

ADR 案例報告 — Adalimumab

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報告日期：2013.10.19

病人基本資料

- 李 ○ ○ 女士
- 出生日期：50/XX/XX
- 初診日期：2010/01
- 診斷：類風濕性關節炎

Subjective in 2010/01

- Myalgia and arthralgia over knees, ankles, shoulders, elbows and back since 2009-4
- Bilateral finger joints soreness and painful swelling since 3-4 months ago with morning stiffness for more than an hour

Objective in 2010/01

- Swelling with tenderness over bilateral hands
MCPs and PIPs joints
- Fibromyalgia tenderness points x 11 pts

		2012/12/18	2013/02/05
Methotrexate 2.5mg	2tab tiw		
Rofecoxib 200mg	1cap qd		
Hydroxychloroquine 200mg	1tab qd		
Leflunomide 20mg	1tab qd		
Folic acid 5mg	1tab qd		
Tears naturale 15ml	1gtt qidou		
Epsilon	1tab qd		
Pilocarpine 5mg	1tab qid		
Methylprednisolone 4mg	1tab qd		
Adalimumab 40mg/0.8ml	1# q2w		
Carbomer gel 10g	1tub hsou		

Subjective in 2013/02

- Urticaria, acute onset with systemic attack for days
- Skin rash with itching, erythema multifome present

Objective in 2013/02

- Skin rash, macular and papular noted urticaria with itching

2/11入院治療

檢驗名稱	參考值	單位	檢驗值	
			2013/1	2013/2
W.B.C	4 ~ 11	10 ³ /ul	5.2	6.64
R.B.C	4.2 ~ 6.2	10 ⁶ /ul	4.18	4.57
Hb	12.3 ~ 18.3	g/dl	13.4	14.6
Hct	39 ~ 53	%	38.2	41.3
MCV	79 ~ 99	fl	91.4	90.4
MCH	26 ~ 34	pg	32.1	31.9
MCHC	30 ~ 36	g/dl	35.1	35.4
Platelet	120 ~ 400	10 ³ /ul	247	273
RDW-SD	36 ~ 46	fl	41.4	41.9
RDW-CV	11.5 ~ 14.5	%	12.8	12.9
WBC DC				
meta	0 ~ 1	%		
band	0 ~ 1	%		
Seg	40 ~ 75	%	49.4	71.5
Eos	0.5 ~ 6	%	2.9	0.9
Baso	0 ~ 1	%	0.4	0.2
Lym	20 ~ 45	%	36.5	20.9
Mono	2 ~ 10	%	10.8	6.5
ESR	0 ~ 20	mm/hr	29	23
Antinuclear ab	40X(-)	FA. Titer	1:320X(+)	1:40X(+)
ANA Pattern			speckle	speckle
eosinophil count	50 ~ 400			30

檢驗名稱	參考值	單位	檢驗值		
			2013/1	2013/2	2013/2
GLUCOSE	74 ~ 106	mg/dl		106	
Creatinine	0.7 ~ 1.2	mg/dl	0.7	0.6	
eGFR			93.76	112.02	
Uric acid	3.4 ~ 7	mg/dl	3.7		
Cholesterol total	0 ~ 200	mg/dl			
Cholesterol-HDL	45 ~ 65	mg/dl			
Cholesterol-LDL	0 ~ 100	mg/dl			
Triglyceride	0 ~ 200	mg/dl			
GOT(AST)	0 ~ 37	IU/L		18	
GPT(ALT)	0 ~ 41	IU/L	28		
K (Potassium)	3.4 ~ 5.1	mEq/L		4	
Na (Sodium)	136 ~ 145	mEq/L		142	
CRP	0 ~ 0.8	mg/dl			
HbA1c	4.3 ~ 5.9	%			
RA test	0 ~ 14	IU/ml	64.5	42.9	
IgE		IU/ml		44.2	
HLA-B*57:02基因檢測					negative

ADVERSE EFFECT OF ADALIMUMAB

Adverse event

- >10%
 - Central nervous system: Headache (12%)
 - Dermatologic: Skin rash (6% to 12%)
 - Hematologic & oncologic: Positive ANA titer (12%)
 - Immunologic: Antibody development (3% to 26%; significance unknown)
 - Infection: Serious infection (adults 1.4-6.7 events/100 person years; children 2 events/100 person years [Burmester, 2012])
 - Local: Injection site reaction (12% to 20%; includes erythema, itching, hemorrhage, pain, swelling)
 - Neuromuscular & skeletal: Increased creatine phosphokinase (15%)
 - Respiratory: Upper respiratory tract infection (17%), sinusitis (11%)

- 5-10%
 - Cardiovascular: Hypertension (5%)
 - Endocrine & metabolic: Hyperlipidemia (7%), hypercholesterolemia (6%)
 - Gastrointestinal: Nausea (9%), abdominal pain (7%)
 - Genitourinary: Urinary tract infection (8%), hematuria (5%)
 - Hepatic: Increased serum alkaline phosphatase (5%)
 - Hypersensitivity: Hypersensitivity reaction (children 6%; adults 1%)
 - Local: Injection site reaction (8%; other than erythema, itching, hemorrhage, pain, swelling)
 - Neuromuscular & skeletal: Back pain (6%)
 - Respiratory: Flu-like symptoms (7%)
 - Miscellaneous: Accidental injury (10%)

Cutaneous reactions

- Psoriasis and psoriatic-like skin
- Eczematous dermatitis
- Cutaneous manifestations of systemic lupus erythematosus
- Leukocytoclastic vasculitis
- Lichen planus and lichen planus-like eruptions
- Cutaneous viral, bacterial, and fungal infections

Rate of selected adverse events

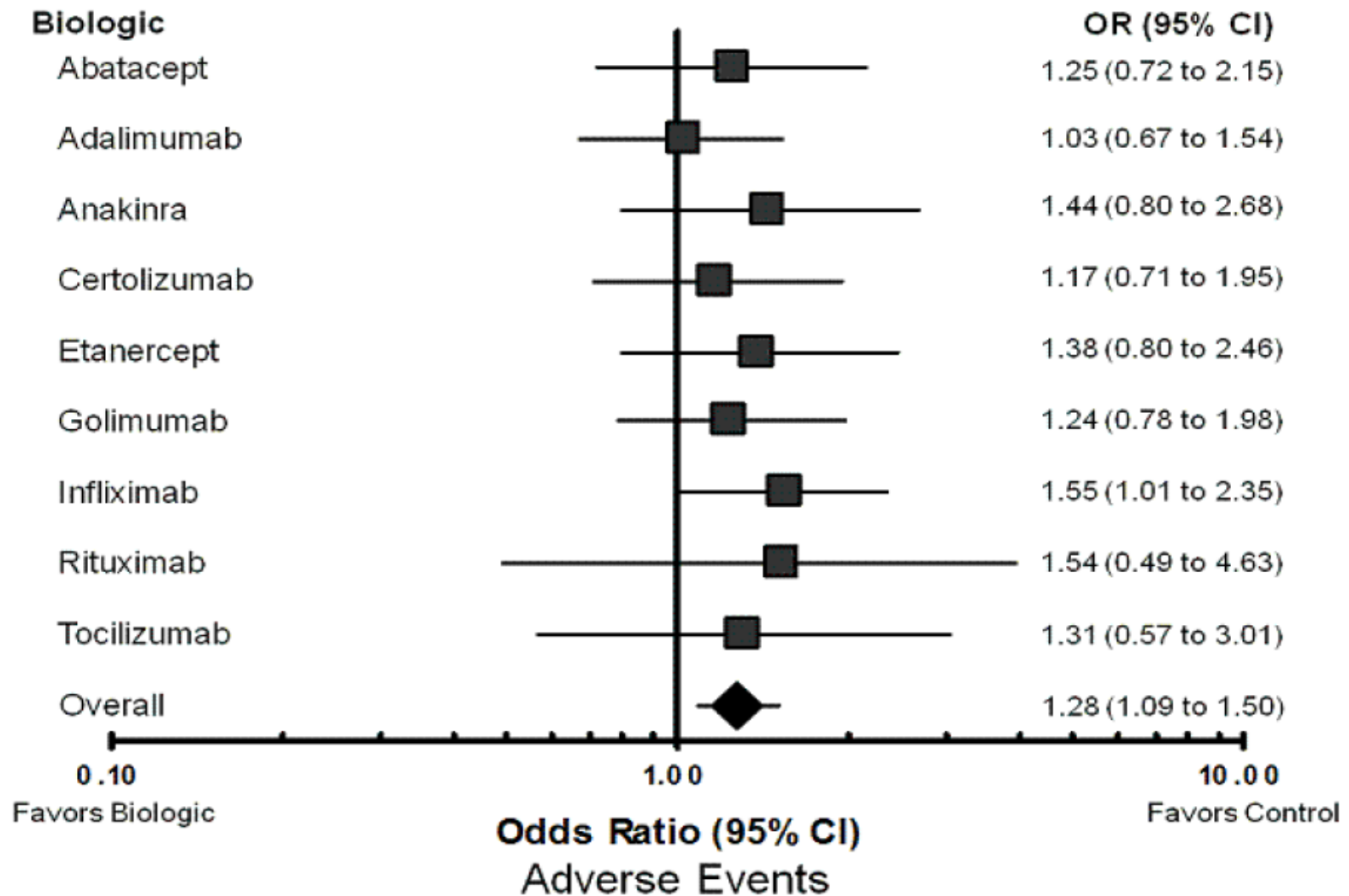
	All RA trials as of 31 August 2002(E/100PYs)*	All RA trials as of 15 April 2005 (E/100PYs)#
Tuberculosis	0.27	0.27
Histoplasmosis	0.06	0.03
Demyelinating disease	0.08	0.08
Lymphoma	0.21	0.12
SLE/ lupus like syndrome	0.08	0.1
Congestive heart failure	0.29	0.28

•N = 2468, 4870 Pys, # n = 10050, 12506 Pys
E/ 100 Pys, events per 100 patient-years.

**Selected events in the US postmarketing period:
31 December 2002 to 30 June 2005**

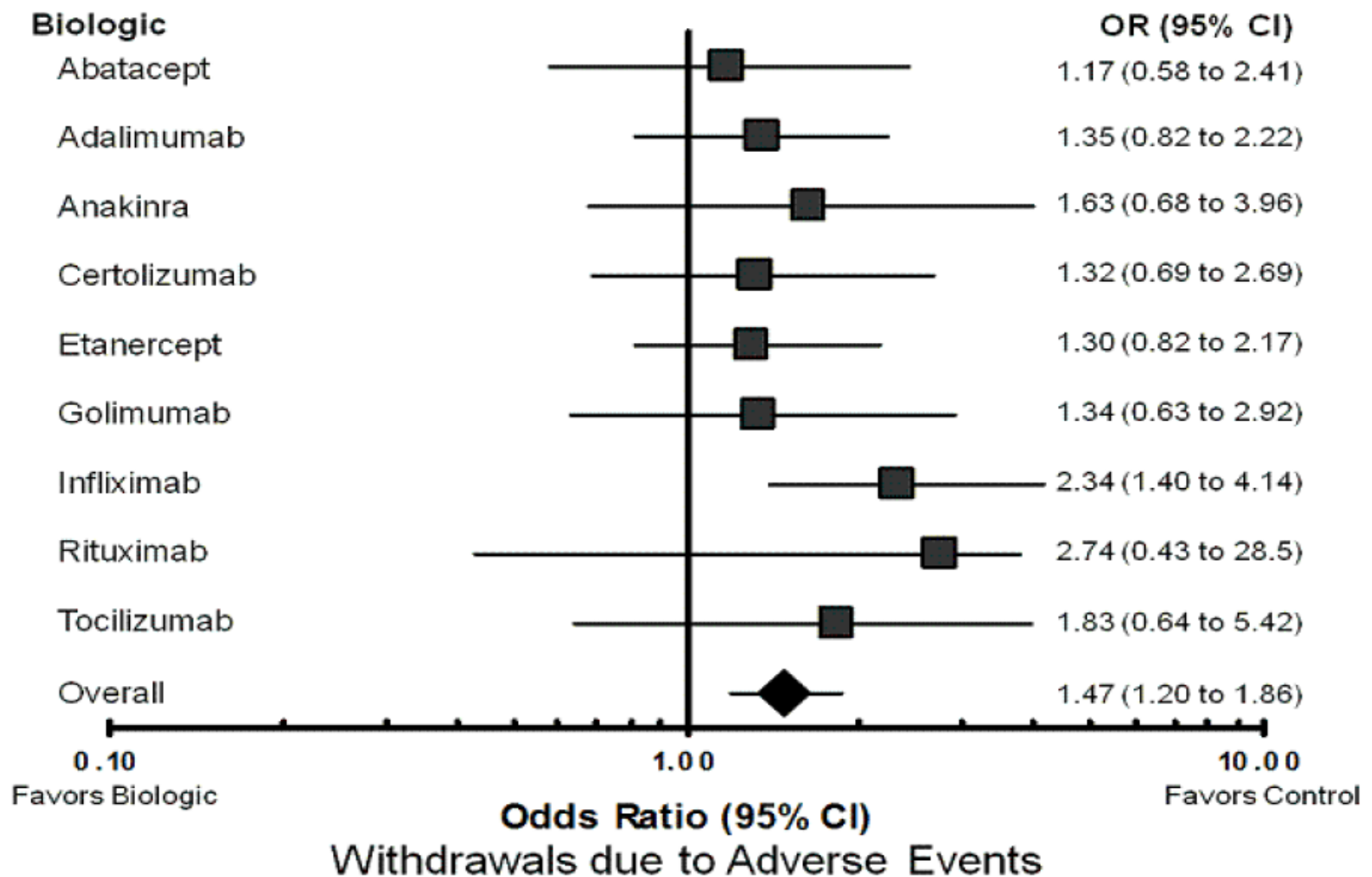
AES	Reported rates* (E /100 Pys)
Tuberculosis	0.02
Lymphoma	0.04
Congestive heart failure	0.06
Demyelinating disease	0.01
Systemic lupus erythematosus	0.03
Opportunistic infections	0.06
Blood dyscrasias	0.08
* 78522 PYs	

Figure 2. Forest plot of network meta-analysis: total adverse events



Ref: 2013 The Cochrane Collaboration.

Figure 3. Forest plot of network meta-analysis: withdrawals due to adverse events



Thank you for your attention