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Original article

Compliance with vaccination against tick-borne encephalitis virus in Germany

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ABSTRACT

Objectives: The goal of this study was to analyse patients' compliance with vaccination against tick-borne encephalitis (TBE) virus in Germany.
Methods: The present study included 7266 patients from 638 general practices and 4194 patients from 114 paediatric practices. Patients were included if they had received the first dose of one of two vaccines against TBE virus (FSME-Immune® and Encepur®). The immunization schedule of these vaccines consisted of three injections. Patients were considered compliant if they received the second and third doses at the recommended time or within a period of ±25% around the recommended time (tolerance period).
Results: Of the recruited patients, 28% received both the second and the third injections within the tolerance period. Individuals treated in paediatric practices had a higher likelihood of receiving vaccine doses within the tolerance period compared with individuals treated in general practices (OR 2.15; 95% CI 1.92–2.41). Moreover, patients <18 years old were more likely to be compliant than patients >65 years old (OR 1.22; 95% CI 1.02–1.46), whereas patients aged between 18 and 30 years were least likely to be compliant (OR 0·77; 95% CI 0.61–0.96).
Conclusions: Compliance with vaccination against the TBE virus was low. This compliance was significantly associated with age and the type of practices in which patients were treated. **L. Jacob, CMI 2017;■:1**
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Introduction

Tick-borne encephalitis (TBE) is a human infectious disease that involves the central nervous system and is caused by a virus transmitted through tick bites [1–3]. TBE is considered one of the most frequent viral tick-borne diseases in Europe. In fact, its incidence has significantly increased over the past 40 years in this area of the world [4,5]. In 2012, approximately 2500 cases were reported in European countries, with 80% of them being subsequently confirmed [6].

As no effective curative drugs exist for TBE, vaccination against this viral infection is highly recommended for people who live in, work in, or travel to areas at high risk for TBE [7]. One of the first TBE vaccines was introduced in the 1970s in Austria and was prescribed to approximately 30 000 forest workers at risk of being infected by the virus [8]. Interestingly, none of these vaccinated individuals developed TBE, and the initial infection rate was approximately 0.1% in the at-risk population [7]. Other products have since been launched onto the market, and several vaccines are currently available in Europe. According to the recommendations of the World Health Organization and the findings of several studies [9,10], vaccination against TBE should follow strict immunization schedules [5]. In 2007, Heinz *et al.* discovered that the effectiveness of TBE virus vaccines was slightly lower in patients with a history of irregular vaccination (about 95%) compared with patients with a history of regular vaccination (about 99%) [11]. That same year, Vene *et al.* found similar results in 535 Swedish patients, as the activity of neutralizing antibodies against the TBE virus persisted before the third dose in 77% of vaccinated patients and before the fourth to sixth doses in 89%–95% of vaccinated patients [12]. Although recommendations and conclusions regarding TBE virus vaccination have been promoted for many years in various European countries, they are generally not followed [13]. This lack of

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compliance is of particular concern because it may impair the seroprotection provided by the TBE virus vaccination. Unfortunately, the compliance of patients receiving a first TBE vaccine dose and the associated risk factors remain poorly understood.

Therefore, the goal of the present study was to analyse patients' compliance with vaccination against the TBE virus in Germany.

Materials and methods

Database

The Disease Analyser database (IMS Health) compiles drug prescriptions, diagnoses, and basic medical and demographic data obtained directly and in anonymous format from computer systems used in the practices of general practitioners [14]. Diagnoses (International Classification of Diseases, 10th revision (ICD-10)), prescriptions (Anatomical Therapeutic Chemical Classification System), and the quality of reported data have been monitored by IMS Health based on a number of criteria (e.g. completeness of documentation and linkage between diagnoses and prescriptions).

In Germany, the sampling methods used to select physicians' practices are appropriate for obtaining a representative database of primary-care practices [14]. The sampling method for the Disease Analyzer database is based on summary statistics from all doctors in Germany, which are published every year by the German Medical Association. The IMS Health statistical unit uses these statistics to determine the panel design according to the following strata: specialist group, German federal state, community size category, and age of physician. This panel design forms the basis for acquiring the practices processed in the Disease Analyzer. The acquisition of data is performed by cooperating software companies with a standardized interface, enabling the practices to collect the required data and send them to IMS Health in an anonymized form [14].

Prescription statistics for several drugs were very similar to data available from pharmaceutical prescription reports [14]. The age groups for given diagnoses in the Disease Analyzer also agreed well with those in corresponding disease registries [14]. Finally, the Disease Analyzer database has already been effectively used to perform pharmaco-epidemiological studies [15–17].

In Germany, database studies based on absolutely anonymous data do not need approval from an ethics committee. Approval by an ethics commitee is needed for clinical studies.

Study population and compliance definition

The present study included 7266 patients from 638 general practices and 4194 patients from 114 paediatric practices. These 638 general and 114 paediatric practices were all practices in the database where at least one patient received the study vaccine. These practices were located throughout Germany. Patients were included if they had received the first dose of one of the two following vaccines against TBE virus between January 2011 and December 2014: FSME-Immune® or Encepur®. The follow-up period lasted 18 months and ended in July 2016. The immunization schedule of the vaccines consisted of three injections (Table 1). Patients were considered compliant if they received the second and third doses at the recommended time or within a period of ±25% around the recommended time (tolerance period). This compliance was estimated using prescription data and ICD codes related to the TBE virus vaccination (Z24.1: need for immunization against arthropod-borne viral encephalitis; Z25.8: need for immunization against other specified single viral diseases; and Z26: need for immunization against other single infectious diseases).

Statistical analyses

Demographic data included age, gender, type of health insurance coverage (public or private) and physician specialty. In Germany, adolescents are treated by both paediatricians and general practitioners. Therefore, we included both age groups and physician specialties in the present analysis. Shares of patients receiving the second and third vaccine injections within the tolerance period around the recommended time or at any time were estimated. Logistic regression models (dependent variable: compliance) were used to identify risk factors for low compliance. As only a few variables were available, only one model was created, which included compliance as the dependent variable and age group, gender, health insurance coverage and physician specialty as impact variables. No stepwise or backward selections were performed, and all effects (significant and non-significant) were displayed. Values of $p < 0.05$ were considered statistically significant. The analyses were carried out using SAS version 9.3.

Results

Patient characteristics are shown in Table 2. Of the 11 460 patients, 6028 (52.6%) were men, 7266 (63.4%) were followed in general practices, and 8274 (72.2%) had private health insurance coverage. Mean age was 32.6 years (SD 23.7 years). Compliance with vaccination against the TBE virus is displayed by age and physician specialty (Fig. 1). Of the patients included in this study, 5730 (50%) received the second vaccine injection within the tolerance period and 6647 (58%) received it at any time, while 3209 (28%) received both the second and the third vaccine doses within the tolerance period, and 3438 (30%) received the second dose within the tolerance period and the third dose at any time. The share of compliant individuals was slightly higher in patients <18 years of age than in patients aged >65 years (second dose: 57%–67% versus 42%–50%; third dose: 36%–39% versus 20%–22%), whereas it tended to be lower in people aged between 18 and 30 years (second injection: 41%–46%; third injection: 17%–19%). This share was higher in paediatric than in general practices (second dose: 59%–69% versus 44%–52%; third dose: 39%–43% versus 21%–23%) (Fig. 1). No significant difference was found between men and women (second injection: 49%–57% versus 50%–60%; third

Table 1
Immunization schedules for the vaccination against tick-borne encephalitis virus

Product	Immunization schedules				
	First dose	Second dose (recommended time)	Second dose (tolerance period)	Third dose (recommended time)	Third dose (tolerance period)
Encepur	0	7 days	5–9 days	21 days	16–26 days
	0	14 days	10–18 days	9–12 months	270–450 days
	0	1-3 months	68–113 days	9–12 months	270–450 days
FSME Immune	0	14 days	10–18 days	6–12 months	270–450 days
	0	1-3 months	68–113 days	5–12 months after the 2nd injection	270–450 days

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