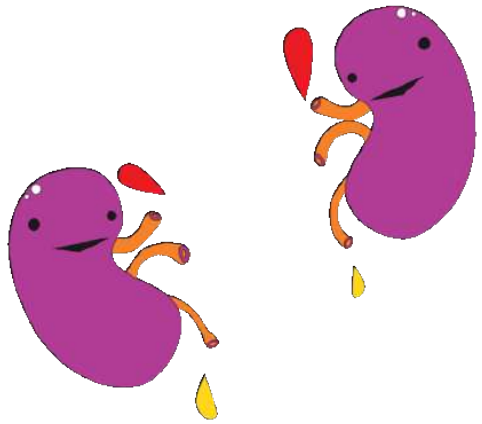
NİÇG
KLİMİK DERNEĞİ NAKİL
İNFEKSİYONLARI ÇALIŞMA GRUBU

BÖBREK NAKLİNDE ZOR OLGULAR



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REJEKSİYON

FIRSATÇI ENFEKSİYON

İmmünsupresif dozu

Böbrek nakil alıcısında 2 enfeksiyon etkeninden kurtulma hakkın var

The Third International Consensus Guidelines on the Management of Cytomegalovirus in Solid-organ Transplantation

Camille N. Kotton, MD,[1] Deepali Kumar, MD,[2] Angela M. Caliendo, MD, PhD,[3] Shirish Huprikar, MD,[4] Sunwen Chou, MD,[5] Lara Danziger-Isakov, MD, MPH,[6] and Atul Humar, MD[7]
on behalf of the The Transplantation Society International CMV Consensus Group

Abstract: Despite recent advances, cytomegalovirus (CMV) infections remain one of the most common complications affecting solid organ transplant recipients, conveying higher risks of complications, graft loss, morbidity, and mortality. Research in the field and development of prior consensus guidelines supported by The Transplantation Society has allowed a more standardized approach to CMV management. An international multidisciplinary panel of experts was convened to expand and revise evidence and expert opinion-based consensus guidelines on CMV management including prevention, treatment, diagnostics, immunology, drug resistance, and pediatric issues. Highlights include advances in molecular and immunologic diagnostics, improved understanding of diagnostic thresholds, optimized methods of prevention, advances in the use of novel antiviral therapies and certain immunosuppressive agents, and more savvy approaches to treatment resistant/refractory disease. The following report summarizes the updated recommendations.

(*Transplantation* 2018;102: 900–931)

The past 5 years has seen exciting advances related to the understanding, diagnosis, and treatment of Cytomegalovirus (CMV). We currently stand on the cusp of modernizing the management of CMV infection posttransplant. Despite these advances, CMV remains one of the most common complications affecting solid organ transplant recipients (SOTR), still befitting the designation: "a transplantation troll."[1] In addition to the direct effects of CMV infection convened in 2008 and 2012 by The Infectious Diseases Section of The Transplantation Society to develop consensus guidelines on CMV management, subsequently published in 2010[4] and 2013.[5] Topics included diagnostics, immunology, prevention, treatment, resistance, and pediatrics. Given numerous recent advances in the field, a third meeting of experts was convened in March 2017 to update these guidelines.

The expert panel rated the quality of evidence on which

42 yaş ♂

- 6 ay önce kadavradan renal nakil
- İNDÜKSİYON: ATG, prednol
- İDAME: takrolimus, MMF, prednol

	Alıcı	Verici
Toxo IgG	+	-
EBV IgG	+	+
CMV IgG	+	+
VZV IgG	+	+
HBsAg/AntiHBs	-/-	-/+
Anti HBcIgG	-	-
Anti HCV	-	-
Anti HIV	-	-
VDRL	-	-

Şikayet: Halsizlik, yorgunluk, iştahsızlık
Kullandığı ilaçlar: TMP-SMX, takrolimus, MMF, prednizolon
FM: Özellik yok.

WBC: 2000 K/Ul
PNL: 1000
Hb: 12 g/dL
Plt: 102000

ESR: 54
CRP: 32 mg/L

AST: 56 U/L
ALT: 40 U/L
ALP: 109 U/L
GGT: 100 U/L
T bil/D bil: 0.5/ 0.4
Kreatinin: 1,43 mg/dl
GFR: 65 ml/dk/1.73 m^2

CMV?

İlaçlar? (TMP-SMX, MMF??)

Rejeksiyon?

Oral alımı azdı, dehidratasyon?

BK?

Başka bir enfeksiyon?

Tetkik Adı	Sonuç	Durum	Birim	Referans Aralığı / Karar Sınırı
Cytomegalovirus CMV DNA PCR, EDTAlı Plazma	POZİTİF : 22165 Artus QS-RG Q Real-Time PCR ile çalışılmıştır. CMV (copies/ml) PLAZMA 1 copies/ml =1.64 IU/ml Lineer aralık : 79.4-1 x 100000000 copies/ml Analitik sentivite : 42.5 copies/ml		IU/mL	
BK Virus PCR, İdrar	POZİTİF: 334551078 Artus QS-RG Q Real-Time PCR ile çalışılmıştır. PLAZMA ve İDRAR Lineer aralık :50 - 9.26 x 10000000 copies/ml Analitik sentivite : 26.7 copies/ml		Kopya/mL	
BK Virus PCR, EDTAlı Tam Kan	BK VIRUS DNA SAPTANMADI Artus QS-RG Q Real-Time PCR ile çalışılmıştır. PLAZMA ve İDRAR Lineer aralık :50 - 9.26 x 10000000 copies/ml Analitik sentivite : 26.7 copies/ml		Kopya/mL	


BK
CMV
REJECT
imgflip.com

Table 1. Charactristics of kidney transplant recipients and prevelence of rejection in CMV infection and control group

Variable	CMV infection	Control	*P* value
Sex			0.89
Female	37.9%	39.1%	
Male	62.1%	60.9%	
Age			0.752
Mean ± SEM	36.91 ± 1.67	36.16 ± 16.77	
Duration of Dialysis			0.112
Mean ± SEM	33.59 ± 2.72	32.09 ± 1.32	
Rejection			0.000
No	63.6%	90.6%	
Yes	36.4%	9.4%	
Cause of ESRD			0.642
ADPKD	9.2%	7.8%	
GN	10.8%	7.8%	
HTN	26.2%	15.6%	
Diabetes	21.5%	25%	
Reflux	4.6%	10.9%	
Unknown	21.5%	26.6%	
Other	6.2%	6.2%	

Hasanzamani B et al. The effect of cytomegalovirus infection on acute rejection in kidney transplanted patients. J Renal Inj Prev. 2016;5(2):85-88.

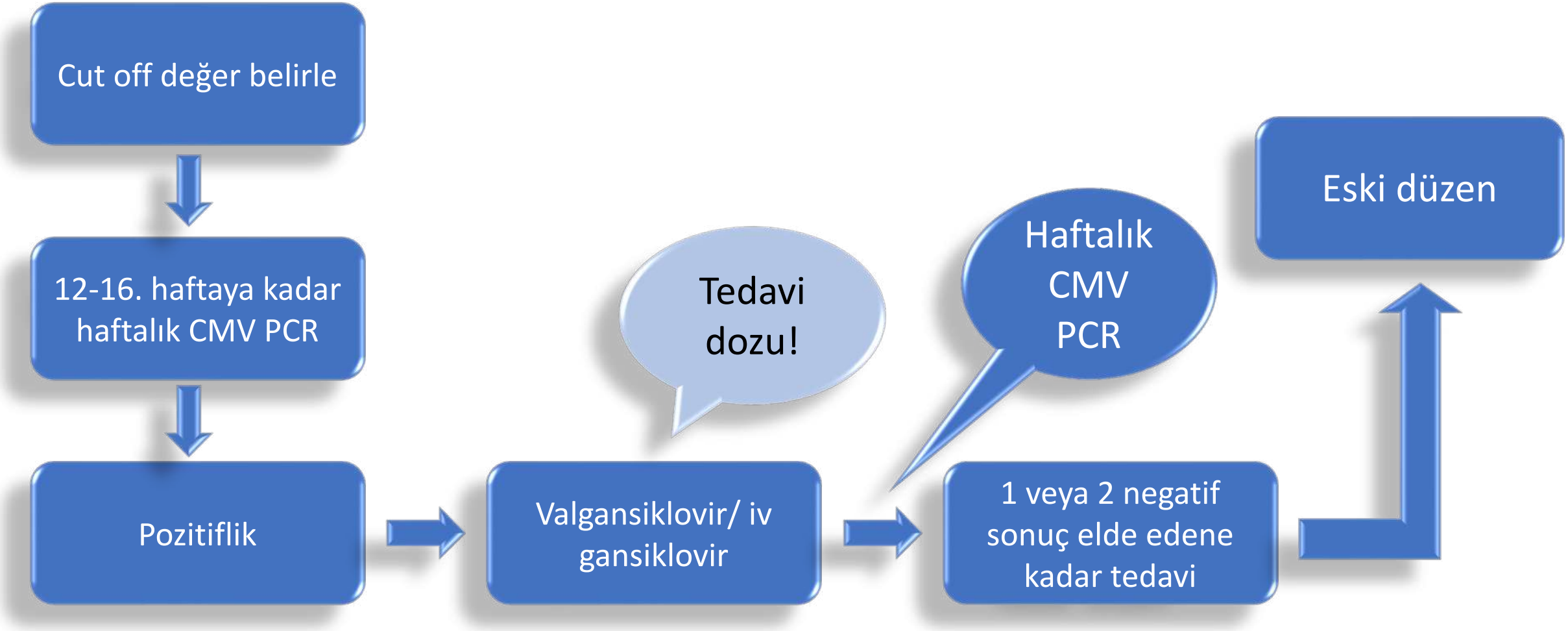
CMV KORUNMA

TABLE 2 Characteristics of antiviral prophylaxis and preemptive therapy

	Antiviral prophylaxis	Preemptive therapy
Clinical efficacy	Yes (based on large randomized controlled clinical trials)	Yes (based on fewer and smaller trials), including D+/R− kidney and liver recipients
Ease of application	Easier to coordinate	More difficult to coordinate Viral load thresholds not defined; each program should develop viral load thresholds for various clinical indications
Delayed-onset CMV disease	Common in CMV D+/R− transplant recipients (post-prophylaxis delayed-onset CMV disease)	Less common
Cost	Higher drug costs	Higher laboratory costs
Toxicity	Greater drug toxicity (myelosuppression)	Lesser drug toxicity with shorter courses of antiviral therapy
Indirect effects (graft loss, mortality, and opportunistic infections)	Positive impact (meta-analyses and limited comparative trials)	Very limited data
Drug resistance	Yes	Yes

Razonable RR et al. Cytomegalovirus in solid organ transplant recipients-Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019 Sep;33(9):e13512

Preemptif tedavi yaklaşımı



CMV TANI

- Serolojinin yeri yok.
- Hastanın riskini belirlemede yardımcı → En riskli grup: D+/R-

- Tanı ve tedavi yanıtı takibinde → Viral yük

- pp65 antijenemi testi →
  - Standardizasyonu yok
  - Subjektif
  - Nötrofil sayısı < 1000 olduğunda duyarlılığı düşük
- Qantiferon CMV (henüz net değil)

CMV-negative blood or leuko-depleted blood products **(strong, high)**.

- For the prevention of postprophylaxis delayed-onset CMV disease:
  - CMV QNAT at least once weekly for 3 months may be considered for surveillance to detect CMV replication after completion of antiviral prophylaxis **(strong, low)**. Detection of CMV DNA above a predefined threshold should be preemptively treated with valganciclovir or intravenous ganciclovir.
  - Transplant recipients should be counseled of the risk of postprophylaxis delayed-onset CMV disease upon discontinuation of antiviral prophylaxis (**strong, low**). Close clinical follow-up is highly recommended **(strong, low)**.
  - Measures of lymphopenia **(weak, low)** and impairment in global (nonspecific) and CMV-specific T-cell responses **(strong, moderate)** at the end of antiviral prophylaxis may be used to assess the risk of postprophylaxis delayed-onset CMV disease.

9 | FUTURE RESEARCH DIRECTIONS

There are a number of areas that are being actively explored in basic, translational and clinical research fields related to CMV disease diagnosis, prevention, and treatment. Despite widespread adaption of the WHO International Reference Standard for calibration, there remains clinically significant variability in viral load values. Hence, the search continues to define widely applicable viral load thresholds that should guide risk stratification, preemptive therapy, and therapeutic assessments. Clinical and commercial laboratories are encouraged not only to calibrate CMV QNAT assays based on the recently available WHO International Reference Standard, but also to work further to standardize the other steps in CMV QNAT. In the meantime, transplant providers should develop center-specific/assay-specific and patient population-specific viral load thresholds for different CMV QNAT clinical applications.

Numerous in-house (laboratory-developed) and commercial assays for the assessment of CMV-specific T-cell immunity are available to predict the risk of CMV disease in adults.[82,113,161] However, studies to assess the validity and utility of CMV immune assays in

Future Directions

- Directly compare QNAT monitoring in plasma, whole blood, and BAL specimens with respect to disease prediction and monitoring response to therapy with an emphasis on using commercially available testing systems.
- Determine commutability and harmonization using the WHO International Standard for whole blood and BAL.
- To improve harmonization of QNAT, determine the viral form (virions, fragmented, or genomic CMV) and viral kinetics in whole blood.
- Assess the role of digital QNAT to improve standardization of copy number assignment for secondary standards.
- Once viral load tests are harmonized, establish thresholds and kinetics for DNAemia for initiating preemptive therapy.
- Compare the performance characteristics of the different serologic tests and assess the utility of CMI assays and QNAT using a variety of sample types for the interpretation of passive immunity.
- Standardized/optimize/harmonize tests measuring neutralizing antibody in epithelial cells and fibroblasts when used to

TANIMLAR

CMV enfeksiyonu

Semptom ve bulgular olmadan izole CMV replikasyonu

CMV hastalığı

CMV sendromu

Ateş, halsizlik, lökopeni, trombositopeni

+ Viral replikasyon

Doku invaziv CMV

Organ hasarına ait bulgular (kolit, hepatit, pnomoni, nefrit, retinit)

+

CMV sendromu

Virüs izolasyonu, hızlı kültür, antijenemi ve NAT ile kanda CMV saptanması

+

En az ikisi

- ≥ 2 gündür olan ≥ 38 ° C ateş
- Yeni/artmış halsizlik (toxG2) veya Yeni/artmış yorgunluk (toxG3)
- En az 24 saat ara ile alınmış 2 ölçümde lökopeni/nötropeni
- ≥ %5 atipik lenfosit
- Trombositopeni
- ALT ve AST'de 2 kat artış (KC dışı nakillerde)

TEDAVİ

Oral tolerasyon?
Emilim ile ilgili süphe?
Hastalık ciddiyeti

- iv gansiklovir (5 mg/kg 12 saatte bir)
- Valgansiklovir (900 mg tb 2x1)

- İmmünsupresyonu azaltma (orta- ağır hastalıkta)
- Asiklovir veya oral gansiklovir önerilmiyor.
- Foskarnet ikinci tercih (ciddi nefrotoksik)
- Cidofovir üçüncü tercih (ciddi nefrotoksik)
- Letermovir, maribavir, brincidovir için daha fazla veriye ihtiyaç var.

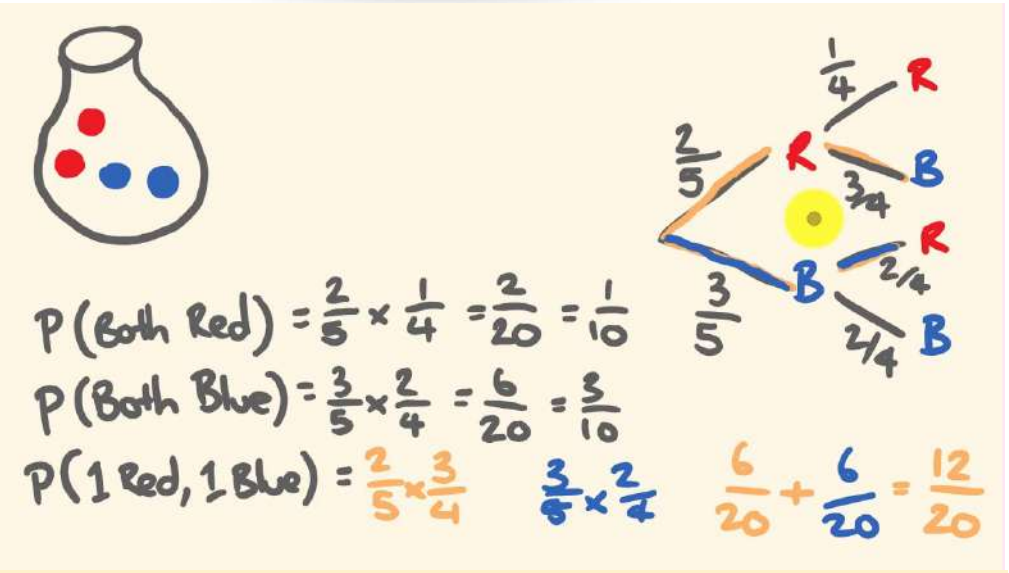
Razonable RR et al. Cytomegalovirus in solid organ transplant recipients-Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019 Sep;33(9):e13512

Hastamıza ne oldu?

PEKİ BKV??? (10^8 kopya/ml idrarda) Bir anlamı var mı???

Kreatinin: 1,43 mg/dl buarada

iv gansiklovir başladık



ihtimaller denizi……

İMMÜNSUPRESYON

DÜŞÜK DOZ

REJEKSİYON

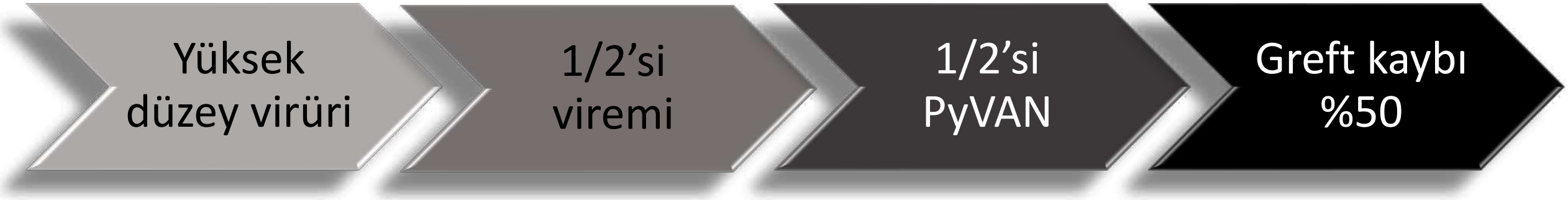
YÜKSEK DOZ

BK VİREMİSİ

BK NEFROPATİSİ

GREFT KAYBI

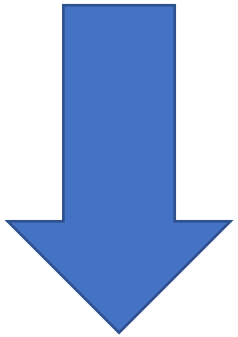
Böbrek nakil hastalarında %1-10 oranında polyoma virüs ilişkili nefropati (PyVAN)



Hirsch HH et al.BK polyomavirus in solid organ transplantation-Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019 Sep;33(9):e13528..

Nasıl izleyelim?

İlk 9 ay aylık, sonrasında post-tx 2 yıla kadar 3 ayda bir BKPyV-DNAemi



Hastaların%80-90'ı PyVAN greft fonksiyonlarında bozulmaya yol açmadan saptanabilir

Hirsch HH et al.BK polyomavirus in solid organ transplantation-Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019 Sep;33(9):e13528..

BK virüri/ viremi

İdrarda viral yük > 10^7 kopya/ml
Kanda > 10^4 kopya/ml

Probable PyVAN

BKPyV-DNAemi 3 hafta ara ile 2 ölçümde
>10^3 kopya/ml

Presumptive PyVAN

BKPyV-DNAemi en az bir ölçümde
>10^4 kopya/ml

Hirsch HH et al.BK polyomavirus in solid organ transplantation-Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019 Sep;33(9):e13528..

PyVAN TANI

- Kesin tanı = Dokuda BK virüse bağlı sitopatik değişikliklerin gösterilmesi, immünhistokimya veya in situ hibridizasyon ile doğrulanması

- Minimum 2 biyopsi parçası alınmalı ve tercihen medullar doku içermeli

- Patolojik tanı semi-kantitatif olmalı. Standart değerlendirme ve raporlama için kategorileri mevcut (PyVAN-A, PyVAN-B, PyVAN-C)

Pattern	Description	Extent of biopsy core	Graft function	Risk of graft loss
PyVAN-A				
Viral cytopathic changes	Mild	≤25%	Mostly baseline	<10%
Interstitial inflammation	Minimal	≤10%		
Tubular atrophy	Minimal	≤10%		
Interstitial fibrosis	Minimal	≤10%		
PyVAN-B[a]				
Viral cytopathic changes	Variable	11%->50%	Mostly impaired	50%
Interstitial inflammation	Significant	11%->50%		
Tubular atrophy	Moderate	<50%		
Interstitial fibrosis	Moderate	<50%		
PyVAN-B1				
Interstitial inflammation	Moderate	11%-25%	Slightly above baseline	25%
PyVAN-B2				
Interstitial inflammation	Significant	26%-50%	Significantly impaired	50%
PyVAN-B3				
Interstitial inflammation	Extensive	>50%	Significantly impaired	75%
PyVAN-C				
Viral cytopathic changes	Variable	Variable	Significantly impaired	>80%
Interstitial inflammation	Variable	Variable	Progressive failure	
Tubular atrophy	Extensive	>50%		
Interstitial fibrosis	Extensive	>50%		

PyVAN class-1		PyVAN class-2		PyVAN class-3	
PyVL	Banff *ci* score	*PyVL*	Banff *ci* score	*PyVL*	Banff *ci* score
1	0-1	1	2-3	–	–
–	–	2	0-3	–	–
–	–	3	0-1	3[b]	2-3

Hidrasyon sonrası takipte kreatinin 1,65 mg/dl

İmmünsupresyonu azaltalım mı?

Biyopsi yapalım mı?

Reject riski yoks… bozulma yoksa imm… biyop… …nda …önce

Tamam da kanda BKPyV negatif

civarındadır (ct1/ci1). Tübül epitel hücrelerinde yer yer belirginleşe
ve nükleol belirginlikleri dikkati çekmiştir.
Belirgin arter veya arteriol saptanmamıştır.

UYGULANAN ÖZEL YÖNTEMLER

910.260 - Böbrek, Biyopsi İğne / 911.180-11.1 - İmmünhistokimyasal İnceleme -
911.180-137.1 - İmmünhistokimyasal İnceleme - SV40 (MRQ-4)
911.160-5 - Histokimyasal Boyamalar - Massosn´s Trichome
911.160-6 - Histokimyasal Boyamalar - Periodic Acid Schiff
911.160-3 - Histokimyasal Boyamalar - Congo Red for Amyloid
911.160-4.1 - Histokimyasal Boyamalar – Kristal Violet (CV)

Histokimyasal olarak yapılan kristal viole veya kongo red ile belirgi
İmmunfloresan inceleme biyopsi materyalinin tanısal yeterliliğinin
İmmunhistokimyasal olarak yapılan C4d ile, sınırlı bir alanda peritü
undan azında boyanma vardır (c4d1).
SV40 antikoru ile tübül epitel hücrelerinde, biyopsi materyalinin %
saptanmıştır.

TANI **POLYOMA VİRÜS NEFROPATİSİ (CLASS 3); Transplant böbrek (**

ICD-O KODU 0000/0 - Neoplazma rastlanmamıştır.

YORUM / NOT Biyopsi materyalinin tanısal yeterliliği sınırlı olup, interstisyel aland
kapillerler, vasküler yapılar ve glomerüler kompartmanlarla ilişkisi
rejeksiyon niteliği hakkında ileri yorum yapılamamıştır.

Böbrek nakil alıcılarında proven PyVAN'de kanda, idrarda veya greftte BKPyV-DNAemi saptanmazsa JCPyV nefropatisinden şüphelenilmeli

Tedavi azaltılması = İmmünsupresyonun

1- Kalsinörin inhibitörünün %25-50 azaltılması
2- Antiproliferatif ilaçların %
azaltılması
3- Antiproliferatif ila

1- roliferatif ilaçların %50
asi
nhibitörünün %25-50
if ilaçların kesilmesi

Eş zamanlı reject varsa önce anti-reject tedavisi

g/mL
rolimu < 6 ng/mL
- MMF günlük doz ≤ 1000 mg

İmmünsupresyonun azaltılması rağmen devam eden viremi varlığında

- Sidofovir??
- Leflunomid??
- IVIG??
- Florokinolonlar???

Üstünlükleri gösterilmedi!

Helikaz üzerinden antiBKV etkileri olduğu belirtilse de 2 RCT faydası olmadığını göstermiştir

PyVAN nedeniyle greft kaybı gelişen hastaya tekrar böbrek transplantasyonu yapılabilir mi?

BKV replikasyonu olmadığından eminsen

Hastanın immünsupresif dozu azaltıldı. CMV ne durumda?

Refrakter CMV enfeksiyonu mu?

Kesin: 2 hafta uygun dozda tedaviye rağmen >1 log artış

Olası: 2 hafta uygun dozda tedaviye rağmen <1 log artış veya aynı düzey

Hastanın kliniği daha iyi, CMV DNA neden düşmedi?

- Aynı tip örnek (tam kan/plazma)
- Aynı cihaz
- Aynı kit
- WHO onaylı

Kitler arasında 10^3 kopyaya kadar farklılık bildirilmiş.

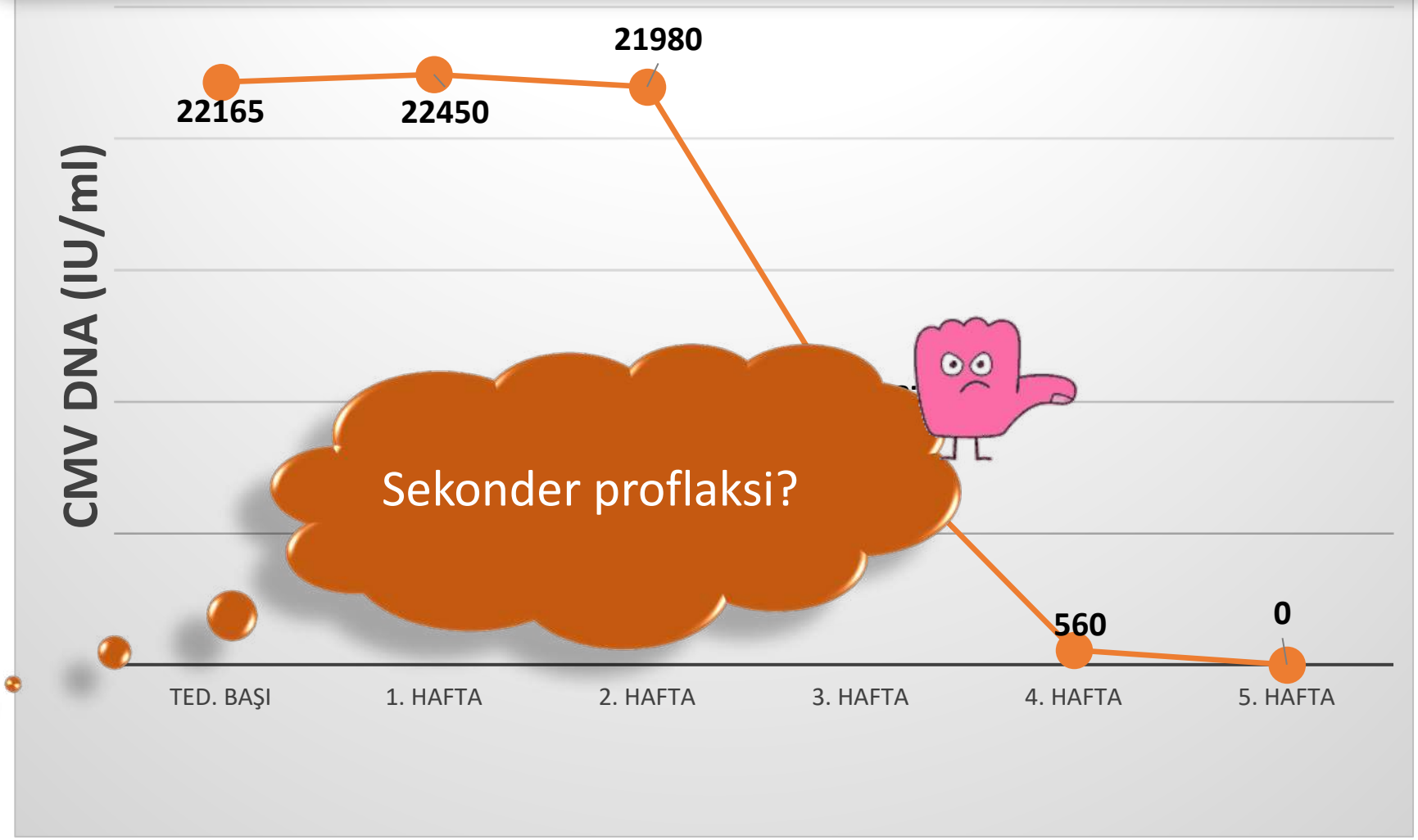
Hem hücre içi hem de hücre dışı virüsler saptandığı için tam kanda viral yük daha fazla (yaklaşık 10 kat- 1 log-)

Pang XL et al. Interlaboratory comparison of cytomegalovirus viral load assays. Am J Transplant 2009; 9: 258–268
Lisboa LF, al. The clinical utility of whole blood versus plasma cytomegalovirus viral load assays for monitoring therapeutic response. Transplantation 2011; 91:231

Kantitatif PCR

- 2010’da WHO CMV için International Reference Standard geliştirdi.
- IU/mL
- FDA tarafından onaylı 3 test

Hastanın kemik iliği supresyonu düzeldi, şikayetleri geriledi. Tedaviye aynı şekilde devam



Tedavi Süresi

- En az 14 gün
- Klinik düzelme
- QNAT veya antijenemi testi negatifleşene kadar
- 1-2 negatif sonuç

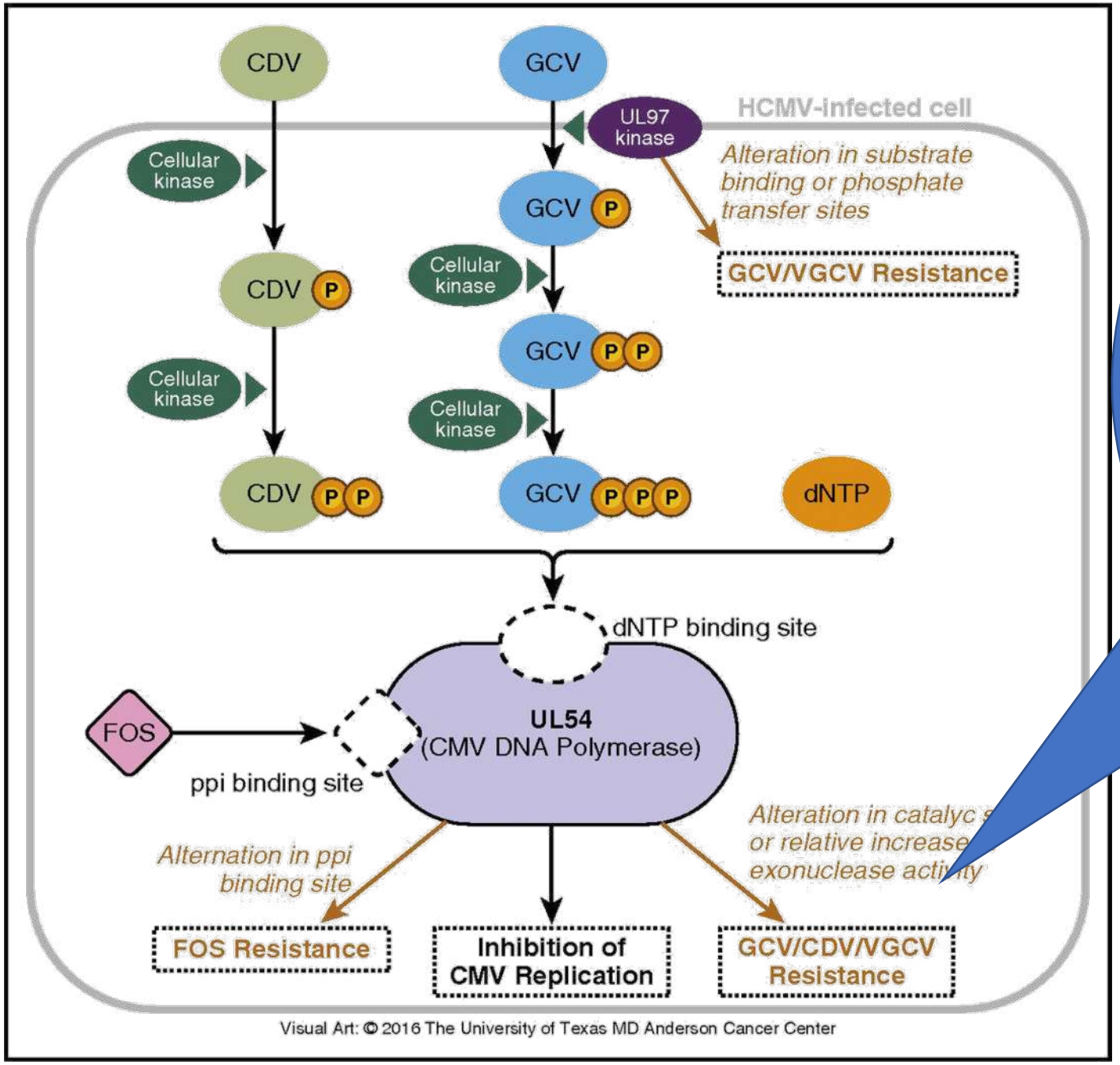
Refrakter CMV enfeksiyonu

- Yoğun immünsupresyon
- Subterapötik antiviral konsantrasyonu
- Gansiklovir direnci

Risk Faktörü

Gansiklovir direnci Risk faktörü

- Uzamış subterapötik antiviral maruziyeti
- D+/ R– serostatus
- Yoğun immünsupresyon



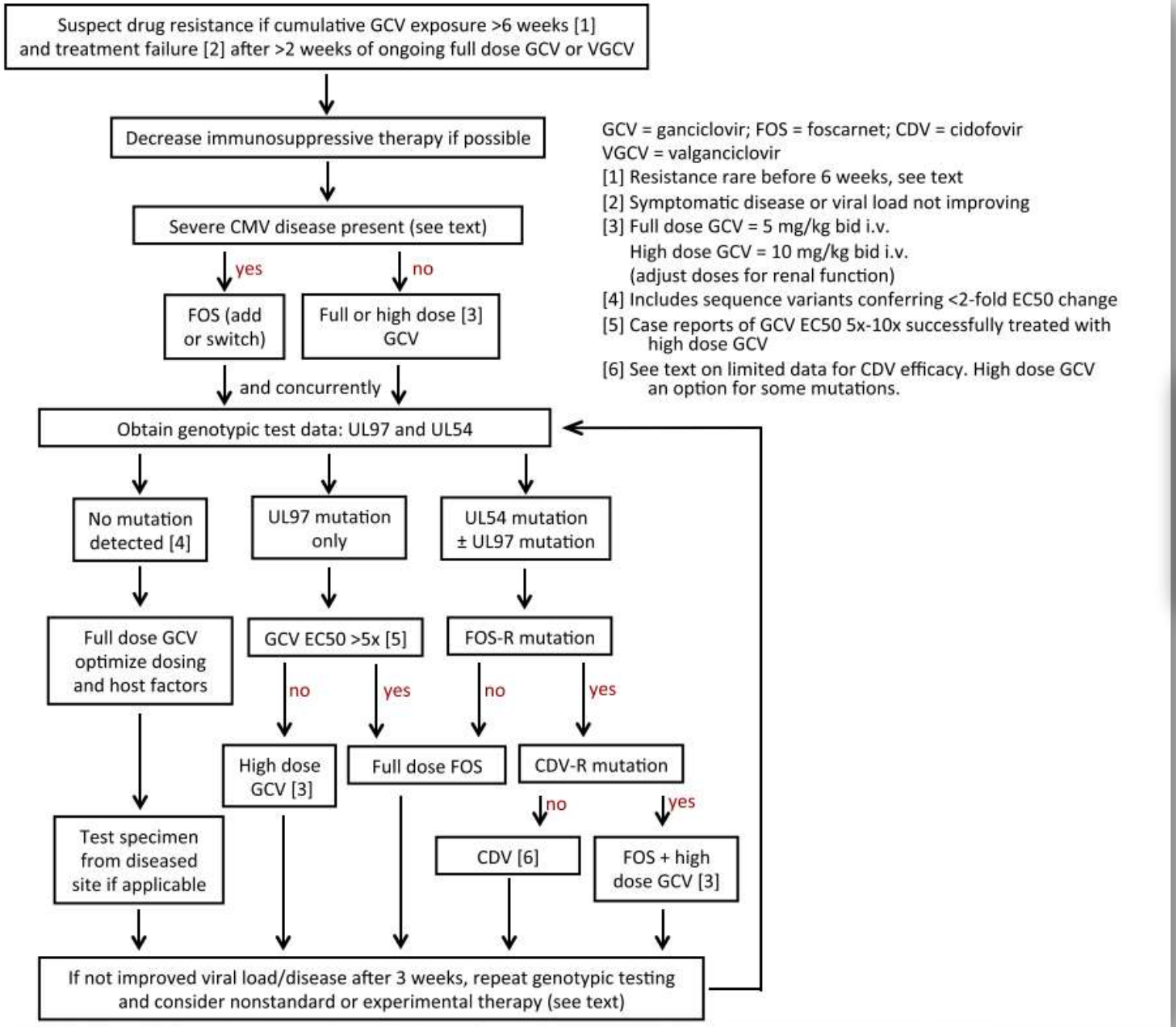
Genellikle D+/R-
Akciğer tx

Böbrek tx CMV enfeksiyonu veya hastalığında gansiklovir direnci %1-2

Lurain NS, Chou S. Clin Microbiol Rev 2010; 23: 689.
Myhre HA et al.. Transplantation 2011; 92: 217
Fisher CE et al. Clin Infect Dis. 2017 Mar 29

- UL54 mutasyonu nadir, genellikle UL97 (%90)
- UL97 + UL54 → Yüksek düzey gansiklovir direnci
- Direnç analizi için >1000 kopya/ml gerekli
- UL97 mutasyonuna bağlı gansiklovir dirençli CMV izolatları genellikle foskarnet ve sidofovire duyarlı

Gansiklovire yanıtsız CMV hastalığı mevcut hastaların çoğunda mutasyon saptanmıyor



Dirençli/ refrakter CMV'de maribavir faz 3 çalışması mevcut..

Alternatifler

Sirolimus ve diğer mTOR inhibitörleri CMV hastalığı açısından daha düşük riskli immünsupresif ajanlar

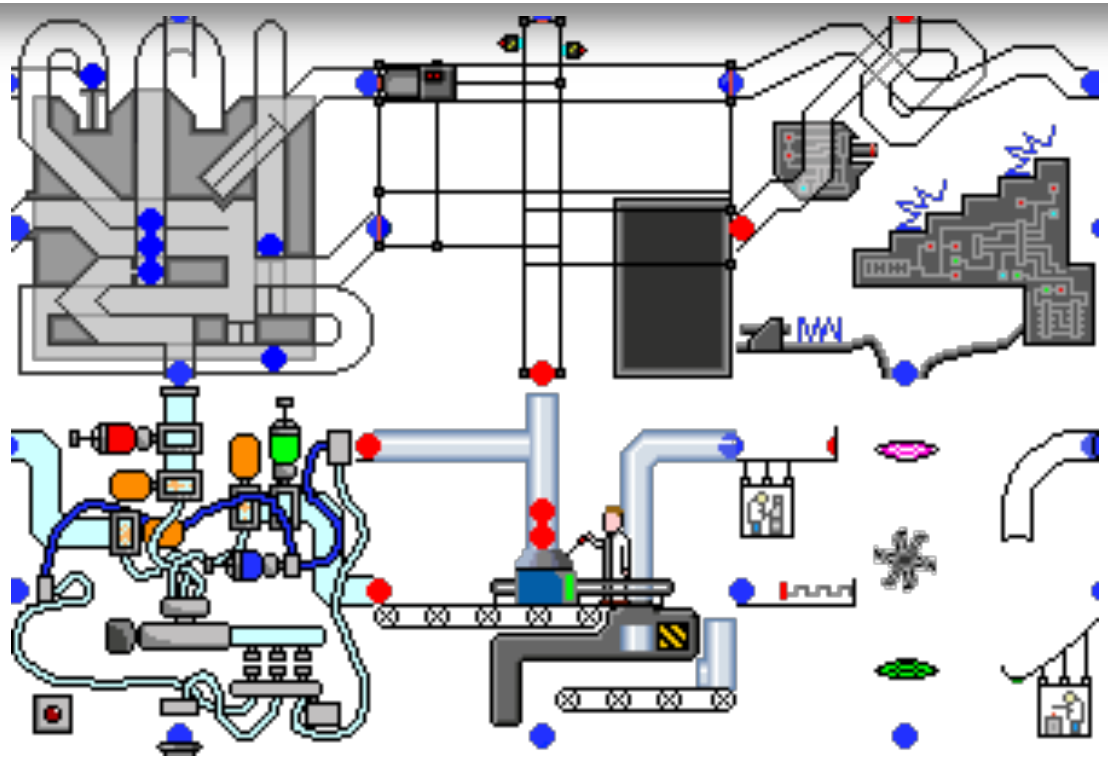
Tedavi modifikasyonu

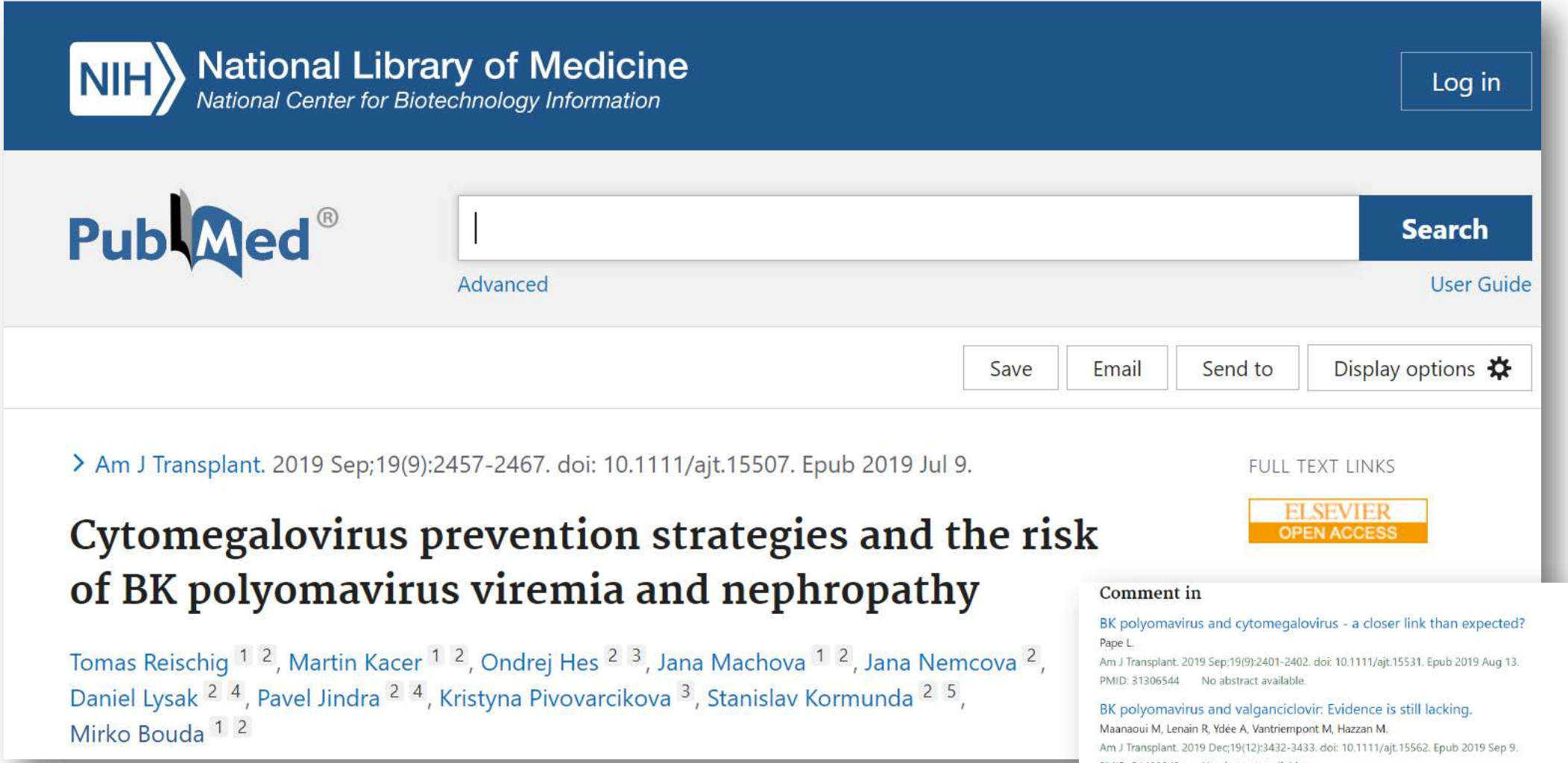
CMV Ig

Transplantation. 2013 Dec 27;96(12):1097-103. doi: 10.1097/TP.0b013e3182a6890d.

CMV Viremia is associated with a decreased incidence of BKV reactivation after kidney and kidney-pancreas transplantation

Nissreen Elfadawy [1], Stuart M Flechner, Xiaobo Liu, Jesse Schold, Titte R Srinivas, Emilio Poggio, Richard Fatica, Robin Avery, Sherif B Mossad

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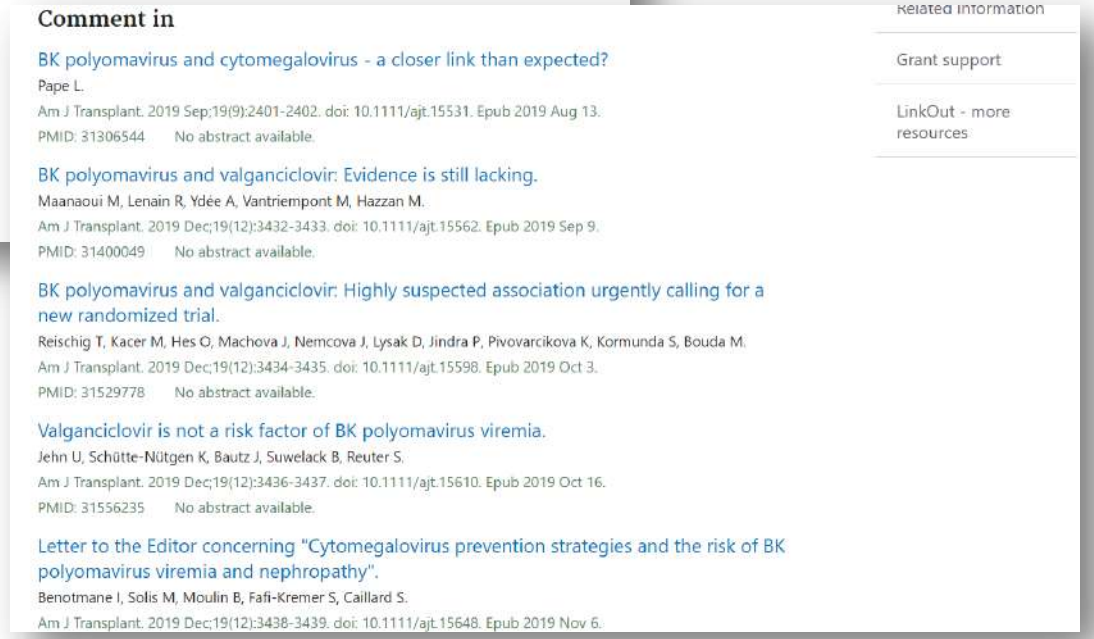
Send to
Display options
Am J Transplant. 2019 Sep;19(9):2457-2467. doi: 10.1111/ajt.15507. Epub 2019 Jul 9.
FULL TEXT LINKS
ELSEVIER
OPEN ACCESS
Cytomegalovirus prevention strategies and the risk of BK polyomavirus viremia and nephropathy
Tomas Reischig [1 2], Martin Kacer [1 2], Ondrej Hes [2 3], Jana Machova [1 2], Jana Nemcova [2], Daniel Lysak [2 4], Pavel Jindra [2 4], Kristyna Pivovarcikova [3], Stanislav Kormunda [2 5], Mirko Bouda [1 2]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Am J Transplant. 2019 Dec;19(12):3438-3439. doi: 10.1111/ajt.15648. Epub 2019 Nov 6.
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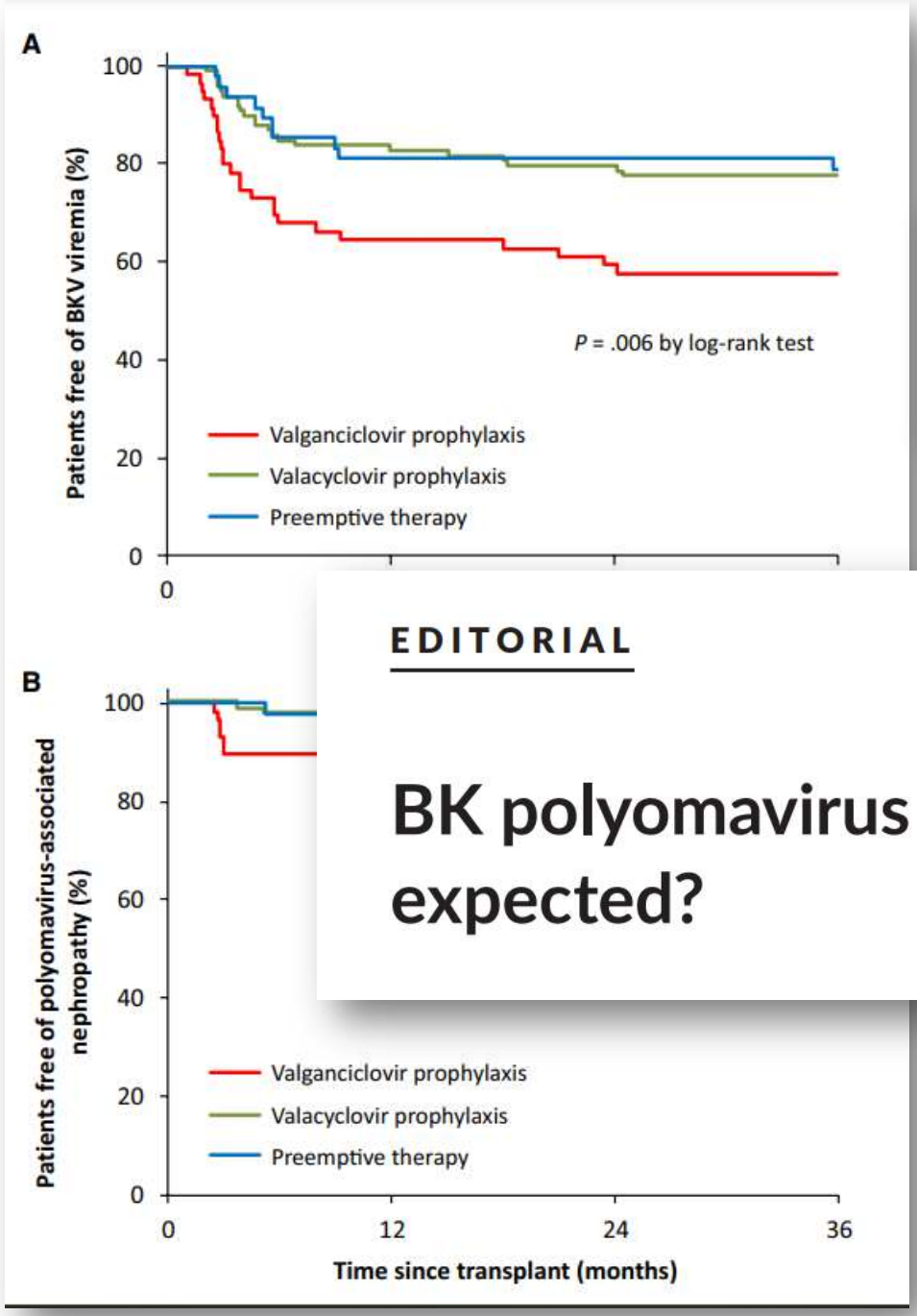

Gansiklovir BKV-specific T cell immünitesini inhibe ediyor olabilir??

EDITORIAL

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BK polyomavirus and cytomegalovirus – a closer link than expected?

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Ulrich Jehn • Katharina Schütte-Nütgen • Joachim Bautz • Barbara Su

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Ilies Benotmane • Morgane Solis • Bruno Moulin • Samira Fafi-Kremer • Sophie Caillard

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Clinical features of BK-polyomavirus and cytomegalovirus co-infection after kidney transplantation

Ulrich Jehn[1]✉, Katharina Schütte-Nütgen[1], Joachim Bautz[1], Hermann Pavenstädt[1], Barbara Suwelack[1], Gerold Thölking[1,2] & Stefan Reuter[1]

Brief Communication

Outcome of Renal Transplant Recipients with Cytomegalovirus and BK Polyomavirus co-infection Nephropathy

Anupma Kaul[1], Shashi Kumar[1], Dharmendra Bhaduaria[1], Vinita Agrawal[2], R. K. Sharma[1], Narayan Prasad[1], Amit Gupta[1], Rishi Kumar[1]

Departments of [1]Nephrology and [2]Pathology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, Uttar Pradesh, India

Hastamıza ne oldu?

6 hafta gansiklovir tedavisi

BKPyVAN için tüm immünsupresif ajanlarının dozu azaltıldı

Kreatinin değeri 1. ayın sonunda normale döndü

İmmünsupresif dozu tekrar hiç arttırılmadı


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