23.8 ± 10). In group 2 (self management), the total numbers of INR values was 1526 (mean = 61.04 ± 27) [$p < 0.001$].

The mean INR value was 3.0 ± 0.95 in group 1 and 3.3 ± 0.99 in group 2 ($p = 0.01$). The number of INR values per patient within the target range (2.5—4.5) was significantly higher in the self management group ($72.9 \pm 11\%$) than in the conventional management group ($53.9 \pm 14\%$) [$p = 0.01$] (Fig. 1).

We have also calculated the total periods of time (in days) during which the INR value for each patient was outside the target range. This 'period of risk' was presented as a percentage of the whole follow up period (one year). This percentage was significantly higher in group 1 (28.6 ± 14) than in group 2 (22.2 ± 10) [$p < 0.001$] (Table 1).

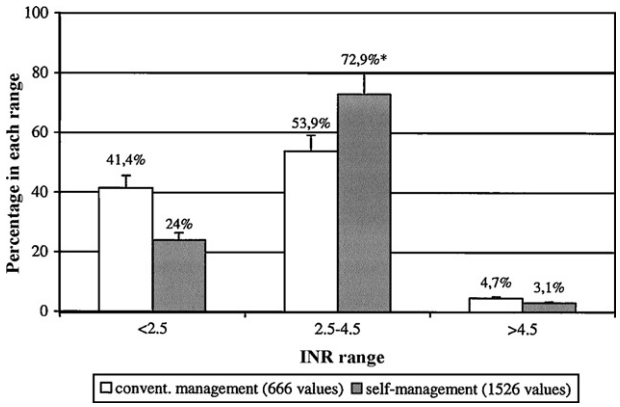

Fig. 1. Mean percentage of INR values within the target range in both groups. (*) Statistically significant.

Table 1
Comparison of the mean period of risk between the two groups.

	Total period (days) (mean)	Period of risk (days)(mean)	%
Conventional management	336.3 ± 96.3	96.4 ± 45	28.7
Self management	360.6 ± 69	80.1 ± 40	22.2*

* $p < 0.001$.

Table 2
Postoperative mortality and complications in both groups.

	Conventional measurement	Self measurement
Mortality	1 (sudden death)	1 (mediastinitis)
Major bleeding	1 (intestinal resection)	1 (pericardial drainage)
Minor bleeding	–	–
CVA	1	–

CVA: Cerebro-vascular accident.

Table 2 shows both the mortality and the postoperative complications within one year after the operation. There was no significant difference between the two groups in this regard.

Fig. 2 shows that the improvement in the postoperative quality of life scores in group 1 was statistically not significant in almost all the components. Only two components, physical functioning and role physical, showed significant post-operative improvement. Fig. 3 shows physical component summary (PCS) and mental component summary (MCS). The postoperative improvement in group 1 was not significant with regards to both summaries.

On the other hand, patients of group 2 showed a statistically significant postoperative improvement in all components except bodily pain (Fig. 4). Fig. 5 shows that the postoperative improvement was statistically significant only in the physical summary (PCS) ($p = 0.001$).

Difference in the quality of life scores between the preoperative and postoperative state is calculated in percentage for every patient. Comparison between the mean percentages in both groups is shown in Table 3.

4. Discussion

This prospective randomized study was designed to evaluate the safety of the self management program in controlling oral anticoagulant therapy compared to the Dutch National Thrombosis Service. We have confirmed that INR self management improves the anticoagulation control and minimizes the periods of risk during which the INR values are outside the target range. Improvement in the quality of life was documented using a standard questionnaire.

During the inclusion period (30 months), 421 patients have undergone elective mechanical aortic valve replacement and were possible candidates for the study. Only 138 patients (32.8%) have fulfilled the inclusion criteria. Sixty-two patients (45%) have given an informed consent. This means that a certain group of patients are still not feasible enough for self management. This can be either due to exclusion criteria; e.g. neurological deficits or due to the patient himself who does not have enough selfconfidence. This was also concluded by different authors [8,9,11]. However, others have found that all patients who are able to lead

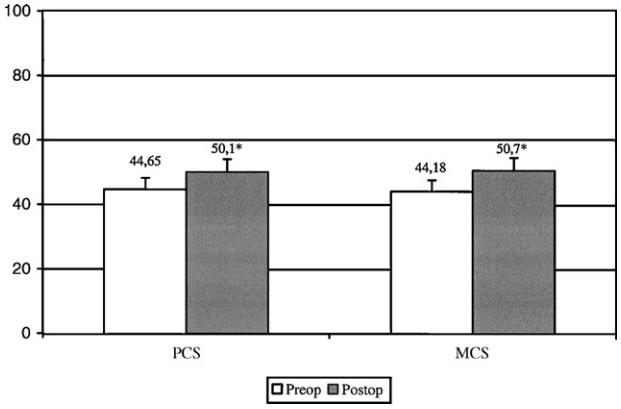

Fig. 3. Postoperative improvement in both physical component summary (PCS) and mental component summary (MCS) in group 1 (conventional management). (*) Non-significant.

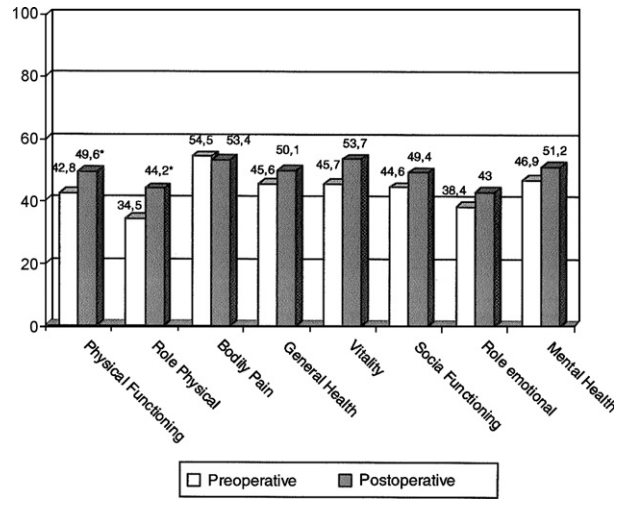

Fig. 2. Postoperative change in the quality of life scores in group 1 (conventional management). (*) Statistically significant.

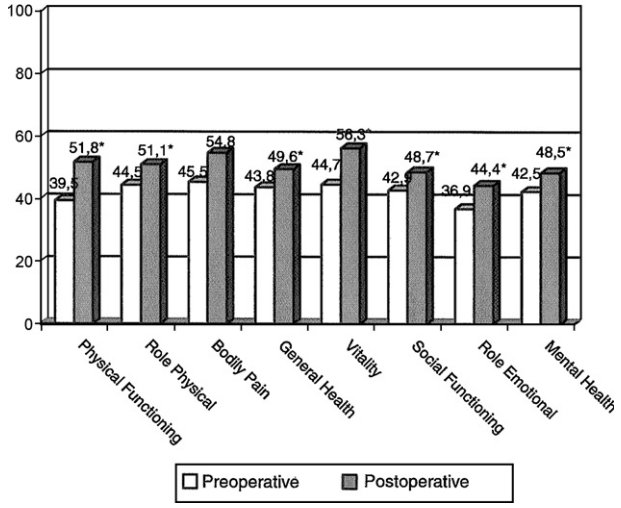

Fig. 4. Postoperative change in the quality of life scores in group 2 (self management). (*) Statistically significant.

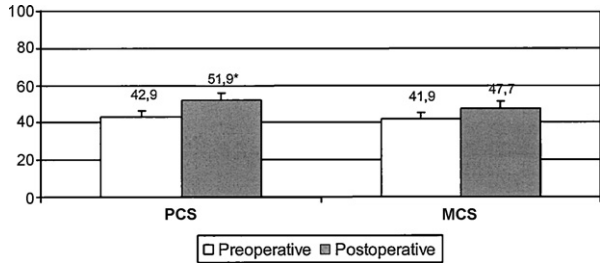

Fig. 5. Postoperative improvement in the physical component summary (PCS) and mental component summary (MCS) in group 2 (self management). (*) Statistically significant.

an independent and self-supporting life are capable of self management of anticoagulation, irrespective of education and social status [12]. Although we have selected patients for this study, this selection was also applied to the conventional management group. The two groups were equal concerning age, educational level and social status. Moreover, other studies have included patients on chronic anticoagulation therapy [13] while our patients were randomized and trained before starting anticoagulants.

With regards to INR values within the target range, the number of values was significantly higher in the self management group than in the conventional group, 72.9% vs 53.9%, respectively. This confirms the statement that self management improves the quality of INR control. Several studies have been in agreement with this finding [5,9,10,13–15]. One possible limitation is the big difference in the total number of INR values, 666 values in the conventional management group vs 1526 values in the self management group. This means that patients of the self management group tend to measure the INR more often than the conventional group. If the measuring points are close to each other, this makes many measuring points of less importance or weight [16].

The weight of every point depends on the time interval between that point and the closest point of measurement. The longer the time, the more important the point counts. In other words, if some points are very close to each other, they are per point less important because they cover a shorter period of time. That is why we have calculated, in days, how long the INR value for every patient was outside the target range. This period of risk is calculated as a percentage of the whole follow up period (one year). Comparison between the mean percentages in both groups has shown that patients of the self management group have significantly shorter periods of risk (22.2%) than patients of the conventional management group (28.7%). This can lower the risk of bleeding and thrombo-embolism [3].

Table 3
Difference in the postoperative improvement in the quality of life scores (%) between the two groups.

	Conventional measurement	Self measurement	*p*-value
PF (physical functioning)	15.8	13.2	NS
RP (role physical)	28.3	27.4	NS
BP (bodily pain)	−2.0	7.3	0.02
GH (general health)	9.9	13.4	NS
VT (vitality)	17.6	25.9	0.02
SF (social functioning)	10.8	13.3	NS
RE (role emotional)	12.1	20.0	0.01
MH (mental health)	9.2	14.2	NS
PCS (physical component summary)	9.8	20.9	0.03
MCS (mental component summary)	9.1	13.7	NS

NS: non-significant.

We did not find a significant difference in the incidence of complications between the two groups possibly because of the relatively small number of patients in our group. However, this was not our primary endpoint. In the majority of previous studies, the number of included patients has been limited as well [17]. Other investigators [10,18] have shown that fewer adverse events by better INR management may translate into improved long-term survival.

Improvement in the quality of life was investigated using a well-known standard questionnaire (SF-36v2)® [19]. Although both groups have shown a postoperative improvement in quality of life components, improvement was statistically significant in the self management group. Again, we have calculated the postoperative improvement in each component for every patient as a percentage. The difference in the postoperative improvement between the two groups was significant with regards to the physical summary only. However, looking to the different components, we found a significant difference concerning three components: bodily pain, vitality and role emotional. These components are also closely related to the mental status and cannot be only translated as physical components.

Although both groups were matched concerning age and level of education, patients of the self management group have shown better quality of life at one year follow-up. There are possible reasons for this difference. Patients of the self management group have a more detailed knowledge about anticoagulant therapy and the influence of diet, infectious diseases, alcohol, drug interactions, etc. than patients of the conventional group. They are therefore very much aware of the potential complications concerning this treatment. Furthermore, the patients have a higher degree of compliance because they are highly motivated, since they do not need to go to the 'Local Thrombosis Service' for blood specimen and dose adjustment. This allows the patients to travel and manage their job without interruption which conventional management has on their daily life.

Although some studies have also pointed out that self management improves the quality of life [20,21], our study was unique in adopting a standard well-known questionnaire (SF-36v2)®.

In conclusion, this study has confirmed the efficacy of the self management in improving the INR control in this group of patients. Although we did not investigate incidence of complication, patients of the self management group had significantly shorter periods of risk than the conventional group. Improvement in the quality of life was only significant in the self management group concerning only the physical summary.

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