

West Coast Transplant Infectious Diseases Meeting

June 12th, 2024

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Stanford
MEDICINE

Case Introduction

- ███ year old █████ with PMH with AML with myelodysplastic changes s/p 3 cycles of azacitidine/venetoclax w/ CR1+MRD now s/p 9/10 mmURD allo-BMT with course complicated by neutropenic fever, ocular “floaters”, and development of rash/skin lesions.
- ID consulted to assist with evaluation of positive blood culture.

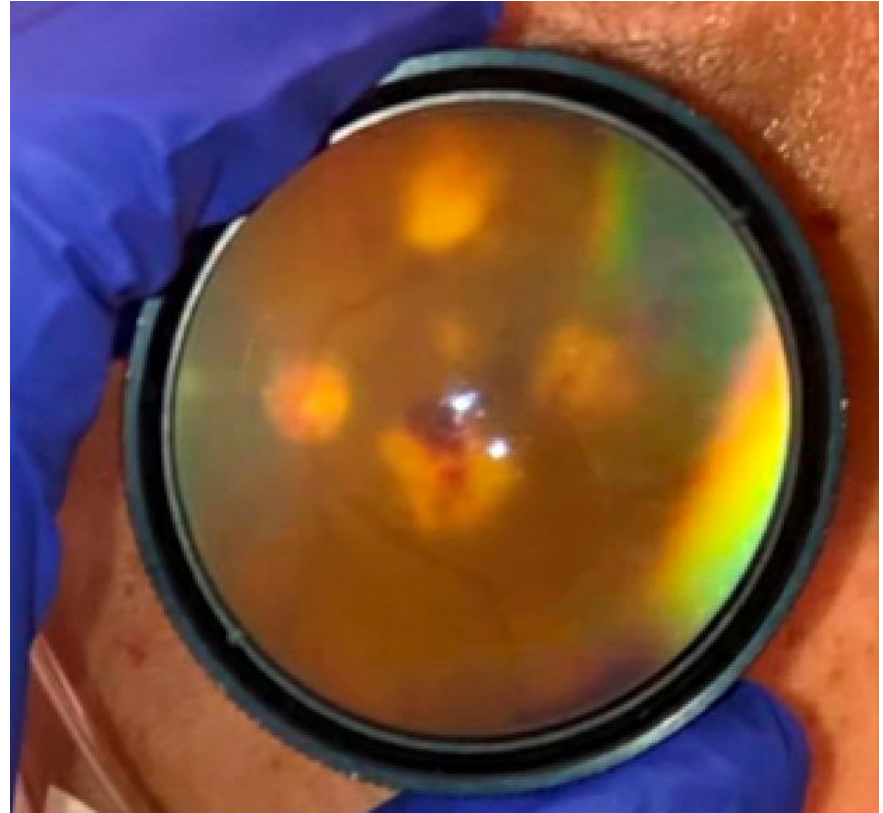
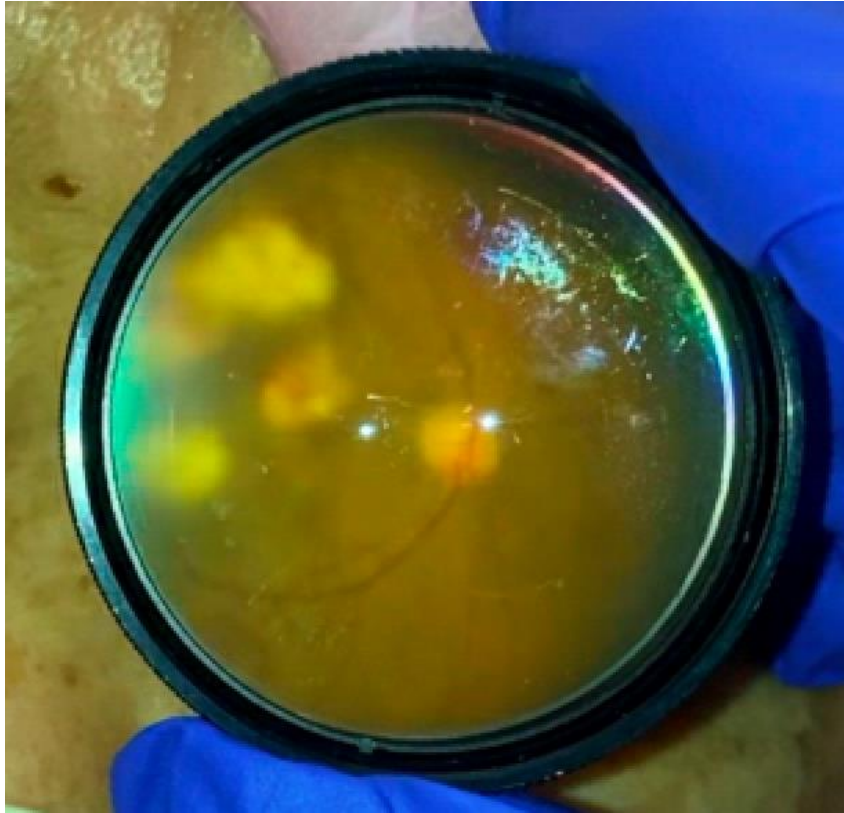
Clinical Course

- Day +4: Neutropenic fever treated with cefepime and maintained on acyclovir and isavuconazole prophylaxis; no clear source identified and fever resolved
- Day +16: Early engraftment
- Day +26: Patient reports “floaters” with associated redness of the left eye. Ophthalmology exam notable for multiple foci of “irregular subretinal masses”
- Day +28: Vitreous aspirate of left eye with initiation of empiric voriconazole, ceftazidime and vancomycin via intravitreal injections
- Day +29: Blood cultures positive for “fungal organisms”
- Day +32: Diagnostic vitrectomy
- Day +33: ID Consulted

Clinical Course - Skin Findings



Clinical Course - Ocular Findings



Clinical Course

- Day +34: Intravitreal cultures positive for fungal organisms
 - Dermatology performs skin biopsy and culture of peripheral nodular lesions
- Day +36: Bilateral elbow pain and left knee pain/swelling s/p aspirate with 9,050 WBCs (96% - PMNs) in addition to skin biopsy pathology suggestive of fungal elements.
- Day +41/45: MRI of left and right knees concerning for septic arthritis, intramuscular abscesses, and distal femur/patella/tibia/fibula osteomyelitis.
- Day +43/48: Operative I&D with washout of the left and right knees with operative concern for infection and cultures later positive for fungal species.

Clinical Course - Musculoskeletal Findings



Question 1:

Given the information presented thus far, which pathogen might be most consistent with our patient's clinical presentation?

- *Candida glabrata*
- *Cryptococcus neoformans*
- *Fusarium solani* complex
- *Histoplasmosis capsulatum*
- *Rhizopus arrhizus*
- *Sporothrix schenckii*

Case #2 - Clinical Course

Susceptibility

	Fusarium solani complex MIC MCG/ML	
Amphotericin B	2 ug/mL	No Interpretation
Isavuconazole	>8 ug/mL	No Interpretation
Itraconazole	>16 ug/mL	No Interpretation
Posaconazole	>8 ug/mL	No Interpretation
Voriconazole	4 ug/mL	No Interpretation

- Day +34: Fungal organism in blood culture identified as *Fusarium solani* complex and intravitreal cultures positive for mold
 - Voriconazole started in place of isavuconazole c/b prominent hallucinations
- Day +41: Left knee aspirate culture notable for *Fusarium*.
- Day +42: Early development of AKI, although stable with ongoing Ambisome therapy
- Day +43/48: Operative I&D with washout of the left and right knees are eventually culture positive for *Fusarium*.

Clinical Course

- Day +57: Acute onset diarrhea with CT A/P notable for proctocolitis with negative GI pathogen PCR.
- Day +59: EGD and Colonoscopy with duodenal and colon biopsy concerning for GVHD grade I. Budesonide initiated with ongoing tacrolimus.
- Day +62: Patient continued on voriconazole and IV Ambisome with PET-CT notable for numerous intramuscular abscesses in bilateral lower extremities, multiple subcutaneous nodules in upper arms, uptake in bilateral knees and left elbow joint.
- Day +66: Left knee synovial aspirate remains positive for *Fusarium*

Question 2:

At this point in the patient's course, which antifungal regimen would you select for the management of his disseminated fusariosis?

- Liposomal amphotericin B monotherapy
- Posaconazole monotherapy
- Voriconazole monotherapy
- Liposomal amphotericin B + Posaconazole
- Liposomal amphotericin B + Voriconazole
- Other antifungal regimen

Final Fungal Testing Report

Ordering Physician: [REDACTED]
Source: Blood
Species ID Provided: Fusarium solani complex
Date Collected: [REDACTED]
Clinical Diagnosis: [REDACTED]

RESULTS OF ANTIFUNGAL SUSCEPTIBILITY TESTING:

DRUGS:	RESULTS:	INTERPRETATION:
Manogepix (MGX)	<= 0.008 mcg/ml	See Note Below

Methodology: CLSI M38

Comments:

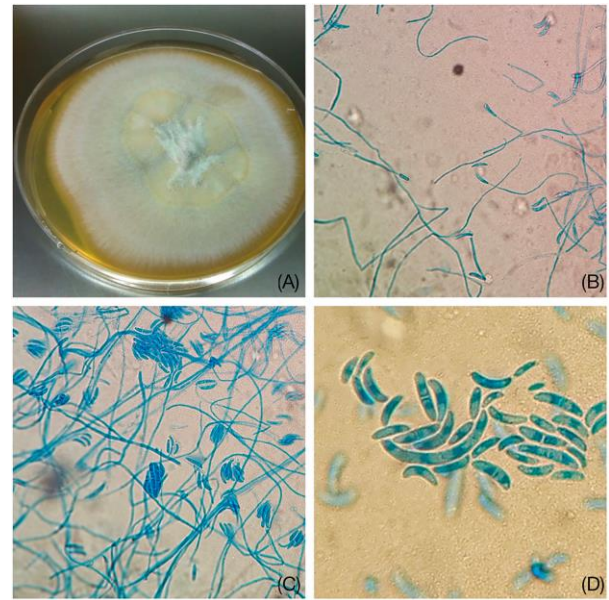
Fosmanogepix, the prodrug of the active moiety of manogepix, is not currently approved by the FDA for routine clinical use in humans and is currently in clinical trials. Manogepix in vitro susceptibility testing is performed by established CLSI broth dilution methods. Clinical breakpoints for susceptibility and resistance have not been established, so the results should be interpreted with caution.

Clinical Course

- Day +68: Patient initiated fosmanogepix 800mg daily in addition to ongoing combination therapy with voriconazole and IV Ambisome
- Day +78: Left elbow and Left ankle arthrotomy with debridement and washout as well as Left knee synovectomy and debridement with meniscectomies.
 - Single culture from left elbow positive for Fusarium
 - Left ankle and left knee cultures negative
- Course progressively complicated by post-operative pain and delirium, atrial fibrillation, volume overload, possible aspiration pneumonia/pneumonitis contributing to hypoxic respiratory failure.
- Although the patient was stabilized ██████ remained chronically ill with persistent delirium and joint pain. After thoughtful discussion the patient transitioned to hospice and passed away surrounded by ██████ family on Day +92.

Fusarium spp.

- Ubiquitous organisms found in soil and organic debris
- Numerous subspecies
 - F. solani (~50%), F. oxysporum (20%), F. verticillioides and F. moniliforme (~10%)
- Immunocompetent Infections
 - Keratitis, onychomycosis, soft tissue mycetoma
- Immunocompromised Infections
 - Disseminated disease typically from ingestion, inhalation (sinus/lung) or cutaneous sources
- Prognosis is poor and optimal therapy has yet to be established



Karadağ AS. doi: 10.1111/dth.14203. Epub 2020 Sep 23.
PMID: 32829501

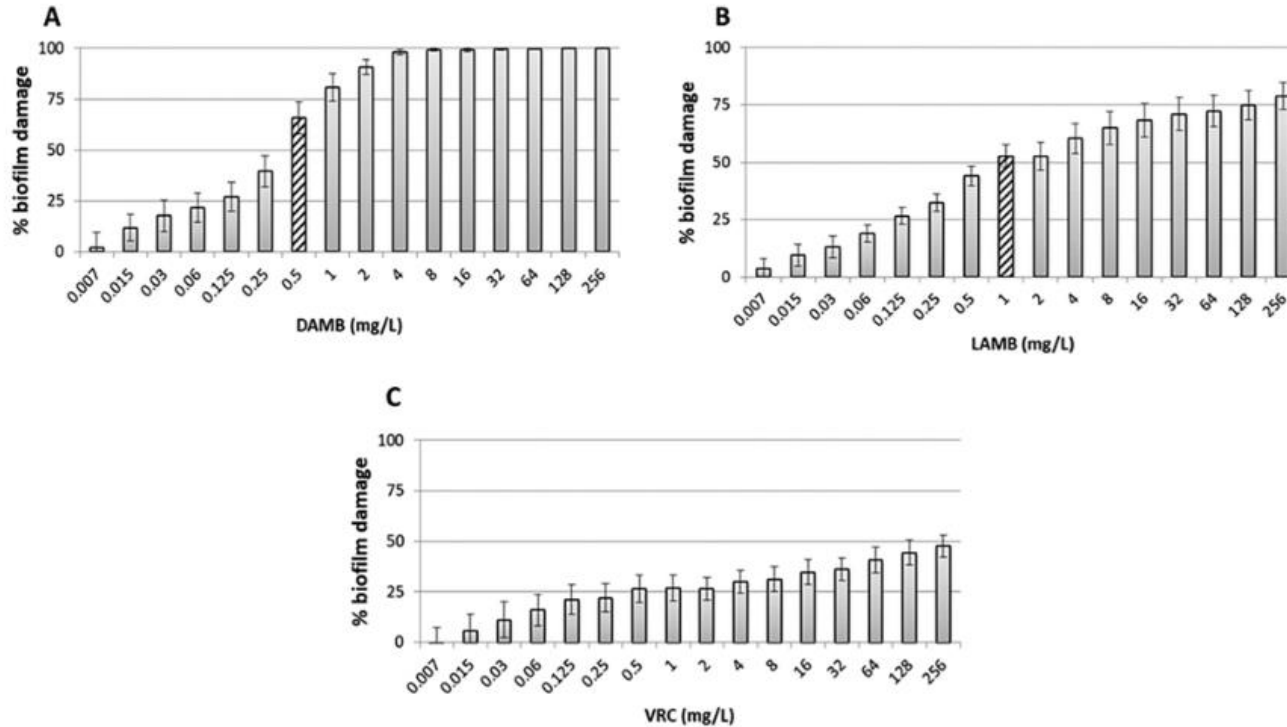
Nucci M, Anaissie E. Fusarium infections in immunocompromised patients. Clin Microbiol Rev. 2007 Oct;20(4):695-704. doi: 10.1128/CMR.00014-07. PMID: 17934079; PMCID: PMC2176050.

Bennett JE, Dolan R, and Blaser MJ. (2020) *Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases 9th Edition*. Philadelphia, PA. Elsevier Inc.

Fusarium In-vitro Susceptibility

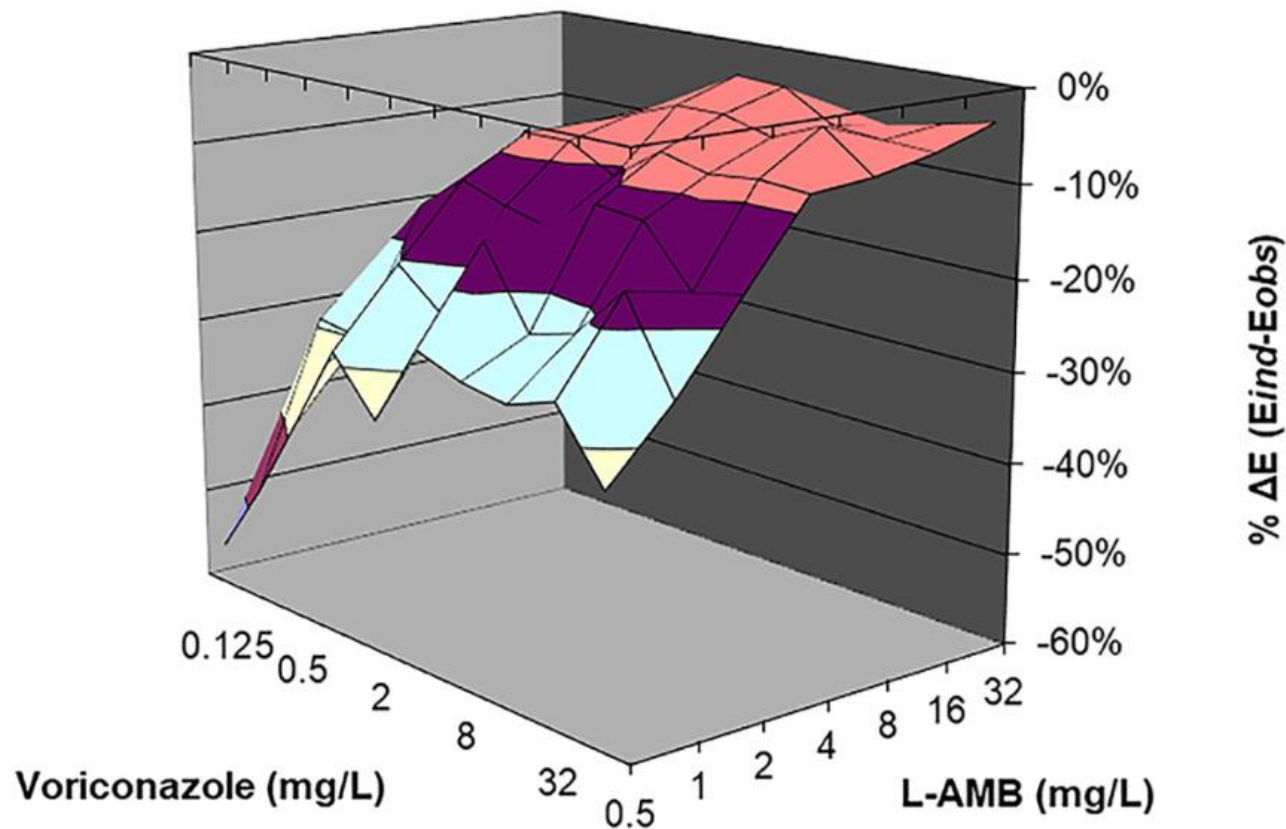
Agent	Species or SC ^b	No. of labs	No. of isolates tested	No. of isolates ^c with a MIC ($\mu\text{g/ml}$) of:								
				≤ 0.25	0.5	1	2	4	8	16	>16	
Amphotericin B	<i>F. dimerum</i> SC	8	50	3	7	16	13	5	5	1		
	<i>F. fujikuroi</i>	3	10		1	6	3					
	<i>F. proliferatum</i>	10	82	1	5	16	31	22	5	1	1	
	<i>F. verticillioides</i>	9	151		1	27	84	28	6	5		
	<i>F. incarnatum-F. equiseti</i> SC ^d	6	20		3	3	5	6	3			
	<i>F. oxysporum</i> SC	14	226	1	10	37	107	61	8	2		
	<i>F. solani</i> SC	15	608	8	46	120	265	125	29	15		
Itraconazole	<i>F. dimerum</i> SC	7	45				3	1		15	25	1
	<i>F. fujikuroi</i>	3	10								1	9
	<i>F. proliferatum</i>	10	60				1		4	14	21	20
	<i>F. verticillioides</i>	7	96				2	4	5	27	41	17
	<i>F. incarnatum-F. equiseti</i> SC	6	20				1	1	2	8	6	2
	<i>F. oxysporum</i> SC	9	148				2	2	4	29	87	24
	<i>F. solani</i> SC	11	338		2	1	7	5	90	220	13	
Posaconazole	<i>F. dimerum</i> SC	7	48		1	2	3	5	25	11		1
	<i>F. fujikuroi</i>	3	10		2	3	4	1				
	<i>F. proliferatum</i>	9	49			7	16	6	8	5		7
	<i>F. verticillioides</i>	7	113	15	43	33	9	3				10
	<i>F. incarnatum-F. equiseti</i> SC	6	19		3	2	5	6	2	1		
	<i>F. oxysporum</i> SC	10	148		1	20	53	37	13	22		2
	<i>F. solani</i> SC	8	357			8	15	42	163	113		16
Voriconazole	<i>F. dimerum</i> SC	7	53			3	9	15	24	2		
	<i>F. fujikuroi</i>	3	10				2	5	1	2		
	<i>F. proliferatum</i>	10	74			3	10	29	24	6		2
	<i>F. verticillioides</i>	8	143		1	25	70	35	2	2		8
	<i>F. incarnatum-F. equiseti</i> SC	6	20		1	2	5	8	3			1
	<i>F. oxysporum</i> SC	13	200		5	10	36	94	47	5		3
	<i>F. solani</i> SC	16	555		3	9	51	123	243	119		7

Fusarium In-vitro Biofilm Assessment

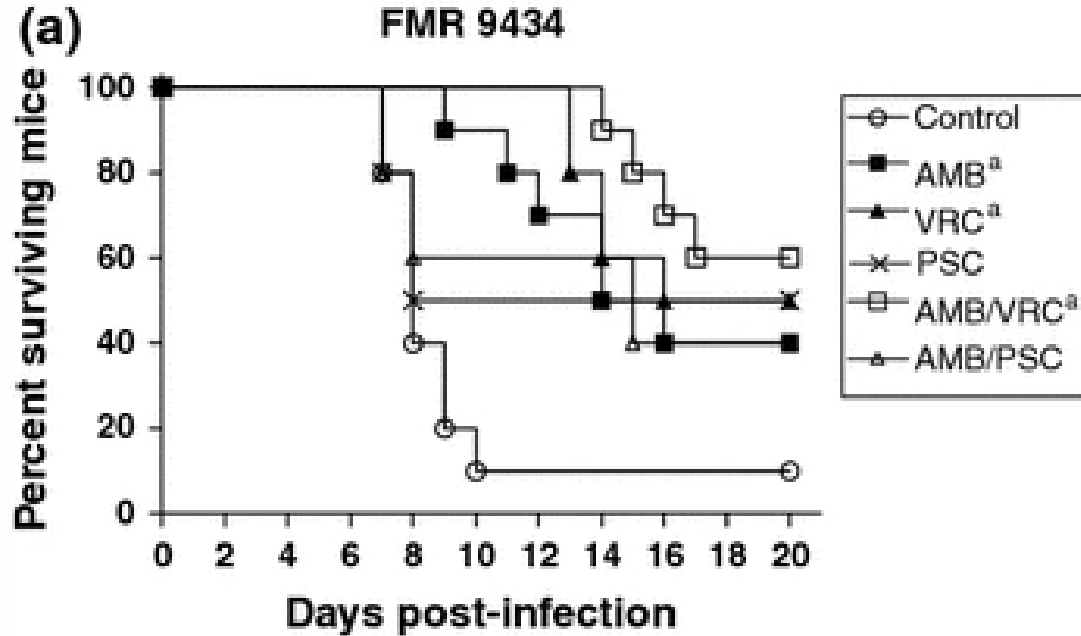


Vikelouda K, et al. Activity of Amphotericin B Formulations and Voriconazole, Alone or in Combination, against Biofilms of *Scedosporium* and *Fusarium* spp. *Antimicrob Agents Chemother.* 2021 Oct 18;65(11):e0063821. doi: 10.1128/AAC.00638-21. Epub 2021 Aug 9. PMID: 34370583; PMCID: PMC8522719.

Fusarium In-vitro Biofilm Assessment



Fusarium In-vivo Murine Model



Fusarium Clinical Outcomes

TABLE 2
Factors Associated with Lower Survival in 84 Patients with Hematologic Diseases and *Fusarium* Infection

Variables	Univariate analysis		Multivariate analysis	
	HR	95% CI	HR	95% CI
Persistent neutropenia	5.17	2.62–10.20	5.43	2.64–11.11
Disseminated infection	3.81	1.19–12.15	3.57	0.46–27.77
Use of corticosteroids	2.17	1.33–3.57	2.18	1.98–3.96
SCT	1.69	1.03–2.78	1.52	0.86–2.69

HR: hazard ratio; 95% CI: 95% confidence interval; SCT: stem cell transplantation.

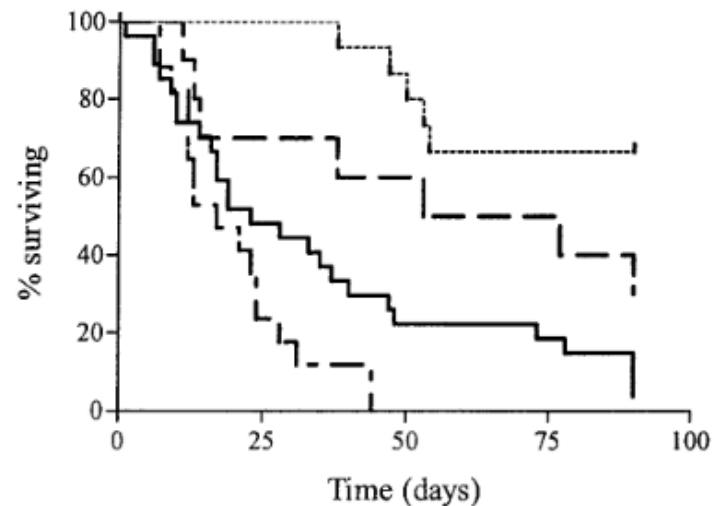


FIGURE 1. Survival of patients with fusariosis according to the presence of prognostic factors ($P < 0.0001$, log rank test). Line with small dashes: bone marrow recovery with no steroid use; line with large dashes: bone marrow recovery with use of steroids; unbroken line: persistent neutropenia with no steroid use; line with small and large dashes: persistent neutropenia with use of steroids.

Nucci M, Anaissie EJ, Queiroz-Telles F, Martins CA, Trabasso P, Solza C, Mangini C, Simões BP, Colombo AL, Vaz J, Levy CE, Costa S, Moreira VA, Oliveira JS, Paraguay N, Duboc G, Voltarelli JC, Maiolino A, Pasquini R, Souza CA. Outcome predictors of 84 patients with hematologic malignancies and *Fusarium* infection. *Cancer*. 2003 Jul 15;98(2):315-9. doi: 10.1002/cncr.11510. PMID: 12872351.

Nucci M, Marr KA, Queiroz-Telles F, Martins CA, Trabasso P, Costa S, Voltarelli JC, Colombo AL, Imhof A, Pasquini R, Maiolino A, Souza CA, Anaissie E. *Fusarium* infection in hematopoietic stem cell transplant recipients. *Clin Infect Dis*. 2004 May 1;38(9):1237-42. doi: 10.1086/383319. Epub 2004 Apr 15. PMID: 15127334.

Fusarium Clinical Outcomes

Table 5. Distribution of MIC of voriconazole and amphotericin B in 72^a haematological patients with invasive fusariosis

Primary therapy	No.	No. of isolates with MIC (mg/L)									MIC ₅₀	
		0.25	0.5	1	2	4	8	16	32	64		
Voriconazole	22											
survival	14	0	0	2	3	3	3	2	1	0	4	
death	8	0	0	2	0	1	2	2	1	0	8	
Amphotericin B	21											
survival	13	0	1	3	4	4	0	1	0	0	2	
death	8	0	1	2	3	1	0	0	1	0	2	
Amphotericin B + voriconazole	29											
amphotericin B												
survival	19	2	2	3	8	3	0	0	0	1	2	
death	10	0	2	1	5	1	0	1	0	0	2	
voriconazole												
survival	19	0	1	2	3	2	6	0	3	2	8	
death	10	0	0	1	4	0	2	2	1	0	4	

^aOne patient with haematological disease received posaconazole and one received isavuconazole + micafungin.

Fusarium Therapy and Clinical Outcomes

Treating disseminated fusariosis: amphotericin B, voriconazole or both?

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Case Reports

Combination antifungal therapy for disseminated fusariosis in immunocompromised patients : a case report and literature review

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J Infect Chemother (2013) 19:1173–1180
DOI 10.1007/s10156-013-0594-9

CASE REPORT

Combination therapy of voriconazole and terbinafine for disseminated fusariosis: case report and literature review

Shojiro Inano · Masahiro Kimura · Jun Iida · Nobuyoshi Arima

Fusarium Therapy and Clinical Outcomes

TABLE 2. Clinical manifestations and treatment of 233 patients with invasive fusariosis

Characteristic	Total, N = 233	Period 1, N = 121	Period 2, N = 112	p-Value
Skin involvement	143 (61)	70 (58)	73 (65)	0.25
Lung involvement	114 (49)	60 (50)	54 (48)	0.83
Sinusitis	72 (31)	34 (28)	38 (34)	0.34
Fungaemia	86 (37)	31 (26)	55 (49)	<0.001
Disseminated disease	166 (72)	89 (74)	77 (69)	0.48
Received treatment	206 (88)	102 (84)	104 (93)	0.04
Deoxycholate amphotericin B	110 (47)	76 (63)	34 (30)	<0.001
Lipid formulation of amphotericin B ^a	34 (15)	22 (18)	12 (11)	0.11
Voriconazole	38 (16)	2 (2)	36 (32)	<0.001
Combination therapy ^b	21 (9)	1 (1)	20 (18)	<0.001
Other ^c	3 (1)	1 (1)	2 (2)	
Receipt of G-CSF or GM-CSF ^d	106 (47)	45 (37)	59 (53)	0.02
Granulocyte transfusion ^d	28 (12)	20 (16)	8 (7)	0.03

Numbers in parentheses represent percentages.

G-CSF, granulocyte colony-stimulating factor; GM-CSF, granulocyte-monocyte colony-stimulating factor.

^aLipid formulation of amphotericin B: liposomal amphotericin B (n = 20; 11 in period 1 and nine in period 2), amphotericin B lipid complex (n = 8; six in period 1 and two in period 2), and amphotericin B colloidal dispersion (n = 6; five in period 1 and one in period 2).

^bCombination therapy consisted of voriconazole (19 cases) plus liposomal amphotericin B (n = 10), deoxycholate amphotericin B (n = 5), amphotericin B lipid complex (n = 2) and terbinafine (n = 2), and posaconazole plus liposomal amphotericin B (n = 1).

^cOther treatment: itraconazole (one case, period 1), posaconazole and surgery (one case each, period 2).

^dAfter the diagnosis of fusariosis.

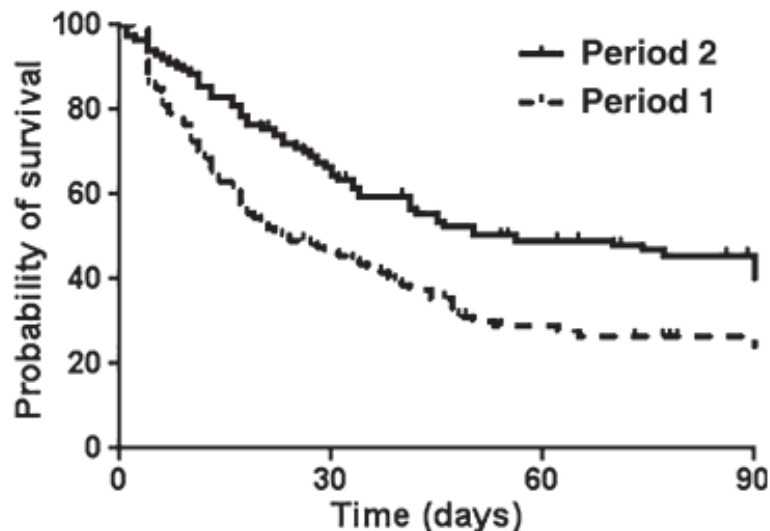


FIG. 1. Probability of 90-day survival of 233 patients with invasive fusariosis in period 1 (1985–2000) and period 2 (2001–2011).

Fusarium Therapy and Clinical Outcomes

TABLE 3. Factors associated with poor outcome (death 90 days after diagnosis) in 206 patients with invasive fusariosis who received treatment

Variable	Unadjusted		Adjusted	
	HR (95% CI)	p	HR (95% CI)	p
Haematological disease	5.70 (0.79–41.24)	0.08	5.26 (0.71–38.73)	0.11
Receipt of corticosteroids	2.21 (1.24–3.94)	0.007	2.11 (1.18–3.76)	0.01
Neutropenia at end of treatment	2.61 (1.52–4.46)	<0.001	2.70 (1.57–4.65)	<0.001
Disseminated disease	1.72 (0.90–3.26)	0.09	1.45 (0.72–2.94)	0.30
Primary treatment with deoxycholate amphotericin B ^a	1.75 (1.02–3.01)	0.04	1.83 (1.06–3.16)	0.03
Primary treatment with voriconazole ^a	0.61 (0.34–1.11)	0.09	0.77 (0.38–1.55)	0.47

HR, hazard ratio.

^aAs a single agent. Neither lipid amphotericin B (HR 0.67, 95% CI 0.27–1.69) or combination therapy (HR 1.20, 95% CI 0.63–2.28) was significant by univariate analysis.

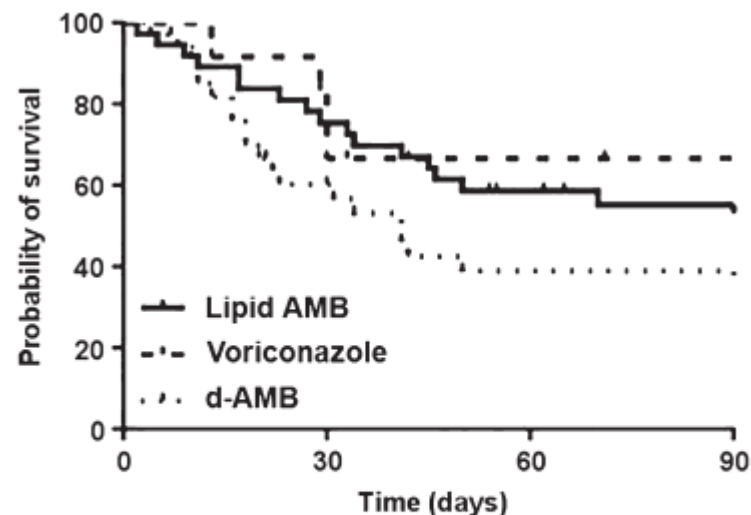


FIG. 2. Probability of 90-day survival of 83 patients with invasive fusariosis in period 2 treated with deoxycholate amphotericin B (d-AMB), voriconazole, or a lipid formulation of amphotericin B (Lipid AMB).

Fusariosis Treatment Guidelines

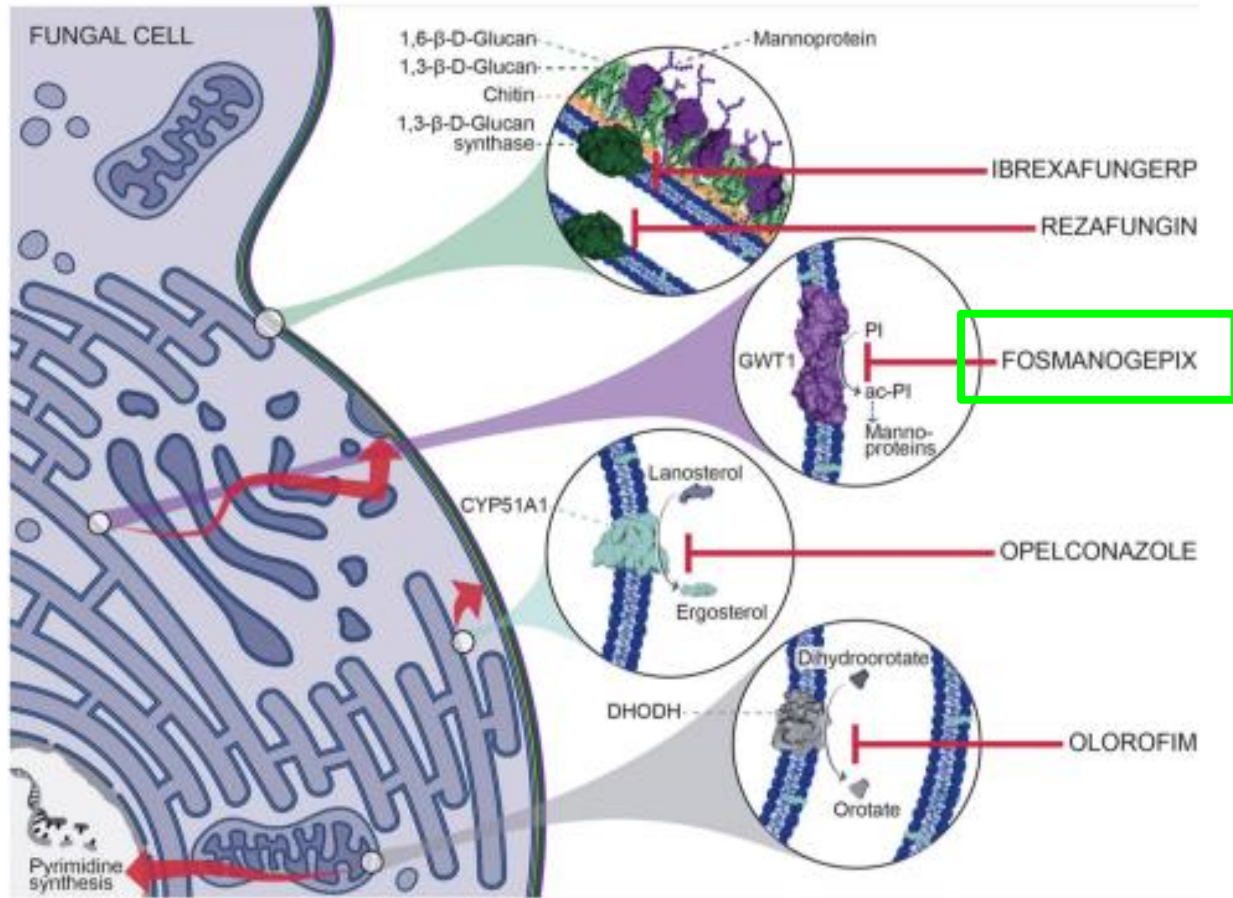
TABLE 5. Summary of recommendations for treatment of *Fusarium* infection

Population	Intention	SoR	QoE	Comment
Immunocompromised patients	First-line treatment Voriconazole	A	II,t,r	Therapeutic drug monitoring required Response rate was associated with underlying condition and infection site
	Liposomal amphotericin B	B	II,t,r	Fungi may be resistant to amphotericin B
	Amphotericin B lipid complex	C	III	Limited case reports
	Amphotericin B deoxycholate	D	II,t,u	Fungi often resistant to amphotericin B Breakthrough infections may occur Excessive toxicity
	Any echinocandin	D	III	Intrinsically resistant
	Any combination therapy	C	III	Limited reports Combination not better than voriconazole alone
	Salvage treatment Posaconazole	A	II	Overall success rate 50% Breakthrough infections Therapeutic drug monitoring required
	Voriconazole	A	III	Substantial efficacy Therapeutic drug monitoring required

QoE, quality of evidence; SoR, strength of recommendation.

Tortorano AM, et al; European Society of Clinical Microbiology and Infectious Diseases Fungal Infection Study Group; European Confederation of Medical Mycology. ESCMID and ECMM joint guidelines on diagnosis and management of hyalohyphomycosis: *Fusarium* spp., *Scedosporium* spp. and others. Clin Microbiol Infect. 2014 Apr;20 Suppl 3:27-46. doi: 10.1111/1469-0691.12465. PMID: 24548001.

Hoenigl M, et al. Global guideline for the diagnosis and management of rare mould infections: an initiative of the European Confederation of Medical Mycology in cooperation with the International Society for Human and Animal Mycology and the American Society for Microbiology. Lancet Infect Dis. 2021 Aug;21(8):e246-e257. doi: 10.1016/S1473-3099(20)30784-2. Epub 2021 Feb 16. Erratum in: Lancet Infect Dis. 2021 Apr;21(4):e81. PMID: 33606997.

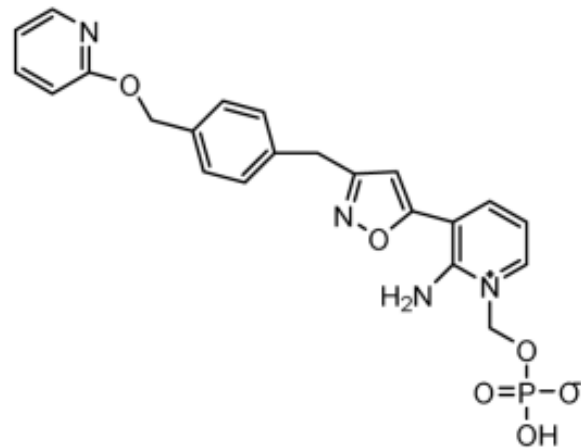


Hoenigl M, Sprute R, Egger M, Arastehfar A, Cornely OA, Krause R, Lass-Flörl C, Prattes J, Spec A, Thompson GR 3rd, Wiederhold N, Jenks JD. The Antifungal Pipeline: Fosmanogepix, Ibrexafungerp, Olorofim, Opelconazole, and Rezafungin. *Drugs*. 2021 Oct;81(15):1703-1729. doi: 10.1007/s40265-021-01611-0. Epub 2021 Oct 9. PMID: 34626339; PMCID: PMC8501344.

Fosmanogepix

- Novel Class - Glycosylphosphatidylinositol (GPI) inhibitor
- Mechanism of action
 - Inhibits fungal enzyme (Gwt1) to disrupt GPI-anchor protein modification
- Pro-drug -> manogepix (active agent)
- Wide volume of distribution
- Oral and IV Formulation
- Anticipated adverse effects
 - Infusion reactions, phlebitis, minor CYP3A4 inhibitor
- Anticipated Antimicrobial Spectrum
 - Aspergillus spp., endemic mycoses, Lomentospora/Scedosporium
 - Fusarium (Species-dependent activity)

Fosmanogepix (APX001)



Fosmanogepix - Key Clinical Trials

- Fosmanogepix and Candidemia (Phase 2 - completed 2023)
- Fosmanogepix and *C. auris* Candidemia (Phase 2 - completed 2023)
- AEGIS (Phase 2 - terminated 2022 with early results)

Fosmanogepix - Key Clinical Trials

- AEGIS - Open-label Study of APX001 for Treatment of Patients with Invasive Mold Infections Caused by Aspergillus or Rare Molds
 - Terminated early (prioritization of phase 3 trial)
- Multicenter, open label, non-comparative, single arm study, mITT
- Study Population: Proven/probable Invasive fungal infection due to Aspergillus spp. Scedosporium spp. Fusarium spp, or Mucor/Rhizopus spp.
 - Exclusion Criteria: Refractory hematologic malignancy, chronic aspergillosis/aspergilloma or ABPA and major hepatic impairment
- Primary Endpoints - “Global Response” and survival at day 42
- Secondary Endpoints
 - All-cause mortality, TEAEs, and SAEs

AEGIS (Phase 2)

- 21 participants
 - Average age 62.38 years
 - 19/21 - Male
 - 20/21 - White
 - 1 - lost to follow up
- Treatment responses (n = 20)
 - Complete response - 20%
 - Partial Response - 20%
 - Stable Response - 10 %
 - Progressive fungal disease - 30%
 - Death - 20%
- Secondary Outcomes (n = 21)
 - All-cause mortality - 42.86%
 - TEAEs - 100%
 - SEAs - 61.9%

Fosmanogepix - Upcoming Clinical Trials

- A Study to Learn about the Study Medicine (Fosmanogepix/PF-07842805) in People with Candidemia and/or Invasive Candidiasis
 - Active, not yet recruiting
- Phase 3 Treatment of Aspergillus/Rare Molds
 - Yet to be announced

Fosmanogepix (APX001A) In-vitro Data

Species (no. tested)		EUCAST (mg/L)				CLSI (mg/L)			
		AMB	POS	MFG	APX001A	AMB	POS	MFG	APX001A
<i>F. oxysporum</i> (10)	GM	1.000	12.126	4.000	0.371	0.933	5.278	4.000	0.074
	MIC/MEC ₅₀	1	16	4	0.25	1	8	4	0.015
	MIC/MEC ₉₀	4	16	4	16	2	16	4	16
	range	0.5–4	4–16	4–4	0.015–16	0.5–2	2–16	4–4	0.015–16
<i>F. verticillioides</i> (10)	GM	2.297	12.996	4.000	11.314	2.297	4.595	4.000	1.130
	MIC/MEC ₅₀	2	16	4	16	1	16	4	16
	MIC/MEC ₉₀	32	16	4	16	32	16	4	16
	range	0.5–32	2–16	4–4	0.5–16	1–32	0.5–16	4–4	0.015–16

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JOURNAL ARTICLE

Fosmanogepix Therapy of Disseminated *Fusarium* Infection

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Conclusions

- Fusariosis remains a significant treatment and management challenge in our immunocompromised patients
- Fosmanogepix may offer a new treatment option for traditionally challenging to manage invasive mold infections including *Fusarium* species

Thank you!

- A big thanks to the entire Stanford ICHS team for their collective care of this complicated patient
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