Enabling patient self-management

Christian Schaefer argues that it makes sense to give the anti-coagulated patients more responsibility and to transfer to them the responsibility of coagulation self-management

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The longevity of a drug, even one with many rumoured disadvantages (such as the coumarins), says something about that drug. The question Dr Jack Ansell has posed is: How many drugs could be listed that reduce the frequency of the devastating effects of a pathological cardiac rhythm to two-thirds?[1] The fact that taking a vitamin K antagonist should be closely monitored to comply with the prescribed therapeutic range, and thus minimise negative consequences, is sufficiently well known. These checks are primarily performed by either laboratories, anticoagulation clinics or doctors.

Would it not make sense to give the anti-coagulated patients more responsibility and to transfer to them the task of coagulation self-management?

The beginning

A young student with an artificial heart valve took coagulation self-management into her own hands in February 1986. The constant visits to the doctor significantly reduced the time allocated to her studies. In addition, it was not easy to deal with the unstable coagulation values, maintaining them in the good and safe therapeutic range set. So she looked at and learned from the process of coagulation control in the laboratory, and procured for herself a coagulation monitor (KC1A). Luckily, her health insurance company was willing to assume the cost. From that time, repeated visits to the doctor were no longer needed. She gained independence and time, which increased her quality of life.

This student gave a seminar on the opportunity of coagulation self-management to 400 participants in Bad Berleburg (Germany) during a doctor–patient event on May 2nd 1986.

The idea engaged Dr Carola Halhuber, Director of the cardiovascular clinic in Bad Berleburg. Together with Dr Angelika Bernardo, they trained patients in small groups to learn about coagulation self-management. Within three years, there were 146 patients, including myself. Sixty-five patients participated in the first field trial. In her dissertation (1990), Dr Bernardo wrote that most of the trained patients very quickly succeeded in achieving a sufficient anticoagulation level and in adjusting the anticoagulant adequately. Almost 80% of all self-determined Quick values were within the therapeutic range, and self-testing was carried out every 8.4 days on average. During the trial, in which statistical data were collected from 534 patients, neither major bleeding nor thromboembolic complications occurred.

This field trial started in 1986 and became a study, which was completed in 1992 by Dr Bernardo.[2] There were 216 patients included, with an average time within the therapeutic range (TTR) of 83.1%. No serious complications were observed during the time of the study. It is also noteworthy that these 216 patients carried out their self-determined coagulation values over six years, with a coagulation monitor (KC1A) that was very complicated and with which each measurement took about 45 minutes.

Reimbursement

Reimbursement by health insurance providers was an essential condition for the success story of patient self-management in Germany. In the beginning, health insurers were willing to assume the costs on an individual basis only. The breakthrough came in 1996, when there was a legal basis for the reimbursement for the coagulation monitor and accessories. Today, 200,000 anti-coagulated patients benefit from it in Germany.

Reimbursement from health insurance providers for coagulation self-management is still a problem in many European countries. Thus, for example, INR self-management was in operation in Switzerland for 11 years without reimbursement, which implied that patients were willing to carry the costs themselves. In 2011, successful reimbursement was achieved.

In Denmark, France (for children up to age 18), Greece, Luxembourg, The Netherlands and Austria (in some states),

total costs are now covered. Test strips are reimbursed in Belgium, Finland, Sweden, Czech Republic, Italy and in some regions of Spain. The national patient organisations have actively worked in collaboration with physicians to obtain reimbursement.

Towards an approved method

The positive results of the pioneering work of this first patient, driving the coagulation self-management in Germany, was the starting point for countless scientific studies that followed worldwide. The aim of these studies was to investigate whether coagulation self-determination is really safe, whether the risks associated with anticoagulation are minimised and whether compliance and quality of life are improved. In addition, the following questions have been posed: Who is eligible for coagulation self-management? Who needs training programmes? How often should patients determine their INR? Can a patient change the dose him/herself? Are dosing programmes required? Has the frequency of testing had an influence on the TTR? Should additional tests be performed by the doctor? How is dosage calculated? What is the impact on the relationship between doctor and patient? Does the doctor want his patient to be responsible for coagulation self-management?

Patients taking responsibility for their therapy

From many studies, it is clear that both the efficiency and management of complications of long-term anticoagulation depend primarily on the quality and frequency of testing. Through self-management of anticoagulation, the patient is involved in his/her own treatment.

The prerequisite is that the patient has the intellectual capabilities and manual skills to use a point-of-care device to determine the INR values and to derive therapeutic consequences, such as dosage adjustment, for him/herself.[3]

Professor Torben Bjerregaard Larsen from Alborg, Denmark indicated at the 8th International Patient/Doctors Conference of ISMAAP 2012 in Vienna that, in his view, self-management is the 'first-line' therapy of choice and that this improves the quality of treatment with anticoagulants. Also in Denmark, the patient can convince the doctor that he wants to perform self-management.[4]

Who is eligible?

One-half of anti-coagulated patients would certainly be able to perform self-management, according to Thomas Decker Christensen.[5]

Dr Carl Heneghan (Oxford) considers that 'Our analysis shows that self testing and self management are a safe choice for eligible patients of all ages'.[6]

Dr Paul Kyrle and colleagues (Vienna), commenting on the analysis of Heneghan in the same edition, stated that, in his view, self-management is to be offered only to patients with heart valve replacement who are aged less than 55 years. The authors also see no place for self-testing in other diseases in which anticoagulation is necessary.

By contrast, in Germany there is a lack of understanding, even among experts, about the fact that only 20% of anti-coagulated patients practice coagulation self-management.[7]

Dr Andrea Siebenhofer and colleagues (Graz/Austria) say that 'Older people benefit from coagulation self management, because the risks are minimised.'[8]

"In the beginning, health insurers were willing to assume the costs on an individual basis only."

Two readers comment in the patient counsellor booklet Coagulation, which appears in Germany, Austria and Switzerland: 'Many old people are quite capable of perform this. I am 82 years old and since the age of nine performing INR Self-testing. I am happy with this kind of control, because I have very bad veins, and it is always a problem to take blood sample from me' and 'I can only agree with the author of the booklet. I am 83 years old and have been doing self-testing since 2004, without any problem.'[9]

From the work of national patient organisations, we know that age is no obstacle to performing coagulation self-testing, even if the patient is suffering from dementia or other disabilities. Partners are trained and are capable of performing INR self-testing at home. Likewise, parents are trained to determine the INR in their anti-coagulated young children.

Training

In Germany, the cost of teaching and training the treatment programme for patients with oral anticoagulation (SPOG) is covered by health insurance. Only after completing the training does the patient receives his/her prescription for the coagulation monitor.

Frequency of INR measurement

Quality and frequency of controls are a prerequisite for a stable INR. So a weekly measurement is generally recommended. Patients in Germany, Austria and Switzerland test their INR-value more or less once a week. In Germany, health insurance pays for 100 strips a year.[10] Patients with stable INR often measure every two to three weeks.[11] It is undisputed that a weekly INR determination improves the TTR as a percentage and thus also reduces the risk of a thromboembolic incident or severe bleeding.

Approximately 340 anticoagulated patients participated in an online survey at three German sites. One of the questions referred to test frequency. The median value was seven days (1–60).[12] The results of a questionnaire survey of 10,000 coagulation patients in 2003 in Germany showed that 59.7% of these patients measured their INR values weekly and 21.2% fortnightly.[13]

Additional tests?

Data from the same questionnaire survey also revealed that 14.6% of self-management patients agreed to have additional laboratory tests at the doctor's office. Approximately 10.7% said they had an additional control once a year.[13] So it is not surprising that 60% of patients reported that they find it annoying to travel a great distance to the doctor's office and then wait a long time once there.[11]

On average, patients control their INR with laboratory testing on a quarterly basis, often coinciding

with the medical check-up, when the prescription for vitamin K antagonists is given. In addition, the doctor checks the INR values determined by the lab and discusses the dose at the patient's request and in individual cases. This proves not only the partnership relationship with the doctor, but also that these patients show a high degree of compliance.

Dosage

After initiation of treatment with vitamin K antagonists, there is a dose-adjustment phase, because the amount needed will vary from patient to patient. At the beginning, anti-coagulated patients are confused because one patient may only need half a tablet, while another will need three tablets per day to maintain the therapeutic range. An online survey carried out on the website www.die-herzklappe.de of 1600 patients showed that the average is 0.8 tablets per day.

After the adjustment phase comes self-dosage, based on personal experience in 88% of cases. Only 9% prefer a dosing algorithm.[12]

Coagulation self-management involves a great amount of self-confidence. The experience of self-dealing with anticoagulation brings a higher quality of life. The patient feels actively involved in his/her own therapy treatment with anticoagulants.

Delegation

It is certainly true that not every patient is able to assess correctly treatment with anti-clotting medications and some patients are not willing to deal with coagulation self-management. There are also a number of patients who fail to obtain a stable adjustment of INR values.

However, coagulation self-management should be delegated by the physician to one-half of all anti-coagulated patients. For the physician, it is not always an easy task. Technical possibilities, such as telemedicine, are an additional helpful tool. For the technically interested anti-coagulated patients, Apps and special software programs support coagulation self-management.

Anticoagulation and patient cooperation belong together

If we assume – as the numbers of a UK survey show – that only:

Twenty-five per cent of patients seek further information,[14] then it is not surprising that the treatment of life-threatening conditions with anticoagulants raises a red flag for physicians and their patients.

Coagulation self-management could be the key to effective patient compliance.

Does motivation not begin with the weekly INR determination and the question: Am I in the therapeutic range? If not, what have I done wrong and what can I change in my life to possibly improve?

As Hugo ten Cate says: 'The quality of life and the time in the therapeutic range can be positively influenced by self-management'.[15]

TTR target

Dr Lader asked his readers 'Is 70% TTR the best we can do?'[16] Surely a TTR of 80% (and higher) is achievable in daily routine, provided that the group of motivated anti-coagulated patients are recognised as capable of self-management and given their own responsibilities, from their doctor's/medical point of view.

When already 20% of anti-coagulated patients practice coagulation self-management in Germany, why could not as high a percentage be enrolled across Europe – north, south or central? ✦

"Coagulation self-management involves great self confidence. The experience of self-dealing with anticoagulation brings a higher quality of life"

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