Il ruolo della conoscenza per una corretta *governance* dell' HCV ed HIV

Giustino Parruti

UOC Malattie Infettie

AUSL Pescara

FONDAZIONE ONLUS
CAMILLO DE LELLIS
per l'innovazione e la ricerca in medicina

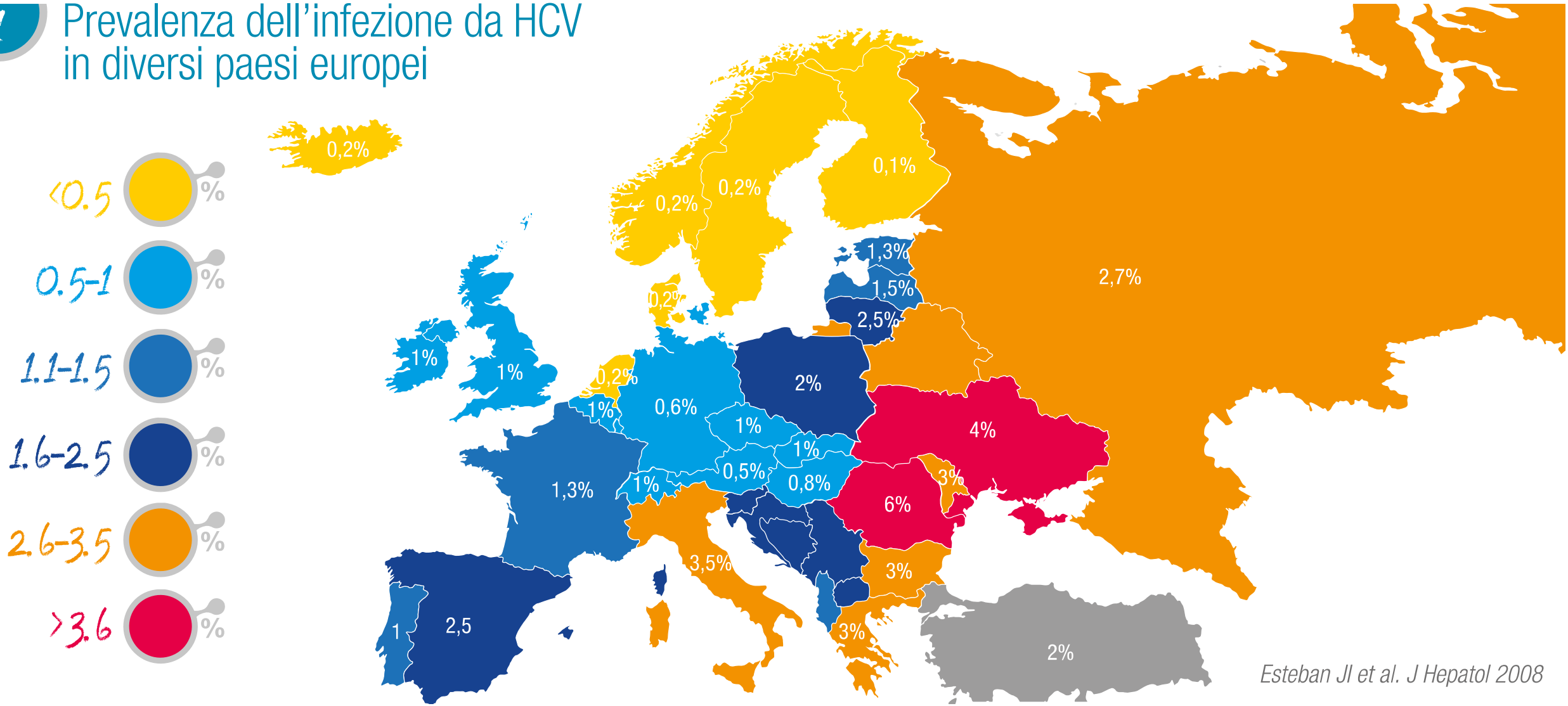
Azienda USL di Pescara

Parte 1: come la RWE ci ha aiutato per la lotta all'eradicazione di HCV?

- Da cosa siamo partiti in Abruzzo: quanti sono i nostri pazienti?
- Il nostro accesso ai "big datasets"
- La rivalutazione sulla scorta del dato "reale"
- La quantificazione della domanda assistenziale per HCC mediante analisi RWE basate sui dati delle Schede di Dimissione Ospedaliera

FIGURA 1

Prevalenza dell'infezione da HCV in diversi paesi europei



Esteban JI et al. J Hepatol 2008

I dati sull'Italia

- In Italia i dati di sieroprevalenza sono disomogenei, suggerendo un'aggregazione di aree antropiche tra loro differenti

ARTICLE IN PRESS

Review

EASL EUROPEAN ASSOCIATION FOR THE STUDY OF THE LIVER | JOURNAL OF HEPATOLOGY

Global epidemiology and genotype distribution of the hepatitis C virus infection

Erin Gower, Chris Estes, Sarah Blach, Kathryn Razavi-Shearer, Homie Razavi*

Center for Disease Analysis, Louisville, CO, USA

1-2% al Nord

≥3% al Centro

>10% in alcuni distretti del Sud ed Isole

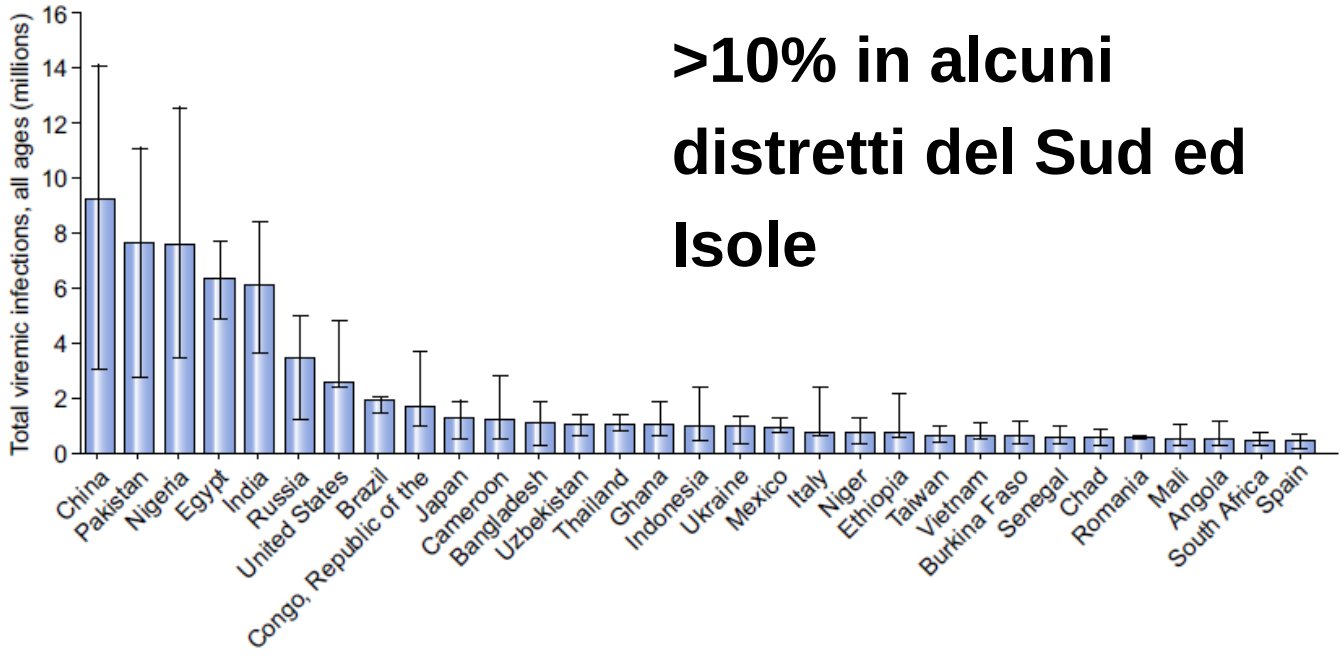


Table 1. Prevalence of anti-HCV in General Population based studies

Authors	Site of study	Target population	n	Year(s) of study	Age	Overall prevalence of anti HCV (%)
Cozzolongo et al [24]	Castellana Grotte (Bari)	Systematic random 1 in 5 sampling procedure from census	2195	2005 - 2007	18 - 93	2.6
Mazzeo et al [25]	Loiano and Monghidoro (Bologna)	All subject were invited to testing	1847	1986 - 1996	18 - 69	3.5
Campello et al [26]	Area of Local healt Unit 22 of Lombardia Region	Inhabitants of areas were invited to partecipate	2570	1994 – 1995	17 – 67	3.3%
Ansaldi et al [27]	20 Italian Hospital	Test were performed from residual serum of European Serum Epidemiology Network	3577	1996 - 1997	0 - 90	2.7

Table 1. Prevalence of anti-HCV in General Population based studies

Authors	Site of study	Target population	n	Year(s) of study	Age	Overall prevalence of anti HCV (%)
Bellentani et al [28]	Campogliano (Modena) and Cormons (Gorizia)	All abitans of 2 towns received a written invitation	6917	1991 - 1993	12- 65	3.2
Guadagnino et al [19]	Sarsale (Catanzaro)	Subject selected from census were invited for blood anti HCV testing	1352	1996	7 – 91	12.6
Guadagnino et al [17]	Sarsale (Catanzaro)	Subject selected from census were invited for blood anti HCV testing	1012	2010	> 18	5.7
Maio et al [18]	Buonalbergo (Napoli)	Subject selected from census by cluster random procedure	488	1997	6 – 87	16.2
Di Stafano et al [20]	Camporeale (Palermo)	800 subject were selected random from census	721	1999 – 2000	10-90	10.4
Pendino et al [22]	Citanova (Reggio Calabria)	Systematic random 1 in 5 sampling procedure from census	1645	2002 – 2003	12 – 95	6.5
Fabris et al [23]	Vicenza	Tests were offered at a quarter of the city	965	2002	0 - 90	2.6
Raffaele et al [21]	Gioia dei Marsi and Lecce dei Marsi (L'Aquila)	Random sampling from census	250	1997	> 16	22.4

Che ne è dell'Abruzzo

- Nella Regione Abruzzo erano disponibili scarsi dati recenti
- Negli ultimi 20 anni, ad ogni modo, sono state raccolte informazioni su piccoli campioni di popolazione ed in ristrette aree geografiche
- Sono state rilevate in tutti i casi prevalenze superiori alla media nazionale

European Journal of Epidemiology **17**: 41–46, 2001.

High prevalence of HCV infection among the general population in a rural area of central Italy

A. Raffaele[1], M. Valenti[2], M. Iovenitti[1], A. Matani[1], M.L. Bruno[1], E. Altobelli[2], A. D'Alessandro[3], R. Barnabei[3], B. Leonardis[3] & G. Taglieri[1]
[1]*Chair of Geriatrics;* [2]*Chair of Epidemiology, Department of Internal Medicine and Public Health, University of L'Aquila;* [3]*Clinical Pathology Service, Ospedale San Salvatore, Local Health Unit 04, L'Aquila, Italy*

Accepted in revised form 20 March 2001

- **Studio condotto da marzo e luglio 1997**
- **344 individui selezionati casualmente da un totale di 3308 abitanti (età >16 anni) residente nei comuni di Gioia dei Marsi e Lecce dei Marsi**
- **250 pazienti accettarono di sottoporsi al test**
- **La prevalenza riscontrata è stata del 22.4%**

Infection
DOI 10.1007/s15010-015-0841-3

ORIGINAL PAPER

High seroprevalence of HCV in the Abruzzo Region, Italy: results on a large sample from opt-out pre-surgical screening

Ennio Polilli[1] · Monica Tontodonati[1] · Maria Elena Flacco[2,3] · Tamara Ursini[1] · Palmira Striani[4] · Dante Di Giammartino[5] · Maurizio Paoloni[6] · Luigi Vallarola[7] · Gabriella Lucidi Pressanti[7] · Giorgia Fragassi[2] · Patrizia Accorsi[4] · Lamberto Manzoli[2,3] · Giustino Parruti[1]

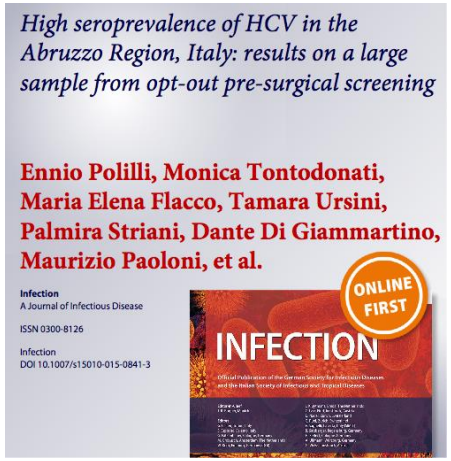


Table 1 Overall characteristics of the patients

	Overall	Pescara general hospital		Teramo general hospital
		Surgery unit	Orthopedic unit	Orthopedic unit
Screened patients, *n*	55,533	23,213	20,306	12,014
HCV prevalence, (%)	4.43	5.13	4.88	2.34
Males, %	48.7	52.2	46.0	46.4
Mean age in years (SD)	58.5 (22.3)	58.3 (21.1)	58.6 (24.0)	58.5 (21.4)
Age class in years, *n*				
<30	7524	2932	3164	1428
30–39	4692	2171	1591	930
40–49	5377	2322	1872	1183
50–59	6102	2557	1972	1573
60–69	7207	3300	2223	1684
70–79	9692	4151	3327	2214
>79	10,580	3891	4624	2065
Among anti-HCV-positive patients				
Males, %	49.2	55.8	42.4	48.5
Age, mean ± SD (years)	63.8 ± 19.6	62.0 ± 19.5	60.0 ± 20.1	63.6 ± 19.4

Infection
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High seroprevalence of HCV in the Abruzzo Region, Italy: results on a large sample from opt-out pre-surgical screening

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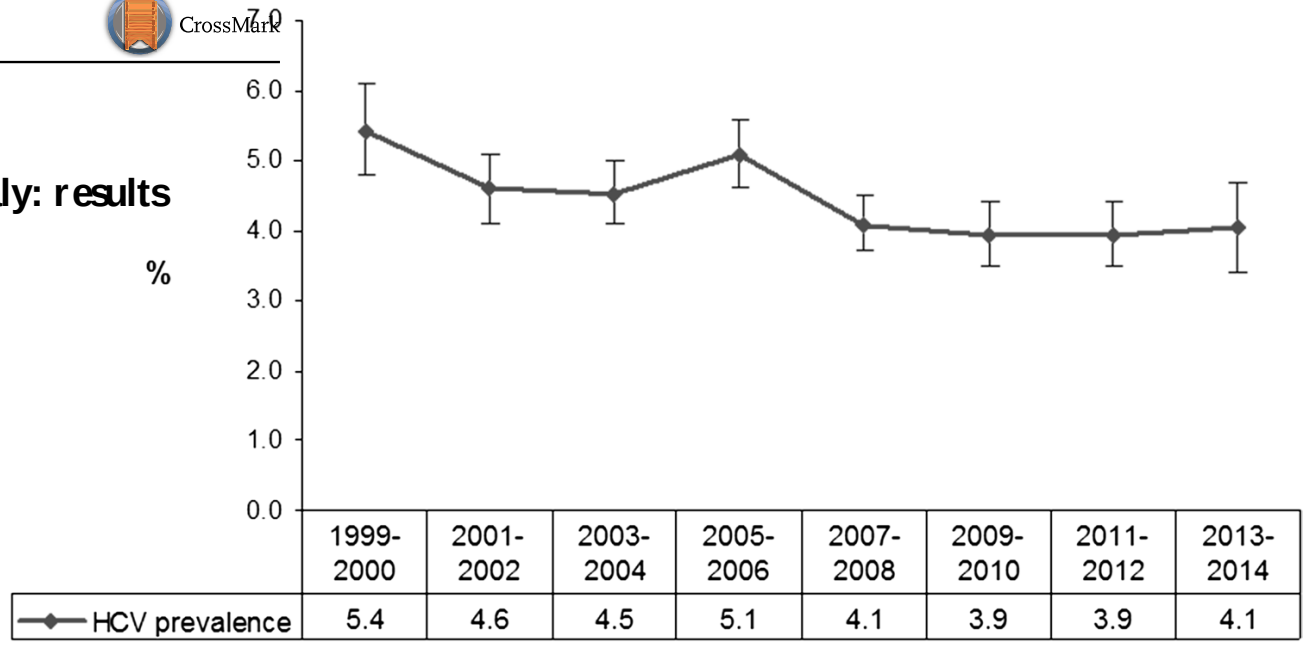
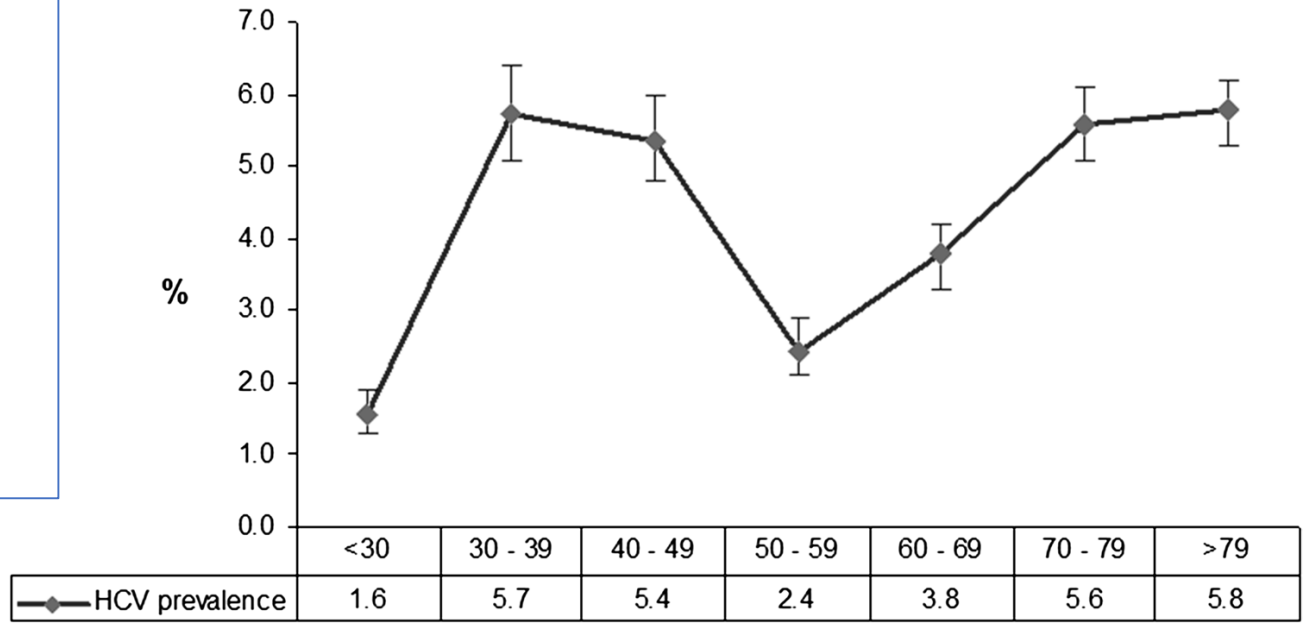
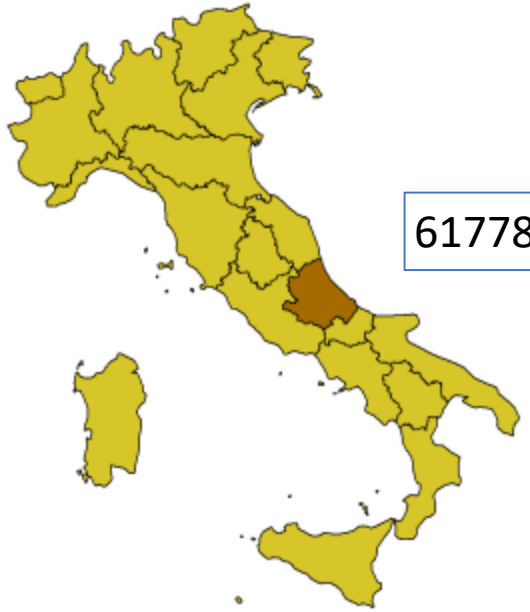


Un risultato imprevisto:

- In termini di entità del problema
- In termini di fasce di età interessate
- Lo stimolo a elaborare una strategia di cattura in cura efficace
- La prospettiva di una catastrofica incidenza di HCC per altri 20 anni in assenza di una strategia appropriata

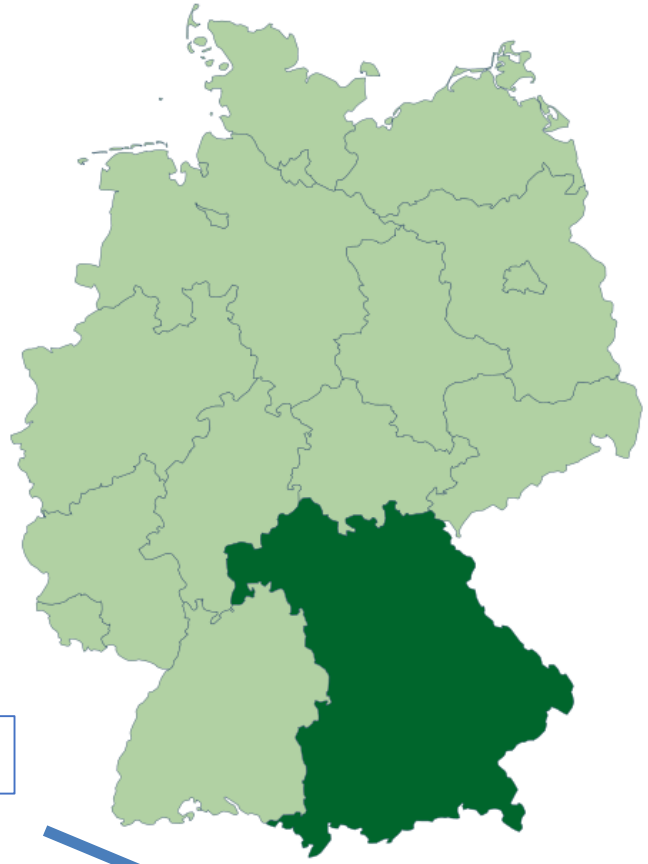




61778 infetti cronici

HCV 4.6%

HCV 0.4%



50332 infetti cronici

Historical population		
Year	Pop.	±%
1861	858,000	—
1871	906,000	+5.6%
1881	946,000	+4.4%
1901	1,070,000	+13.1%
1911	1,116,000	+4.3%
1921	1,131,000	+1.3%
1931	1,168,000	+3.3%
1936	1,202,000	+2.9%
1951	1,277,000	+6.2%
1961	1,206,000	−5.6%
1971	1,167,000	−3.2%
1981	1,218,000	+4.4%
1991	1,249,000	+2.5%
2001	1,262,000	+1.0%
2011	1,343,000	+6.4%

Source: ISTAT 2001

Population and area [edit]

Administrativ region	Capital	Population (2011)		Area (km²)		No. municipalities	
Lower Bavaria	Landshut	1,192,641	9.48%	10,330	14.6%	258	12.5%
Lower Franconia	Würzburg	1,315,882	10.46%	8,531	12.1%	308	15.0%
Upper Franconia	Bayreuth	1,067,988	8.49%	7,231	10.2%	214	10.4%
Middle Franconia	Ansbach	1,717,670	13.65%	7,245	10.3%	210	10.2%
Upper Palatinate	Regensburg	1,081,800	8.60%	9,691	13.7%	226	11.0%
Swabia	Augsburg	1,788,729	14.21%	9,992	14.2%	340	16.5%
Upper Bavaria	Munich	4,418,828	35.12%	17,530	24.8%	500	24.3%
Total		**12,583,538**	**100.0%**	**70,549**	**100.0%**	**2,056**	**100.0%**

AIDS PATIENT CARE and STDs
Volume 30, Number 10, 2016

DOI: 10.1089/apc.2016.0082

Web-Based HIV Testing in Abruzzo, Italy: Analysis of 15-Month Activity Results

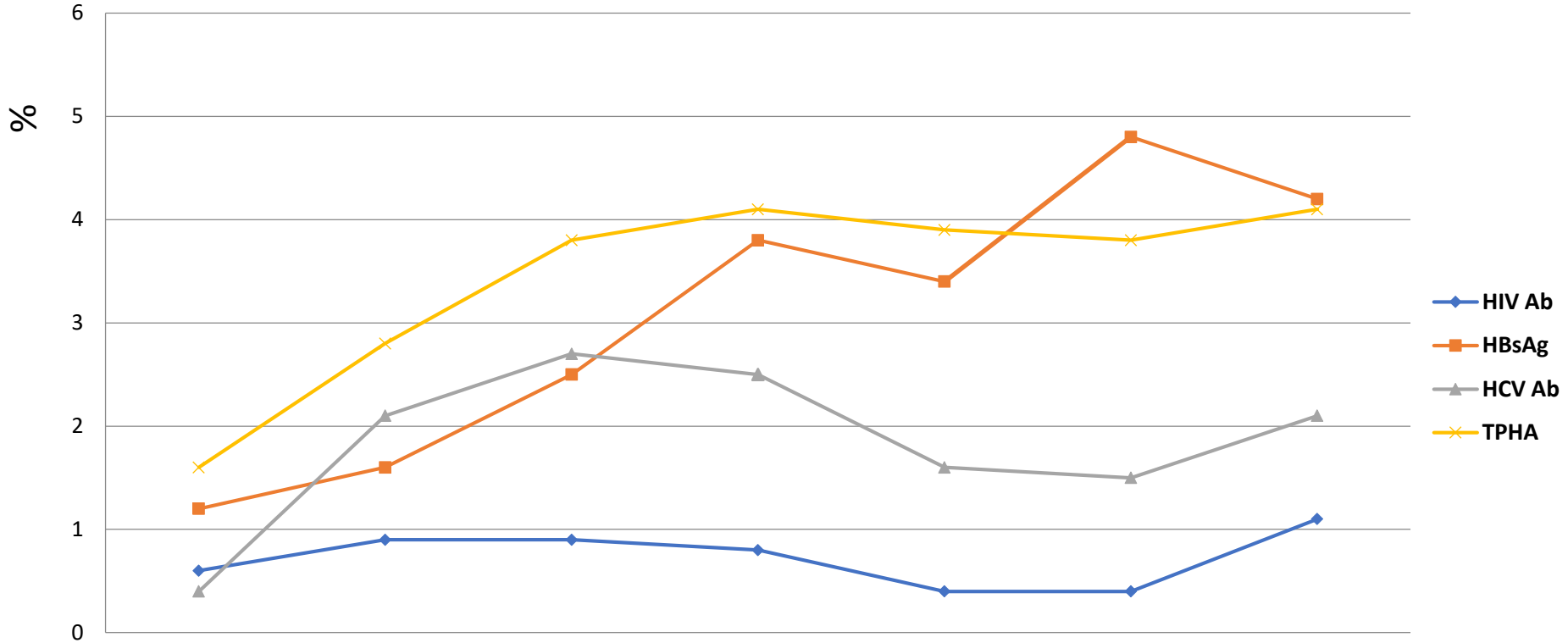
Ennio Polilli, BSc,[1] Federica Sozio, MD,[1] Paola Di Stefano, LPsy,[1] Antonina Sciacca, BMS,[1] Tamara Ursini, MD,[1] Maurizio Paoloni, MD,[2] Jacopo Vecchiet, MD,[3] Dante Di Giammartino, MD,[4] Maria Pina Sciotti, MD,[5] Alessandro Grimaldi, MD,[6] Valerio Cortesi, MD,[7] Paolo Fazii, MD,[8] Elena Ricci, ScD, PhD,[9] Claudio D'Amario, MD,[10] Giuseppe Ippolito, MD,[11] Lucio Pippa, MD,[12] and Giustino Parruti, MD, PhD[1]

Abstract

Undiagnosed cases of HIV infection in developed countries are estimated at 20–30% of individuals living with HIV. Web-based strategies may represent a new approach to easier, wider, and unrestricted access to early testing. The Abruzzo Region, Italy, developed a Web-based tool to recruit persons at high risk of HIV and other sexually transmitted infections (STIs). At the Website www.failtestanchetu.it, browsers found information on STIs (HIV, hepatitis B and C, and syphilis), a structured questionnaire called ''risk calculator'' to assess one's own risk behaviors and direct booking of their test at one of six sites throughout the region. The Website was advertised on local media and in pharmacies, high schools, sports facilities, and factories. Between February 1, 2014, and May 31, 2015, about 6000 users visited the Website; 3046 people attended a visit for counseling on risk behaviors, signs, or symptoms of STIs and accepted blood drawing for HIV, hepatitis B Virus (HBV), hepatitis C Virus (HCV), and syphilis tests. Fifty-eight (1.90%) subjects were positive for HCV, 56 (1.84%) for HBsAg, 90 (2.95%) for *Treponema pallidum* antibodies, and 28 (0.92%) for HIV. Ninety-two percent of HIV-positive patients were successfully linked to care. Late presenters were less frequent in this sample than in the population diagnosed with HIV in Italy in 2014. An overall 7% proportion of HIV, HBV, HCV, and syphilis-unaware cases were all transferred to care, with the exception of three people. HIV seropositivity among testers was higher than 2/1000, the cost-effectiveness threshold suggested for effective testing. Therefore, our Web-based unrestricted and free access methodology appears worth further and wider evaluation.

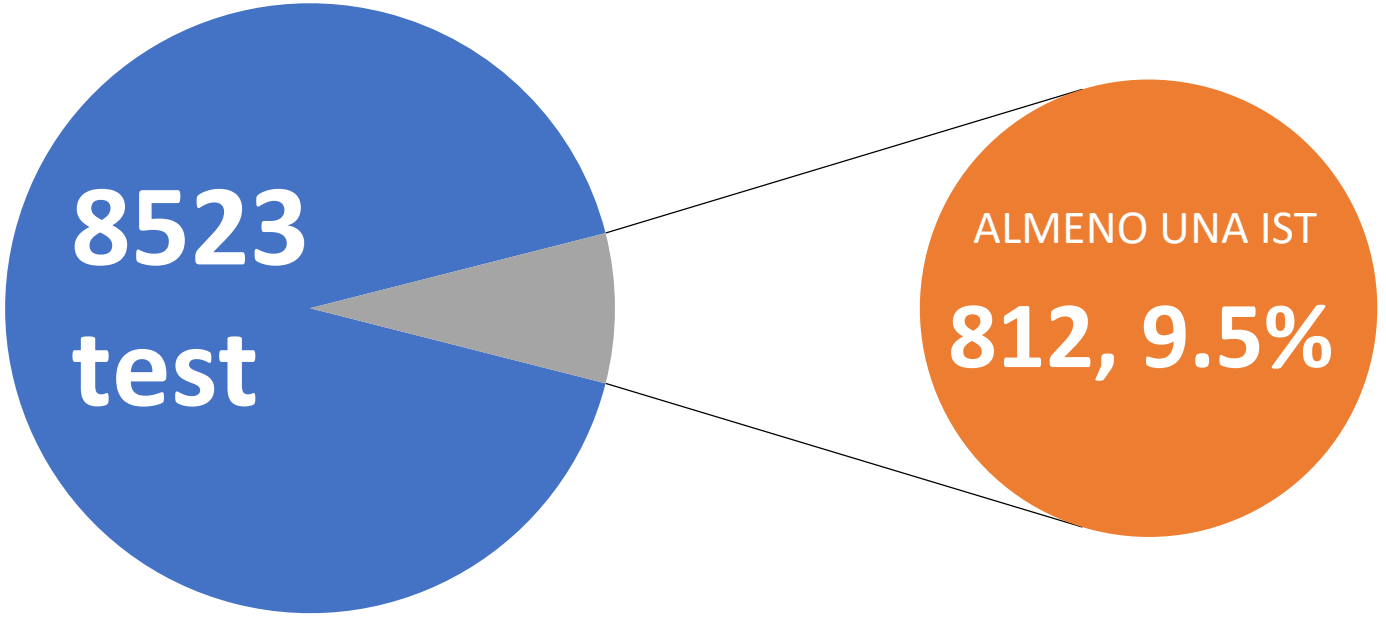
Keywords: web testing, HIV, AIDS, late presentation, STIs testing

Andamento delle infezioni testate negli anni di osservazione a Giugno 2017



	Gen – Giu 2014	Lug – Dic 2014	Gen – Giu 2015	Lug – Dic 2015	Gen – Giu 2016	Lug – Dic 2016	Gen – Giu 2017	totale
HIV Ab	3 (0,6)	13 (0,9)	12 (0,9)	11 (0,8)	6 (0,4)	6 (0,4)	11 (1,1)	62
HBsAg	6 (1,24)	24 (1,64)	32 (2,46)	50 (3,76)	47 (3,41)	76 (4,79)	41 (4,2)	276
HCV Ab	2 (0,42)	31 (2,11)	35 (2,69)	34 (2,5)	22 (1,59)	24 (1,51)	20 (2,1)	168
TPHA	7 (1,6)	41 (2,8)	50 (3,8)	54 (4,1)	54 (3,9)	60 (3,8)	40 (4,1)	306

% INFEZIONI SU TOTALE SCREENATI FEBBRAIO 2014 – GIUGNO 2017

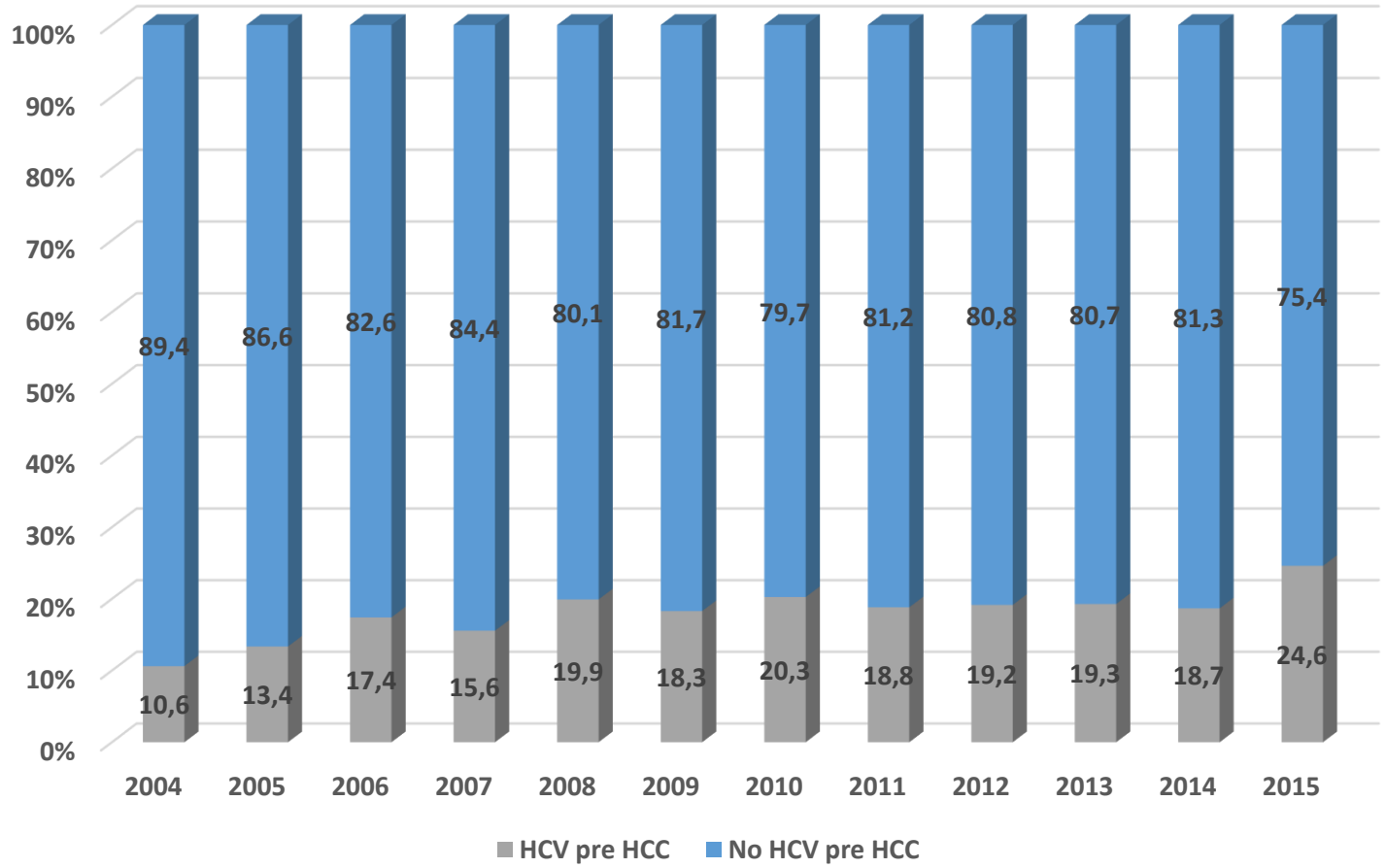


HIV n(%)	HBV n(%)	HCV n(%)	TPHA n(%)	TOT INF n(%)
62 (0,72)	276 (3,2)	168 (1,9)	306 (3,6)	812 (9,5)

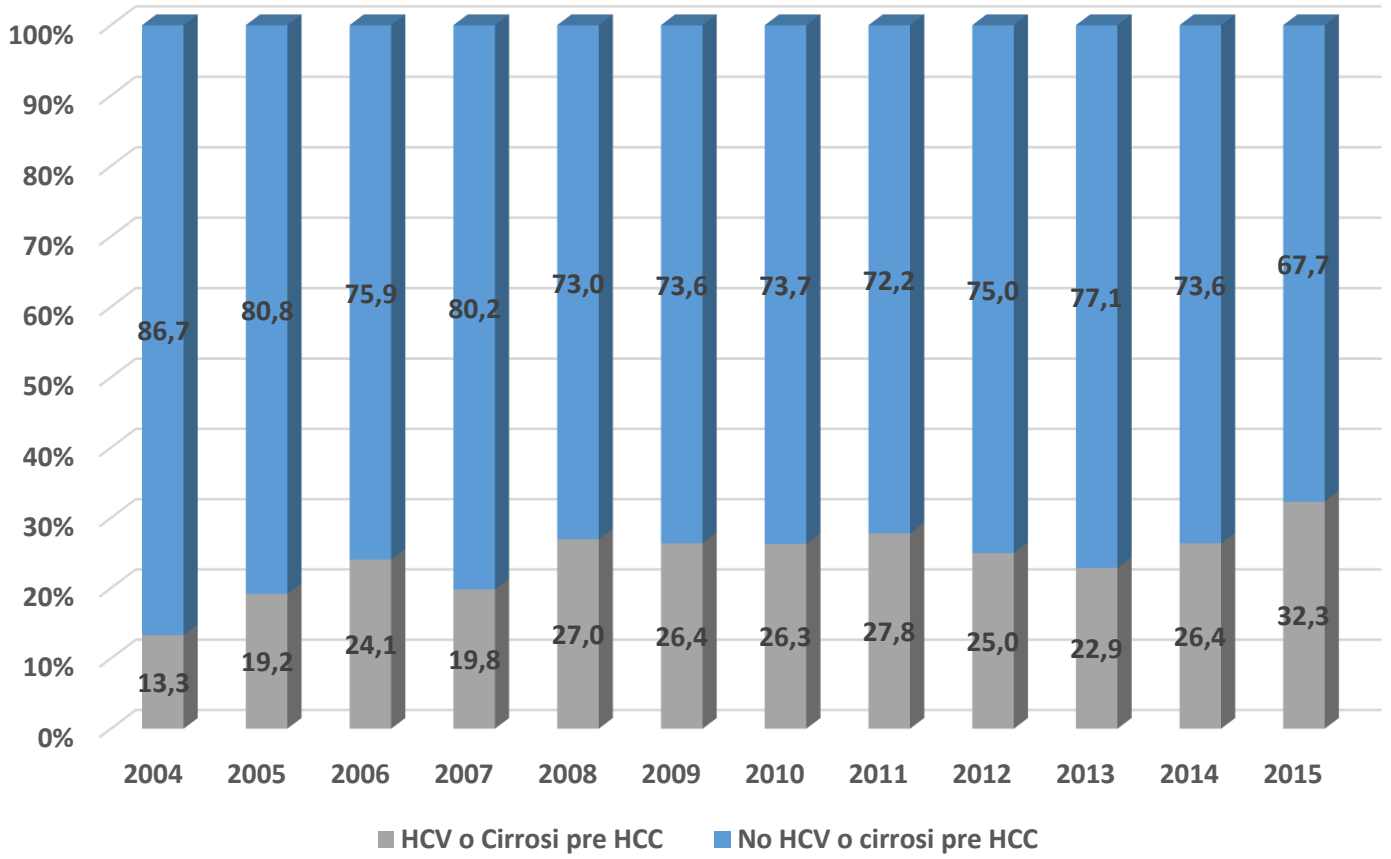
Parte 1: come può la RWE aiutarci per la lotta alla eradicazione di HCV?

- Da cosa siamo partiti in Abruzzo: quanti sono i nostri pazienti?
- Il nostro accesso ai “big datasets”
- La rivalutazione sulla scorta del dato “reale”
- **La quantificazione della domanda assistenziale per HCC mediante l’utilizzo delle analisi RWE basate sui dati delle Schede di Dimissione Ospedaliera**

HCV pre HCC

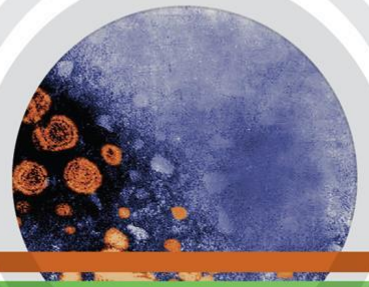

100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
89,4
86,6
82,6
84,4
80,1
81,7
79,7
81,2
80,8
80,7
81,3
75,4
10,6
13,4
17,4
15,6
19,9
18,3
20,3
18,8
19,2
19,3
18,7
24,6
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
HCV pre HCC
No HCV pre HCC

HCV o Cirrosi pre HCC



Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 61 / No. 4
August 17, 2012

Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965



ecdc
EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

SURVEILLANCE REPORT

Hepatitis C surveillance in Europe

2013

Hepatitis C virus infection

Key facts

- In 2013, 31 513 cases of hepatitis C were reported in 26 EU/ EEA Member States, a crude rate of 9.6 per 100 000 population.
- Of cases reported in 2013, 569 (1.8%) were reported as 'acute', 4 776 (15.2%) as 'chronic', 23 230 (73.7%) as 'unknown' and 2 938 cases (9.3 %) were not classified due to incompatible data formats.
- The male-to-female ratio was 1.9 to 1. The most affected age group were those between 25 and 34 years of age (29.3 cases per 100 000 in males, 15.1 cases per 100 000 in females).
- The most common route of transmission reported across all disease categories was injecting drug use, which accounted for 80.7% of all cases with complete information. Nosocomial transmission is an uncommon route of transmission in most countries, but remains a commonly reported transmission route in a small number of countries.
- The interpretation of hepatitis C data across countries is hampered by differences in surveillance systems and difficulties in defining the cases as acute or chronic. In addition, surveillance of hepatitis C, which is largely asymptomatic until a late stage, is challenging, with reported notifications reflecting testing practices rather than true occurrence of disease.

HCV beyond the Liver

FIGURA 1

Sindrome dismetabolica associata a HCV

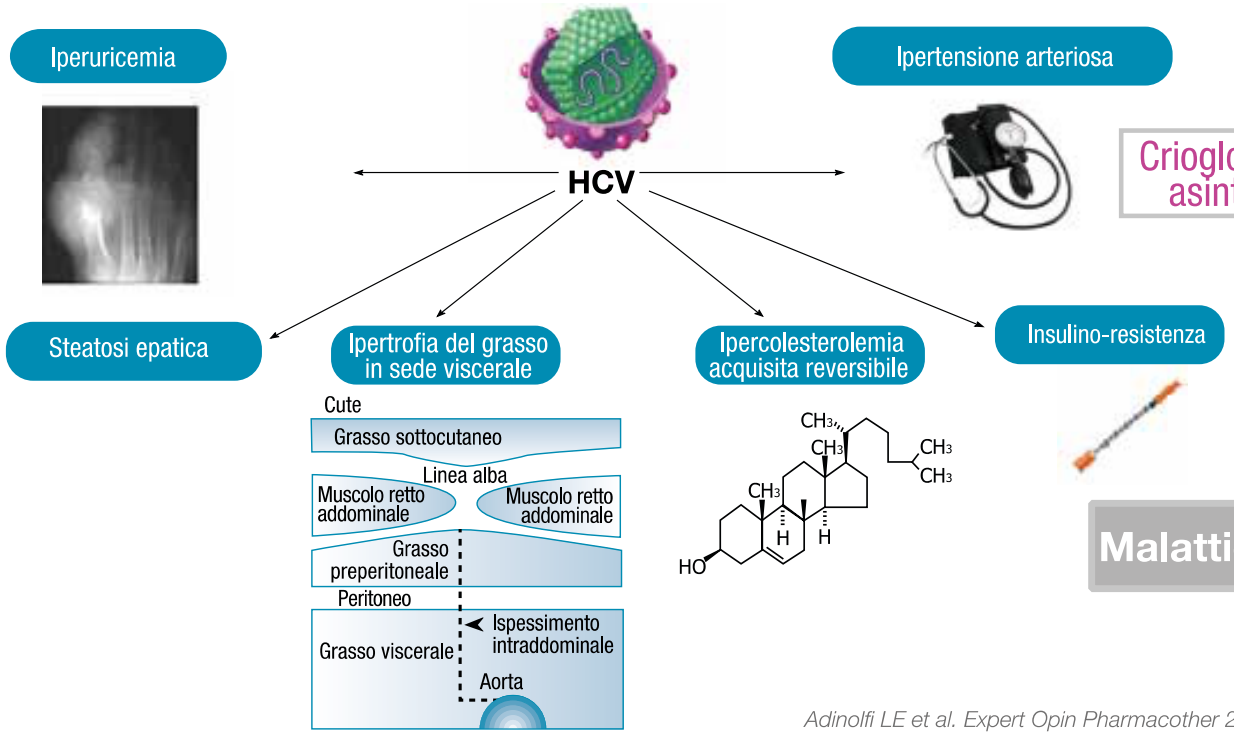
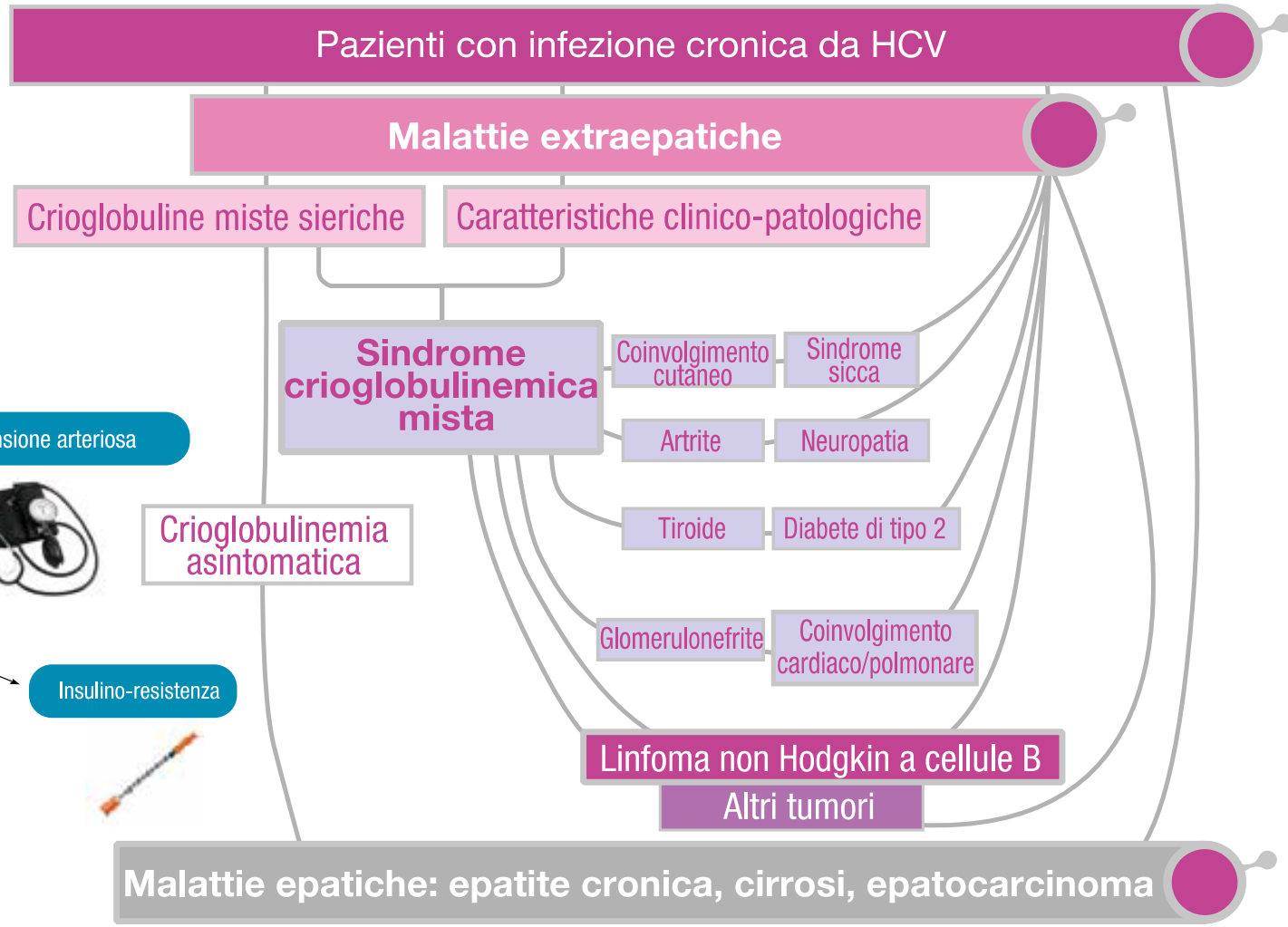


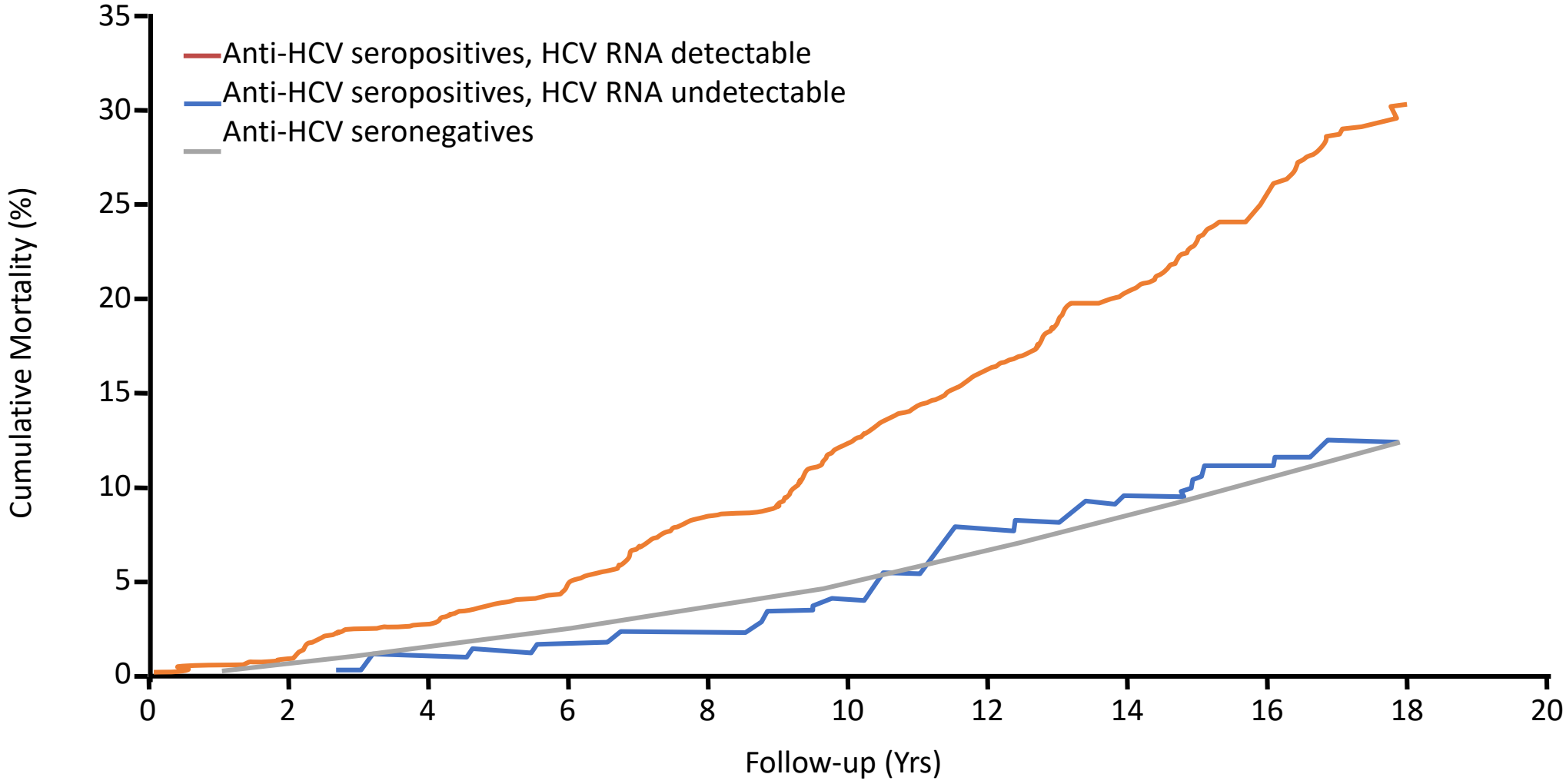
FIGURA 1

Il network delle malattie HCV-relate



Adinolfi LE et al. Expert Opin Pharmacother 2011

HCV Replication Associates With All-Cause Mortality

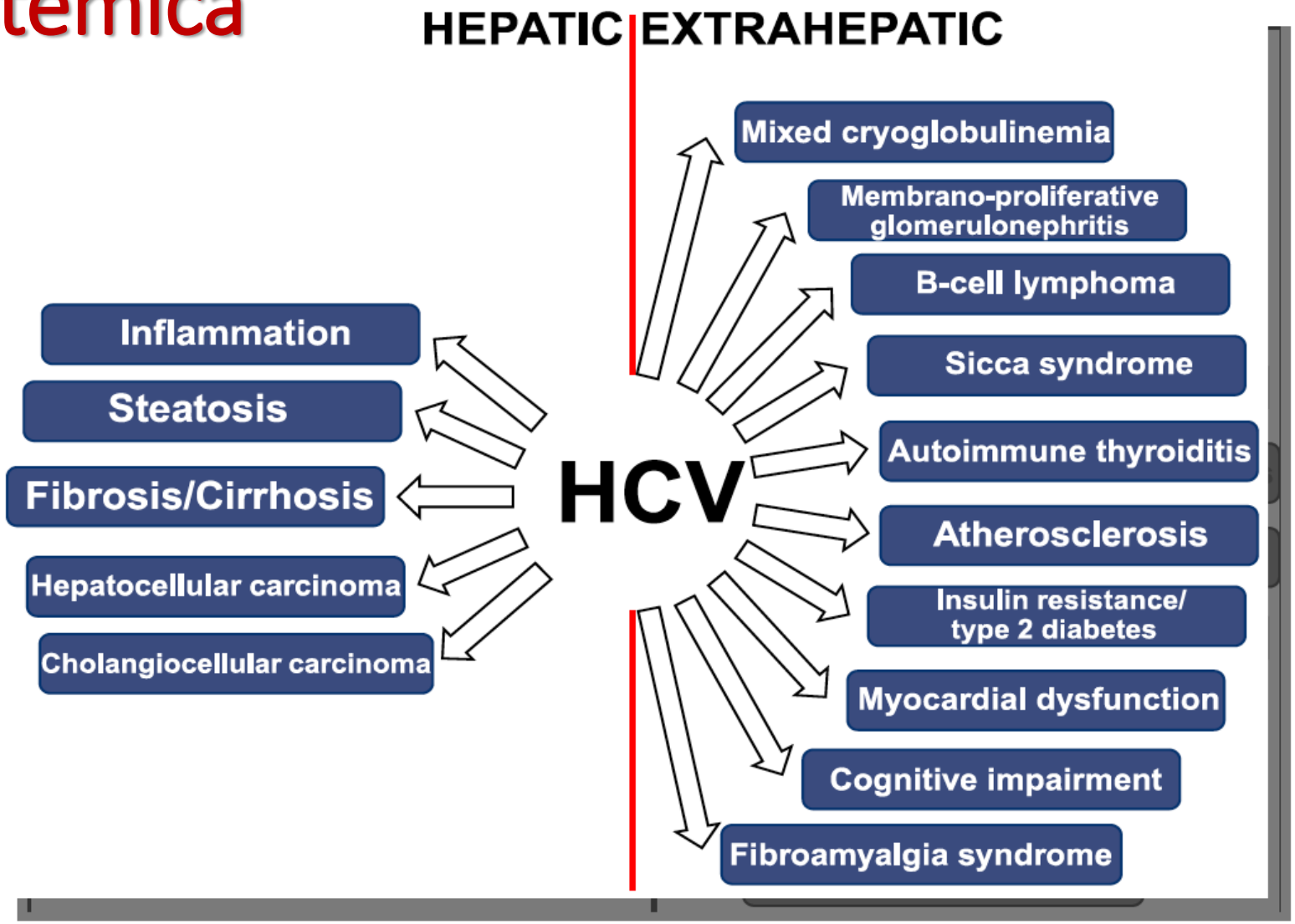


Lee MH, et al. J Infect Dis. 2012;206:469-477.

HCV: malattia sistemica

In ciascuna delle categorie di pazienti affianco elencate, l'infezione cronica viremica da HCV ha una probabilità di prevalenza superiore a quella della popolazione generale di prevalenza

Le azioni di screening devono tenere conto in modo privilegiato di queste popolazioni ad incrementato rischio



Negro F, J Hepatol 2014

Progetto PON Abruzzo 2017 in area 10: costituzione di una rete oncologica regionale

- Stiamo tentando di trasformare in opportunità di sviluppo per l'intera Regione i dati derivanti da una così alta stima di fabbisogno sanitario:
  - Sviluppo di una rete di screening regionale per favorire il proattivo accesso alla terapia antiretrovirale da parte degli infetti consapevoli ed esitanti o inconsapevoli
  - Ricerca molecolare di nuovi predittori di progressione degli infetti ad HCC mediante screening Whole Genome (in corso, progetto HIRMA)
  - Avvio di tutte le nuove diagnosi alla caratterizzazione precoce delle lesioni epatiche sospette
  - Creazione di un HUB avanzato per la gestione oncologica ed assistenziale dei casi non eleggibili a trapianto epatico

Il primo ambito da beneficiare: i coinfetti HIV

- Ricognizione proattiva di tutti i co-infetti HIV HCV assistiti in Regione, viremici e tuttora non trattati
- Offerta proattiva del trattamento contestualmente ad una rivalutazione delle terapia antiretrovirale, occasione di semplificazione/detossificazione

Allora cominciamo dai co-infetti..

- Vista l'alta resa in termini di prevenzione di progressione di malattia:
  - riduzione della viremia residua di HIV e dei rischi correlati, con conseguente ampliamento delle opzioni terapeutiche per HIV (terapie mono e dual)
  - riduzione della progressione della patologia epatica in HIV, incluso rischio di HCC
  - riduzione del RCV, molto più che nei mono-infetti
  - riduzione rischio di linfomi HCV ed HIV correlati

Ma avremo un bel da fare..

- All’avvio un programma proattivo per trattare:
  - Con il SerD: pazienti HCV in stabile terapia sostitutiva
  - Con le Unità di dialisi: pazienti HCV in attesa di trapianto e comunque con replica attiva
  - Con i MMG: pazienti con sieropositività anti HCV sin qui non perseguita, se HCV RNA presente
  - Con Neurologia e Psichiatria, per HCV in Parkinson ed altre neuropatie/psicopatie correlabili

Il trattamento dei detenuti

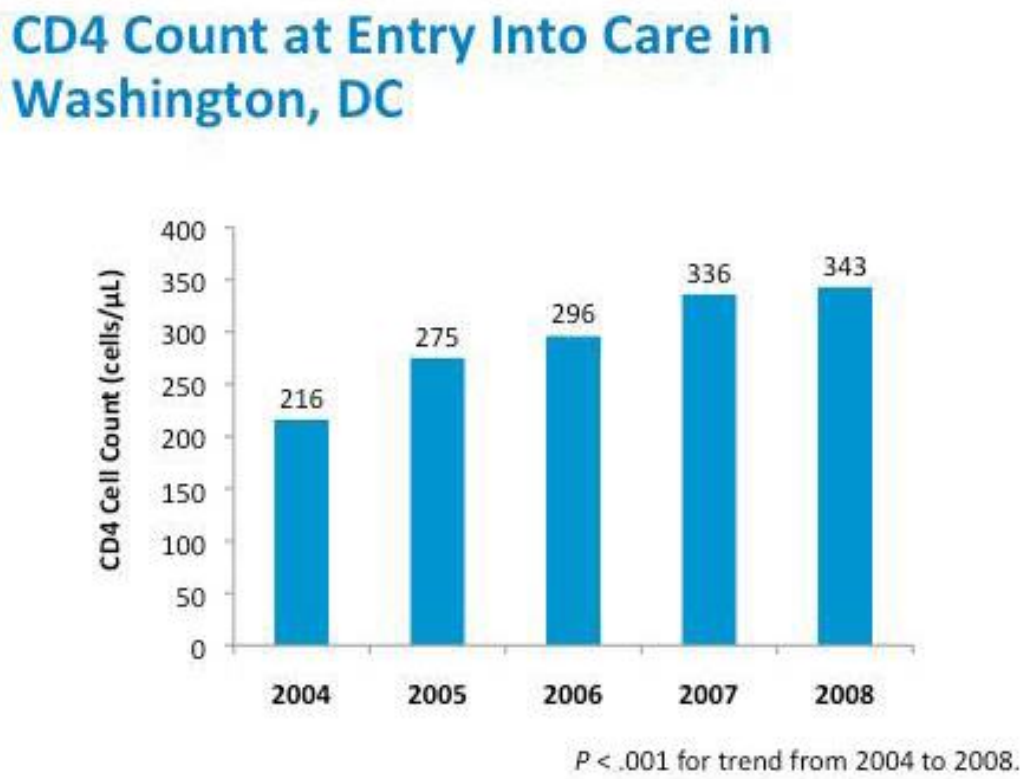
- La semplificazione del trattamento apre la possibilità di una gestione negli ambulatori penitenziari
- C’è una tendenza a porre un’indebita latenza tra fattibilità e trattamento sistematico nei penitenziari
- Si tratta di un ambito in cui il trattamento tempestivo avrebbe il valore aggiunto di una riduzione del rischio di trasmissione
- Le UOC di Mal Inf/Epatologia debbono farsi HUB per l’applicazione dei criteri di *equità di accesso*

Parte 2: come può la RWE aiutarci per mantenere alte ed adeguate le risorse per HIV?

- Nonostante i notevoli successi della HAART il recupero immune e la riduzione dello stato flogistico HIV correlato è parziale in quasi un terzo dei pazienti in follow-up
- Le conseguenze dell'*aging* sono evidenti nella popolazione HIV cronica, con comorbilità ingravescenti (ipertensione, vasculopatia, danno osseo, renale, tumori)
- L'alta proporzione di sommerso ancora esistente è fonte di frequente presentazione tardiva
- La presentazione tardiva si associa ad un pesante carico di morbilità e moralità aggiuntive

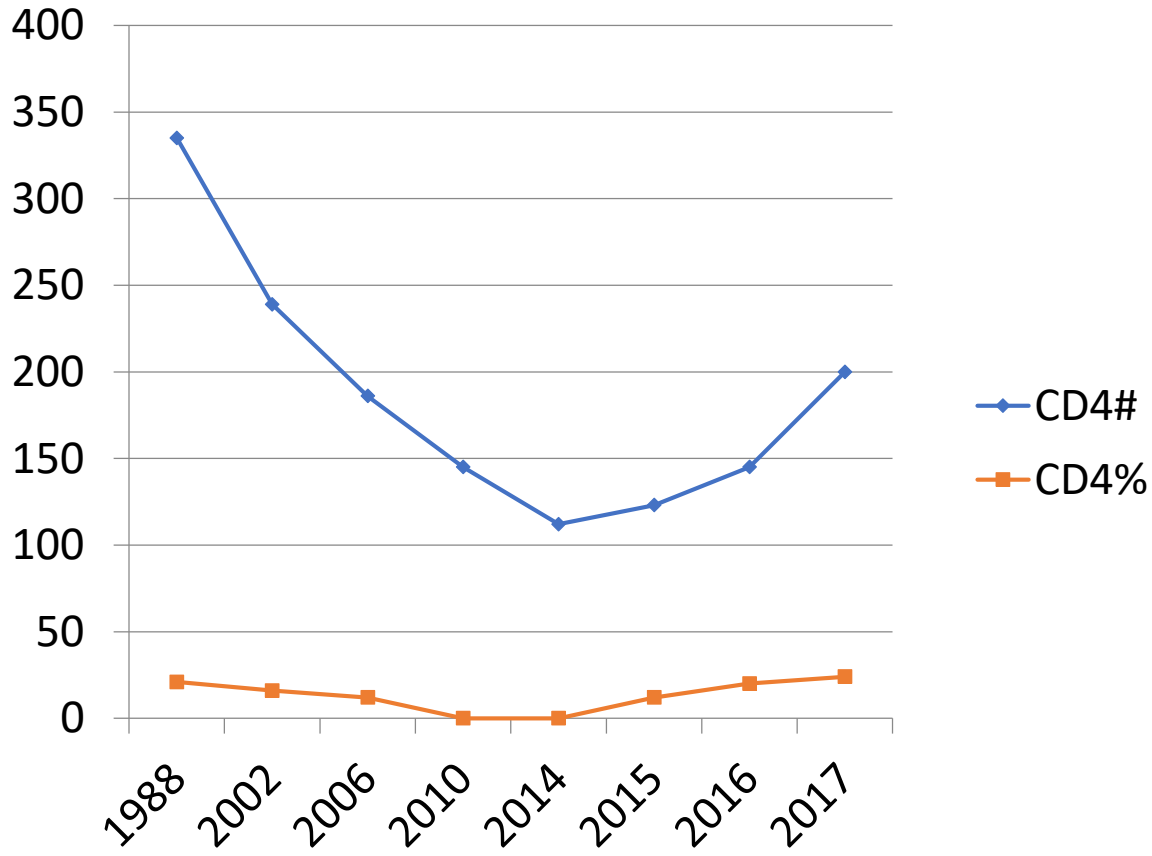
Il contesto Abruzzese: presentazione tardiva

Stati Uniti: screening policy



Castel A, et al. 17th CROI. San Francisco, 2010. Abstract 34.

Pescara – screening dal 2014



Punti critici della cronicità

- Con l'allungamento della sopravvivenza, la prevalenza dell'ipertensione nei pazienti HIV cresce come esito multifattoriale di HIV, immunodeficit, coinfezioni (CMV, HCV)
- Senza un impegno di formazione, la gestione dello stato ipertensivo (e del rischio cardiovascolare!) rimane subottimale in quasi il 50% dei pazienti
- È necessario che un'attenzione particolare venga rivolta alla considerazione dei pazienti con **multipli** e contestuali fattori di rischio CV

Time trend in hypertension prevalence, awareness, treatment, and control in a contemporary cohort of HIV-infected patients: the HIV and Hypertension Study

Received 2 June 2016 **Revised** 28 August 2016 **Accepted** 16 September 2016

J Hypertens 34:000–000

DOI:10.1097/HJH.0000000000001150

Giuseppe Vittorio De Socio[a], Elena Ricci[b], Paolo Maggi[c], Giustino Parruti[d], Benedetto Maurizio Celesia[e], Giancarlo Orofino[f], Giordano Madeddu[g], Canio Martinelli[h], Barbara Menzaghi[i], Lucia Taramasso[j], Paolo Bonfanti[k], and Giacomo Pucci[l], Giuseppe Schillaci[l], for the CISAI study group

Background: Hypertension control is often inadequate in HIV patients. In a contemporary, nationwide cohort of Italian HIV-infected adults, we assessed time trends in hypertension prevalence, awareness, treatment, and control. We also evaluated predictors of cardiovascular events and of new-onset hypertension.

Methods: Multicenter prospective cohort study, sampling 961 consecutive HIV patients (71% men, mean age 46 ± 9 years, 30% hypertensive) examined in 2010–2014 and after a median follow-up of 3.4 years.

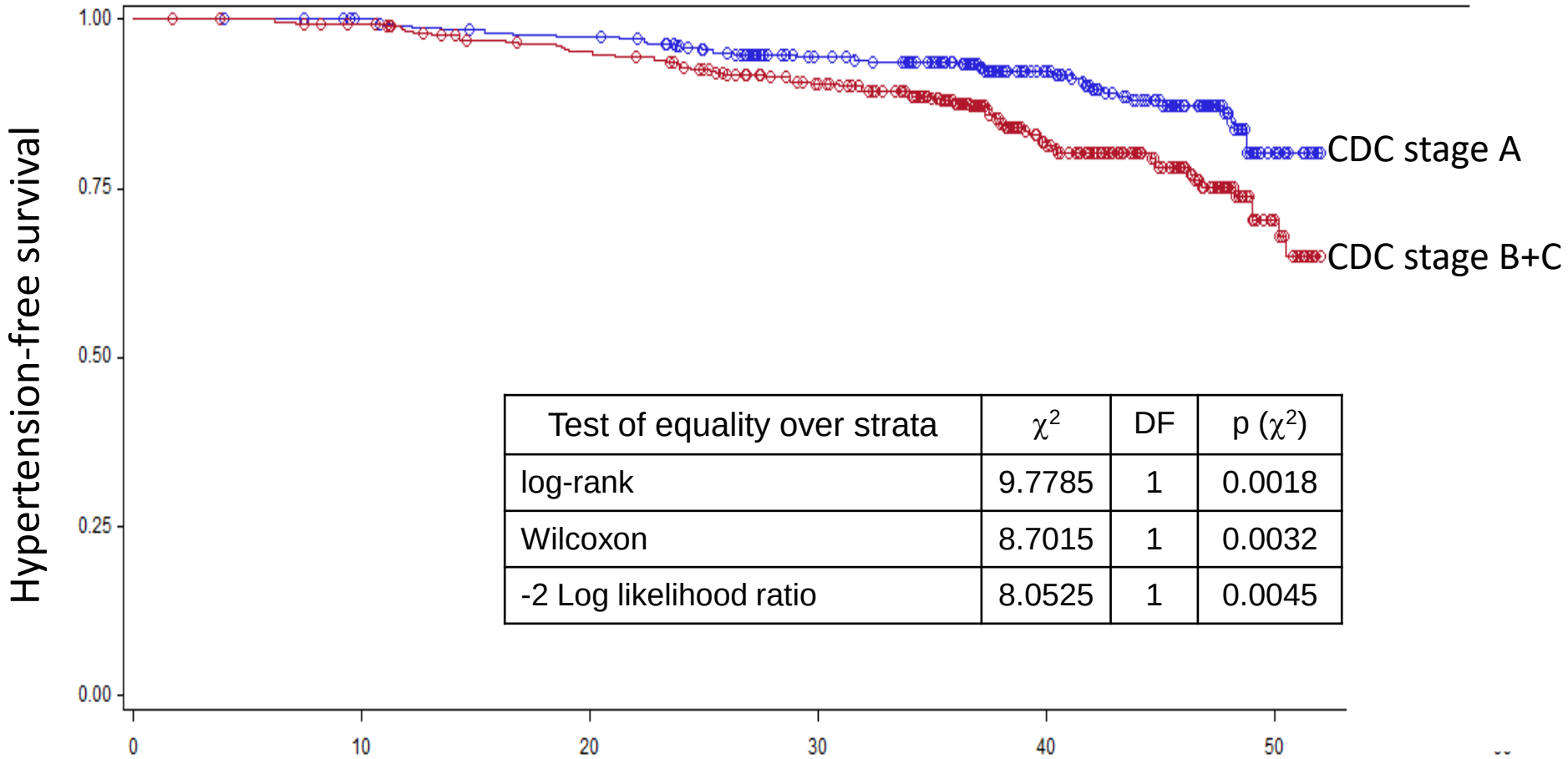
Conclusion: Hypertension awareness, treatment, and control rates all improved in adult Italian HIV patients over the last few years, although hypertension remains highly prevalent (41%) in middle-aged HIV patients, and significantly impacts cardiovascular morbidity. Traditional risk factors and advanced HIV disease predict new-onset hypertension, whereas $CD4^+$ cell count favorably affects future cardiovascular events.

Results: Among hypertensive patients, hypertension awareness (63% at baseline and 92% at follow-up), treatment (54 vs. 79%), and control (35 vs. 59%) all improved during follow-up. The incidence of new-onset hypertension was 50.1/1000 person-years (95% confidence interval, 41.2–60.3). Multivariable-adjusted predictors of hypertension were age, BMI, estimated cardiovascular risk, blood pressure, and advanced HIV clinical stage.
In total, 35 new cardiovascular events were reported during follow-up (11.1/1000 person-years). In a multivariate model, baseline cardiovascular risk and hypertensive status predicted incident cardiovascular events, whereas a higher $CD4^+$ cell count had a protective role. In treated hypertensive patients, the use of integrase strand transfer inhibitors at follow-up was associated with a lower SBP (average yearly change, -3.8 ± 1.6 vs. -0.9 ± 0.5 mmHg in integrase strand transfer inhibitor users vs. nonusers, respectively, $P = 0.02$).

Variable	No hypertension (n=562)	Hypertension (n=106)	Crude HR (95% CI)	Adjusted† HR (95% CI)	p
Female gender, %	33.3	29.2	0.76 (0.49-1.16)	-	-
Age (years), mean (SD)	44.2 (8.7)	48.6 (9.3)	1.05 (1.03-1.07)	1.04 (1.02-1.06)	0.0006
Previous CV events, n (%)	10 (1.8)	6 (5.7)	3.48 (1.52-7.95)	2.35 (0.98-5.63)	0.05
10-year Framingham Risk, n (%)					
<10	432 (76.9)	62 (58.5)	1	1	
10-20	88 (15.7)	25 (23.6)	1.84 (1.15-2.93)	1.72 (1.06-2.80)	0.03
>20	22 (3.9)	13 (12.3)	3.80 (2.08-6.94)	3.20 (1.69-6.06)	0.0004
CDC stage, n (%)					
A	277 (50.1)	38 (36.9)	1	1	
B	130 (23.5)	28 (27.2)	1.78 (1.08.2.92)	1.99 (1.18-3.35)	0.009
C	146 (26.4)	37 (35.9)	1.99 (1.26-3.16)	1.90 (1.18-3.03)	0.007
Systolic BP (mm Hg), mean (SD)	116.4 (9.9)	124.0 (8.9)	1.07 (1.05-1.09)	1.06 (1.04-1.09)	<0.0001
Diastolic BP (mm Hg), mean (SD)	74.5 (6.8)	78.0 (5.8)	1.08 (1.04-1.11)	1.06 (1.03-1.10)	0.0005

Multivariable-adjusted predictors of hypertension were estimated CV risk, blood pressure, and advanced HIV clinical stage

Hypertension-free Kaplan-Meier survival curves in HIV patients and CDC stage A (*blue line*), or CDC stage B or C (*red line*).



Test of equality over strata	χ^2	DF	p (χ^2)
log-rank	9.7785	1	0.0018
Wilcoxon	8.7015	1	0.0032
-2 Log likelihood ratio	8.0525	1	0.0045

Oltre l'incremento dell'IA…

- La correzione ottimale dell'ipertensione è stata ottenuta solo in una frazione modesta dei trattati (27%)
- Il numero dei pazienti non trattati e dei pazienti inconsapevoli è rimasto in assoluto rilevante
- L'attenzione al problema IA presso i centri aderenti potrebbe non rispecchiare quella nei centri di cura non partecipanti

Infection (2016) 44:589–597
DOI 10.1007/s15010-016-0893-z

ORIGINAL PAPER

Statins and Aspirin use in HIV-infected people: gap between European AIDS Clinical Society guidelines and clinical practice: the results from HIV-HY study

Giuseppe Vittorio De Socio[1] · Elena Ricci[2] · Giustino Parruti[3] · Leonardo Calza[4] · Paolo Maggi[5] · Benedetto Maurizio Celesia[6] · Giancarlo Orofino[7] · Giordano Madeddu[8] · Canio Martinelli[9] · Barbara Menzaghi[10] · Lucia Taramasso[11] · Giovanni Penco[12] · Laura Carenzi[2] · Marco Franzetti[13] · Paolo Bonfanti[14]

Received: 17 January 2016 / Accepted: 23 March 2016 / Published online: 5 April 2016

Abstract
Objectives To investigate the use of statins and acetylsalicylic acid (ASA) in HIV people in clinical practice.
Design A multicenter, nationwide, prospective cohort study, including 1182 consecutive HIV patients was conducted.
Methods Statin and ASA prescription was evaluated in primary and secondary cardiovascular disease prevention, according to the European AIDS Clinical Society (EACS) guidelines.
Results Followed-up patients (998) were mostly males (70.9 %) with a mean age at enrolment of 46.5 years (SD 9.5). The mean time of follow-up was 3.3 years (SD 0.8). At the last follow-up visit, statins would have been recommended for 31.2 % and ASA for 16 % by EACS guidelines. Conversely, only 15.6 and 7.6 % of patients were on statin and ASA treatment, respectively; only 50.3 % of patients treated with statins achieved recommended low-density lipoprotein cholesterol (LDL-c) levels. At the last follow-up visit, agreement between statin therapy and EACS recommendation was 0.58 (95 % CI 0.52–0.63). The corresponding figure for ASA therapy was 0.50 (95 % CI 0.42–0.58), whereas the agreement for ASA therapy in secondary prevention was 0.59 (95 % CI 0.50–0.68).
Conclusions The prescription of statins and ASA in HIV-infected patients remains largely suboptimal, as only about 50 % of patients requiring statins and ASA are properly treated. Higher attention on this relevant issue and further investigation are warranted in this at risk population.

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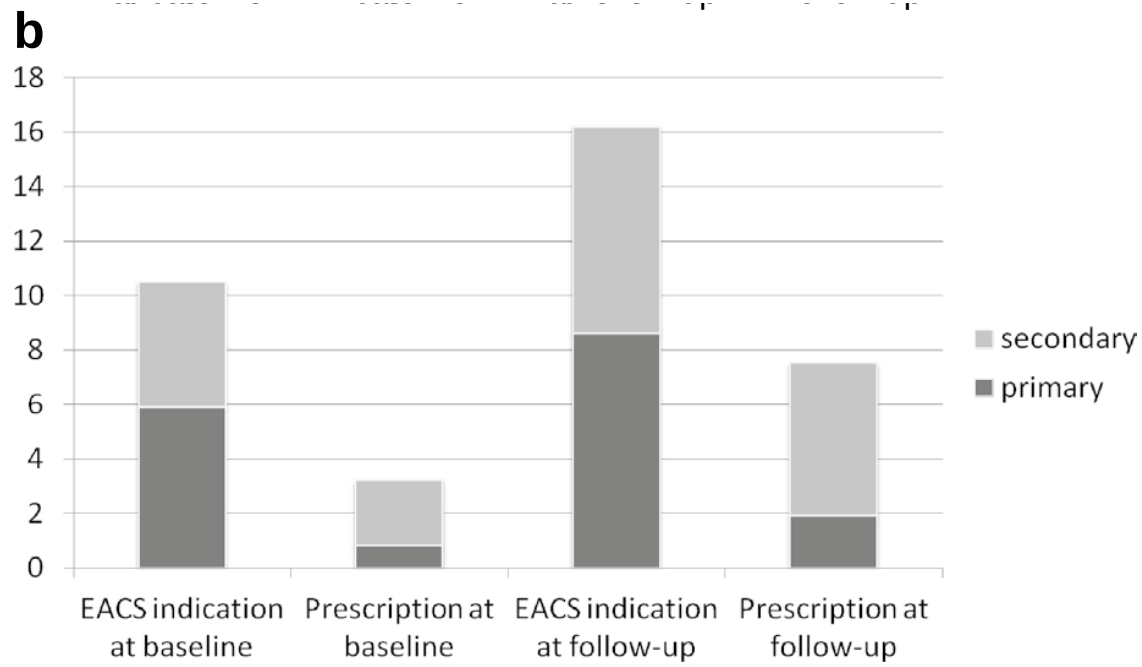

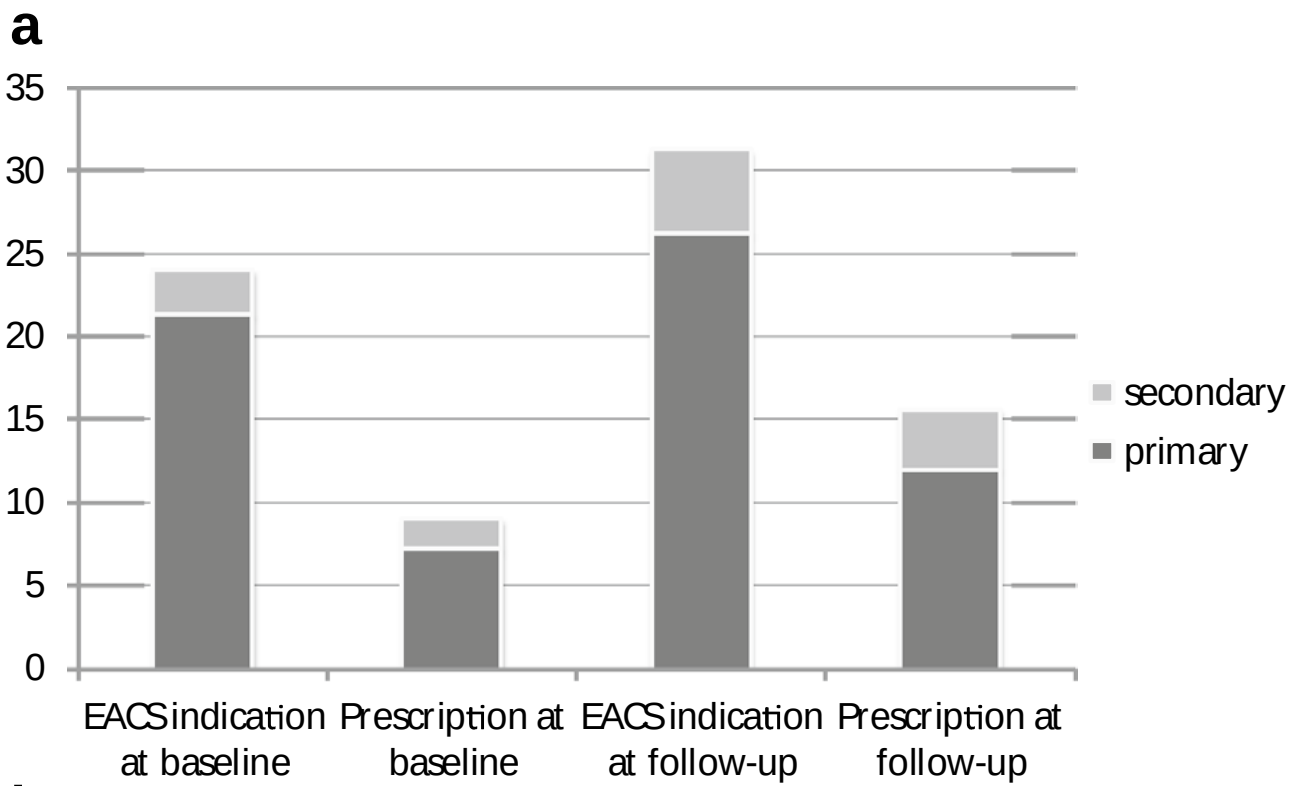

Fig. 2 The agreement between recommendation of statin (**a**) and aspirin (**b**) according to the European AIDS Clinical Society (EACS) guidelines and real life prescription. Baseline and last follow-up (FU) data from HIVHY study

Infection (2016) 44:589–597
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ORIGINAL PAPER

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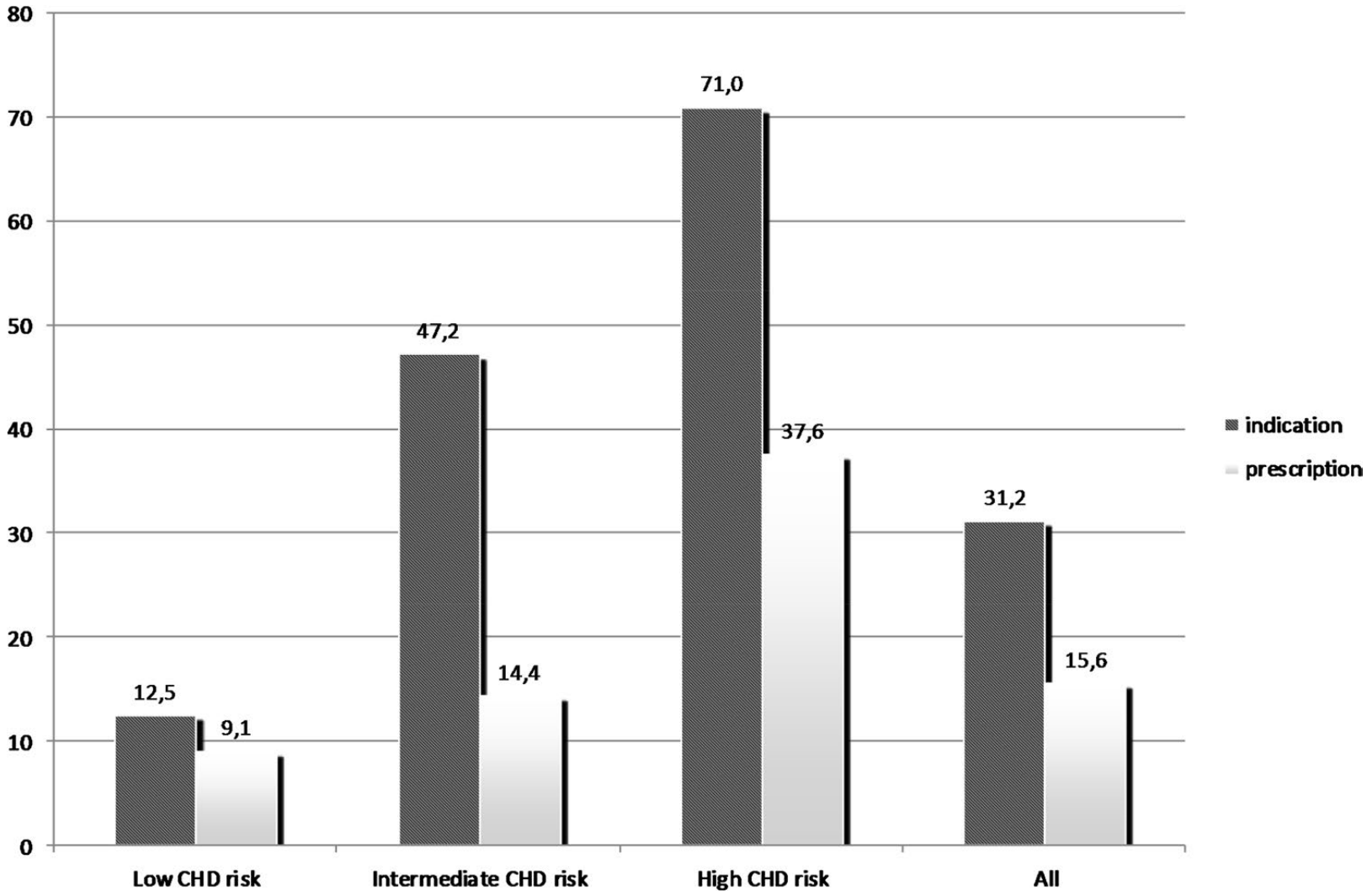

Fig. 3 Cardiovascular risk stratification (Framingham coronary heart disease risk: low CHD <10 %; intermediate CHD 10–20 %; high CHD ≥ 20 %) and statin recommendations according to the European AIDS Clinical Society (EACS) guidelines compared with clinical practice prescriptions

AIDS PATIENT CARE and STDs
Volume 29, Number 4, 2015

DOI: 10.1089/apc.2014.0205

Prevalence and Predictors of Low Bone Mineral Density and Fragility Fractures Among HIV-Infected Patients at One Italian Center After Universal DXA Screening: Sensitivity and Specificity of Current Guidelines on Bone Mineral Density Management

Elena Mazzotta, MD,[1] Tamara Ursini, MD,[1] Adriana Agostinone, MD,[2] Angelo Domenico Di Nicola, MD,[3] Ennio Polilli, BSc,[4] Federica Sozio, MD,[2] Francesco Vadini, PsyD, PhD,[2] Alessandro Pieri, MD,[2] Francesca Trave, MD,[2] Valerio De Francesco, MD,[3] Lorenzo Capasso, MD,[5] Marco Borderi, MD,[6] Lamberto Manzoli, MD, MPH,[5] Pierluigi Viale, MD,[6] and Giustino Parruti, MD, PhD[2]

TABLE 2. PREVALENCE OF OSTEOPENIA AND OSTEOPOROSIS IN THE TOTAL SAMPLE ($N = 163$)

Site	*Osteopenia criterion 1 (Z-score ≤ −2)* %	*Osteoporosis (T-score ≤ −2.5)* %	*Osteopenia criterion 2 (−2.5 < T-score < −1)* %	*Osteopenia or osteoporosis (T-score < −1)* %
Either femoral or lumbar	19.6	13.5	49.7	63.2
Femoral	9.3	5.6	40.7	46.3
Lumbar	16.6	11.0	44.8	55.8

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Table 3. Comparison Between Italian Guidelines Indication to Perform DXA and Result Universal BMD Screening (163 Patients)

	Indication to screen for osteopenia[a] % (n)	*No indication to screen for osteopenia* % (n)	*Total* % (n)	*Guidelines criteria specificity* % (95% CI)	*Guidelines criteria sensitivity* % (95% CI)
Diagnosis based upon Z-score [b]				81.2 (63.0–92.1)	32.1 (24.3–40.9)
Osteopenia at any site	81.2 (26)	18.8 (6)	19.6 (32)		
No osteopenia	67.9 (89)	32.1 (42)	80.4 (131)		
Total	70.6 (115)	29.4 (48)	100 (163)		
Diagnosis based upon T-score [c]				68.9 (58.9–77.5)	26.7 (16.5–39.9)
Osteopenia at any site	68.9 (71)	31.1 (32)	63.2 (103)		
No osteopenia	73.3 (44)	26.7 (16)	36.8 (60)		
Total	70.5 (115)	29.5 (48)	100 (163)		

[a]According to current Italian guidelines.[10,11] [b] Z-score ≤ −2, [c] T-score between −2.5 and −1.
BMD, bone mineral density; DXA, dual-energy X-ray absorptiometry.

Journal of Infection (2008) **57**, 33—40

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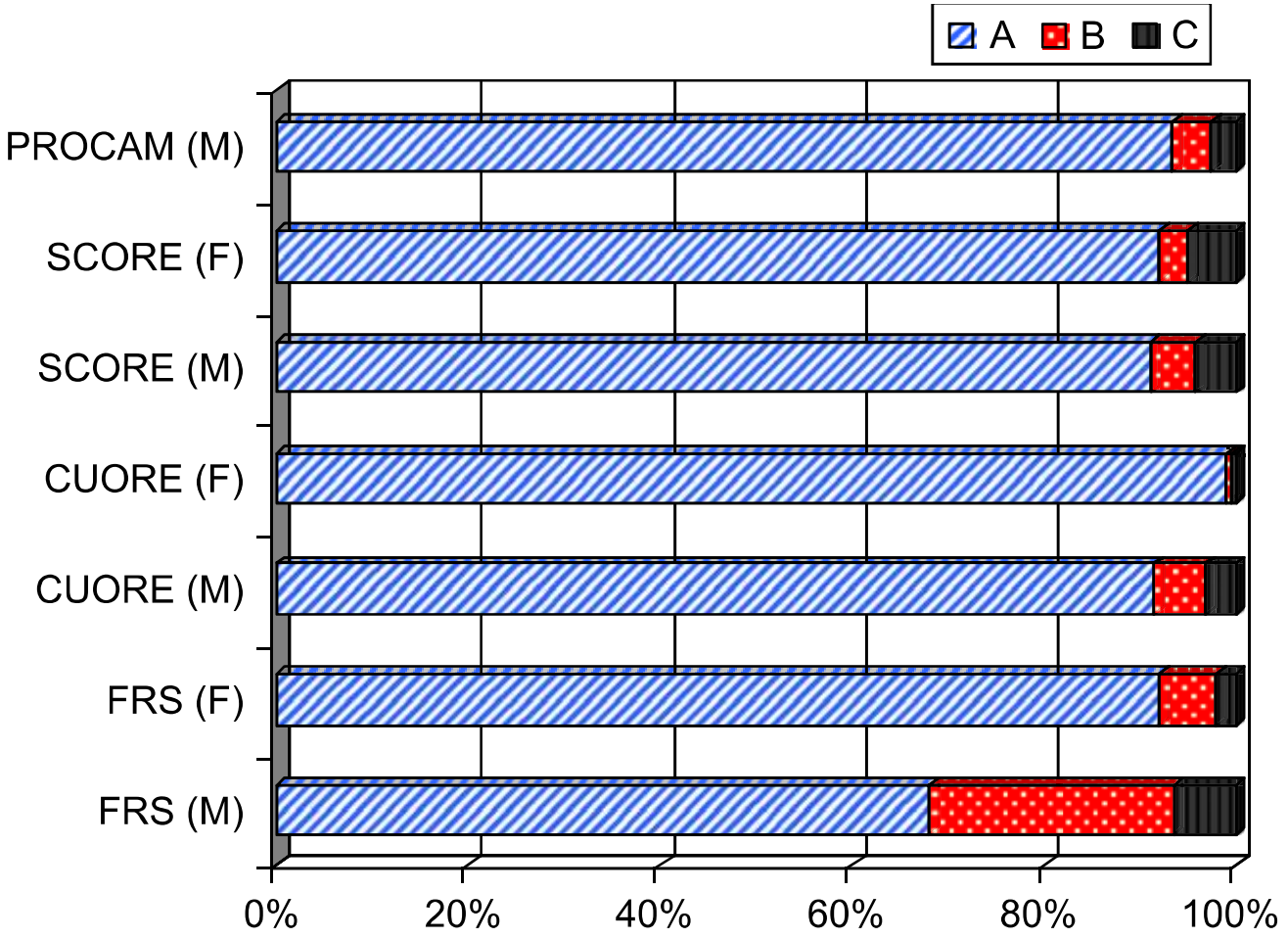
BRITISH INFECTION SOCIETY

www.elsevierhealth.com/journals/jinf

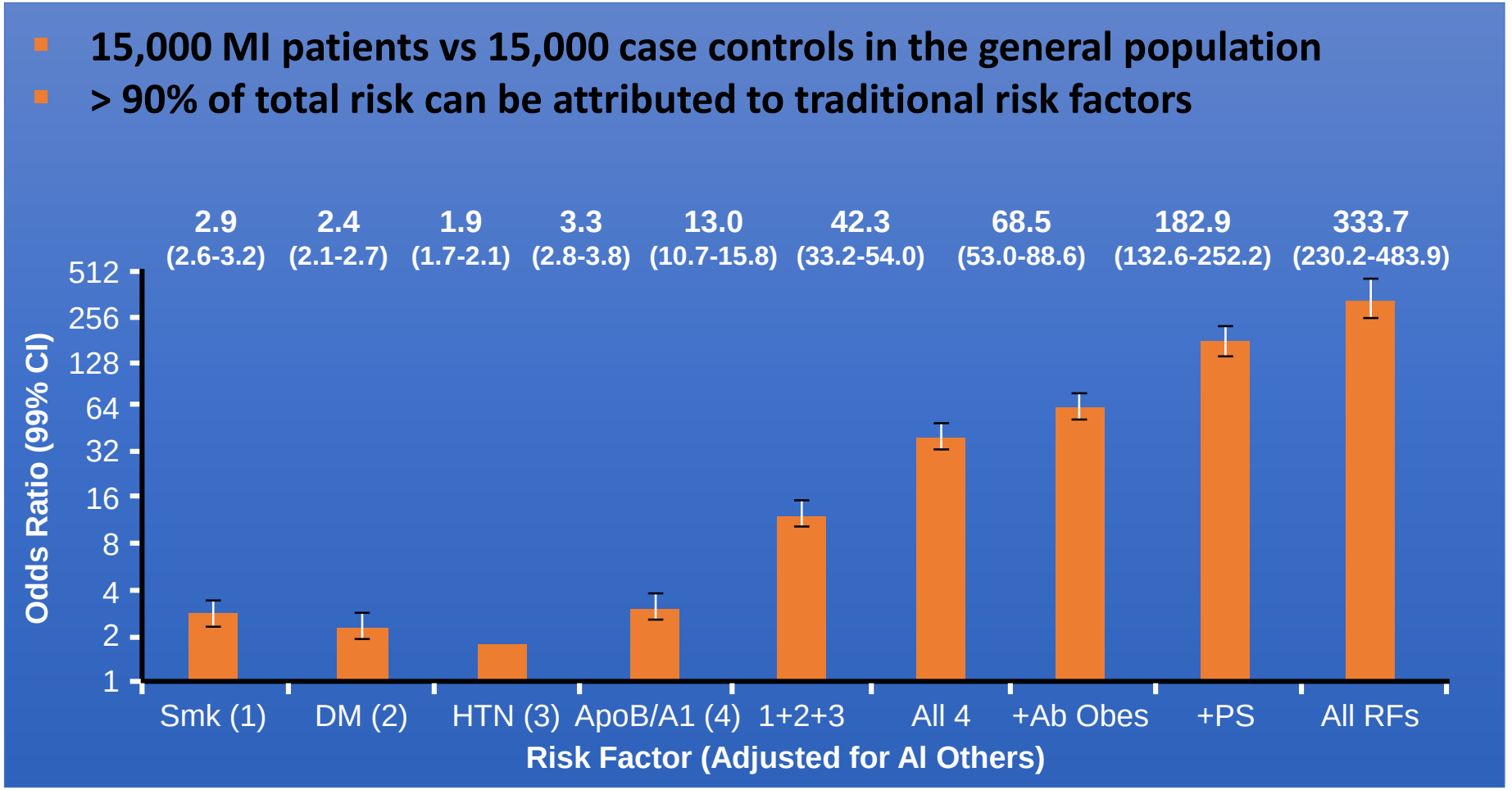
Identifying HIV patients with an unfavorable cardiovascular risk profile in the clinical practice: Results from the SIMONE study

Giuseppe Vittorio L. De Socio [a,*], Giustino Parruti [b], Tiziana Quirino [c], Elena Ricci [d], Giuseppe Schillaci [e], Beatrice Adriani [f], Patrizia Marconi [g], Marzia Franzetti [h], Canio Martinelli [i], Francesca Vichi [j], Giovanni Penco [k], Claudio Sfara [a], Giordano Madeddu [l], Paolo Bonfanti [d], for the CISAI study group



INTERHEART: Il rischio aumenta proporzionalmente all'aggiunta di fattori di rischio per MI

- 15,000 MI patients vs 15,000 case controls in the general population
- > 90% of total risk can be attributed to traditional risk factors



Ab obes, abdominal obesity; ApoB/A1, Apolipoprotein B/A1 ratio; DM, diabetes mellitus; HTN, hypertension; PS, psychosocial; RF, risk factors; Smk, smoking.

Yusuf S, et al. Lancet. 2004;364:937-952.

Cos’altro manca?

DIAGNOSI ED INTERVENTI su ASPETTI PSICOSOCIALI

I tratti di personalità si associano alla variazione individuale del rischio cardiovascolare in modo molto significativo nella popolazione generale - ed in quella HIV

tratti di personalità e RCV

THE LANCET

Lancet 1996; **347:** 417–21

Personality as independent predictor of long-term mortality in patients with coronary heart disease

Johan Denollet, Stanislas U Sys, Nathalie Stroobant, Hans Rombouts, Thierry C Gillebert, Dirk L Brutsaert

Variable	Odds ratio (95% CI)	p
Type-D personality	4·1 (1·9–8·8)	0·0004
Impaired left ventricular function	3·0 (1·1–8·0)	0·03
Three-vessel disease	2·4 (1·1–5·2)	0·03
Poor exercise tolerance	2·4 (1·1–5·3)	0·03
Thrombolysis after myocardial infarction	0·2 (0·03–1·2)	0·07

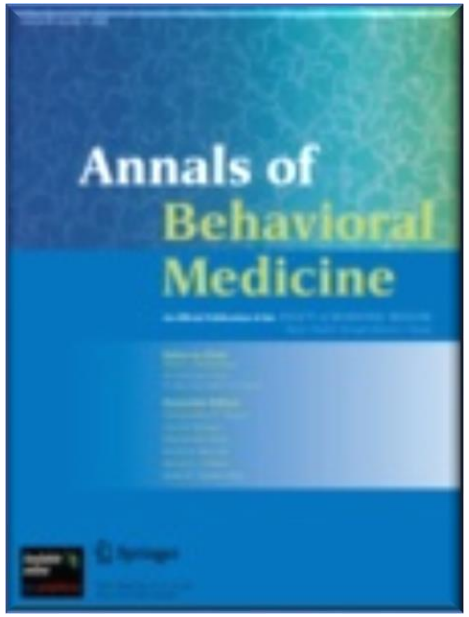
Table 4: **Predictors of 6–10 year mortality by multiple logistic regression**

tratti di personalità e RCV

Association Between Type D Personality and Prognosis in Patients with Cardiovascular Diseases: a Systematic Review and Meta-analysis

ann. behav. med. (2012) 43:299–310

Gesine Grande, Dr. p.h. · Matthias Romppel, M.Sc. · Jürgen Barth, Ph.D.



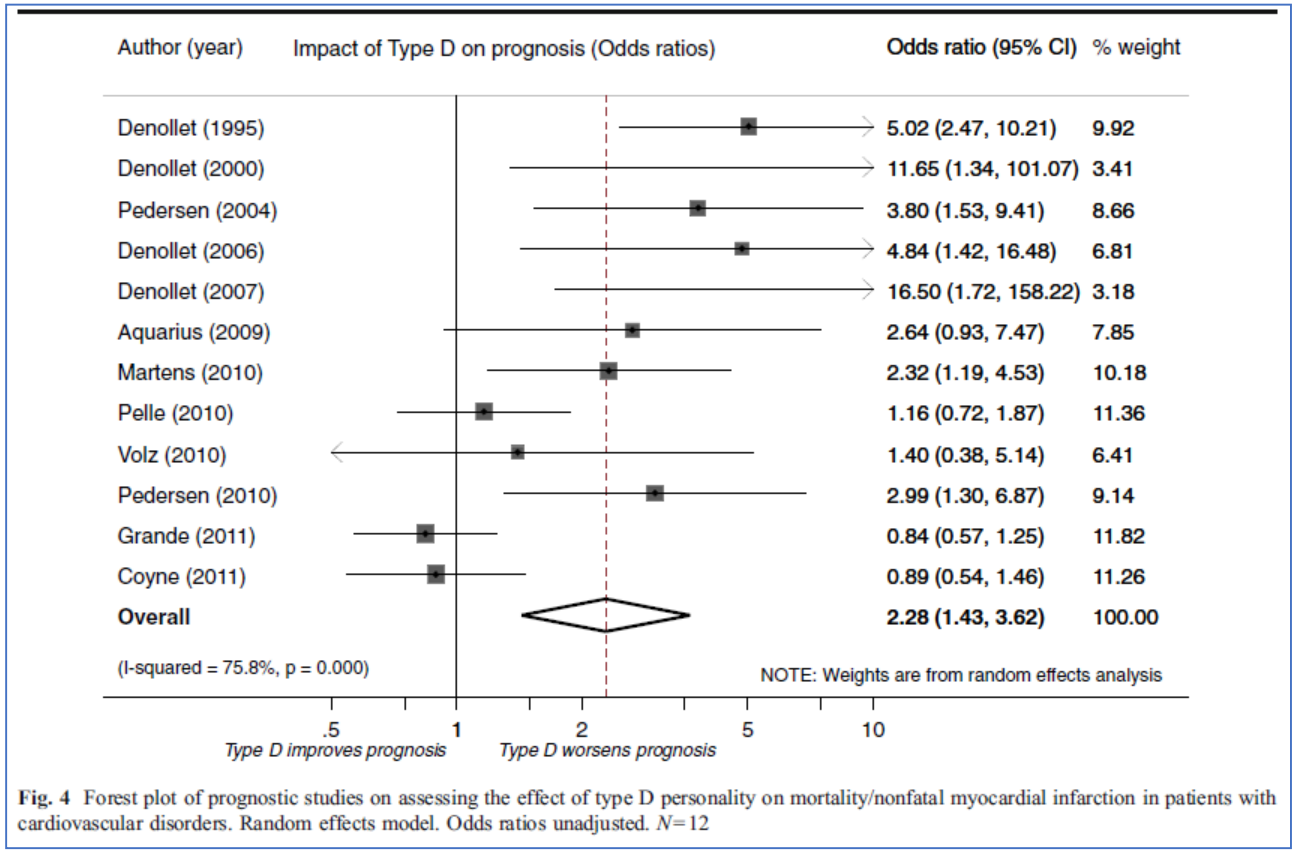


Fig. 4 Forest plot of prognostic studies on assessing the effect of type D personality on mortality/nonfatal myocardial infarction in patients with cardiovascular disorders. Random effects model. Odds ratios unadjusted. $N=12$

Management of psychosocial factors

	Class	Level	GRADE
Multimodal behavioural interventions, integrating health education, physical exercise and psychological therapy for psychosocial risk factors and coping with illness, should be prescribed.	I	A	Strong
In case of clinically significant symptoms of depression, anxiety and hostility, psychotherapy, medication or collaborative care should be considered. This approach can reduce mood symptoms and enhance health related quality of life, although evidence for a definite beneficial effect on cardiac endpoints is inconclusive.	IIa	A	Strong

European Guidelines on cardiovascular disease prevention in clinical practice (version 2012)

www.escardio.org/guidelines

European Heart Journal 2012:33;1635–1701
European Journal of Preventive Cardiology 2012;19: 4:585-667

EUROPEAN SOCIETY OF CARDIOLOGY

Il ruolo dell'alessitimia

- Alessitimia vuol dire incapacità di conoscere e nominare le emozioni
- Ognuno ha una determinata capacità di "metabolizzare" cognitivamente le emozioni elaborandone il significato e moderandone l'impatto
- L'efficienza della capacità elaborativa delle emozioni è misurabile come tratto relativamente stabile di personalità ed è normalmente distribuita nella popolazione

l'alessitimia

- Si dicono "alessitimici" i soggetti per cui l'efficienza nell'elaborazione delle emozioni è ridotta oltre una soglia critica
- Il livello di alessitimia è misurabile con una batteria di test ben validata, che fornisce un valore puntuale (Toronto Alexithymia Score, TAS)
- Alessitimia lieve moderata: punteggio TAS >50 e <61; severa con punteggio >60

Alexithymia Is Associated With Increased Cardiovascular Mortality in Middle-Aged Finnish Men

Tommi Tolmunen, MD, PhD, Soili M. Lehto, MD, PhD, Maria Heliste, MB, Sudhir Kurl, MD, PhD, and Jussi Kauhanen, MD, PhD

Objective: To explore the associations between alexithymia and increased somatic morbidity. The mechanisms underlying these associations, however, are still unclear. Furthermore, data on the association between alexithymia and mortality are scarce. **Methods:** A total of 2321 Finnish men, aged 46 to 61 years, were followed up for an average of 20 years. Mortality rates were obtained from the national register. The associations between baseline alexithymia and cardiovascular disease (CVD), all-cause, injury, and cancer deaths were examined with adjustments for age and several behavioral (smoking, alcohol consumption, physical activity), physiological (low- and high-density lipoprotein cholesterol, body mass index, systolic blood pressure, history of CVD), and psychosocial (marital status, education, depression) factors. **Results:** After all adjustments, the risk of CVD death was increased by 1.2% for each 1-point increase in Toronto Alexithymia Scale-26 scores. **Conclusions:** Alexithymia is associated with increased cardiovascular mortality. **Key words:** alexithymia, mortality, cardiovascular.

TABLE 2. Increase of Risk Ratios (95% Confidence Intervals) for CVD Death During an Average Follow-Up Period of 20 yr Using Cox Proportional Hazards

	RR[a] (95% CI) in Probable Alexithymia	*df*	Wald	*p*
Model 1	1.023 (1.013–1.034)	6	19.16	<.001
Model 2	1.018 (1.008–1.029)	9	12.05	<.001
Model 3	1.015 (1.004–1.025)	14	7.25	.007
Model 4	1.012 (1.00–1.023)	17	4.14	.042

[a] RR shows the increase in the risk of cardiovascular disease death with each 1-digit increase in Toronto Alexithymia Scale (TAS)-26 scores.
RR = risk ratio; CI = confidence interval; *df* = degrees of freedom; Model 1 = Adjusted for age examination year; Model 2 = Model 1 and further adjustment for smoking (pack-years), weekly alcohol consumption, physical activity; Model 3 = Model 2 further adjusted for low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, body mass index, hypertension, cardiovascular diseases; Model 4 = Model 3 further adjusted for marital status, education, and Human Population Laboratory Depression Scale scores.

PSYCHOSOMATIC MEDICINE
Journal of Biobehavioral Medicine

Psychosomatic Medicine 72:187–191 (2010)

Psychological Factors, Including Alexithymia, in the Prediction of Cardiovascular Risk in HIV Infected Patients: Results of a Cohort Study

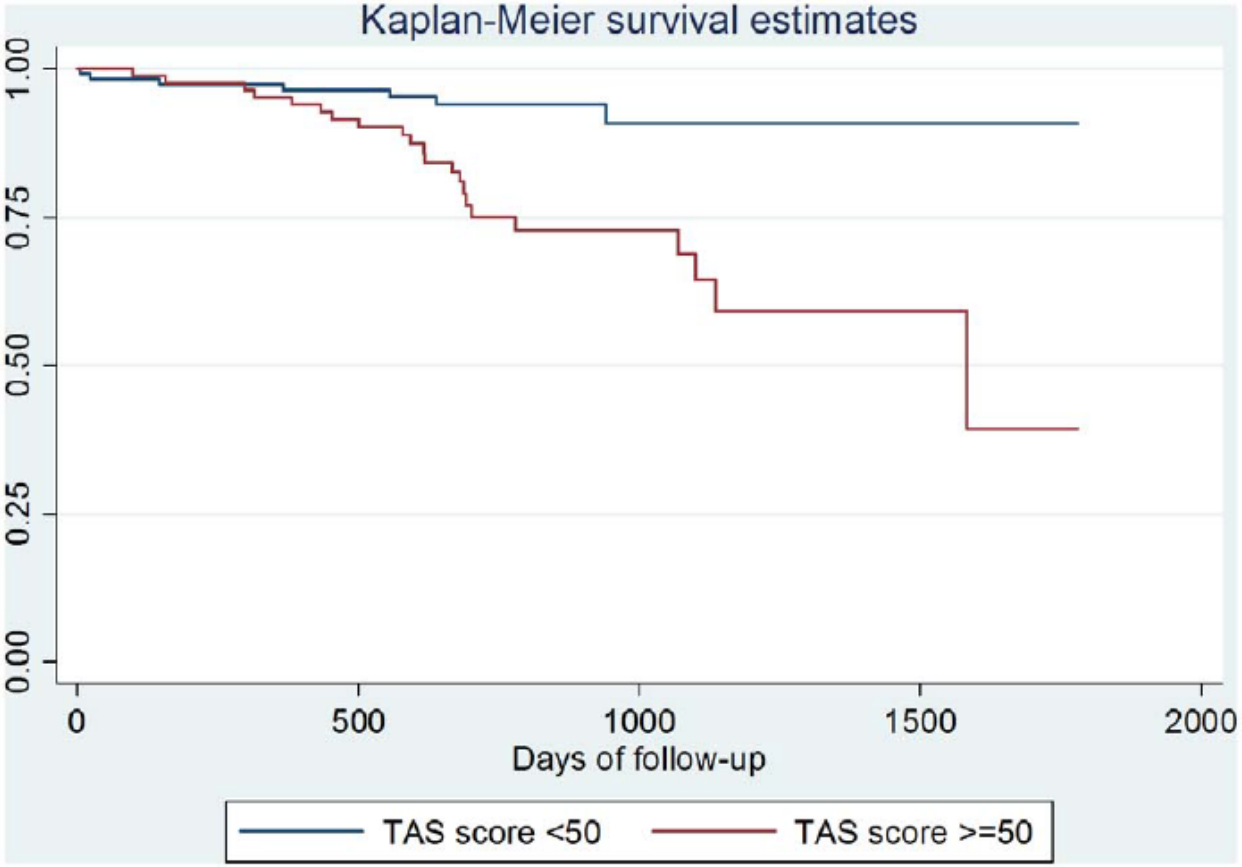
Alexithymia in predicting vascular events

Table 7. Results from the Cox proportional hazards regression analyses predicting time to vascular events.

	Hazard Ratio	(95% CI)	p
Age, 5-year increase	1.55	(1.19–2.02)	0.001
Infection duration, 1-year increase	0.98	(0.91–1.05)	0.5
Hypertension	0.44	(0.13–1.50)	0.2
Current smoking	3.87	(1.25–12.0)	0.019
Total cholesterol, 10 mg/dL increase	1.06	(0.98–1.14)	0.13
Alexithymia TAS-20 score ≥50 vs <50	5.58	(1.44–21.6)	0.013

Parruti G. et al. PLoS One 2013

Kaplan-Meier estimates of time to vascular events by alexithymia (TAS-20 score <50 versus TAS-20 ≥50).



Multicentric cohort study on Alexithymia and Cardiovascular Risk in HIV

An Italian Endeavor in the CISAI study group

Features at baseline	
Age, y (SD) [N=703]	46.1 (10)
Male sex, n (%)	526 (74.8)
Years from HIV infection, mean (SD)	13.1 (8.1)
HCV coinfection, no (%) [N=686]	182 (26.5)
In HAART, no (%) [N=525]	467 (88.9)
Nadir CD4, mean (SD) [N=655]	243.9 (189)
Lypodistrophy, no (%) [N=580]	166 (28.8)
High Alexithymia, no (%) [N=641]	228 (35.6)

Features at baseline	
Hypertension, no (%) [N=661]	151 (22.2)
Total colesterol, mg/dL, mean (SD) [N=654]	191.9 (49.2)
HDL, mg/dL, mean (SD) [N=640]	44.3 (13.9)
Diabetes, no (%) [N=671]	64 (9.5)
Smoking habits, no (%) [N=670]	321 (48)
Framingham RS, mean (SD) [N=490]	7.7 (8.1)
Carotid IMedia Thickness, cm, m(SD) [N=545]	0.07 (0.04)
Carotid plaque, no (%) [N=480]	150 (31.2)

Censored as at 31 Oct, 2017
3.4 y of average FU

Outcome measures	Total observations	No (%)
Vascular events (VE)	N=720	73 (10.1)
All-cause mortality (ACM)	N=718	38 (5.3)
Cumulative (VE+ACM)	N=719	98 (13.6)

logistic regression predicting the presence of carotid plaques

area under the receiving operator curve (ROC) = 0.85

N=400	Odds Ratio	(95%CI)	P
age	1.08	(1.05-1.12)	<0.001
Male gender	1.73	(.88-3.41)	0.108
Infection duration, 1-y increase	1.05	(1.01-1.09)	0.003
AIDS diagnosis	1.71	(.98-2.97)	0.057
Body Mass Index, 1 unit increase	.95	(.92-.97)	<0.001
Hypertension	2.19	(1.16-4.15)	0.015
Current smoking	1.51	(.85-2.67)	0.151
Physical activity	2.10	(1.13-3.90)	0.018
Total cholesterol (mg/dL)	1.00	(1.00-1.01)	0.006
Diabetes	1.77	(.77-4.02)	0.173
Alexithymia (TAS>50)	**5.94**	**(3.29-10.71)**	**<0.001**

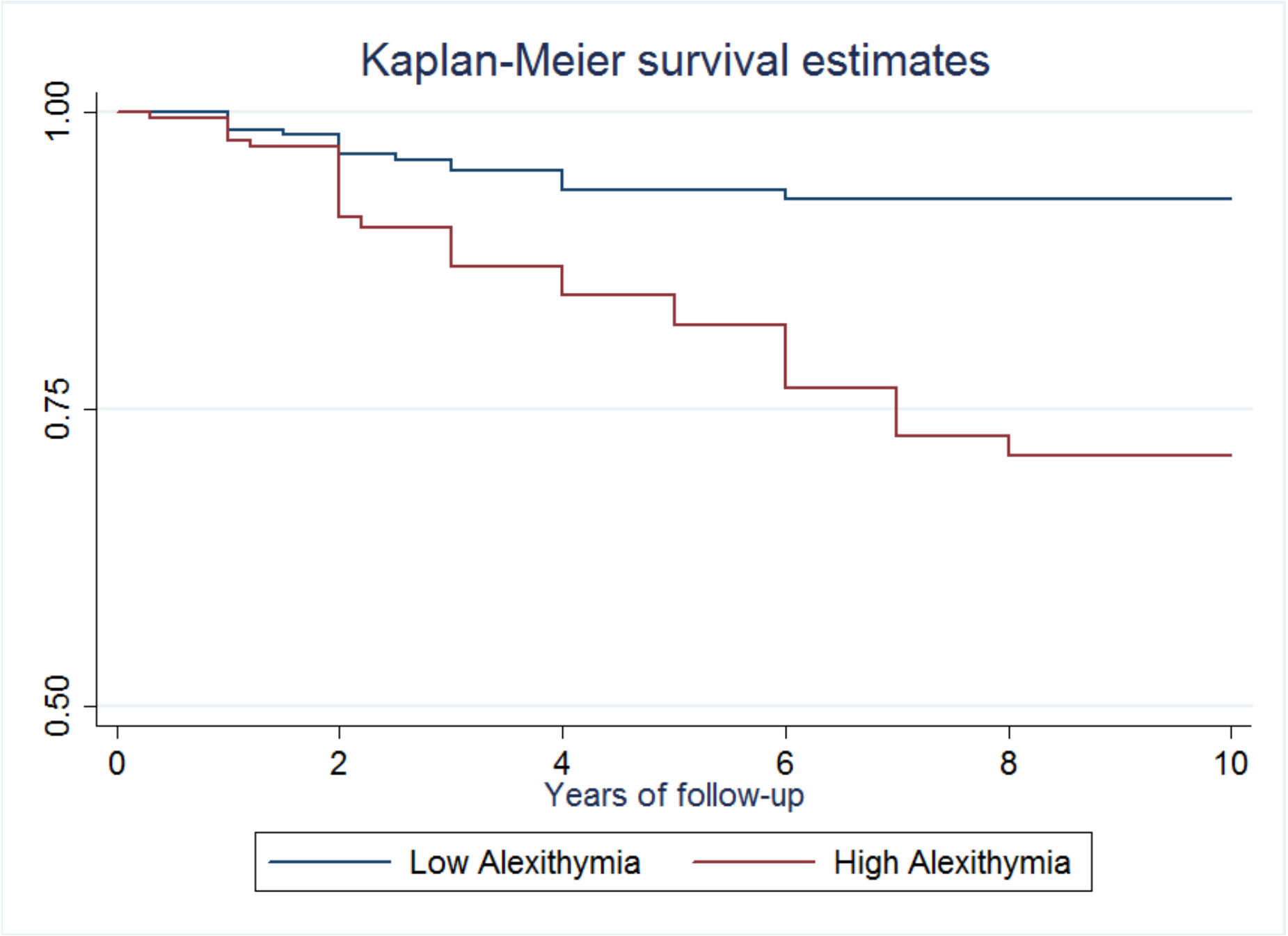
Cox proportional hazards regression analyses predicting time to vascular events.

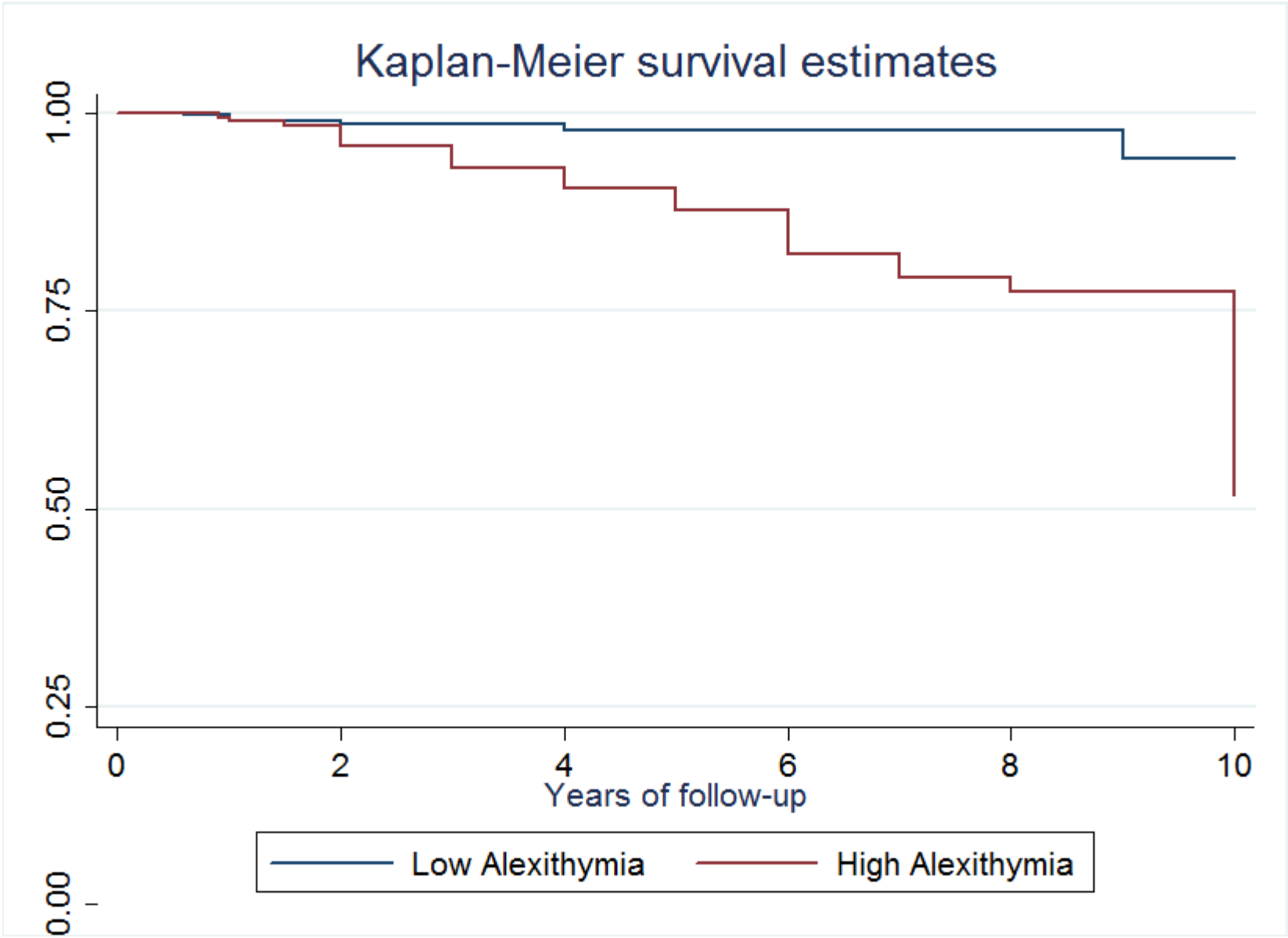
N=570	Hazard Ratio	(95%CI)	p
age	1.07	(1.047-1.110)	0.000
Male gender	2.85	(1.084-7.526)	0.034
Body Mass Index, 1 unit increase	1.04	(.991-1.092)	0.107
Infection duration, 1-year increase	.99	(.955-1.031)	0.709
Hypertension	2.05	(1.085-3.875)	0.027
Current smoking	2.29	(1.200-4.377)	0.012
Physical activity	1.22	(.598-2.505)	0.579
Diabetes	.78	(.364-1.678)	0.529
Total cholesterol (mg/dL)	1.00	(.995-1.007)	0.607
Alexithymia (TAS>50)	**2.39**	**(1.231-4.636)**	**0.010**

Cox proportional hazards regression analyses for time all-cause mortality

	Hazard Ratio	(95%CI)	P
age	1.076542	(1.041-1.109)	0.000
Male gender	2.531995	(.980-6.539)	0.055
CD4 T-cell count at baseline, cell/mmc	1.000307	(.999-1.001)	0.474
AIDS diagnosis	1.30201	(.718-2.353)	0.384
Infection duration, 1-year increase	.9839078	(.945-1.024)	0.428
Hypertension	2.354561	(1.276-4.341)	0.006
Current smoking	2.048783	(1.099-3.817)	0.024
Diabetes	.8492593	(.406-1.775)	0.664
Alexithymia (TAS>50)	**2.353194**	**(1.265-4.374)**	**0.007**

CV events


Kaplan-Meier survival estimates
1.00
0.75
0.50
0
2
4
6
8
10
Years of follow-up
Low Alexithymia
High Alexithymia


Kaplan-Meier survival estimates
1.00
0.75
0.50
0.25
0.00
0
2
4
6
8
10
Years of follow-up
Low Alexithymia
High Alexithymia

Mortality

In questo oneroso contesto..

- La disposizioni ministeriali considerano potenzialmente inappropriato il ricovero in regime ordinario e di DH per i pazienti HIV positivi
- La riduzione dell'entità dei ricoveri per infezioni opportunistiche ha indotto alla rivalutazione degli organici e delle disponibilità logictiche per molte UOC di Malattie Infettive
- La lotta all'AIDS ha perso molto del suo iniziale richiamo ed è considerata da non pochi una priorità inadeguata al contesto attuale…

Impact of comorbidities on the risk and cost of hospitalization in HIV-infected patients: real world data from the Abruzzo Region

LinkHealth
Health Economics, Outcomes & Epidemiology

Azienda USL di Pescara

ASR ABRUZZO
AGENZIA SANITARIA REGIONALE

Popolazione in studio

Soggetti con almeno un ricovero ospedaliero (DH o ordinario) con codice identificativo dell'infezione HIV (ICD9 042, V08 o 79.53), in diagnosi principale o secondaria, nel periodo compreso tra il 1 gennaio 2005 e 31 dicembre 2014

Outcome

Primario: ospedalizzazioni per qualsiasi causa nel 2015

Secondario: ospedalizzazioni per causa specifica utilizzando 18 categorie diagnostiche identificate attraverso l'applicazione di specifici algoritmi*

Covariate

Età, genere, Charlson Comorbility Index (CCI), coinfezione HCV

** Crowell TA. J Acquir Immune Defic Syndr. Vol 65, Number 4, 2014*

Analisi statistica

Modello di Regressione Logistica multivariata per valutare i fattori che influenzano la probabilità di incorrere in un ricovero ordinario

Modello di Regressione Lineare Generalizzato per valutare i fattori che incidono sull'aumentare dei costi ospedalieri (costi DRG*)

*Diagnosis-Related Group

Figure 2. Percentage of hospitalizations during the 2-year follow-up, as stratified by diagnostic categories

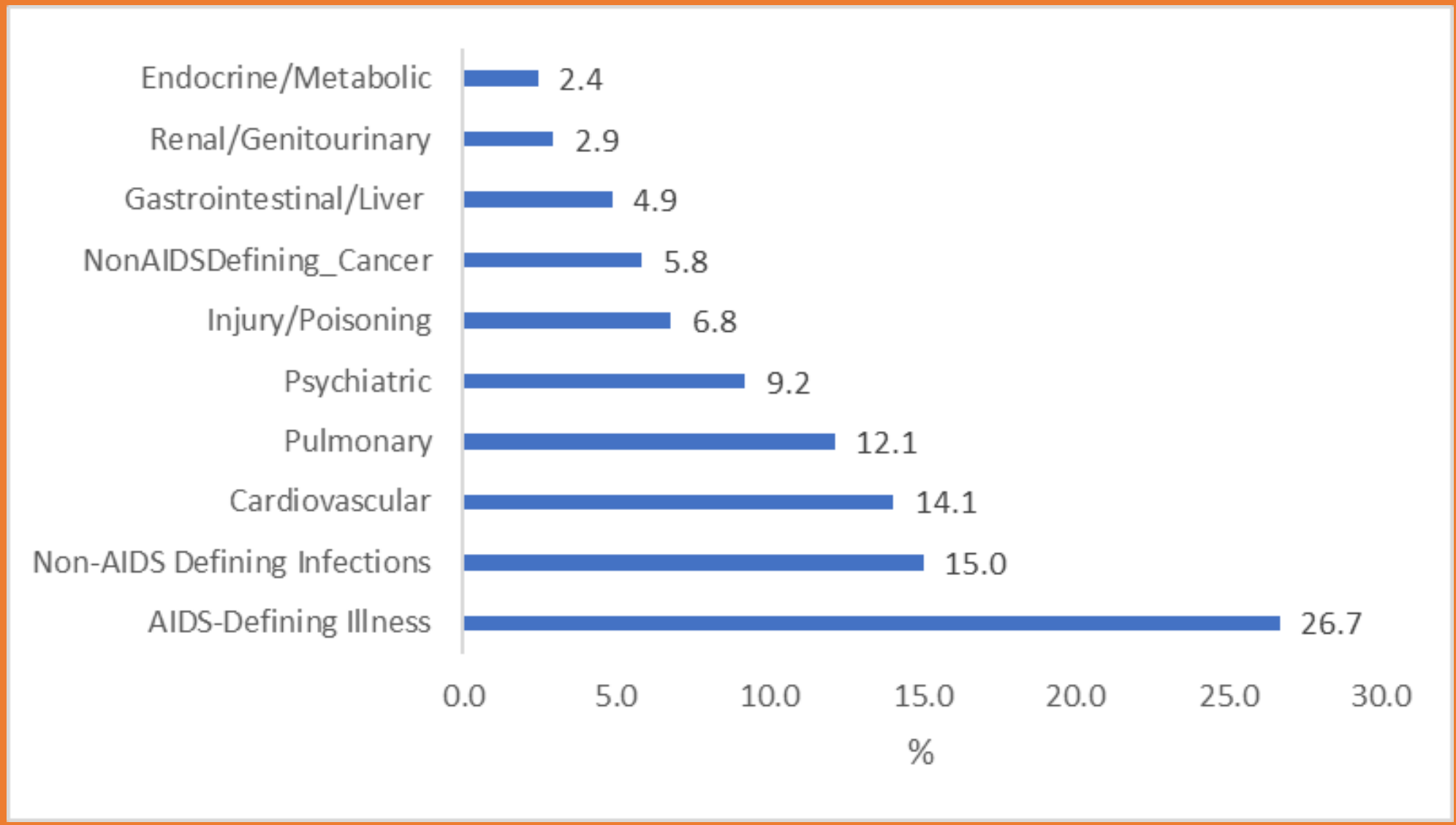
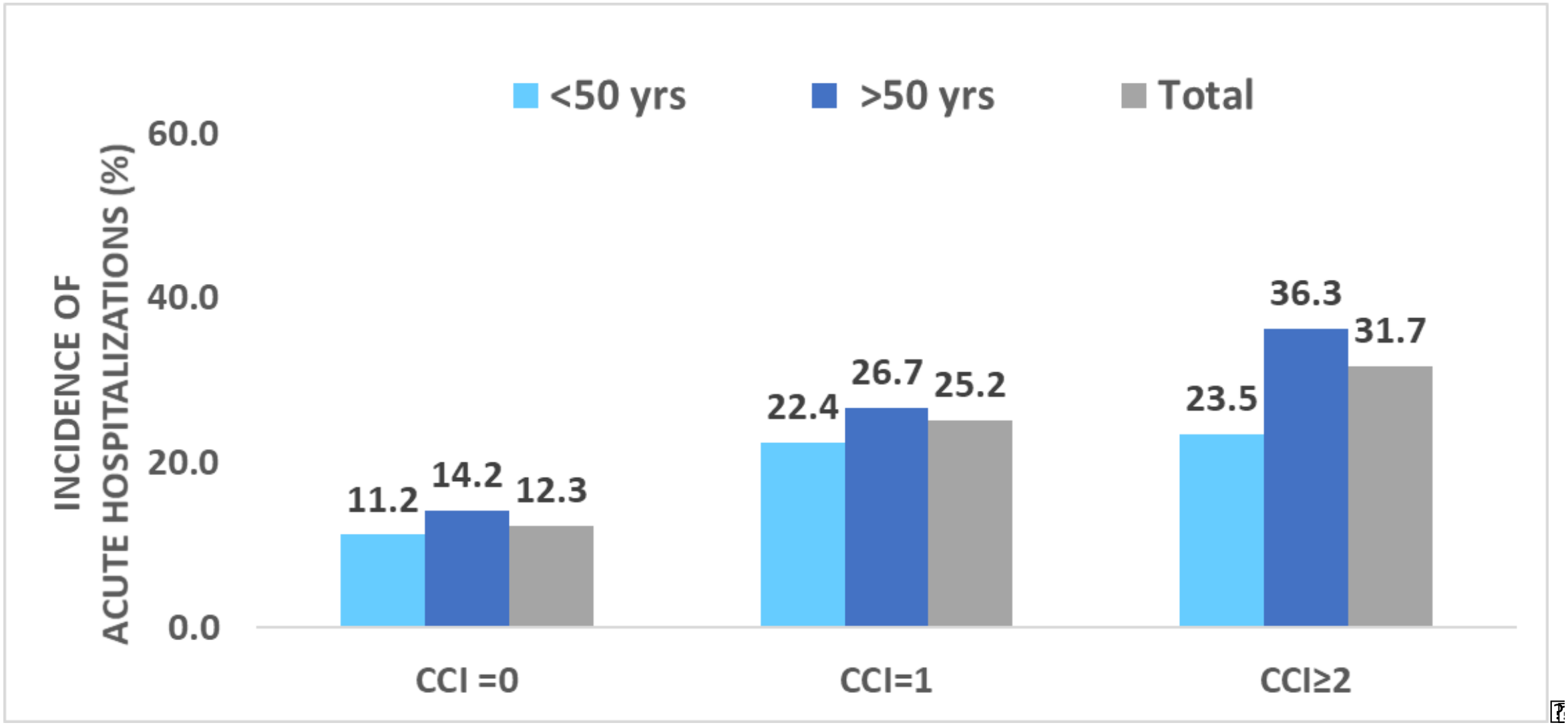


Figure 1. Percentage of HIV patients with hospital admission during the 2-year of follow-up according to Charlson Comorbidity Index (CCI).



	Unadjusted IRR (95% CI)	Adjusted IRR (95% CI)
Male	1.32 (1.03-1.69)	1.13 (0.88-1.46)
Female	Ref	Ref
Age (years)		
≥50	1.89 (1.52-2.35)	1.42 (1.13-1.79)
<50	Ref	Ref
HCV co-infection		
Yes	**2.23 (1.80-2.78)**	**1.98 (1.59-2.47)**
No	Ref	Ref
Renal disease		
Yes	**2.77 (1.81-4.24)**	**2.27 (1.45-3.56)**
No	Ref	Ref
Liver disease		
Yes	**2.99 (2.17-4.12)**	**2.21 (1.57-3.13)**
No	Ref	Ref
Chronic Polmonary disease		
Yes	**2.66 (1.89-3.74)**	**2.32 (1.63-3.32)**
No	Ref	Ref
Cancer		
Yes	**1.52 (1.02-2.26)**	**1.3 (0.86-1.97)**
No	Ref	Ref
Charlson Comorbility Index†		
≥2	**2.87 (2.22-3.72)**	**2.43 (1.86-3.17)**
1	**2.32 (1.79-3.01)**	**2.04 (1.56-2.66)**
0	Ref	Ref

Table 3. Adjusted mean annual costs per hospitalized patient for all-cause estimated by the Generalized Linear Model

	Adjusted Mean Annual cost	**EXP(β) coefficient**	**95% CI**	**p-value**
Male	4643 (3832-5454)	1.1	0.85-1.42	0.465
Female	3808 (2824-4790)	Ref		
Age (years)				
≥50	4685 (3714-5657)	1.24	0.95-1.65	0.106
<50	3773 (2944-4602)	Ref		
HCV co-infection				
Yes	4378 (3254-5502)	1.08	0.81-1.45	0.59
No	4038 (3297-4784)	Ref		
Charlson Comorbility Index				
≥2	**9734 (6691-12778)**	**3.90**	**2.80-5.44**	**<0.0001**
1	**4422 (3166-5679)**	**1.77**	**1.27-2.47**	**<0.0001**
0	**2494 (2041-2948)**	Ref		

conclusioni

- L’analisi dei dati di vita reale conferma che l’impegno clinico della fase cronica dell’infezione da HIV è rilevante anche nella misura dei costi ospedalieri e nell’analisi della loro struttura
- Le decisioni di collocamento delle risorse sanitarie ordinarie e l’indirizzo delle risorse da progettualità nazionali ed europee possono trovare un fermo supporto nell’analisi rigorosa dei dati di *real life* che parta da una condivisa domanda di conoscenza e comprensione dei fenomeni tra clinici ed epidemiologi