Implementation of Outpatient Treatment of Deep-vein Thrombosis in Private Practices in Germany

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Objective. Implementation of outpatient treatment (OT) of deep-vein thrombosis (DVT) is slow despite clear evidence that it is effective, safe and cost-efficient.

Design and method. An initiative was launched with the help of the Professional Association of Phlebologists of Germany and the industry to familiarize physicians in private practice who had no prior experience with OT of DVT. Data on quality of treatment with the low-molecular-weight heparin tinzaparin and phenprocoumon, compliance, clinical outcome, venous ultrasound, patients' satisfaction and quality of life were collected in a registry, which was open from July 1999 to December 2000. The results were published and their impact on further management of patients was assessed in second survey reported here. Patients of both series were followed-up clinically and with ultrasound over the 1st month of treatment.

Results. Of 67 physicians entering 827 patients into the registry 26 answered a questionnaire on how they treated further patients. Their case load had increased by 450% and data were provided on 540 consecutive patients managed between January and June 2002. OT increased overall from 76 to 92%, that of popliteo-femoral DVT from 71 to 92%, and that of pelvic DVT from 38 to 65%. Medical reasons to decide against OT decreased from 89 to 56% (p < .01). Immediate leg compression was changed from bandaging to medical compression stockings in 20 of the 26 centres (p < .05). In total, data were gathered from OT of 1124 patients. No secondary hospitalisations were required and only one patient had a documented progression of the DVT.

Conclusions. OT was successfully implemented in private practices through the initiative of individual physicians with support of the professional association and sponsoring by the industry—to the benefit of the providers but as much of the patients and their cost bearers.

Keywords: Deep-vein thrombosis; Outpatient treatment; Implementation; Sponsoring.

Introduction

A large body of evidence has accumulated demonstrating that outpatient treatment of acute deep venous thrombosis (DVT) with low-molecular-weight heparin (LMWH) is efficient, safe and cost-effective.1–25 In some specialized centres patients are admitted to the ward for 1 or 2 days only, in others they are not admitted but visited at home by nurses, and in again others they are treated on an outpatient basis. Criteria for patient selection have been described26 but no requirement for close follow-up has been reported largely because major problems have not been encountered with this strategy. Neither with the thrombotic event itself or the method of treatment gave rise to complications in more than a small minority of patients. Nevertheless, in some countries outpatient management of deep vein thrombosis is carried out on a very limited scale. A nation-wide survey in Spain showed that 90% of patients are still admitted to the hospital, despite the use of LMWH in 88%, and 66% were advised that absolute bed rest was required.27 According to a recent survey performed in the USA only 55.6% of patients referred to a teaching or community hospital are given LMWH and the hospital stay averaged 7.7 days.28

In our private clinics for vascular diseases we have performed outpatient treatment of DVT routinely since 1979.2,3 We intended to help other vascular physicians to implement a straightforward treatment strategy and set up a prospective registry under the name controlled outpatient management of DVT (COM I). Data were reported from 67 participating practices where 76.3% of 827 patients were treated as outpatients between July 1999 and December 2000.29 During a follow-up period of 1 month no evidence of
clinical recurrence and no episode of secondary hospitalisation was recorded. Anticoagulant treatment was used routinely combined in all patents with leg compression and deliberate ambulation. Relief of symptoms, restoration of quality of life and resumption of daily working capability were prompt.

In July 2002, we assessed the impact of the initiative by a second survey termed COM II. Here, we report how the physicians changed their approach toward patients with DVT.

Methods

In an effort broadly to introduce outpatient treatment of DVT in Germany we launched an initiative with physicians in private practice who were specialized in phlebology but had no experience with the management of DVT yet. It was sponsored by the Professional Association of Phlebologists in Germany and logistically and financially supported by LEO Pharma GmbH, Neu-Isenburg, Germany, and (to a smaller extent) by Ganzoni and Cie SA, St Gallen, Switzerland. Participating centres were invited to use the LWMH tinzaparin (Innohep™, manufactured by LEO Pharma) since this is the only LMWH registered in Germany for once daily use covering all types of DVT and pulmonary embolism. Graduated medical compression stockings (Sigvaris® 503, ankle pressure 23–32 mmHg, and 504, ankle pressure 34–46 mmHg, manufactured by Ganzoni) were recommended since data existed for their use in the management of acute DVT.30,31 The companies had no influence on the recruiting of centres, the monitoring of the program, or the analysis and interpretation of data. Sixty-seven physicians entered 827 patients in the registry termed controlled outpatient treatment of DVT (COM I). Inclusion in this series started in July 1999 and concluded in December 2000. The results were communicated to the participating centres in September 2001.29

In July 2002 a questionnaire was sent to the participating physicians. They were asked to report on their approach toward and experience with further patients with DVT covering the period from January 2002 to June 2002. This second survey was termed COM II. Diagnosis and treatment were the same in COM I and II and based on ACCP guidelines.26,29,32

Results

In the prospective observational survey COM I (which lasted 18 months) 67 centres registered a total of 827 patients. Twenty-six participants (39%) responded to the second enquiry. These physicians† had enrolled 352 patients (43% of all patients) in COM I and provided data on 540 patients treated in COM II (which lasted 6 months). The case load in these practices had increased by 450% from an average of 0.77 DVT/month to 3.46 DVT/month.

The demographic and clinical data of the patients in COM I and II showed no difference. Of the 540 patients included in COM II 211 had crural, 155 popliteal, 137 femoral, and 37 pelvic DVT. OT was chosen for 496 patients. The percentage of OT increased from 76 to 92%. The increase was the higher the more proximal the DVT was localised (Fig. 1).

The criteria for using OT were established before COM I commenced and were the same in COM I and II. They were summarised under two titles, either medical or personal. Medical reasons to exclude the use of OT included a decision to use thrombolysis or thrombectomy for severe ischaemia, severe leg symptoms, pulmonary embolism, or poor general health. Personal reasons included lack of time to provide sufficient patient information and work-up, inability of the patient to comply with the requirements of self-treatment, and unwillingness of patients to give consent for this mode of treatment. The relative proportion of these reasons changed significantly from COM I to COM II: medical reasons not to utilise outpatient treatment were advanced less frequently while the prevalence of personal reasons remained the same.

† A list of the participating practices is provided in the Appendix A.
same (Fig. 2). Obviously, experience led to a reconsid-
eration of the dangers of DVT.

Anticoagulant treatment with LMWH did not show
a difference between COM I and COM II. Tinzaparin
(175 U/kg b.w. once daily) was used in 23 of 26
practices. The start of oral anticoagulation with
phenprocoumon was on day 1 in 90 and 96% in
COM I and II, respectively. No data were collected on
the quality of anticoagulant control in COM II.

The mode of initial treatment with leg compression
showed a significant change of preference in the 26
centres participating in both inquiries. Bandages were
used by 20 centres in COM I but by only eight in COM
II. Correspondingly, medical compression stockings
were used by six centres in COM I but favoured by 18
in COM II (Fig. 3). Sigvaris 503/504 medical com-
pression stockings were used in 21 of 26 centres.

Compliance with treatment was reported to be
100%. By the end of the 1 month follow-up period
there was no clinical suspicion of pulmonary embo-
lism in any patient and no secondary hospitalisation
was necessary. Only one adverse event was docu-
mented (0.2%). A patient experienced asymptomatic
progression of DVT from popliteal to femoral. There
was no clear reason for this progression and the final
outcome was satisfactory resolution of the thrombus.

Fig. 1. Outpatient treatment as a function of the extent of DVT. The proportion of OT is reflected by the height of the columns.
The inserted number refers to the actual number of patients. In total, OT was performed in 631 of 827 patients in COM I (76%)
and in 496 of 540 in COM II (92%). With experience, a greater proportion of proximal DVT were treated on an outpatient basis.

Fig. 2. Reasons why outpatient treatment was not used. The proportion of statements is reflected by the height of the columns.
The inserted numbers refer to the actual number of patients. Initial hesitation vanished with experience: the
decrease of medical reasons is statistically significant ($p<.01$).
Discussion

In view of the uniformly positive results of randomised trials and management studies few would challenge the evidence that patients with acute DVT can be effectively and safely treated on an outpatient basis. The achievable cost savings are enormous and practicability has never been a true issue. Patient satisfaction was high and quality of life restored quickly in all studies that addressed these questions. This and a previous report add more than 1200 cases of successful OT administered by physicians in private practice.

Nevertheless, medical enthusiasm to adopt this new strategy seems low. Claims for careful selection of patients were made and warning criteria established but not assessed in clinical studies.26 Clearly, the number of prerequisites deemed necessary for a safe outpatient treatment determines the proportion of eligible patients. Thus, the process of patient selection implies a political dimension. As shown by surveys in Sweden and Germany, almost 20% of patients eligible for OT were admitted to the ward because time and resources thought to be essential for adequate work-up and patient information were not available.12,25 Nationwide surveys in Spain and the USA showed that the vast majority of patients are still admitted.27,28 It is highly unlikely that the large proportion of hospital admissions would solely be due to the clinical condition of the patients.

We learned from our long personal experience that there is no reason to put the hurdles for outpatient treatment too high. We intended to share our experience and straightforward approach with other physicians in practice and to bypass the traditional ways educational information is distributed and implemented in order to bring training in new treatment methods to physicians in our country.33 Members of the Professional Association of Phlebologists were provided with specific knowledge and material to inform their referring physicians. As a result, the case load increased substantially in dedicated practices. Ambulatory treatment was expanded to the extent that 97% of distal and 88.5% of proximal DVT are now managed on an outpatient basis. Another change of paradigm was noticed: compression therapy with bandages was largely replaced by the use of compression stockings which greatly facilitate the application of compression.

The implementation of outpatient treatment was paralleled by two clinical surveys which documented not only the effectiveness, safety and practicability of the procedures but in as much the sense of responsibility of the participating physicians and their professional organisation. The private enterprise allowed rapid implementation of a new therapeutic approach, which benefited the physicians in private practice. There was also an advantage to the patients who avoided hospital treatment and our healthcare system which was saved the costs of inpatient treatment.

This report clearly has some limitations. Firstly, the survey is not representative for the global situation in Germany. Nationwide data, which would document a shift from in-hospital to outpatient treatment, are not available. Secondly, it suffers selection bias as no information was available from practices that...
participated in COM I but did not respond to the COM II survey. We know that some phlebologists did not want to or could not manage to establish themselves as accepted specialists for the treatment of acute DVT. We have received no report of any adverse experience from physicians involved in these clinical series. Thirdly, patients referred to private practices may more likely be suitable for outpatient treatment as they have less dramatic symptoms than those seen in hospitals. Patient selection may also explain the excellent outcome in which there was no instance of clinically apparent pulmonary embolism or need for hospitalisation. Whilst less severely affected patients may have been treated by the medical practitioners participating in this study, the results demonstrated that this is a safe and effective method of management for this cohort.

Acknowledgements

Contributors. W Blättler was responsible for the idea, the design of the registry of COM I and the survey of COM II and drafted the manuscript. H Gerlach organised and supervised the initiative in Germany and collected and analysed the data. The names of the participating practices for vascular diseases are listed in the Appendix A. Conflict of interest statement. Both authors received honoraria from LEO Pharma Germany for preparation of a speaker’s kit and seminars. Study participants were reimbursed for their expenses when they spoke at conferences. Members of the audience were usually invited for a drink after the presentations.

Appendix A

Practices participating in COM I and II

Altenkämper Henner, Plettenberg; Brunk Erdmann, Lübeck; Dörfeldt Jean, Riebnitz-Damgarten; Emter Michael, Hannover; Franke Dirk, Magdeburg; Friedrich Hans-Georg, Schonach; Gerlach Horst E., Mannheim; Hartmann Michael, Freiburg; Hauss Friedrich, Rheinfelden; Heckmann Frank, Neckargemünd; Hesse Gottfried, München; Hinger Hans-Ulrich, Bergisch- Gladbach; Hoch Wolfgang, Munster; Hornung Bart hold, Marburg; Jung Georg, Hausweiler; Kirsch Ulrike, Oranienburg; Kussmann Karl Stefan, Auenwald; Möbius Eckhart, Schwerin; Müller Gudrun, Erlangen; Riecker Eberhard, Lauffen aN; Schneider Paul, Nettetal; Steinlein Rainer, Herzogenaurach; Tsantilas Dimitrios, Augsburg; Weber Thomas, Overath-Unterschbach; Windorf Reinhard, Ratze burg; Winkler Lothar, Neubrandenburg.

References

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