Patient-tailored implantable cardioverter defibrillator testing using the upper limit of vulnerability: the TULIP protocol

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Received 19 November 2007; accepted after revision 24 April 2008; online publish-ahead-of-print 30 May 2008

Aims We evaluated the feasibility of the TULIP (Threshold test using Upper Limit during ImPlantation) protocol, which was designed to provide a confirmed, low defibrillation energy value during implantable cardioverter defibrillator (ICD) implantation with only two induced ventricular fibrillation (VF) episodes.

Methods and results Ninety-eight patients (62 ± 12 years, 86 male) from 13 clinical centres underwent an active can ICD implantation. A single coupling interval derived from electrocardiogram lead II during ventricular pacing was used for VF induction shocks at 13, 11, 9, and 6 J in a step-down manner until the upper limit of VF induction (UL VI) was determined. If UL VI ≥ 9 J, a defibrillation energy of UL VI + 4 J was tested. For UL VI < 9 J, the defibrillation test energy was 9 J. In 79/98 patients (80.6%), two induced VF episodes were sufficient to obtain confirmed defibrillation energy of 11.1 ± 3.3 J. The mean strength of the successful VF induction shock was 6.8 ± 4.3 J, the coupling interval was 303 ± 35 ms, and the number of delivered induction shocks until the first VF induction was 3.9 ± 1.6.

Conclusion TULIP is a safe and simple device testing procedure allowing the determination of confirmed, low defibrillation energy in most patients with two VF episodes induced at a single coupling interval.

KEYWORDS
Implantable cardioverter defibrillator; Defibrillation threshold; Upper limit of vulnerability; Ventricular fibrillation; Implantation

Introduction

A common practice during implantation of a cardioverter defibrillator (ICD) involves ventricular fibrillation (VF) induction to ensure that the device can reliably detect and convert VF. As there is no standardized method for defibrillation threshold (DFT) testing,1–13 an increasing number of institutions refrain to estimate DFT and only verify that the maximum programmable shock strength reduced by at least 10 J, terminates VF once or twice.1,3–5,10,13 After this so-called defibrillation safety margin test, the first-shock energy is unselectively programmed to the maximum value offered by the ICD (30–40 J).

A patient-tailored approach requires DFT measurement and allows reduction of the first-shock strength to a mean value of 15–20 J (=DFT + safety margin), which has several advantages: (i) shorter charging time allows faster shock delivery, decreasing the likelihood of syncope and resultant trauma; (ii) reduced battery depletion can decrease ICD replacement frequency and thereby the overall therapy cost and the risk of peri- and post-procedural complications; (iii) lower energy shocks may reduce the incidence of myocardial damage and post-shock arrhythmias; (iv) a shorter time to defibrillation reduces shock strength needed for successful defibrillation.1,2,6–8,14 Although an assessment of defibrillation efficacy at implantation is the legal standard of practice and many clinicians appreciate DFT determination, traditional step-down DFT

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protocols are decreasingly used. The reasons are anxiosity of impending haemodynamic deterioration in heart failure patients during the prolonged procedure associated with multiple VF inductions and too lengthy DFT measurement procedures in view of the rapidly growing numbers of ICD implantations.

Vulnerability testing and its drawbacks
Defibrillation threshold can also be assessed by vulnerability testing. While increasing the strength of the T-wave shock delivered during the vulnerable phase of the T-wave, VF can no longer be induced at or above a certain shock strength, termed upper limit of vulnerability (ULV). The maximum shock strength still resulting in VF is termed upper limit of VF induction (ULVI). The success rate of DFT testing for shocks with the strength equal to the ULV is ~90%, and the success rate of shock strength 3–5 J above ULV approximates 100%. The determination of ULV represents a surrogate for DFT assessment, whereby only one induced VF episode is sufficient to assess ULV in a step-down testing procedure.

Vulnerability testing procedures, however, require 12-lead electrocardiogram (ECG) acquisition to analyse the most vulnerable portion of the T-wave. Three or four induction shocks are delivered at coupling intervals varying in 20 ms steps during stable ventricular pacing at 120–150 bpm. The series of three to four induction shocks is repeated at each T-wave shock strength according to a step-down ULV testing procedure until successful VF induction. Alternatively, only one T-wave shock strength between 14 and 21 J can be tested at three to four coupling intervals to perform the so-called vulnerability safety margin test analogous to the defibrillation safety margin test. This method avoids VF induction in >75% of the patients but omits the VF detection test.

Aims of the present study
Both defibrillation and vulnerability safety margin tests are increasingly popular because of their simple and practical approach, but they provide little incremental information and do not allow reduction of the first-shock energy. So far, there are diverging opinions on which test offers the optimal trade-off between accuracy and risk, which constitutes the dilemma of ICD implant testing.

On the basis of the experimental findings presented in Appendix 1, we developed a concept for a simplified and expedient patient-tailored DFT assessment. Theoretically, the minimum number of induced VF episodes necessary to obtain low defibrillation energy with confirmatory testing is two. If this low defibrillation energy can be assessed without prior VF induction by a step-down ULV testing using ECG lead II instead of 12-lead ECG and only one instead of three to four coupling intervals, this would simplify and accelerate the vulnerability testing procedure. To this end, we developed TULIP (Threshold test using Upper Limit during ImPlantation) procedure, described in Figure 1. According to the retrospective data (Appendix 1), TULIP is expected to provide confirmed low defibrillation energy by only two induced VF episodes in ~80% of patients.

The objective of the present multicentre study was to prospectively evaluate the feasibility and reliability of the TULIP testing procedure. The study focused on the following outcome measures: percentage of patients in whom TULIP provided confirmed defibrillation energy by two induced VF episodes, determined defibrillation energy, and the duration of the TULIP procedure.

Methods
Patient selection
Patients with an indication for ICD therapy for primary or secondary prevention of sudden cardiac death were eligible for the study. The study protocol was approved by the International Ethics Committee in Freiburg, Germany. All patients gave their informed consent.

TULIP testing procedure
The ECG lead II was recorded at 50 mm/s during ventricular pacing at a cycle length of 400 ms. Time interval between stimulus and T-wave peak was calculated and used as a single coupling interval (TULIP coupling interval) for T-wave shocks at 13, 11, 9, and 6 J, until successful VF induction. A safety margin of 3–5 J was added to the defibrillation energy at which VF was induced (ULVI) to obtain test defibrillation shock energy (Figure 1). As we did not test defibrillation energy levels below 9 J, we did not regard our result as DFT, but as confirmed low defibrillation energy. Also called ‘augmented step-down DFT’ or ‘DFT plus’, the confirmed defibrillation strength is the energy dose that terminates VF twice without a failure. Confirmation of the defibrillation strength is necessitated by the probabilistic nature of
A defibrillation strength that was successful only once may still represent a dose that in most cases would be insufficient for VF termination, whereas confirmed DFT corresponds to a higher probability of successful defibrillation.\(^1\)

### Implantation procedure

Implantable cardioverter defibrillator implantations were conducted according to the discretion of the respective physician. The TMS 1000 or PMS 1000 programmer (Biotronik, Germany) was used for intraoperative measurements, burst pacing, VF induction shocks, and delivery of the first defibrillation shock. After successful positioning of the ICD leads, the ICD test housing was inserted and the TULIP testing procedure was performed (Figure 1). The confirmatory defibrillation test was conducted by the implanted ICD. All VF induction shocks and defibrillation shocks used the same biphasic waveform. Ventricular fibrillation was defined as arrhythmia faster than 260 bpm (cycle length <231 ms). The protocol required that the interval between VF induction shocks should be at least 1 min and the interval between VF episodes should be 5 min.\(^1\)

When a defibrillation strength selected according to the TULIP testing procedure failed to terminate VF, a traditional step-down protocol was employed.

### Statistical methods

Study results are presented descriptively as mean ± standard deviation. A two-sided 95% confidence interval (CI) was calculated for the success rate of TULIP.

### Results

#### Patients and implantable cardioverter defibrillators

The study was performed in 98 patients from 13 clinical centres in six countries (Appendix 2). The mean age of the patients was 62 ± 12 years, 86 were male and 12 were female. As only 19% of the patients received an ICD for primary prevention of sudden cardiac death associated with impaired left ventricular systolic function, the mean ejection fraction was rather high: 39 ± 16%. The New York Heart Association (NYHA) functional class was I in 39%, II in 34%, III in 25%, and IV in 2% of the patients. Other patient characteristics are shown in Table 1.

Single-chamber ICD systems were implanted in 80 patients (81.7%), dual-chamber ICDs in 15 patients (15.3%), and ICDs with an integrated cardiac resynchronization option in 3 patients (3%). All ICDs were active can devices manufactured by Biotronik, Germany. Implantable cardioverter defibrillator implantation sites were: left submuscular (59 patients), left subcutaneous (34), right subcutaneous (4), and abdominal (1). Single-coil or dual-coil defibrillation leads were implanted in 59 and 41% of the patients, respectively.

### Intraoperative measurements

There were no peri-operative fatalities, life-threatening situations, or complications related to the TULIP procedure. The mean R-wave amplitude was 12.6 ± 6.0 mV. Ventricular pacing threshold and pacing impedance were: 0.8 ± 0.5 V (at 0.5 ms) and 565 ± 136 Ω, respectively. The mean TULIP coupling interval was 303 ± 35 ms.

The first defibrillation shock terminated VF in 85 patients (86.7%), with a mean energy of 11.1 ± 3.2 J. The confirmatory shock failed in six patients (Table 2). Overall, in 79 patients (80.6% of the study population, with a 95% CI of 71.4–87.9%), two induced VF episodes were sufficient to obtain confirmed defibrillation energy of 11.1 ± 3.3 J. The strength of successful VF induction shocks (UL VI) was 6.8 ± 4.3 J and the number of delivered induction shocks until the first VF induction was 3.9 ± 1.6. Time between the first induction shock and the first VF was 2.9 ± 2.7 min, and the mean TULIP procedure time (from the first induction shock to the confirmation shock) was 8.0 ± 2.8 min.

In 13 patients (13.3%), the first shock failed to defibrillate; the failing defibrillation energy was 9 J in 12/13 patients (Table 2). In 19/98 patients (19.4%), the TULIP protocol did not provide confirmed defibrillation energy by two induced VF episodes. The application of a traditional step-down protocol in these patients resulted in a defibrillation requirement of 14.4 ± 3.8 J.

### Discussion

In the present study, we evaluated a novel protocol for the assessment of confirmed low defibrillation energy with only two induced VF episodes (TULIP). The protocol is based on a simplified and accelerated vulnerability testing method using the single ECG lead II and one coupling interval for VF induction shocks. Confirmed defibrillation energy was obtained in 80.6% of the study patients after, on average, 8 min between first induction shock and confirmatory defibrillation. TULIP represents a simplified alternative for patient-tailored ICD implant testing and offers an optimal trade-off between accuracy and minimized risk due to shortened procedure time.

In contrast to other short-cut DFT tests (the briefest among them, Binary Search Algorithm, still requires three
defibrillation test shocks without DFT confirmation), and the simple and short TULIP procedure may re-establish interest in patient-tailored ICD testing approach. Patient-tailored testing is increasingly neglected in clinical practice in favour of more expedient safety margin tests or ICD implantation without any defibrillation. Single coupling interval for ventricular fibrillation induction, procedure duration, and success rate

In this study, a single coupling interval of 0 ms relative to the peak of the T-wave in the ECG lead II was used for VF induction shocks. This constitutes a trade-off between reduced procedure time and ULVI accuracy. The benefit of one coupling interval is most pronounced for lower DFTs. For instance, the determination of an ULVI of 6 J by TULIP requires four T-wave shocks (13, 11, 9, and 6 J) and takes 3 min after the first T-wave shock is instituted. Conversely, the three- or four-coupling interval step-down ULV testing procedure using the same energy steps requires 10–16 T-wave shocks (3 or 4 at 13 J, followed by 3 or 4 at 11 J, 3 or 4 at 9 J, and 1–4 at 6 J) and takes 9–15 min (no. of shocks − 1), which is clearly longer and considerably more burdensing with respect to shocks.

Time between the first induction shock and the first VF was 2.9 ± 2.7 min in the present study, whereas the total procedure time between the first induction shock and confirmatory defibrillation shock was 8.0 ± 2.8 min. The majority of time was spent on the 5 min waiting period between VF episodes, which according to some authors may be abbreviated to 3 min, possibly further reducing the duration of the TULIP procedure.

Swerdlow et al. investigated the influence of the coupling interval on the ULV. They found the peak of the human vulnerable zone to be rather narrow, i.e. ~40 ms, and to be situated around the peak of the T-wave in 95% of cases. The underestimate of ULV (i.e. ULVI) due to not exactly determined coupling interval may be up to 5 J. Taking these data into account, TULIP compensated for the possible inaccuracy of ULVI by the addition of a 3–5 J margin to determine defibrillation test shock energy and by request of a successful confirmation shock (Figure 1). By this means, TULIP provides a confirmed defibrillation requirement (known to have >50% probability for successful defibrillation) and is therefore as reliable as an ‘augmented step-down DFT’ or ‘DFT plus’ assessment. Nevertheless, ULVI underestimation is mostly likely the reason for TULIP failure in ~20% of the patients. This outcome was predicted by the experimental study (Appendix 1) and is confirmed by the present finding of 19.6% combined defibrillation failure and 13.3% first-shock failure.

Induced ventricular fibrillation episodes

The number of induced VF episodes for different ICD testing procedures published in the literature ranges from zero (in >75% of patients who undergo vulnerability safety margin test) or one VF episode (for a defibrillation safety margin test or step-down ULV assessment, both without confirmatory defibrillation testing), to over six VF episodes in other protocols. Avoidance of VF induction during ICD implantation may be advisable in very sick patients with a high risk of acute cardiac decompensation. However, most patients are healthy enough to tolerate induced VF and test shocks. The defibrillation test is not only the legal standard but also permits VF sensing verification, avoids unselective implantation of a more expensive high-energy ICD device, and allows adequate reduction of the programmed energy for the first shock. Certainly, the number of induced VF episodes and the procedure time should be minimized to reduce operative risks and accommodate for the increasing number of ICD implantations. Theoretically, a minimum of two VF inductions is necessary to determine and confirm defibrillation energy. The TULIP protocol confirms defibrillation energy with two induced VF episodes in 80% of the patients (95% CI: 71.4–87.9%). In patients in whom TULIP is not successful, the testing may be completed according to a traditional step-down protocol.

However, if minimizing the number of VF episodes is the priority, a one-shock defibrillation safety margin test (maximum output reduced by 10–15 J) may be applied after failure of the first defibrillation shock within TULIP. In case of a successful initial defibrillation in TULIP and failed confirmatory defibrillation, the initial successful shock may be accepted as the defibrillation safety margin test. There were six such patients in the present study, and the strength of the successful first defibrillation shock was 9–15 J. Safety margin between maximum output and these values is large and even if failed to be confirmed, the probabilistic nature of DFT is not so pronounced as to jeopardize the safety of defibrillation with the maximum shock strength. Thus, all patients in whom TULIP failed would be checked for unconfirmed but relatively large safety margin with the identical procedure duration and

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**Table 2** Success rate of the TULIP testing procedure

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<th>Defibrillation test at (J)</th>
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SD, standard deviation; ULVI, upper limit of VF induction; and VF, ventricular fibrillation.

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number of VF episodes as those in whom TULIP was successful.

If the determination of low-energy requirement remains the priority after TULIP failure, the Binary Search Algorithm described by Shorofsky et al. may be applied to complete testing. Accordingly, if a 9 J shock failed to defibrillate initially or at confirmation, the ‘extension test strength’ would be 18 J, followed by 13 J (if 18 J defibrillated VF) or 24 J (if 18 J failed to defibrillate). If 13 or 15 J shocks failed to defibrillate initially or at confirmation in TULIP, then the ‘extension test strength’ would be 18 J, followed by 24 J if 18 J failed to defibrillate. Overall, the Binary Search Algorithm testing after TULIP failure would require a maximum of two additional VF episodes to decide between 13, 18, and 24 J defibrillation energy requirements, provided no patient has a DFT >24 J. Bearing in mind that the TULIP protocol failed in the present study in 13 patients at the initial defibrillation and in 6 patients at the confirmation defibrillation, the extension using the Binary Search Algorithm would end up in a maximum of 3 VF episodes in 13 patients and 4 VF episodes in 6 patients, thus requiring <2.25 VF episodes, on average, in the 98 enrolled patients.

In comparison, even the briefest step-down DFT protocols with four energy levels (15-10-8-5 J) require a calculated mean of 3.2 ± 0.8 induced VF episodes to find DFT and an additional VF episode for DFT confirmation. A step-down protocol with six test energy levels (14-11-9-7-5-2 J) requires more than five induced VF episodes, on average per patient, for a confirmed DFT. Therefore designed the Binary Search Algorithm (24-18-13-9-6-4 J) combining step-down and step-up DFT methods so that only three induced VF episodes per patient are needed to obtain a non-confirmed DFT.

The TULIP protocol requires less VF episodes than any other DFT protocol and is very close to the theoretical minimum of two VF episodes necessary for confirmed defibrillation testing.

Defibrillation energy

Swerdlow et al. recently scrutinized the literature data to deduce that mean DFTs were in the range of 8–10 J for dual-coil leads and 10–12 J for single-coil leads. As dual-coil leads slightly prevailed in our study (59%), an expected mean DFT in our patients would be between 9 and 10 J. Despite the use of simplified (approximate) ULV I assessment, the TULIP protocol resulted in the mean defibrillation requirement of 11.1 ± 3.3 J in 80% of the patients, which allows programming of ICD shock energies significantly below the maximum energy output. With a 5 or 10 J or ‘2 × DFT’ defibrillation safety margin, the first-shock energy may be set at 16.1 ± 3.3, 21.1 ± 3.3, or 22.2 ± 6.6 J, respectively. These energy levels are clearly lower than the programmable maximum of 30–40 J. Neuzner et al. reported on the programmed energy for the first shock of 18.9 ± 6.7 J (2 × DFT), Carlsson et al. used 12.9 ± 3.0 J (DFT + 5 J) and 17.9 ± 3.0 J (DFT + 10 J), and Swerdlow et al. programmed the first-shock strength to 17.5 ± 5.2 J (ULV + 5 J).

A fine-tuning of DFT below 8 J can slightly reduce a mean defibrillation energy when compared with our 11.1 ± 3.3 J. By comparison, a mean confirmed DFT obtained by Neuzner et al. was 9.8 ± 3.4 J (using steps 15-10-8-5 J, no active can ICDs) and by Gold et al. 8.7 ± 3.7 J (steps 14-11-9-7-5-2 J, active can). The TULIP study resulted in a mean of 3.2 J (DFT + 5 J /C2 + DFT). Carlsson et al. observed a 1.8 s shorter charging time for DFT + 5 J (mean shock energy 12.9 J) compared with DFT + 10 J (shock energy 17.9 J). The TULIP protocol allows for decreased shock energy from 30–40 to 15–20 J. This may reduce charging time by 3–8 s, possibly preventing syncope and impending injuries. Although charging times in newer ICD devices with a fresh battery are faster, gradual battery exhaustion after several years of ICD use will result in at least 20% slower ICD charging and will thus augment the charging time difference for 15–20 vs. 30–40 J shocks.

TULIP in primary prevention patients?

In the present study, the proportion of patients receiving ICD for primary prevention of sudden cardiac death was relatively low (19%). The mean ejection fraction of 39% was in line with the traditional ICD literature but does not reflect well patients with severely reduced systolic left ventricular function who receive ICD for primary prevention. Severe heart failure patients tend to have higher DFTs than those with normal hearts, but this should not pose problems as TULIP employs test defibrillation strengths in the 9–18 J range. In contrast, it is unknown if severe heart failure and low ejection fraction may increase the dispersion of the optimal coupling interval for ULV I determination relative to the T-wave peak.

Comparison with ASSURE

Parallel with the TULIP study, the clinical trial ASSURE enrolled 426 patients to test the feasibility of inductionless or limited shock testing in most patients. The authors recommended either a vulnerability safety margin testing by applying 14 J T-wave shocks at three different coupling intervals during the vulnerable period (thereby avoiding VF induction in 76.7% of the patients) or a single defibrillation safety margin test shock at 14 J (82.5% odds for success). In case of successful outcome with either method, the 21 J first-shock strength was programmed, which proved to be effective in 84% of spontaneous arrhythmia episodes during 12-month follow-up. Owing to the fact that ‘ASSURE’ methodology does not represent patient-specific testing and (in study implications) does not require confirmation defibrillation shock, the defibrillation testing procedure is shorter and associated with less VF inductions (zero or one VF in ~80% of the patients) than TULIP (two VF). TULIP,
however, results in lower defibrillation energy requirement (mean 11.1 J in 80.6% of responders) than ASSURE (14 J, ~80% of responders) and includes confirmatory testing.

**Conclusion**

A patient-tailored approach to ICD testing is used with decreasing frequency in clinical practice due to the need for multiple VF inductions and the longer duration of the procedure. In the present study, we evaluated a novel TULIP protocol for the assessment of confirmed low defibrillation energy requirement by only two induced VF episodes in most patients. The protocol is based on a simplified and accelerated vulnerability testing method, using only one coupling interval for VF induction shock determined in a single ECG lead. The number of delivered induction shocks until the first VF induction was 3.9 ± 1.6, the time period between the first induction shock and the first VF was 2.9 ± 2.7 min, and the total TULIP procedure time between first induction shock and confirmatory defibrillation shock was 8.0 ± 2.8 min. In 79 of 98 patients (80.6%), two induced VF episodes were sufficient to obtain confirmed defibrillation energy of 11.1 ± 3.3 J. As TULIP offers an optimal balance between accuracy and procedure duration and complexity (i.e. risk), it may be considered as a potential solution for the dilemma of optimal ICD implant testing.

**Conflict of interest:** B.L. received financial support for travel and lectures from study sponsor. S.M. and D.D. are employees of Biotronik GmbH & Co. KG.

**Funding**

The study was sponsored by Biotronik GmbH & Co. KG, Berlin, Germany.

**Appendix 1**

**Experimental data leading to TULIP conception**

Our unpublished experimental pilot study was conducted in 40 patients during ICD implantation. A mean DFT of 9.3 ± 5.0 J (mean ± SD) was measured in a step-down procedure using shock strengths of 24–1 J (seven steps). The ULV in each patient was then determined by delivering a T-wave shock after 8 × 400 ms burst ventricular stimulation and using the same shock strength protocol as for DFT. The coupling intervals for T-wave shocks were changed in 20 ms steps at each test energy level. The highest (true) ULV value was obtained in different patients at coupling intervals ranging from −60 to +60 ms relative to the time Stimulus-Peak (T-wave) on the ECG lead II. Maximum ULV of 10.6 ± 6.3 J was measured at a mean relative coupling interval of +12.0 ± 24.7 ms.

These findings suggest that exact ULV determination requires scanning of the vulnerable phase of the T-wave on the ECG lead II with six to seven coupling intervals in 20 ms steps. This is fairly impracticable for routine clinical practice because the interval between T-wave shocks should be at least 1 min. Thus, only one test energy level for ULV would require 6 min for six induction shocks, whereas the total ULV determination procedure time would approximately be 6 min multiplied by the number of energy levels tested until successful VF induction.

To find a way to speed up the procedure and reduce the amount of T-wave shocks, we assessed ULV underestimation for a single coupling interval of 0 ms relative to the Stimulus-Peak (T-wave) time measured in ECG lead II. The mean ULV (at 0 ms) was 82 ± 25% of the true ULV (at the individually most effective coupling interval), and the following probabilities were computed retrospectively:

1. If ULVI (at 0 ms) ≥ 9 J, then a shock energy of ULVI (at 0 ms) + 4 J will be higher or equal to the DFT with a probability of 88.9%.
2. If ULVI (at 0 ms) < 9 J, then a shock energy of 9 J will be higher or equal to the DFT with a probability of 80.6%.

These probabilities were judged as a reasonable background to prospectively test a protocol that would use only one coupling interval for each T-wave shock test energy level. The protocol would thus require only one shock and 1 min per energy level and still be able to ‘locate’ DFT in at least 80% of the patients. The TULIP testing procedure (Figure 1) was designed accordingly and evaluated in the present study.

**Appendix 2**

**TULIP investigators**

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**Austria:** F. Schonhol (Rehabilitation Centre, Grossgmain). **Hungary:** Zoltán Csándi (Clinical Centre, Szeged). **Slovak Republic:** J. Bodnár (L. Pasteur Hospital, Košice).

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