Impact of the Use of Drugs and Substitution Treatments on the Antiviral Treatment of Chronic Hepatitis C: Analysis of Compliance, Virological Response and Quality of Life (CHEOBS)

P. Melin,[1] J.-P. Lang,[2] D. Ouzan,[3] M. Chousterman,[4] M. Varastet,[5] M. Rotily,[5] T. Fontanges,[6] P. Marcellin,[7] P. Cacoub[8]

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Abstract

Background and aims: CHEOBS is a French multicenter, prospective, observational study that aimed to analyse the factors associated with adherence to treatment with peginterferon alfa-2b and ribavirin in chronic hepatitis C patients. The present analysis focuses on adherence to antiviral dual therapy, virological response, and quality of life (QoL) according to whether the patients were active drug users or under substitution treatment (ADU), ex-drug users (EDU), or non-drug users (NDU).

Patients and methods: Between 2003 and 2006, 184 clinicians evaluated 2001 hepatitis C patients every 3 months during treatment and 6 months after the end of treatment. Among these patients, 141 were excluded from the analysis. The studied population included 244 ADU, 578 EDU and 1038 NDU. Good adherence was defined by >80% of the dose and duration of the antiviral dual therapy prescribed. Sustained virological response (SVR) was defined by a negative PCR ≥12 weeks after the end of treatment. QoL was assessed using the SF-36 questionnaire.

Results: The patient profile in the EDU group was between that in the ADU and NDU groups for mean age, body mass index (BMI), liver fibrosis, level of education or debt difficult to manage, high consumption of alcohol, psychiatric disorders, or chronic diseases. The proportion of good adherents to dual therapy was similar in all three groups: NDU, 49.4%; EDU, 48.6%; ADU, 52.2% (p=0.7). The SVR rate was also similar: 49.3%, 50.9%, and 57.8%, respectively (p=0.1). The QoL in the ADU group was less altered on the physical and mental levels than in the other groups.

Conclusions: The rate of SVR was similar in the three groups. Excess consumption of alcohol, a precarious socio-economic situation, and the psychiatric disorders observed in drug users in this study had no negative impact on the treatment outcomes. On the contrary, young age, recent contamination, high prevalence of genotype 3 infection, lower BMI, less severe liver fibrosis, and good adherence to treatment seem to have balanced the negative parameters.

Background

- The French Consensus Conference of February 2002 recommended treating patients infected with hepatitis C virus (HCV) with stable drug use[1]
- Key findings from the Hepacom Study, a 12-month, multicenter, observational prospective study of treatment-naive chronic hepatitis C patients treated in the French health care system, were[2]:
  - Only one-third of patients with access to health care initiated antiviral treatment
  - Access to treatment was more difficult among these patient populations:
    - Women
    - HIV-coinfected patients
    - Drug users receiving substitution therapy
- Data from Hepacom revealed that health care access was still limited for drug users, suggesting that further study of this patient population was needed

Aim

- This analysis from the CHEOBS study compared the efficacy, tolerability, compliance, and effect on quality of life of pegylated interferon (PEG-IFN) alfa-2b (PegIntron®; Schering-Plough) + ribavirin (RBV) in 3 groups of patients with chronic hepatitis C
  - Non-drug users (NDU)
  - Ex-drug users (EDU)
  - Active drug users or users undergoing substitution treatment (ADU)

Patients and Methods

Patients

- Patients aged 18 and older who had chronic hepatitis C and initiated treatment with PEG-IFN alfa-2b (1.5 µg/kg/wk) alone or in combination with RBV (800-1200 mg/d, depending on body weight) were eligible for enrollment
- Patients were treatment naive or were nonresponders or relapsers to previous anti-HCV therapy

Study Design

- The CHEOBS study was a prospective, multicenter, observational study conducted between 2003 and 2006
- Patients were enrolled from 184 centers in France that specialize in the management of hepatitis C

Questionnaires

- Both the investigator and the patient completed questionnaires at baseline, approximately every 3 months during treatment, and 6 months after treatment cessation
- The investigator questionnaire collected the following information:
  - Patient sociodemographic data
  - History of HCV infection
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  - Hepatitis C therapy received before inclusion in the CHEOBS study
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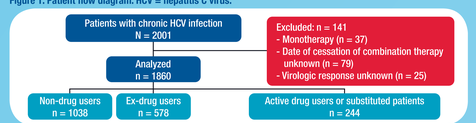
  - Planned hepatitis C treatment
  - Treatment modifications
  - Virologic status of the patient 6 months after treatment cessation
- Patient self-questionnaires collected the following information:
  - Quality-of-life assessment (SF-36 form)
  - Compliance with PEG-IFN alfa-2b + RBV treatment

Results

- This analysis includes 1860 patients who were classified as NDU, EDU, and ADU (including patients undergoing substitution therapy) (**Figure 1**)
  - Of the 244 ADU, 72 patients were receiving methadone therapy and 137 were receiving buprenorphine substitution treatment

Figure 1. Patient flow diagram. HCV = hepatitis C virus.



- Patient sociodemographics, comorbidities, and risk factors are shown in Table 1
- Hepatitis C disease characteristics for enrolled patients are shown in **Table 2**

Table 1. Baseline Characteristics of Patients

	NDU n = 1038	EDU n = 578	ADU n = 244	*P*
Sociodemographics	n/n (%)	n/n (%)	n/n (%)	
Men	512/1035 (49)	428/578 (74)	198/243 (82)	<0.001
Age, y, mean ± SD	51.7 ± 12.6	41.7 ± 6.3	37.5 ± 6.2	<0.001
BMI, kg/m², mean ± SD	25.3 ± 4.5	23.6 ± 4.2	23.2 ± 3.7	<0.001
Employment status				<0.001
Professional activity	575/1035 (56)	385/578 (67)	138/244 (57)	
Unemployed	70/1035 (7)	114/578 (20)	88/244 (36)	
Other	390/1035 (38)	79/578 (14)	18/244 (7)	
Education level				<0.001
Low	570/1023 (56)	337/569 (59)	182/242 (75)	
High	453/1023 (44)	232/569 (41)	60/242 (25)	
Indebtedness				<0.001
Difficult to manage	30/832 (4)	42/471 (9)	28/206 (14)	
None or easy to manage	802/832 (96)	429/471 (91)	178/206 (86)	
Comorbidities				
Psychiatric history				
Depression	183/1036 (18)	175/578 (30)	95/242 (39)	<0.001
Suicide attempt	31/1032 (3)	48/577 (8)	45/241 (19)	<0.001
Hospitalization for mental illness	46/1031 (5)	63/575 (11)	47/242 (19)	<0.001
Psychiatric illnesses	168/1023 (16)	138/576 (24)	97/240 (40)	<0.001
Other chronic illnesses	366/1020 (36)	95/571 (17)	30/239 (13)	<0.001
Risk factors				
Alcohol consumption, >20 g/d	23/169 (14)	44/187 (24)	34/93 (37)	<0.001
Tobacco consumption	218/1021 (21)	424/569 (75)	217/242 (90)	<0.001

ADU = active drug user or user undergoing substitution treatment; BMI = body mass index; EDU = ex-drug user; NDU = non-drug user.

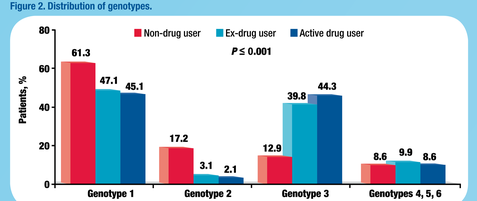
Table 2. Hepatitis C Disease Characteristics and Etiology

	NDU n = 1038	EDU n = 578	ADU n = 244	*P*
Source of HCV infection	n/n (%)	n/n (%)	n/n (%)	
Transfusion	474/1019 (47)	19/578 (3)	3/244 (1)	<0.001
Drug abuse	12/1019 (1)	546/578 (95)	234/244 (96)	<0.001
Other	542/1019 (53)	28/578 (5)	9/244 (4)	<0.001
Duration of HCV infection, y, mean ± SD	23.5 ± 9.7	19.8 ± 7.6	15.0 ± 7.0	<0.001
Serum HCV RNA				0.175
≤800,000 IU/mL[a]	440/770 (57)	240/430 (56)	116/182 (64)	
>800,000 IU/mL[a]	330/770 (43)	190/430 (44)	66/182 (36)	
HIV coinfection	10/1034 (1)	38/578 (7)	15/242 (6)	0.001
HBV coinfection	6/1025 (1)	10/575 (2)	8/241 (3)	0.003
METAVIR activity grade or equivalent				0.040
A0 or A1	408/891 (46)	241/489 (49)	74/192 (39)	
A2 or A3	483/891 (54)	248/489 (51)	118/192 (62)	
METAVIR fibrosis stage or equivalent				0.025
F0 or F1	301/895 (34)	174/492 (35)	74/193 (38)	
F2 or F3	439/895 (49)	250/492 (51)	103/193 (53)	
F4	155/895 (17)	68/492 (14)	16/193 (8)	

ADU = active drug user or user undergoing substitution treatment; EDU = ex-drug user; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; NDU = non-drug user.
[a]Or equivalent.

- The distribution of genotypes was significantly different across the 3 patient groups ($P \leq 0.001$; **Figure 2**)
  - The proportions of patients with genotype 3 infection were higher among EDU and ADU than among NDU
  - Among NDU, most patients had genotype 1 or 2 infection

Figure 2. Distribution of genotypes.



Treatment Dosing, Duration, and Adherence

- There was significant heterogeneity across the patient groups in terms of duration of treatment and dosing of PEG-IFN alfa-2b ($P \leq 0.001$; **Table 3**)
  - Mean duration of therapy was longer in NDU than in EDU or ADU
  - Mean PEG-IFN alfa-2b doses were higher in ADU than in NDU or EDU

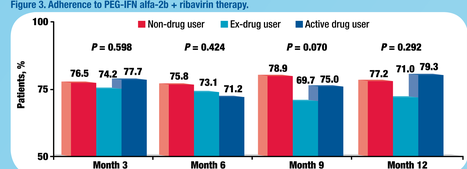
Table 3. Investigator-Reported Dose and Duration

	NDU n = 1038	EDU n = 578	ADU n = 244	*P*
Mean duration of treatment, wk	37.4 ± 17.6	35.0 ± 16.2	33.0 ± 16.6	<0.001
Early discontinuation[a]	315/1038 (30)	169/578 (29)	79/244 (32)	0.653
Therapeutic education	604/1038 (58)	325/578 (56)	160/244 (66)	0.041
Mean cumulative dosage				
PEG-IFN alfa-2b, µg/kg/wk	1.32 ± 0.29	1.35 ± 0.27	1.40 ± 0.21	0.001
Ribavirin, mg/d	890 ± 182	905 ± 155	904 ± 148	0.287
Mean dosage at last treatment				
PEG-IFN alfa-2b, µg/kg/wk	1.3 ± 0.32	1.33 ± 0.3	1.40 ± 0.23	<0.001
Ribavirin, mg/d	879 ± 204	897 ± 171	896 ± 163	0.285

Values are mean ± SD or n/n (%).
ADU = active drug user or user undergoing substitution treatment; EDU = ex-drug user; NDU = non-drug user.
[a]<40 weeks genotype 1 (G1), G4, G5, and G6 infection; <20 weeks for G2 and G3 infection.

- Adherence (>80% of the recommended dose of PEG-IFN alfa-2b and RBV for >80% of the recommended duration [according to genotype]) to therapy was similar in all patient groups (**Figure 3**)

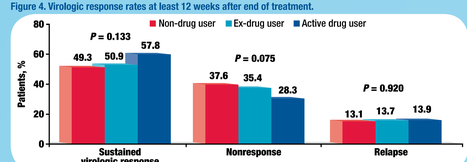
Figure 3. Adherence to PEG-IFN alfa-2b + ribavirin therapy.



Virologic Response

- Virologic response rates assessed at least 12 weeks after completion of therapy were not significantly different among patient groups (**Figure 4**)

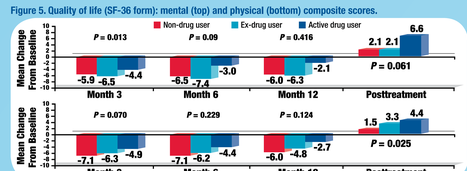
Figure 4. Virologic response rates at least 12 weeks after end of treatment.



Quality of Life

- Changes in quality-of-life scores throughout treatment are shown in **Figure 5**

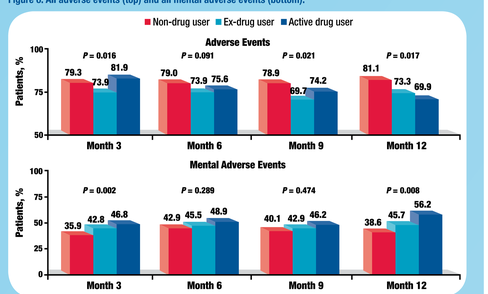
Figure 5. Quality of life (SF-36 form): mental (top) and physical (bottom) composite scores.



Adverse Events

- The incidence of adverse events is shown in **Figure 6**
- Mental adverse events were more common among ADU at month 3 and month 12 than among EDU and NDU

Figure 6. All adverse events (top) and all mental adverse events (bottom).



Summary

- In this study, there was a predominance of genotype 3 infection among EDU and ADU
- Adherence to therapy and virologic response rates were similar in ADU, EDU, and NDU
- Mental adverse events were more frequent among ADU; however, combination therapy had a less negative impact on quality of life in these patients than in EDU or NDU

Conclusions

- In this analysis, active drug use was frequently associated with excessive alcohol intake, vulnerable socioeconomic situation, and psychiatric illness
- However, active drug use did not have a negative impact on
  - Adherence to PEG-IFN alfa-2b + RBV combination therapy
  - Rate of premature discontinuation
  - Sustained virologic response rate
- It is possible that a predominance of favorable characteristics, such as young age, recent HCV infection, high prevalence of genotype 3 infection, low body mass index, and less advanced stage of fibrosis counterbalanced the potentially negative impact of the unfavorable parameters associated with active drug use

References

1. Consensus Conference: Treatment of Hepatitis C; February 27-28, 2002; Paris, France. http://www.anaes.fr. Accessed October 6, 2008.
2. Agostini H et al. *Gastroenterol Clin Biol.* 2007;31:1074-1080.

Disclosures

P. Melin, J.-P. Lang, D. Ouzan, M. Chousterman, M. Rotily, T. Fontanges, P. Marcellin, and P. Cacoub are consultants for Schering-Plough France.
M. Varastet has nothing to disclose.

Presented at the 44th Annual Meeting of the European Association for the Study of the Liver, April 22–26, 2009, Copenhagen, Denmark

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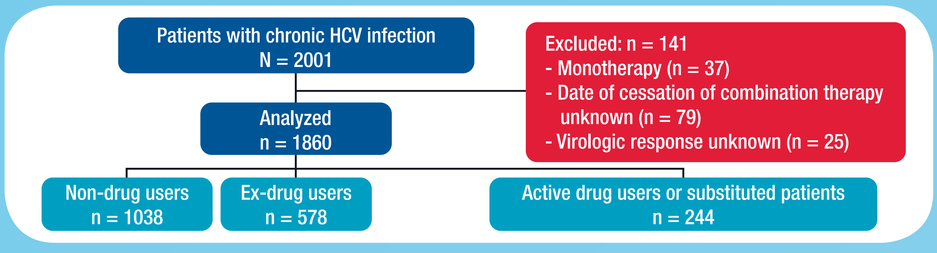

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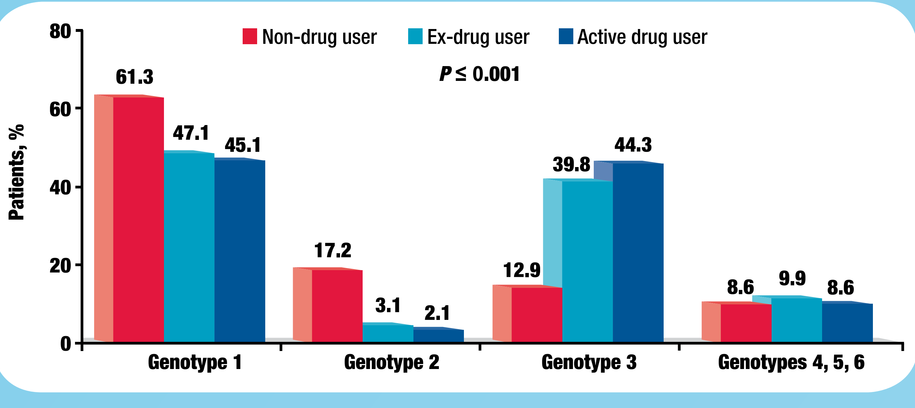

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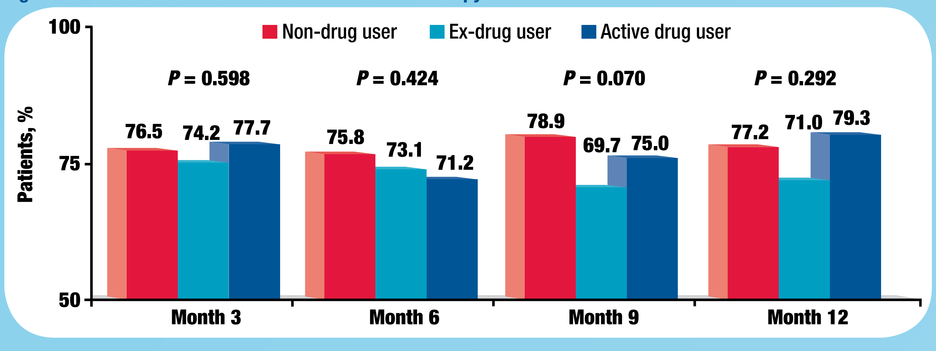
Ribavirin, mg/d	890 ± 182	905 ± 155	904 ± 148	0.287
Mean dosage at last treatment				
PEG-IFN alfa-2b, µg/kg/wk	1.3 ± 0.32	1.33 ± 0.3	1.40 ± 0.23	<0.001
Ribavirin, mg/d	879 ± 204	897 ± 171	896 ± 163	0.285

Values are mean ± SD or n/n (%).
ADU = active drug user or user undergoing substitution treatment; EDU = ex-drug user; NDU = non-drug user.
[a]<40 weeks genotype 1 (G1), G4, G5, and G6 infection; <20 weeks for G2 and G3 infection.

- Adherence (>80% of the recommended dose of PEG-IFN alfa-2b and RBV for >80% of the recommended duration [according to genotype]) to therapy was similar in all patient groups (**Figure 3**)

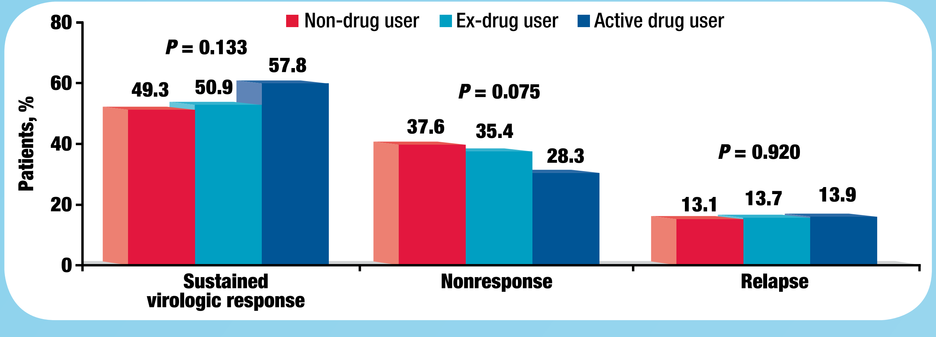
Figure 3. Adherence to PEG-IFN alfa-2b + ribavirin therapy.



Virologic Response

- Virologic response rates assessed at least 12 weeks after completion of therapy were not significantly different among patient groups (**Figure 4**)

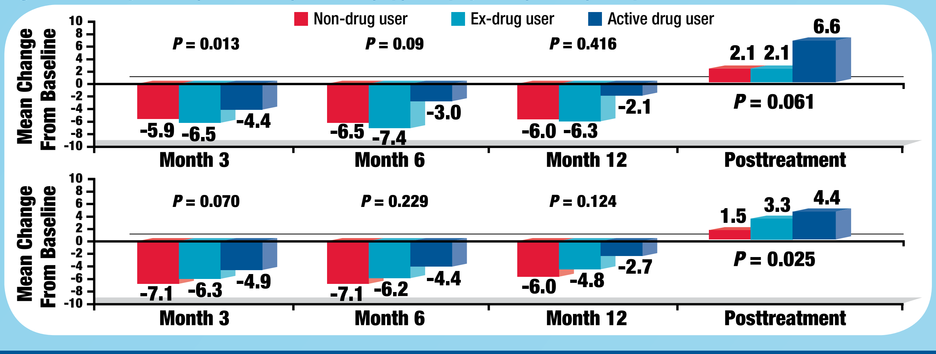
Figure 4. Virologic response rates at least 12 weeks after end of treatment.



Quality of Life

- Changes in quality-of-life scores throughout treatment are shown in **Figure 5**

Figure 5. Quality of life (SF-36 form): mental (top) and physical (bottom) composite scores.



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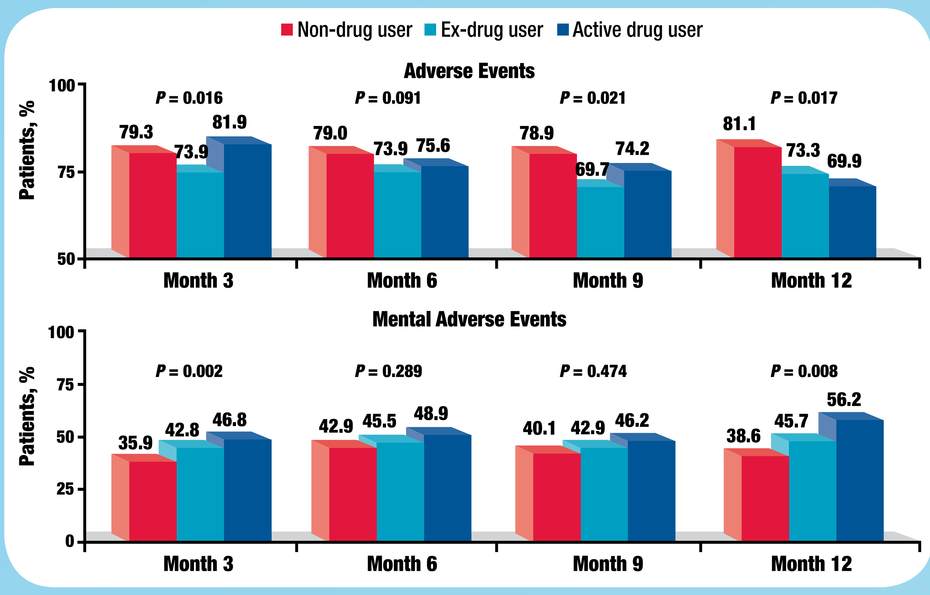
Adverse Events

- The incidence of adverse events is shown in **Figure 6**
- Mental adverse events were more common among ADU at month 3 and month 12 than among EDU and NDU

Figure 6. All adverse events (top) and all mental adverse events (bottom).



Summary

- In this study, there was a predominance of genotype 3 infection among EDU and ADU
- Adherence to therapy and virologic response rates were similar in ADU, EDU, and NDU
- Mental adverse events were more frequent among ADU; however, combination therapy had a less negative impact on quality of life in these patients than in EDU or NDU

Conclusions

- In this analysis, active drug use was frequently associated with excessive alcohol intake, vulnerable socioeconomic situation, and psychiatric illness
- However, active drug use did not have a negative impact on
  - — Adherence to PEG-IFN alfa-2b + RBV combination therapy
  - — Rate of premature discontinuation
  - — Sustained virologic response rate
- It is possible that a predominance of favorable characteristics, such as young age, recent HCV infection, high prevalence of genotype 3 infection, low body mass index, and less advanced stage of fibrosis counterbalanced the potentially negative impact of the unfavorable parameters associated with active drug use

References

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2. Agostini H et al. *Gastroenterol Clin Biol.* 2007;31:1074-1080.

Disclosures

P. Melin, J.-P. Lang, D. Ouzan, M. Chousterman, M. Rotily, T. Fontanges, P. Marcellin, and P. Cacoub are consultants for Schering-Plough France.
M. Varastet has nothing to disclose.

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