Variabili di contesto e dati globali: la gestione della complessità nella misurazione del valore

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Dati globali

Che cosa conosciamo oggi

- Qualità
- Sicurezza (teorica)
- Efficacia (teorica)

- “Prezzo”

Che cosa conosciamo

- **Qualità**
- **Sicurezza (teorica)**
- **Efficacia (teorica)**

- “Prezzo”

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JUNE 26, 2008 VOL. 358 NO. 26

Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty

Bengt I. Eriksson, M.D., Ph.D., Lars C. Borris, M.D., Richard J. Friedman, M.D., Sylvia Haas, M.D., Menno V. Huisman, M.D., Ph.D., Ajay K. Kakkar, M.D., Ph.D., Tiemo J. Bandel, M.D., Horst Beckmann, Ph.D., Eva Muehlhofer, M.D., Frank Misselwitz, M.D., Ph.D., and William Geerts, M.D., for the RECORD1 Study Group*

Che cosa vorremmo conoscere oggi

- **Qualità**
- **Sicurezza (reale/pratica)**
- **Efficacia (reale/pratica)**

- Valore

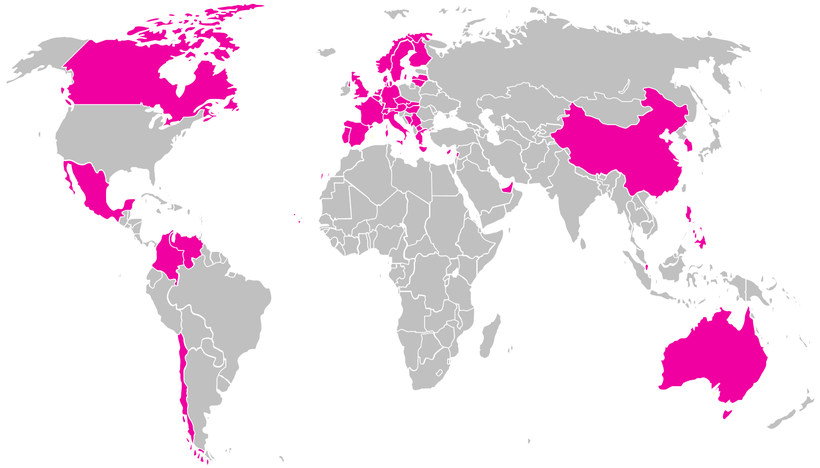
A non-interventional comparison of rivaroxaban with standard of care for thromboprophylaxis after major orthopaedic surgery in 17,701 patients with propensity score adjustment

Alexander G. G. Turpie[1]; Sylvia Haas[2]; Reinhold Kreutz[3]; Lorenzo G. Mantovani[4]; Cassandra W. Pattanayak[5]; Gerlind Holberg[6]; Waheed Jamal[6]; André Schmidt[6]; Martin van Eickels[6]; Michael R. Lassen[7]

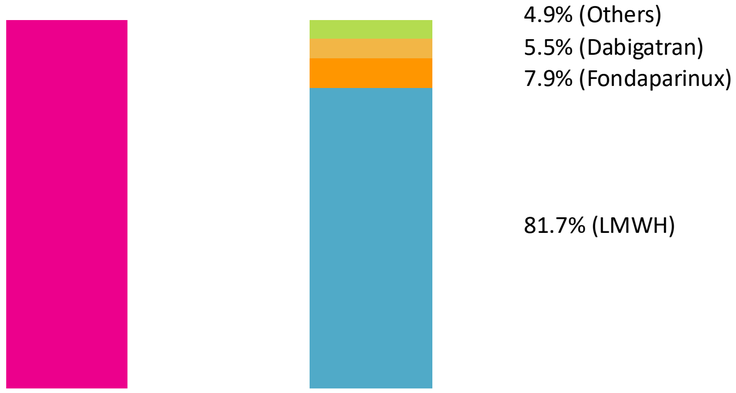
[1]Department of Medicine, Hamilton Health Sciences, Hamilton, Ontario, Canada; [2]Institute for Experimental Oncology and Therapy Research, Technical University of Munich, Munich, Germany; [3]Institut für Klinische Pharmakologie und Toxikologie, Charité-Universitätsmedizin, Berlin, Germany; [4]Dipartimento di Medicina Clinica e Chirurgia, Università degli Studi di Napoli Federico II, Naples, Italy; [5]Harvard University Statistics Department (current address: Quantitative Analysis Institute, Wellesley College, Wellesley, Massachusetts, USA); [6]Bayer HealthCare AG, Berlin, Germany; [7]Glostrup Hospital, Spine Center, Clinical Trial Unit, University of Copenhagen, Glostrup, Denmark

XAMOS: participating countries

- Recruitment began February 2009; database closed in August 2011
  - 17,701 patients from 37 countries and 252 centers



XAMOS: pharmacological VTE prophylaxis



50.4% of the population were assigned to rivaroxaban and 49.6% to SOC
Safety population


Frailty
Metabolic disease
Platelet aggregation inhibitors
Heparin
Vitamin K antagonist
Atrial fibrillation L12M
Atrial fibrillation CNG
Atrial fibrillation L5Y
Atrial fibrillation M5Y
Asian
Hip fracture
Other antithrombotics
Autoimmune CNG
Thrombotic event L12M
Heart failure CNG3
Thrombotic event CNG
Knee
Other race
Myocardial infarction L12M
Myocardial infarction CNG
Heart failure CNG2
Hepatic impairment CNG
Stroke L12M
Severe renal impairment CNG
Myeloproliferative CNG
Severe renal impairment L12M
Thrombocytopenia CNG
Hepatitis CNG
Thrombophilia CNG
Transient ischaemic attack CNG
Stroke CNG
Intracranial haemorrhage L12M
Direct thrombin inhibitors
Neoplasm CNG
Black
Macroscopic haematuria CNG
Gastrointestinal haemorrhage CNG
Intracranial haemorrhage CNG
Neoplasm L12M
Transient ischaemic attack L12M
Macroscopic haematuria L12M
Gastrointestinal haemorrhage L12M
Initial
Subclasses
−0.04
−0.03
−0.02
−0.01
0
0.01
0.02
0.03
Mean in rivaroxaban group – mean in standard-of-care group

Variabili di Contesto

Che cosa vorremmo conoscere oggi

- Qualità
- Sicurezza (reale/pratica)
- Efficacia (reale/pratica)
- **Utilizzo (Per chi? Come?)**

- Valore

ORIGINAL ARTICLE

Comparison of Intensive and Moderate Lipid Lowering with Statins after Acute Coronary Syndromes

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 JANUARY 5, 2012 VOL. 366 NO. 1

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Effect of Platelet Inhibition with Cangrelor during PCI on Ischemic Events

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 SEPTEMBER 10, 2009 VOL. 361 NO. 11

Rivaroxaban in Patients wi… Acute Coronary Synd…

The NEW ENGLAND JOURNAL of MEDICINE

…pidogrel in Patients with Acute …ary Syndromes

Optimal Medical Therapy with or without PCI for Stable Coronary Disease

Table 1. Baseline Clinical and Angiographic Characteristics.*

Characteristic	PCI Group (N=1149)	Medical-Therapy Group (N=1138)
Demographic		
Age — yr	61.5±10.1	61.8±9.7
Sex — no. (%)		
Male	979 (85)	968 (85)
Female	169 (15)	169 (15)

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Letter to the Editor

Burden of acute myocardial infarction

Lorenzo G. Mantovani [a,b], Carla Fornari [a], Fabiana Madotto [a], Michele A. Riva [a], Luca Merlino [c], Marco M. Ferrario [d], Virginio Chiodini [a], Alberto Zocchetti [c], Giovanni Corrao [e], Giancarlo Cesana [a,*]

Epidemiology

Population	Female	Male	Total
N	4416	7633	12049
Age mean (years ± sd)*	76.627 ± 11.540	66.779 ± 12.356	70.389 ± 12.962
Age class:			
< 40	22 (0.5%)	114 (1.5%)	136 (1.1%)
40 – 49	106 (2.4%)	628 (8.2%)	734 (6.1%)
50 – 59	270 (6.1%)	1515 (19.9%)	1785 (14.8%)
60 – 69	651 (14.7%)	2140 (28.0%)	2791 (23.2%)
70 – 79	1456 (33.0%)	2102 (27.5%)	3558 (29.5%)
80 – 89	1464 (33.2%)	975 (12.8%)	2439 (20.3%)
+ 90	447 (10.1%)	159 (2.1%)	606 (5.0%)
Death*°	1600 (36.2%)	1780 (23.3%)	3380 (28.1%)

Come vengono trattati

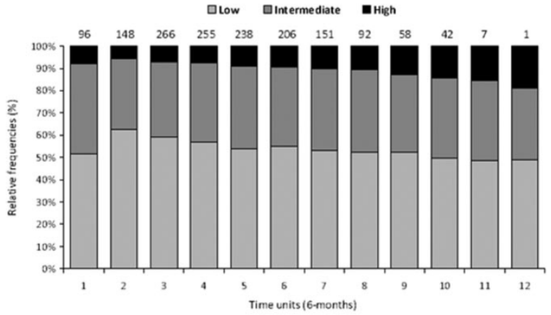


Figure. Relative frequencies (percent) of patient adherence to AHT at baseline (ie, 6 months after index diagnosis) and during follow-up.

Table 3. Multivariable Analysis of the Association of Patient Characteristics With First-Ever Acute Cardiovascular Event Estimated by Cox Proportional-Hazards Models

Adherence Within 6 mo After Diagnosis	HR* (95% CI)	*P*
Model 1†		
Low (PDC <40%)	1.00	<0.001§
Intermediate (PDC, 40% to 79%)	0.87 (0.73–1.03)	0.117
High (PDC ≥80%)	0.50 (0.35–0.69)	<0.001
Model 2†		
Low (PDC <40%)	1.00	<0.001§
Intermediate (PDC, 40% to 79%)	0.86 (0.71–1.03)	0.109
High (PDC ≥80%)	0.62 (0.40–0.96)	0.032

A total of 659 CVEs were considered in the models.

*All models were adjusted for clustering by regional health authority.

†Model 1: adjusted for age, gender, use of antithrombotics, ≥5 concurrent medications, presence of diabetes mellitus, dyslipidemia, and prior hospitalization. Time-dependent covariates included adherence to AHT, use of combination AHT, antithrombotics, ≥5 concurrent medications, presence of peripheral vascular diseases, diabetes mellitus, and dyslipidemia.

‡Model 2: model 1 additionally weighted by the inverse estimated propensity scores.

JCA: A GAME CHANGER!

- Dati globali
- Variabili di contesto
- **INTERAZIONE**
  - Dati globali
  - Variabili di contesto

Che cosa conosceremo dal 1/1/25

- Qualità
- Sicurezza (teorica)
- Efficacia (teorica)
  - «assoluta»
  - **«relativa»**

- “Prezzo”

Che cosa conosceremo dal 1/1/25

- Qualità
- Sicurezza (teorica)
- Efficacia (teorica)
  - «assoluta»
  - **«relativa»: PICO**

- “Prezzo”

Che cosa conosceremo dal 1/1/25

- Qualità
- Sicurezza (teorica)
- Efficacia (teorica)
  - «assoluta»
  - **«relativa»: PICO = attuali alternative di contesto!**

- “Prezzo”

TO PICO OR NOT TO PICO. THAT IS THE QUESTION!

GIA', MA QUALE PICO?

Quello degli studi registrativi?
Quello della pratica clinica?
Quale pratica?

Un esempio … semplice

Farmaco utilizzazione in sclerosi multipla

Numero di soggetti con almeno una prescrizione per anno e principio attivo

Principio attivo	N soggetti con almeno un'erogazione (% colonna) Anno													
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Alemtuzumab						3 (0.40%)	10 (1.25%)	14 (1.63%)	14 (1.56%)	8 (0.85%)	3 (0.33%)	3 (0.30%)	2 (0.19%)	2 (0.18%)
Cladribina										11 (1.17%)	20 (2.18%)	26 (2.62%)	34 (3.31%)	29 (2.61%)
Dimetilfumarato						63 (8.48%)	78 (9.77%)	104 (12.08%)	126 (14.08%)	168 (17.80%)	182 (19.85%)	196 (19.72%)	205 (19.98%)	225 (20.25%)
Fingolimod		1 (0.21%)	22 (4.06%)	13 (3.07%)	53 (8.28%)	66 (8.88%)	79 (9.90%)	99 (11.50%)	113 (12.63%)	106 (11.23%)	100 (10.91%)	106 (10.66%)	102 (9.94%)	95 (8.55%)
Glatiramer Acetato	112 (24.83%)	124 (25.46%)	146 (26.94%)	98 (23.11%)	152 (23.75%)	169 (22.75%)	189 (23.68%)	197 (22.88%)	182 (20.34%)	178 (18.86%)	156 (17.01%)	145 (14.59%)	134 (13.06%)	118 (10.62%)
Interferone Beta 1a	215 (47.67%)	227 (46.61%)	227 (41.88%)	203 (47.88%)	283 (44.22%)	259 (34.86%)	226 (28.32%)	213 (24.74%)	189 (21.12%)	162 (17.16%)	138 (15.05%)	129 (12.98%)	107 (10.43%)	89 (8.01%)
Interferone Beta 1b	88 (19.51%)	94 (19.30%)	98 (18.08%)	78 (18.40%)	86 (13.44%)	79 (10.63%)	69 (8.65%)	60 (6.97%)	50 (5.59%)	39 (4.13%)	29 (3.16%)	25 (2.52%)	20 (1.95%)	15 (1.35%)
Natalizumab	36 (7.98%)	41 (8.42%)	49 (9.04%)	32 (7.55%)	56 (8.75%)	58 (7.81%)	59 (7.39%)	59 (6.85%)	71 (7.93%)	83 (8.79%)	84 (9.16%)	99 (9.96%)	108 (10.53%)	118 (10.62%)
Ocrelizumab									6 (0.67%)	52 (5.51%)	57 (6.22%)	93 (9.36%)	106 (10.33%)	133 (11.97%)
Ofatumumab														38 (3.42%)
Ozanimod												1 (0.10%)	6 (0.58%)	15 (1.35%)
Peginterferone Beta 1a						22 (2.96%)	52 (6.52%)	53 (6.16%)	51 (5.70%)	40 (4.24%)	40 (4.36%)	36 (3.62%)	33 (3.22%)	29 (2.61%)
Ponesimod														3 (0.27%)
Siponimod												6 (0.60%)	15 (1.46%)	18 (1.62%)
Teriflunomide					10 (1.56%)	24 (3.23%)	36 (4.51%)	62 (7.20%)	93 (10.39%)	97 (10.28%)	108 (11.78%)	129 (12.98%)	154 (15.01%)	184 (16.56%)

Stima del numero di switch (tutti i casi)

Prima terapia	N pazienti (% riga) N switch durante il follow-up							
	0	1	2	3	4	5	6	N totale pazienti
Alemtuzumab	7 (63.64%)	4 (36.36%)						11
Cladribina	28 (80.00%)	6 (17.14%)	1 (2.86%)					35
Dimetilfumarato	105 (69.54%)	35 (23.18%)	8 (5.30%)	3 (1.99%)				151
Fingolimod	29 (74.36%)	6 (15.38%)	4 (10.26%)					39
Glatiramer Acetato	111 (39.08%)	100 (35.21%)	45 (15.85%)	17 (5.99%)	7 (2.46%)	3 (1.06%)	1 (0.35%)	284
Interferone Beta 1a	124 (32.12%)	134 (34.72%)	77 (19.95%)	36 (9.33%)	9 (2.33%)	4 (1.04%)	2 (0.52%)	386
Interferone Beta 1b	44 (32.59%)	57 (42.22%)	25 (18.52%)	7 (5.19%)	2 (1.48%)			135
Natalizumab	71 (56.80%)	35 (28.00%)	9 (7.20%)	6 (4.80%)	2 (1.60%)	2 (1.60%)		125
Ocrelizumab	39 (95.12%)	2 (4.88%)						41
Ofatumumab	11 (100.00%)							11
Ozanimod	2 (66.67%)	1 (33.33%)						3
Peginterferone Beta 1a	10 (43.48%)	10 (43.48%)	3 (13.04%)					23
Ponesimod	1 (100.00%)							1
Siponimod	2 (100.00%)							2
Teriflunomide	83 (76.85%)	17 (15.74%)	5 (4.63%)	2 (1.85%)	1 (0.93%)			108
Totale	**667 (49.23%)**	**407 (30.04%)**	**177 (13.06%)**	**71 (5.24%)**	**21 (1.55%)**	**9 (0.66%)**	**3 (0.22%)**	**1355**

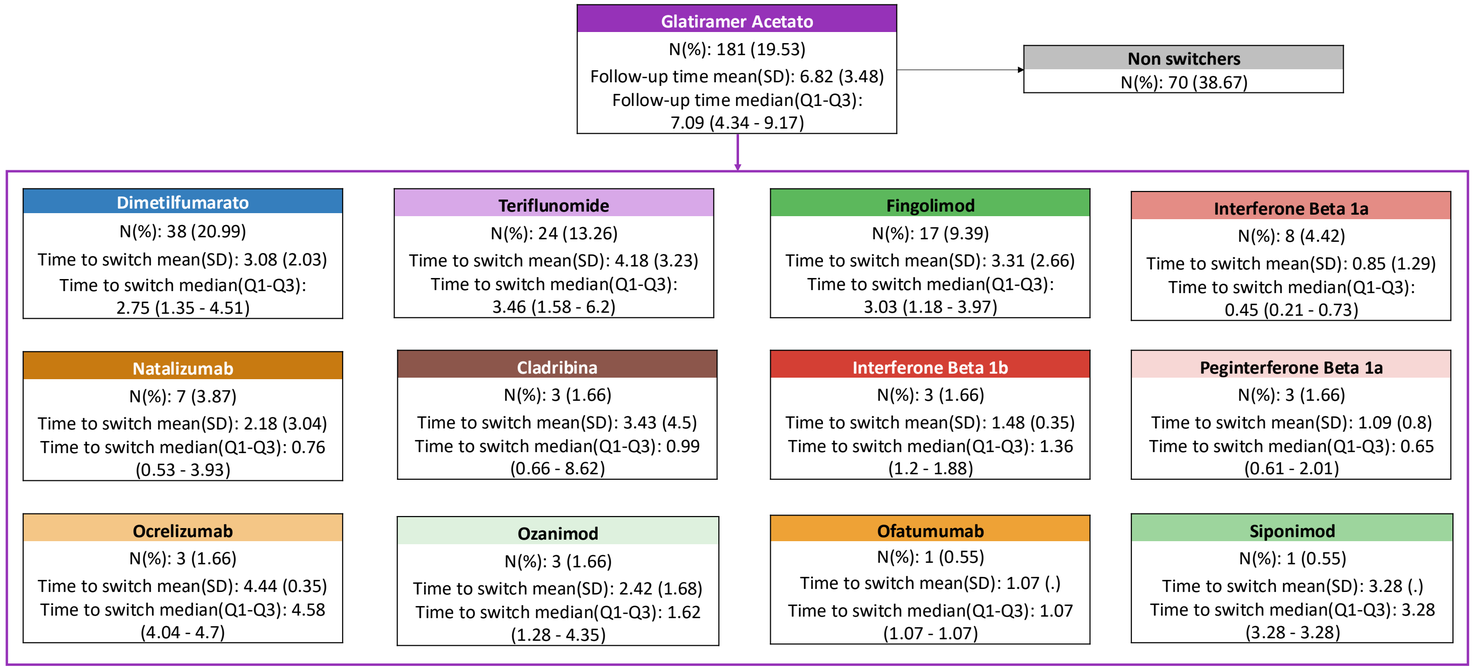
Stima del numero di switch (casi incidenti)

Prima terapia	N pazienti (% riga) N switch durante il follow-up							
	0	1	2	3	4	5	6	N totale pazienti
Alemtuzumab	7 (63.64%)	4 (36.36%)						11
Cladribina	28 (80.00%)	6 (17.14%)	1 (2.86%)					35
Dimetilfumarato	105 (69.54%)	35 (23.18%)	8 (5.30%)	3 (1.99%)				151
Fingolimod	29 (74.36%)	6 (15.38%)	4 (10.26%)					39
Glatiramer Acetato	70 (38.67%)	66 (36.46%)	29 (16.02%)	10 (5.52%)	5 (2.76%)		1 (0.55%)	181
Interferone Beta 1a	52 (29.71%)	67 (38.29%)	31 (17.71%)	15 (8.57%)	6 (3.43%)	3 (1.71%)	1 (0.57%)	175
Interferone Beta 1b	18 (34.62%)	25 (48.08%)	8 (15.38%)	1 (1.92%)				52
Natalizumab	63 (67.02%)	27 (28.72%)	2 (2.13%)	2 (2.13%)				94
Ocrelizumab	39 (95.12%)	2 (4.88%)						41
Ofatumumab	11 (100.00%)							11
Ozanimod	2 (66.67%)	1 (33.33%)						3
Peginterferone Beta 1a	10 (43.48%)	10 (43.48%)	3 (13.04%)					23
Ponesimod	1 (100.00%)							1
Siponimod	2 (100.00%)							2
Teriflunomide	83 (76.85%)	17 (15.74%)	5 (4.63%)	2 (1.85%)	1 (0.93%)			108
Totale	**520 (56.09%)**	**266 (28.69%)**	**91 (9.82%)**	**33 (3.56%)**	**12 (1.29%)**	**3 (0.32%)**	**2 (0.22%)**	**927**

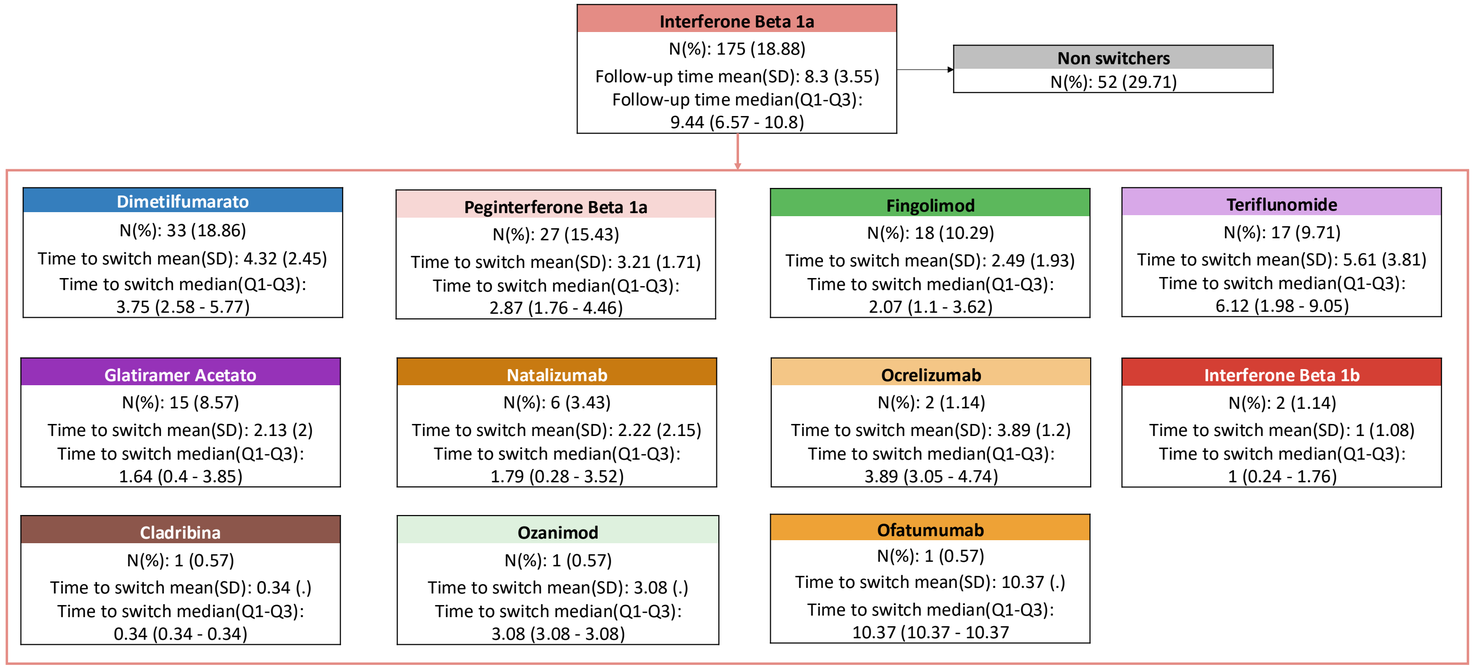
Primo trattamento (casi incidenti dal 2011)

Pazienti con almeno una prescrizione nel periodo 2011-2023 **N totale: 927**	**Glatiramer Acetato** N(%): 181 (19.53) Follow-up time mean(SD): 6.82 (3.48) Follow-up time median(Q1-Q3): 7.09 (4.34 - 9.17)	**Interferone Beta 1a** N(%): 175 (18.88) Follow-up time mean(SD): 8.3 (3.55) Follow-up time median(Q1-Q3): 9.44 (6.57 - 10.8)	**Dimetilfumarato** N(%): 151 (16.29) Follow-up time mean(SD): 3.66 (2.52) Follow-up time median(Q1-Q3): 3.5 (1.22 - 5.67)
Teriflunomide N(%): 108 (11.65) Follow-up time mean(SD):3.29 (2.56) Follow-up time median(Q1-Q3): 2.24 (1.05 - 5.5)	**Natalizumab** N(%): 94 (10.14) Follow-up time mean(SD): 4.33 (3.37) Follow-up time median(Q1-Q3): 3.86 (1.57 - 5.81)	**Interferone Beta 1b** N(%): 52 (5.61) Follow-up time mean(SD): 7.5 (3.88) Follow-up time median(Q1-Q3): 8.89 (3.82 - 10.66)	**Ocrelizumab** N(%): 41 (4.42) Follow-up time mean(SD): 2.07 (1.43) Follow-up time median(Q1-Q3): 1.79 (1.08 - 2.82)
Fingolimod N(%): 39 (4.21) Follow-up time mean(SD): 5.12 (3.04) Follow-up time median(Q1-Q3): 5.78 (2.33 - 7.32)	**Cladribina** N(%): 35 (3.78) Follow-up time mean(SD): 1.35 (1.13) Follow-up time median(Q1-Q3): 1.17 (1.03 - 1.25)	**Peginterferone Beta 1a** N(%): 23 (2.48) Follow-up time mean(SD): 4.91 (2.5) Follow-up time median(Q1-Q3): 4.71 (2.43 - 7.65)	**Alemtuzumab** N(%): 11 (1.19) Follow-up time mean (SD): 2.58 (2.42) Follow-up time median(Q1-Q3): 1.19 (1.17 - 5.08)
Ofatumumab N(%): 11 (1.19) Follow-up time mean(SD): 0.48 (0.19) Follow-up time median(Q1-Q3): 0.47 (0.36 - 0.61)	**Ozanimod** N(%): 3 (0.32) Follow-up time mean(SD): 1.09 (0.76) Follow-up time median(Q1-Q3): 0.91 (0.44 - 1.93)	**Siponimod** N(%): 2 (0.22) Follow-up time mean(SD): 0.25 (0.12) Follow-up time median(Q1-Q3): 0.25 (0.16 - 0.33)	**Ponesimod** N(%): 1 (0.11) Follow-up time mean(SD): 0.82 (.) Follow-up time median(Q1-Q3): 0.82 (0.82 - 0.82)

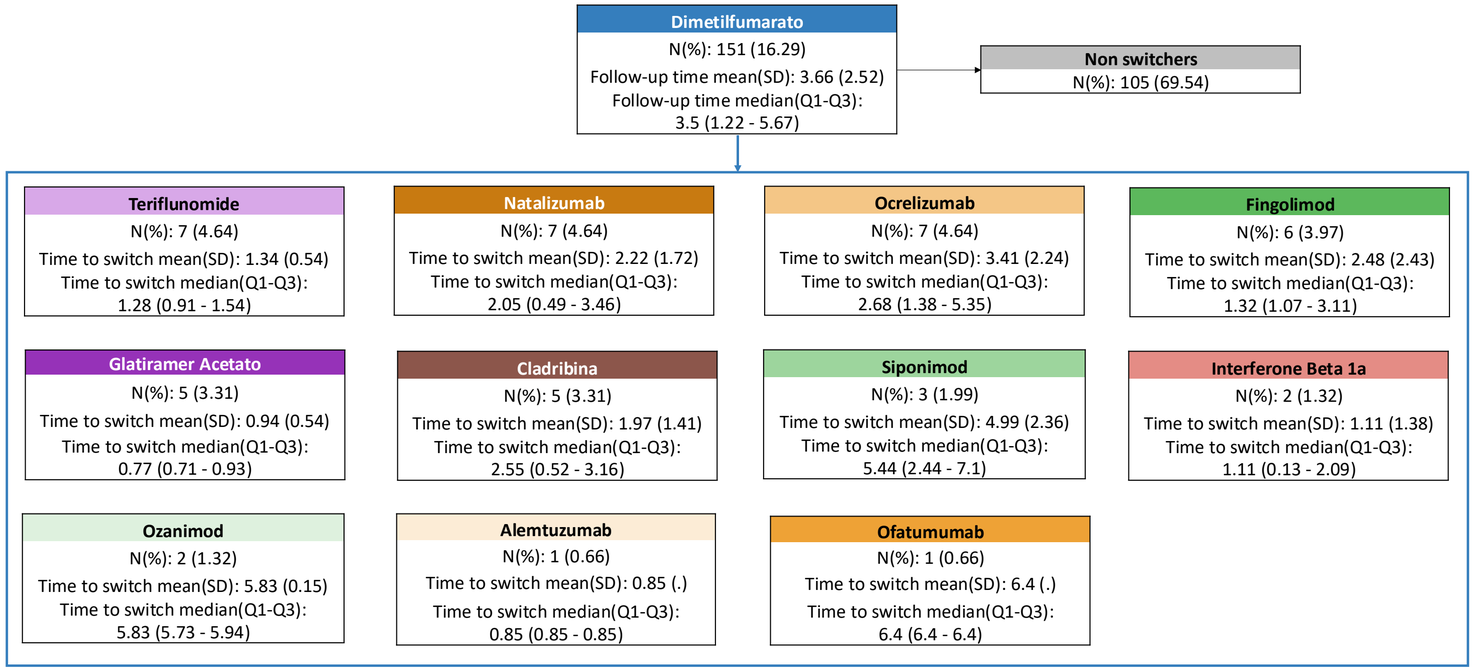
Primo switch (casi incidenti dal 2011)



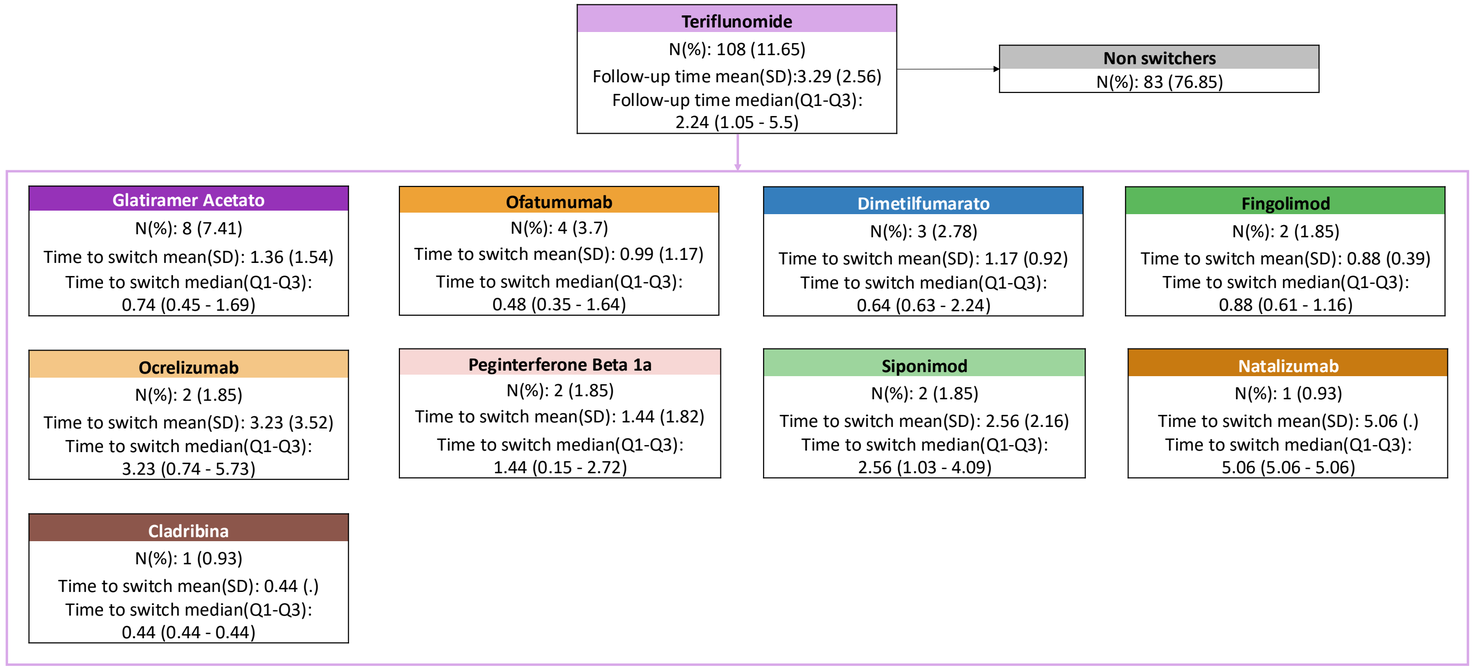
Primo switch (casi incidenti dal 2011)



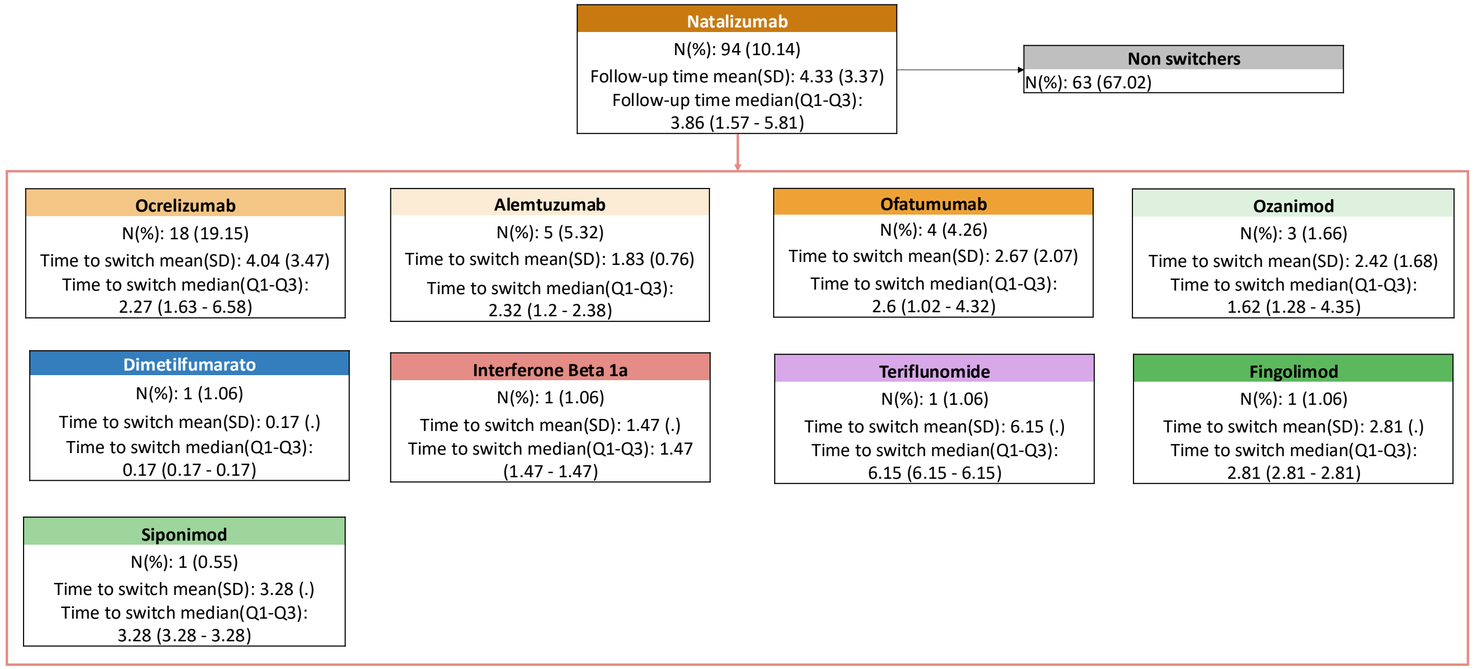
Primo switch (casi incidenti dal 2011)



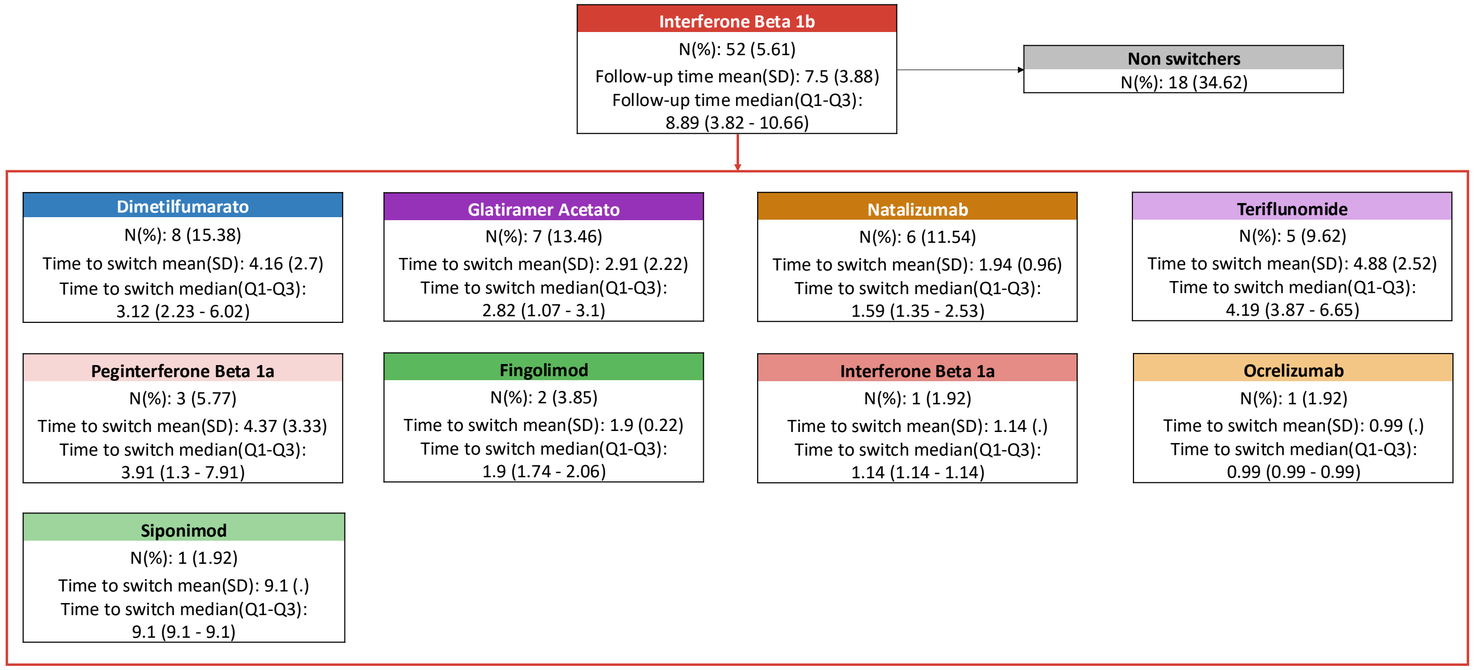
Primo switch (casi incidenti dal 2011)



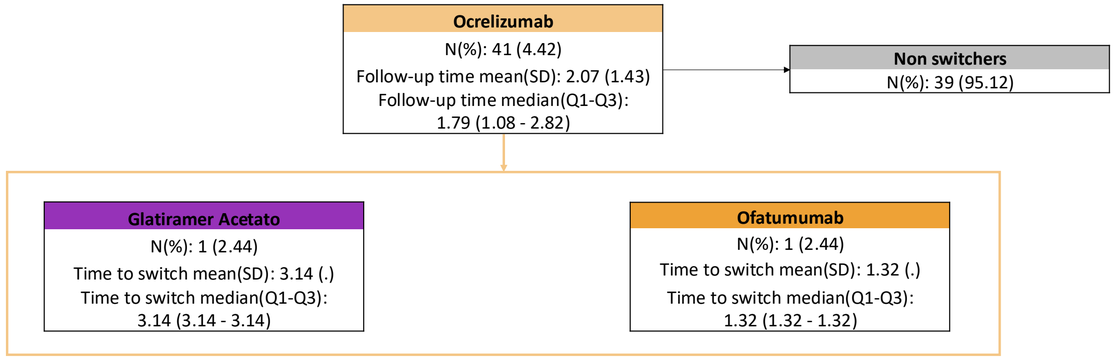
Primo switch (casi incidenti dal 2011)



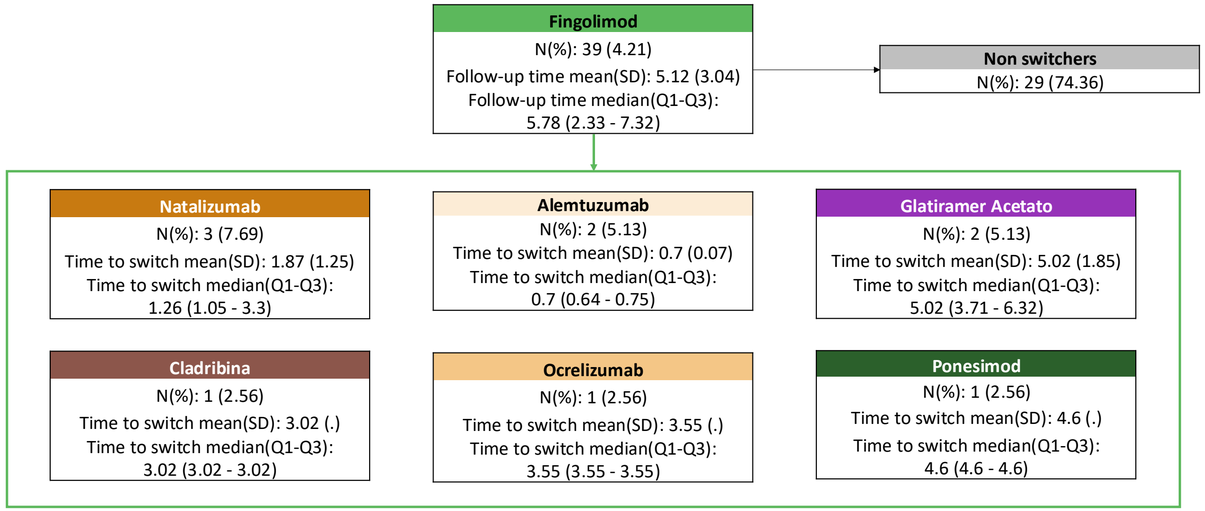
Primo switch (casi incidenti dal 2011)



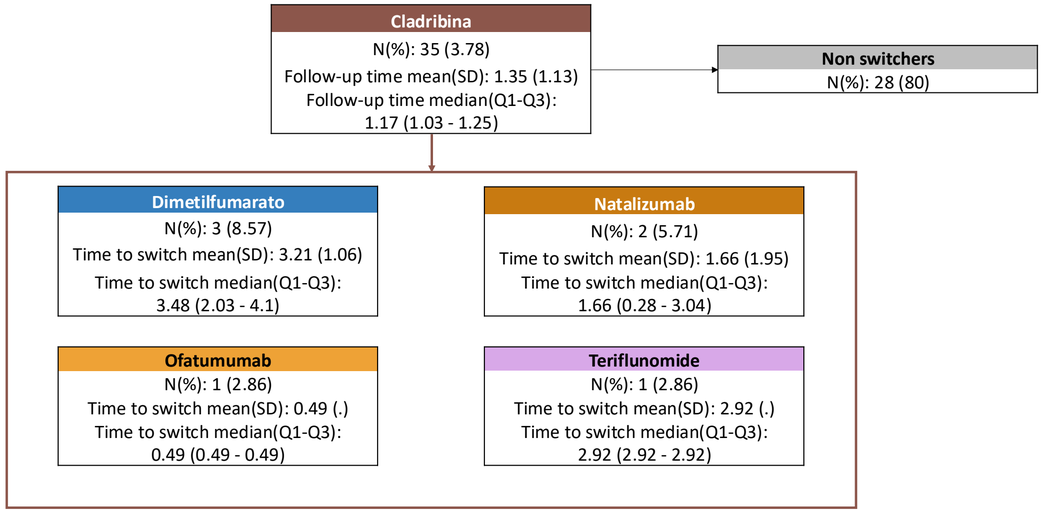
Primo switch (casi incidenti dal 2011)



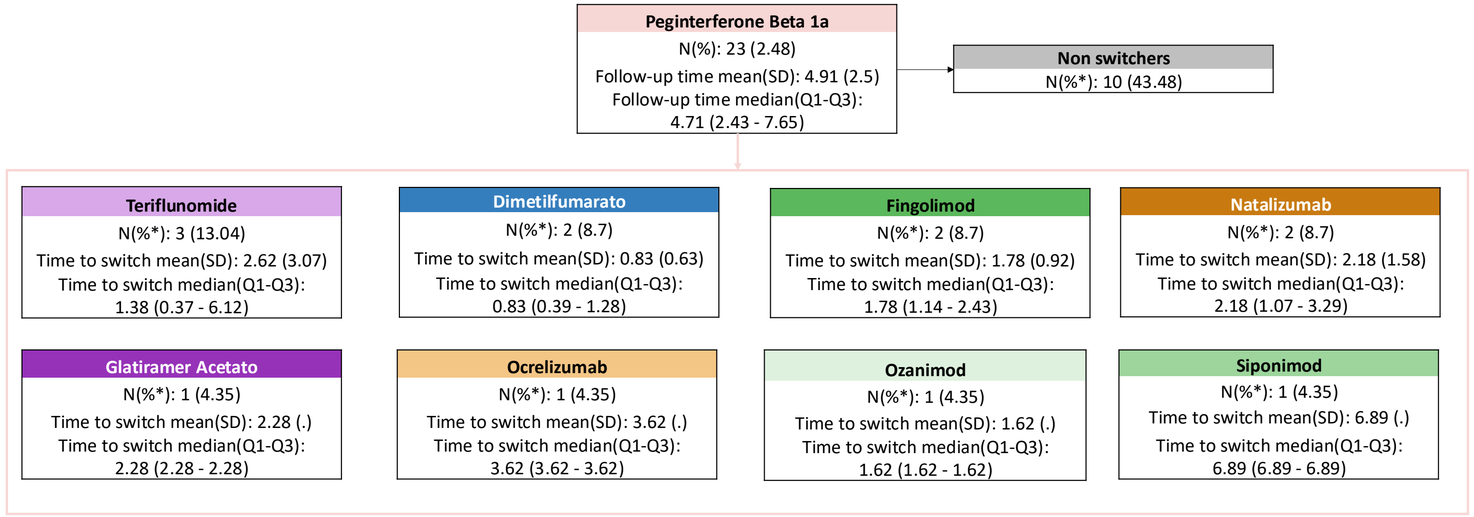
Primo switch (casi incidenti dal 2011)



Primo switch (casi incidenti dal 2011)



Primo switch (casi incidenti dal 2011)



Percorsi più frequenti (casi incidenti dal 2011)

Primo trattamento		Primo switch	N	%
Dimetilfumarato			105	11.33
Teriflunomide			83	8.95
Glatiramer Acetato			70	7.55
Natalizumab			63	6.80
Interferone Beta 1a			52	5.61
Ocrelizumab			39	4.21
Fingolimod			29	3.13
Cladribina			28	3.02
Interferone Beta 1a	→	Dimetilfumarato	20	2.16
Glatiramer Acetato	→	Dimetilfumarato	19	2.05
Interferone Beta 1b			18	1.94
Natalizumab	→	Ocrelizumab	18	1.94
Glatiramer Acetato	→	Teriflunomide	17	1.83
Interferone Beta 1a	→	Teriflunomide	15	1.62
Glatiramer Acetato	→	Fingolimod	12	1.29
Ofatumumab			11	1.19
Interferone Beta 1a	→	Fingolimod	10	1.08
Peginterferone Beta 1a			10	1.08

I percorsi più frequenti prevedono al massimo 1 switch

Percorsi più frequenti (casi incidenti dal 2011 al 2014)

Primo trattamento		Primo switch	N	%
Interferone Beta 1a			36	13.95
Glatiramer Acetato			21	8.14
Interferone Beta 1a	→	Dimetilfumarato	16	6.20
Interferone Beta 1b			11	4.26
Interferone Beta 1a	→	Fingolimod	8	3.10
Interferone Beta 1a	→	Teriflunomide	8	3.10
Natalizumab			8	3.10
Glatiramer Acetato	→	Fingolimod	7	2.71
Interferone Beta 1a	→	Peginterferone Beta 1a	7	2.71
Natalizumab	→	Ocrelizumab	6	2.33

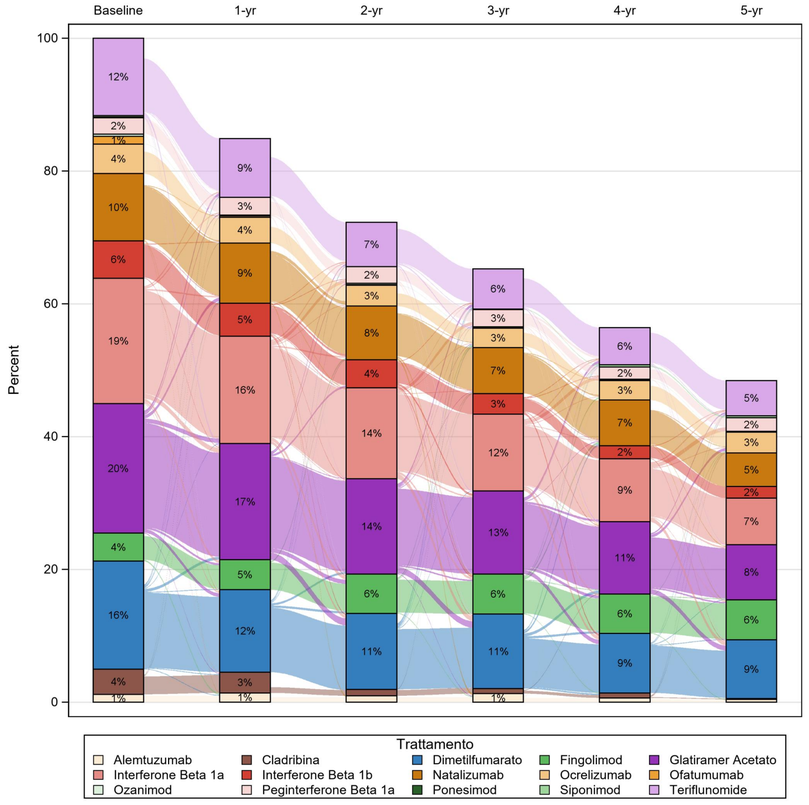
I percorsi più frequenti prevedono al massimo 1 switch

Percorsi più frequenti (casi incidenti dal 2015 al 2023)

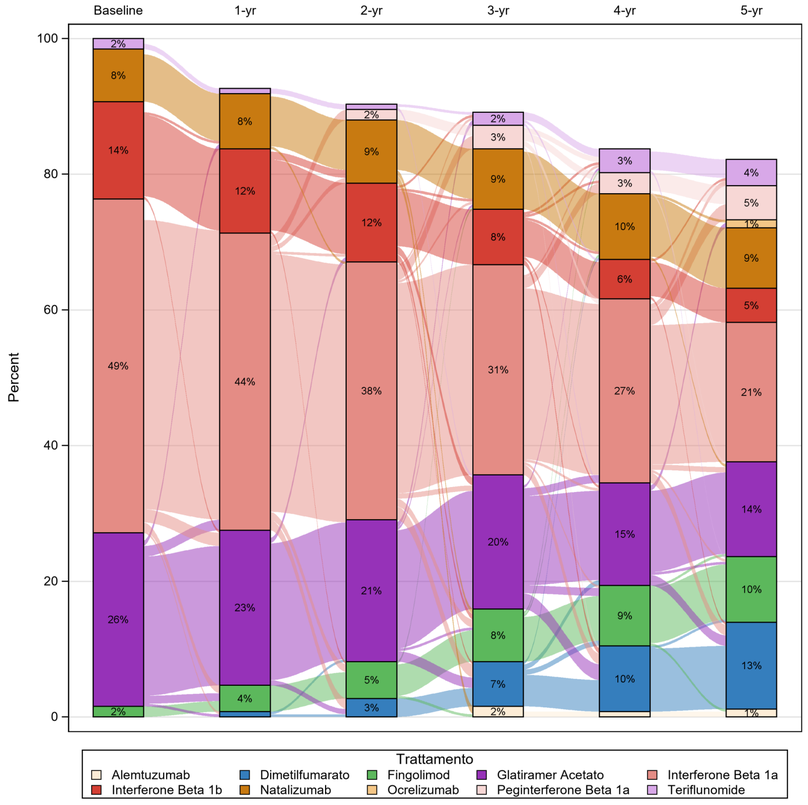
Primo trattamento		Primo switch	N	%
Dimetilfumarato			105	15.70
Teriflunomide			80	11.96
Natalizumab			55	8.22
Glatiramer Acetato			49	7.32
Ocrelizumab			39	5.83
Cladribina			28	4.19
Fingolimod			25	3.74
Interferone Beta 1a			16	2.39
Glatiramer Acetato	→	Teriflunomide	15	2.24
Glatiramer Acetato	→	Dimetilfumarato	14	2.09
Natalizumab	→	Ocrelizumab	12	1.79
Ofatumumab			11	1.64
Peginterferone Beta 1a			10	1.49
Alemtuzumab			7	1.05
Dimetilfumarato	→	Natalizumab	7	1.05
Interferone Beta 1a	→	Teriflunomide	7	1.05
Interferone Beta 1b			7	1.05
Dimetilfumarato	→	Ocrelizumab	6	0.90

I percorsi più frequenti prevedono al massimo 1 switch

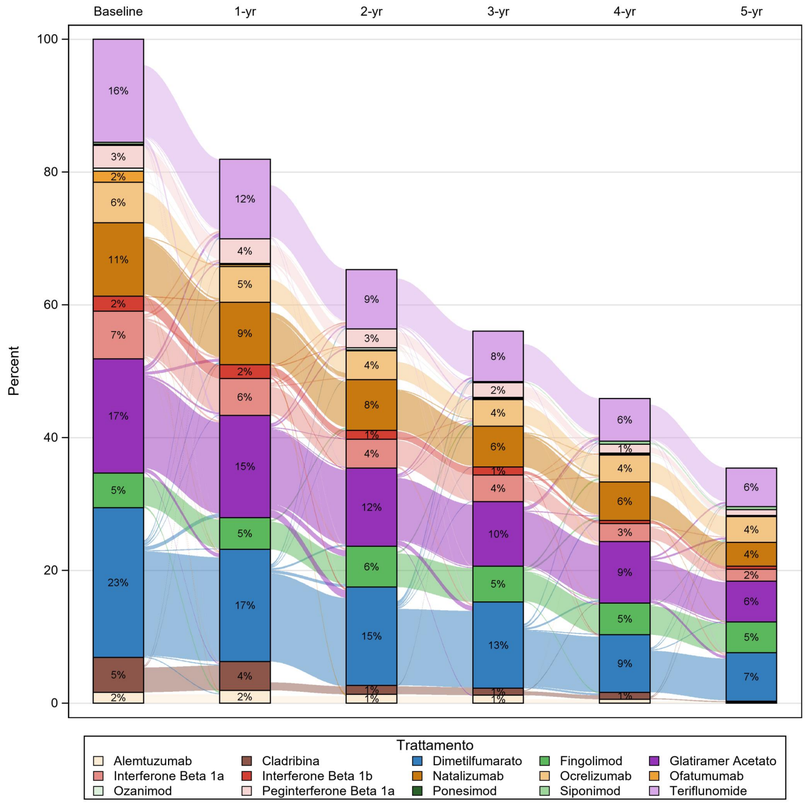
Sankey plot
(casi incidenti dal 2011)



Sankey plot
(casi incidenti dal 2011
al 2014)



Sankey plot
(casi incidenti dal 2015 al 2023)



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Commentary

The agenda of the global patient reported outcomes for multiple sclerosis (PROMS) initiative: Progresses and open questions

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Giancarlo Comi
1947-2024

Ricapitoliamo

- Fino al 31/12/24
  - Qualità
  - Sicurezza
  - Efficacia assoluta
  - Prezzo
- Dal 1/1/25 progressivamente
  - Qualità
  - Sicurezza
  - Efficacia assoluta
  - ***Efficacia relativa (PICO=DI CONTESTO DA VEICOLARE IN JCA-HTAR)***
  - ***Valore aggiunto***

Valore aggiunto

- Clinico= efficacia= quantità e/o qualità di vita
- Economico = efficienza = costo/efficacia
- Organizzativo = praticabilità
- Finanziario = sostenibilità

SIAMO PRONTI?

“ The decision maker has a choice between optimal decisions for an imaginary simplified world or decisions that are "good enough, that satisfice”, for a world approximating the complex real one more closely.”

Herbert A Simon, Nobel Laureate 1978

"... riesce particolarmente pregiudizievole la tendenza a sopravvalutare - spesso, addirittura in modo esclusivo - la ragione che, a mio avviso, è invece utilissima solo a patto di venir considerata come un complemento atto a perfezionare tutte le altre facoltà istintive intuitive psicologiche (ma non - guai! - a surrogarle)"

Bruno de Finetti, Varenna 1959