

Report December 2009

Fungiscope

Global Rare Fungal Infection Registry

Working group of the



Under the auspices of



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Abstract

Introduction

The incidence of invasive fungal infections increases worldwide. Rare fungi - neither belonging to the genera *Aspergillus*, *Candida*, *Pneumocystis* or *Cryptococcus*, nor being endemic, such as *Histoplasma* spp. or *Coccidioides* spp. - are increasingly identified as causative pathogens.

Methods

We are coordinating a global registry for cases of rare invasive fungi. Our objective is to broaden the knowledge on epidemiology, to determine the clinical pattern of disease, to describe and improve diagnostic procedures and therapeutic regimens, as well as to facilitate exchange of clinical isolates among the contributors.

Entry of retrospective data occurs via a web-based registration system (www.clinicalsurveys.net) that focuses on demographic information, underlying diseases, risk factors, details on the infection (pathogen, localization, specimen collection) therapy and outcome.

Inclusion criteria include cultural, histopathological, antigen, or DNA evidence of invasive fungal infection. Infection due to *Aspergillus* spp., *Candida* spp., *Cryptococcus neoformans*, *Pneumocystis jiroveci*, Zygomycetes or any endemic fungal infection, such as coccidioidomycosis or histoplasmosis, as well as mere colonization or other non-invasive infection are exclusion criteria.

Results

By now, 140 cases of rare invasive fungal infections have been documented, including *Absidia corymbifera*, *Cunninghamella bertholletiae*, *Penicillium marneffeii*, *Rhizomucor pusillus*, as well as *Acremonium* spp., *Fusarium* spp., *Coccidioides* spp., *Engyodontium album*, *Scedosporium* spp., *Geotrichum capitatum* and *Trichoderma* spp. Clinical results are partly pending. Most

patients were in an immunocompromised state as a result of their underlying disease, chemotherapy or transplantation.

Discussion

The clinical relevance of invasive fungal infections by rare fungi is increasing steadily. In a short period of time, actual cases from Germany, Austria, India, the Netherlands, Israel and Brazil could be documented, showing a broad spectrum of pathogens.

Further investigators and coordinators are cordially invited to contribute to the success of Fungiscope.

Full protocol

Introduction

The incidence of invasive fungal infections is increasing worldwide. The etiology for this ongoing epidemiological development is not completely understood. However, major contributing factors are the increasing number of transplantation procedures undertaken around the world (estimated at 500,000 per year), a widening of the indications for intensive chemotherapy, and the growing number of other clinical conditions requiring immunosuppressive treatment.

Therapeutic standards have been developed for the most frequent invasive fungal infections, i.e. candidiasis, aspergillosis and cryptococcosis. But, the so called “rare fungi” are also a reason for the increased number of invasive fungal infections. Thus clinicians are now facing infections due to a variety of different fungi without any reliable treatment recommendations. Therapeutic decision making is not evidence based.

This study will collect clinical data related to cases of filamentous fungi, especially zygomycosis, fusariosis and other less common infections caused by, e.g. *Scedosporium*, *Penicillium*, *Acremonium*, *Paecilomyces*, *Trichoderma*, and any other rare fungi, including dematiaceous fungi such as *Alternaria spp.*, *Aureobasidium spp.*, *Bipolaris spp.*, *Cladophialophora spp.*, *Cladosporium spp.*, *Curvularia spp.*, *Exophiala spp.*, and *Phialophora spp.*, and rare yeasts, e.g. *Trichosporon spp.* .

Objectives

The objective is to broaden the knowledge on epidemiology, diagnostic procedures and the clinical course of invasive fungal infections caused by unusual invasive fungi.

The specific objectives are:

1. To determine the fungal species causing invasive fungal infection in different parts of the world.
2. To determine the clinical pattern of disease and document procedures performed for confirmation of the diagnosis.
3. To describe the therapeutic regimens used and their efficacy.
4. To share clinical isolates among the contributors of Fungiscope.
5. To develop molecular biology tools for identification of strains in histopathologically proven invasive fungal infection.

Study period

Start date: March 1, 2004

Patient definition

Inclusion criteria:

- Cultural, histopathological, antigen, or DNA evidence of invasive fungal infection

Exclusion criteria:

- Infection due to *Aspergillus spp.*, *Candida spp.*, *Cryptococcus neoformans*, *Pneumocystis jiroveci*, Zygomycetes
- Any endemic fungal infection such as coccidioidomycosis or histoplasmosis
- Colonisation or other non-invasive infection

In case of any uncertainty whether a specific patient can be included, please contact the chair.

Study Management

- The case report form (CRF) is an internet based form accessed through the following websites: www.fungiscope.net. There the study protocol as well as the full CRF (pdf-version) is available.

- Risk factors

room conditions, i.e. laminar air flow, HEPA filter use, exposition to construction work/dust [including the option: undetermined], status of the underlying condition at onset of IFI, neutropenia, mucositis grade 3-4 (CTC), diabetes mellitus, central venous catheter, total parenteral nutrition, chemotherapy, high dose cytosine arabinoside, radiotherapy, steroids (dose and duration), anti TNF- α , alemtuzumab, rituximab, purine analogues, number of antibiotics, and number of days with antibiotics, previous antifungal prophylaxis, other.

- Demographic data, underlying condition and its current status
- Number of institution's hospital admissions during the last year
- Fungal species, organs involved
- Antifungals and other treatment modalities, treatment results of IFI

- Survival 4 and 12 weeks post treatment cessation or cause of death, and results of post mortem examination [as query issued from the data base].
- Registration in any other trial or registry. Can still be registered with Fungiscope, however, repetitive publication will be avoided or disclaimed.

Data analysis

The evaluation will be descriptive, by causative organism. Diagnostic approach and response to therapy will be compared by fungal disease. For differences between subgroups χ^2 -test or exact test of Fisher will be used with a $p < 0.05$ as limit for statistical significance, with a Bonferroni correction for multiple comparisons.

Strain collection/Fungithek

Isolates will be sent to and stored by the reference laboratories, where formal identification will be done based on culture and molecular biology results.

Susceptibility patterns/MIC according to CLSI and/or EUCAST methods/MFC of the isolates will be done.

Tissue collection

Every effort should be made to obtain tissue samples. If fresh frozen tissue is not available, 10 slices of formaldehyde fixated tissue should be obtained.

Budgetary information

For evaluable patient documentations filled in by the participating center a compensation of € 100 each will be paid. If the documentation workload is too high, centers are encouraged to ask the study office for personnel to be sent to the site.

For isolates made available to the central laboratory an additional € 50 will be paid.

Authorship

It is intended to publish each subset of this cohort at a time. Authorship will be restricted to those centers contributing patients or translational work to the subset published. From each contribution center there will be authorship positions available. This will extend to a maximum of three: one clinician, one microbiologist/medical mycologist, and one pathologist, if applicable.

Patients registered until December 2009

Total documented: 140

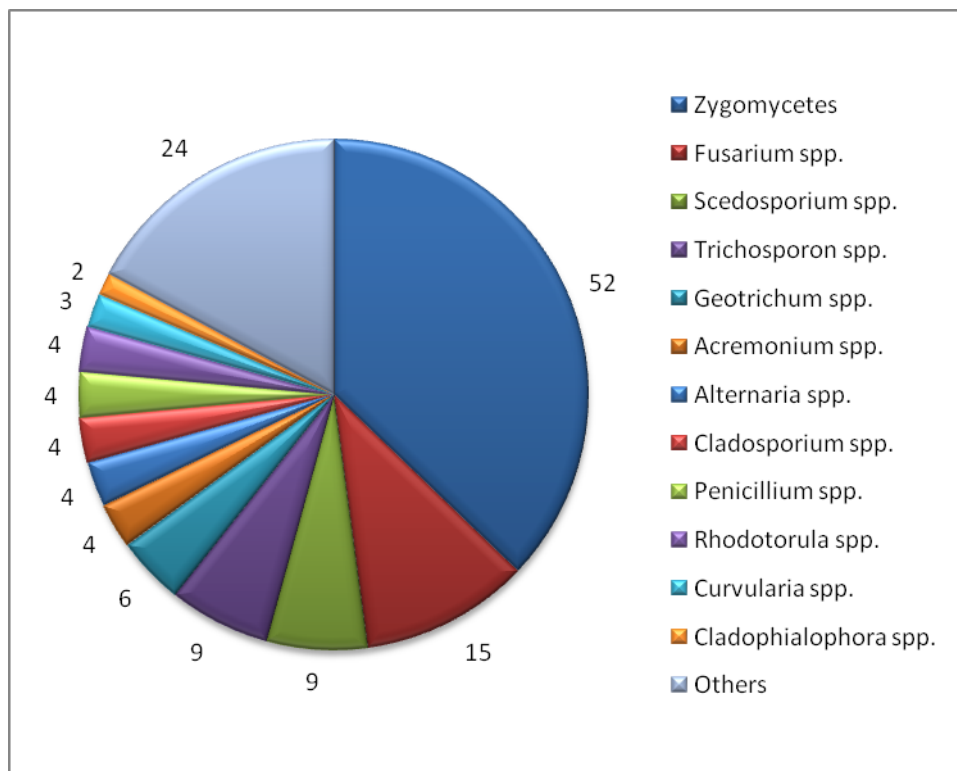


Figure 1: Distribution of 140 documented cases of rare invasive fungal infections

Publication Plan for 2010

April 10-13, 2010	20 th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), Vienna, Austria
June 23-26, 2010	10 th Congress of Infectious Diseases and Tropical Medicine, Cologne, Germany
September 12-15, 2010	50 th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), MA, Boston, USA
September 9-11, 2010	44 th Congress of German Society for Mycology (DMyKG e.V.), Vienna, Austria
October 1-5, 2010	Annual Congress of the German Society for Hematology and Oncology (DGHO), Berlin, Germany

Publications and presentations

- Dec 11, 2009 M.J.G.T. Rüping, W.J. Heinz, A.J. Kindo, V. Rickerts, C. Lass-Flörl, C. Beisel, R. Herbrecht, Y. Roth, G. Silling, A.J. Ullmann, K. Borchert, G. Egerer, J. Maertens, G. Maschmeyer, A. Simon, M. Wattad, G. Fischer, J.J. Vehreschild, O.A. Cornely
Forty-one Recent Cases of Invasive Zygomycosis from a Global Clinical Registry
J Antimicrob Chemother. 2010 Feb;65(2):296-302
- February 7, 2009 Posaconazole Clinical Update Meeting, Miami, FL, USA
- March 12-14, 2009 9th Congress of Infectious Diseases and Tropical Medicine, Freiburg, Germany
- March 4-6, 2009 19th Focus on Fungal Infections, Fort Myers, FL, USA
- May 16-19, 2009 19th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), Helsinki, Finland
- May 25-29, 2009 17th Congress of The International Society for Human and Animal Mycology (ISHAM), Tokyo, Japan
- September 3-5, 2009 43th Congress of German Society for Mycology (DMyG e.V.), Cologne, Germany
- September 9-12, 2009 Weimar Sepsis Update, Weimar, Germany
- September 12-15, 2009 49th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), CA, San Francisco, USA

September 17-19, 2009	11 th Congress of the German Society for Anaesthesiology and Intensive Care (DGAI), Berlin, Germany
October 2-6, 2009	Annual Congress of the German Society for Hematology and Oncology (DGHO), Mannheim, Germany
October 7-11, 2009	18 th Congress of the European Academy of Dermatology and Venerology (EADV), Berlin, Germany
October 18-21, 2009	4 th Trends in Medical Mycology (TIMM), Athens, Greece
February 27-March 1, 2008	9 th Congress of Infectious Diseases and Tropical Medicine, Innsbruck
February 16-20, 2008	12 th Symposium on Acute Leukemia, Munich
March 6-8, 2008	9 th Focus on Fungal Infections, San Antonio, USA
March 29-April 2, 2008	114 th Congress of the German Society for Internal Medicine, Wiesbaden, Germany
April 19-22, 2008	18 th European Congress of Clinical Microbiology and Infectious Diseases, Barcelona
June 19-22, 2008	13 th International Society for Infectious Diseases, Kuala Lumpur, Malaysia
June 22-25, 2008	15 th Symposium on Infections in the Immunocompromised Host, Thessaloniki, Greece
June 26-28, 2008	International MASCC/ISOO Symposium Supportive Care in Cancer, Houston, Texas, USA
July 2008	Rüping MJGT, Albermann N, Ebinger F, Burckhard I, Beisel C, Müller C, Vehreschild JJ, Kochanek M, Fätkenheuer G, Bangard C, Ullmann AJ, Herr W, Kolbe K, Hallek M, Cornely OA.

Posaconazole concentrations in the central nervous system.

J Antimicrob Chemother 2008 Dec;62 (6):1468-70

- | | |
|----------------------|---|
| September 4-6, 2008 | 42th Congress of German-Speaking Society for Mycology (DMykG e.V.), Jena, Germany |
| October 10-14, 2008 | Annual Congress of the German Society for Hematology and Oncology (DGHO), Vienna, Austria |
| November 20-22, 2008 | Posaconazole Clinical Update Meeting, Budapest, Hungary |
| April 19-20, 2007 | Gilead Clinical Studies Workshop, Munich, oral |
| September 6-8, 2007 | International Congress of the German Mycological Society, Berlin, Germany |

Innovations

1. Prof. Sybren de Hoog from the CBS Fungal Biodiversity Center, Institute of the Royal Netherlands Academy of Arts and Sciences (KNAW) has begun to carry out all molecular genetic analyses.
2. A revised version of the eCRF has been programmed and put online in November 2009. An online tool for researching the database will be developed in 2010.
3. A co-operation with the MSG Phaeohyphomycoses Study Group has been confirmed.

As shown above, a large number of high quality publications has been generated from Fungiscope, particularly since 2008. In addition, the increasing number of collected clinical cases, isolates and histopathological samples, has allowed us to establish a network of valuable contributors who are now beginning to initiate sub-projects, e.g. Prof. Sybren de Hoog from the CBS Fungal Biodiversity Center and the MSG Phaeohyphomycoses Study Group. Given this promising development, we aim to further expand the Fungiscope network and to consolidate newly initiated sub-projects within the next three years.

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