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Filière de Santé Maladies Rares du Foie de l'Adulte et de l'Enfant

Publications Marquantes 2018 : Maladies inflammatoires

Dr Pascal POTIER, CHR d'Orléans

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Placebo-Controlled Trial of Bezafibrate in Primary Biliary Cholangitis

C. Corpechot, O. Chazouillères, A. Rousseau, A. Le Gruyer, F. Habersetzer, P. Mathurin, O. Goria, P. Potier, A. Minello, C. Silvain, A. Abergel, M. Debette-Gratien, D. Larrey, O. Roux, J.-P. Bronowicki, J. Boursier, V. de Ledinghen, A. Heurgue-Berlot, E. Nguyen-Khac, F. Zoulim, I. Ollivier-Hourmand, J.-P. Zarski, G. Nkontchou, S. Lemoinne, L. Humbert, D. Rainteau, G. Lefèvre, L. de Chaisemartin, S. Chollet-Martin, F. Gaouar, F.-H. Admane, T. Simon, and R. Poupon

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WILEY AP&T Alimentary Pharmacology & Therapeutics

Biochemical efficacy of tioguanine in autoimmune hepatitis: a retrospective review of practice in the Netherlands

Floris F. van den Brand[1] | Carin M. J. van Nieuwkerk[1] | Bart J. Verwer[2] | Ynto S. de Boer[1] | Nanne K. H. de Boer[1] | Chris J. J. Mulder[1] | Elisabeth Bloemena[3] | Christine M. Bakker[4] | Jan M. Vrolijk[5] | Joost P. H. Drenth[6] | Adriaan C. I. T. L. Tan[7] | Frank ter Borg[8] | Martijn J. ter Borg[9] | Sven J. van den Hazel[10] | Akin Inderson[11] | Maarten E. Tushuizen[11] | Gerd Bouma[1]

[1]Department of Gastroenterology and Hepatology, Amsterdam Gastroenterology and Metabolism, Amsterdam UMC, Vrije Universiteit Amsterdam, Amsterdam, The Netherlands

Summary

Background: Azathioprine (AZA) and mercaptopurine (MP) are the cornerstone of

Aliment Pharmacol Ther. 2018;48:761–767

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Clinical Practice Guidelines

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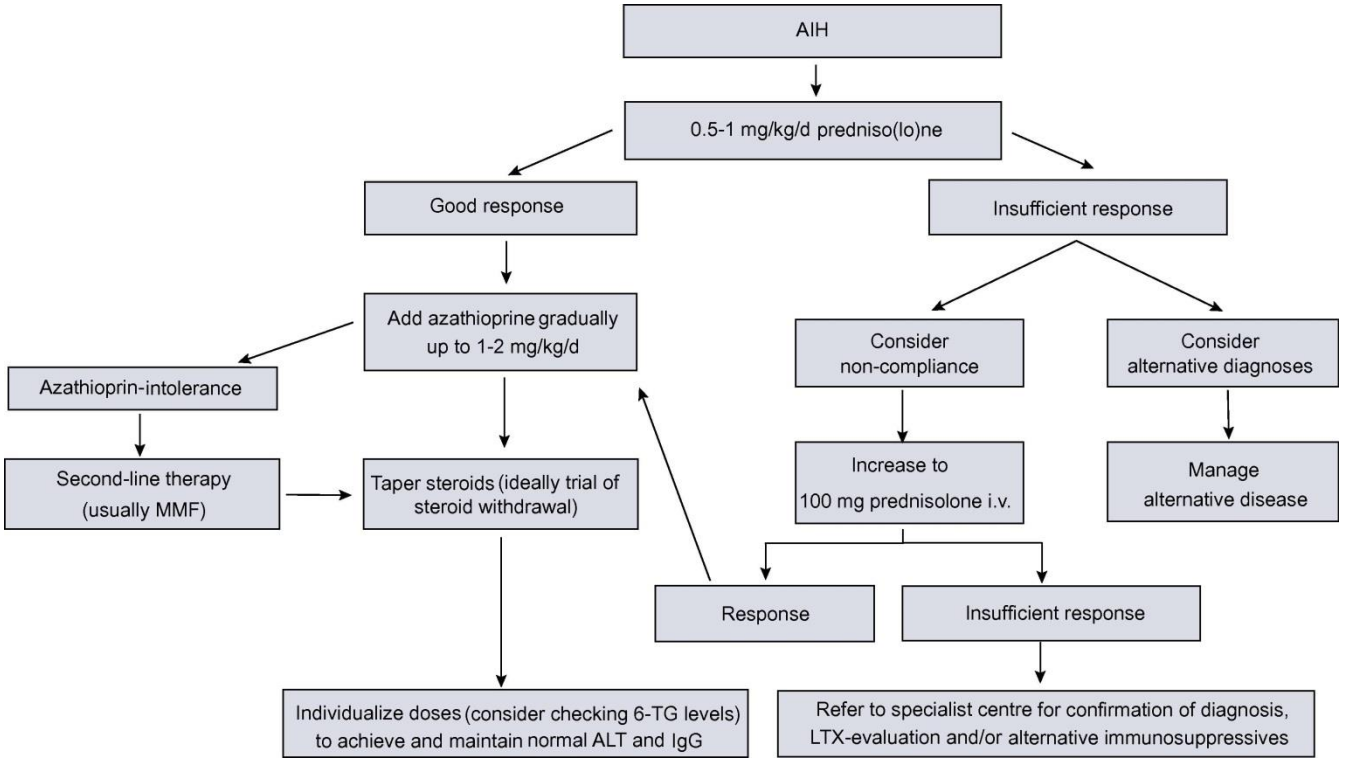
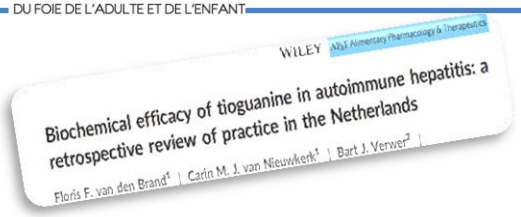
EASL Clinical Practice Guidelines: Autoimmune hepatitis☆

European Association for the Study of the Liver*

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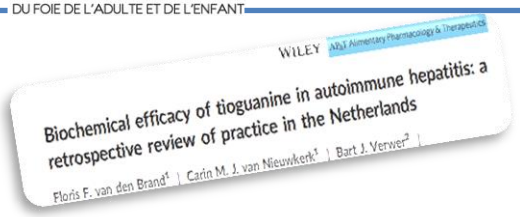
Echec du traitement standard : 10 à 20 % des patients

- Observance
- Insuffisance de réponse
- Syndrome de chevauchement
- Intolérance
- Comorbidités limitant les choix thérapeutiques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1/ Echec par inefficacité

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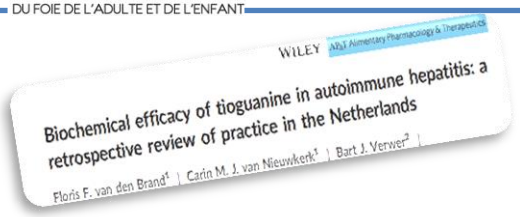
42. In patients requiring high dose, long-term (>20 mg/day) steroid therapy, conventional treatment should be optimized (high doses of predniso(lo)ne combined with 2 mg/kg/day azathioprine). Alternatively, a trial of CNIs (ciclosporine or tacrolimus), infliximab, methotrexate, or cyclophosphamide can be initiated. The relative effectiveness of second line treatments has not been examined in clinical trials. Therefore, these drugs should be used after consultation with a specialist centre only **(II-3)**

2/ Echec par intolérance

49. In patients intolerant to azathioprine, mycophenolate is the second line drug of choice **(II-2)**
The relative efficacy and tolerability of MMF in other patients compared to azathioprine has not been established **(II-2)**
A trial of 6-MP or 6-TG in patients intolerant to azathioprine is an alternative option **(III)**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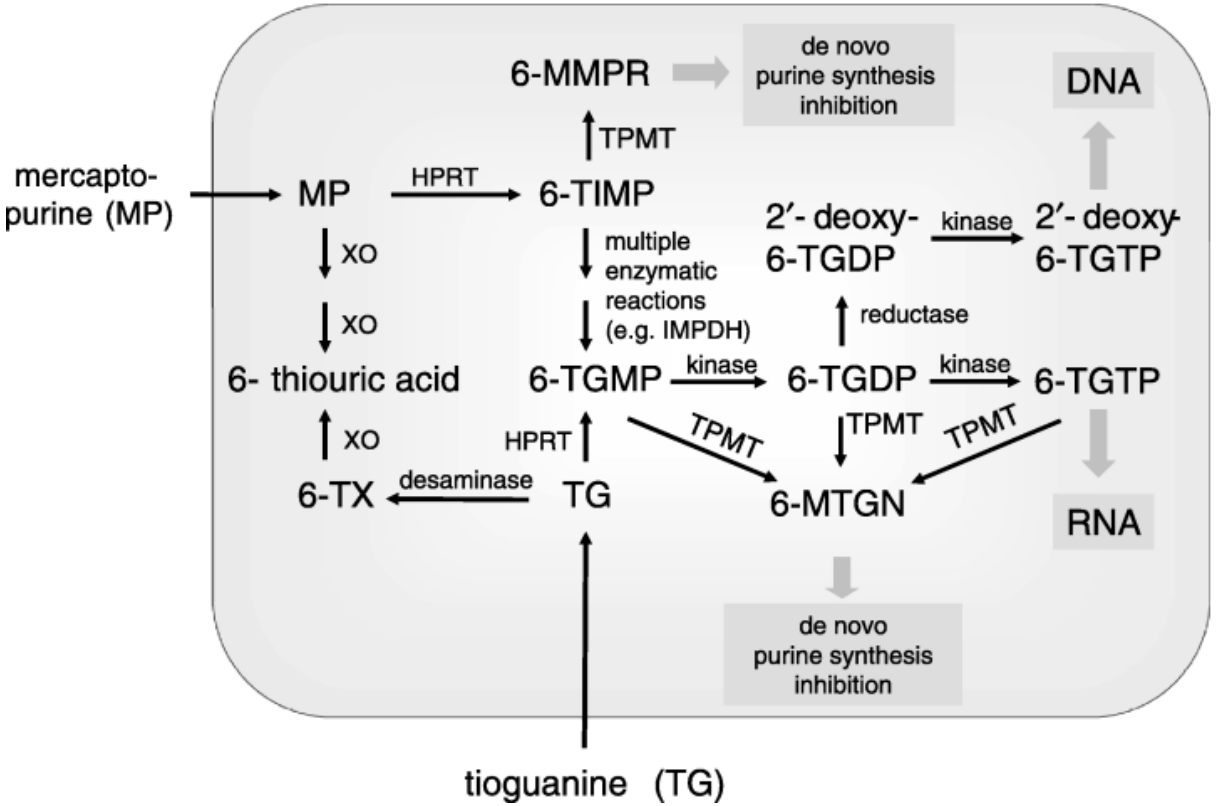

Thioguanine-nucleotides do not predict efficacy of tioguanine in Crohn's disease, Volume: 19, Issue: 12, Pages: 1269-1276, First published: 04 June 2004, DOI: (10.1111/j.1365-2036.2004.01947.x)


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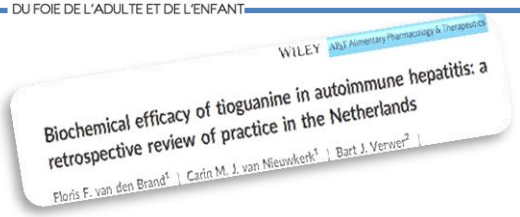
Safety and Efficacy of 6-thioguanine as a Second-line Treatment for Autoimmune Hepatitis

Clémence Legué, Ludivine Legros, Solène Kammerer-Jacquet, Caroline Jézequel, Pauline Houssel-Debry, Thomas Uguen, Caroline Le Lan, Anne Guillygomarc'h, Romain Moirand, Bruno Turlin, Dominique Guyader, Edouard Bardou-Jacquet

17 patients traités par 6-TG pour HAI

- 16 intolérants, 1 non répondeur à l'AZA
- 11 réponses, 4 rechutes, 1 PDV
- 1 cytopénie gérée par diminution de dose
- 1 HNR sur 8 patients biopsiés (pré-existante ?)

Clinical Gastroenterology and Hepatology , 2018, Volume 16 , Issue 2 , 290 - 291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Enquête : 9 centres hospitaliers d'hépatologie néerlandais sur 37 sollicités

Inclusions de patients ayant une HAI selon le score international et traités par TG entre 2001 et 2017

Toxicité hématologique : GB < 4 giga, PS < 150 giga, Hb < 7,5 /femme, 8,5 /homme

Histologie centralisée pour recherche HNR

Epargne cortisonique : baisse de 25% de la dose quotidienne

Réponse complète	ASAT, ALAT, IgG normaux
Réponse incomplète	ALAT < 2N
Non réponse	ALAT > 2N
Rechute	ALAT > 3N ou IgG > 20g/l


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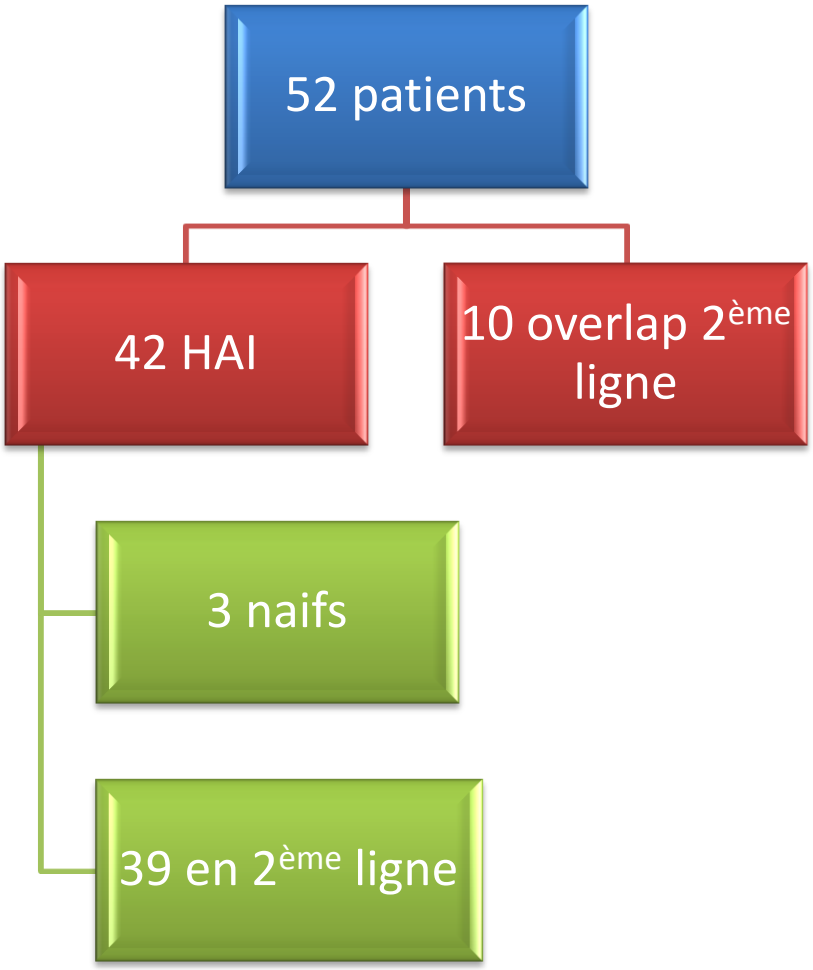

	AIH
N	42
Characteristics at diagnosis	
Female (%)	79
Age (y)	47 (11-71)
ALT (U/L)	558 (57-2214)
IgG (g/L)	20 (8-60)
ANA and or SMA positive, n (%)	27 (69)
LKM-1 positive, n (%)	1 (3)
SLA/LP positive, n (%)	2 (5)
IAIHG score,[a] median (range)	16 (8-21)
Study baseline	
Cirrhosis %, n biopsied	19%, 40
Months diagnosed	18 (0-280)
Tioguanine therapy	
Initial dose	
mg kg^{-1} d^{-1}	0.23 (0.10-0.33)
mg/d	20 (10-24)
Dose at last use (mg/d)	18 (5-30)
Months on tioguanine therapy	12 (2-194)


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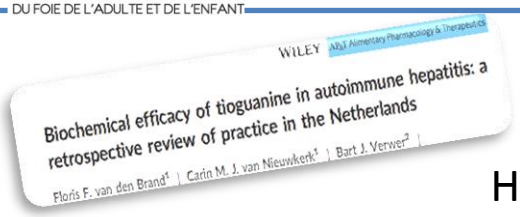
	AZA or MP (N = 49)		TG (N = 52)	
	Tolerable	Intolerable	Tolerable	Intolerable
Patients with an AE	6	38	4	7
Nausea and vomiting	6	20	1	
Headache		2	1	2
Fatigue	2	7	1	
Myalgia/arthralgia	1	6		3
Itch	1		1	
Rash			1	1
Abdominal pain	1	3		1
Fever	1	5		1
Malaise		4		1
Alopecia		2		
Hot flushes		1		
Diarrhoea		1		
Myelotoxicity	2	4	1	

Pas d'apparition d'HTP en cours de traitement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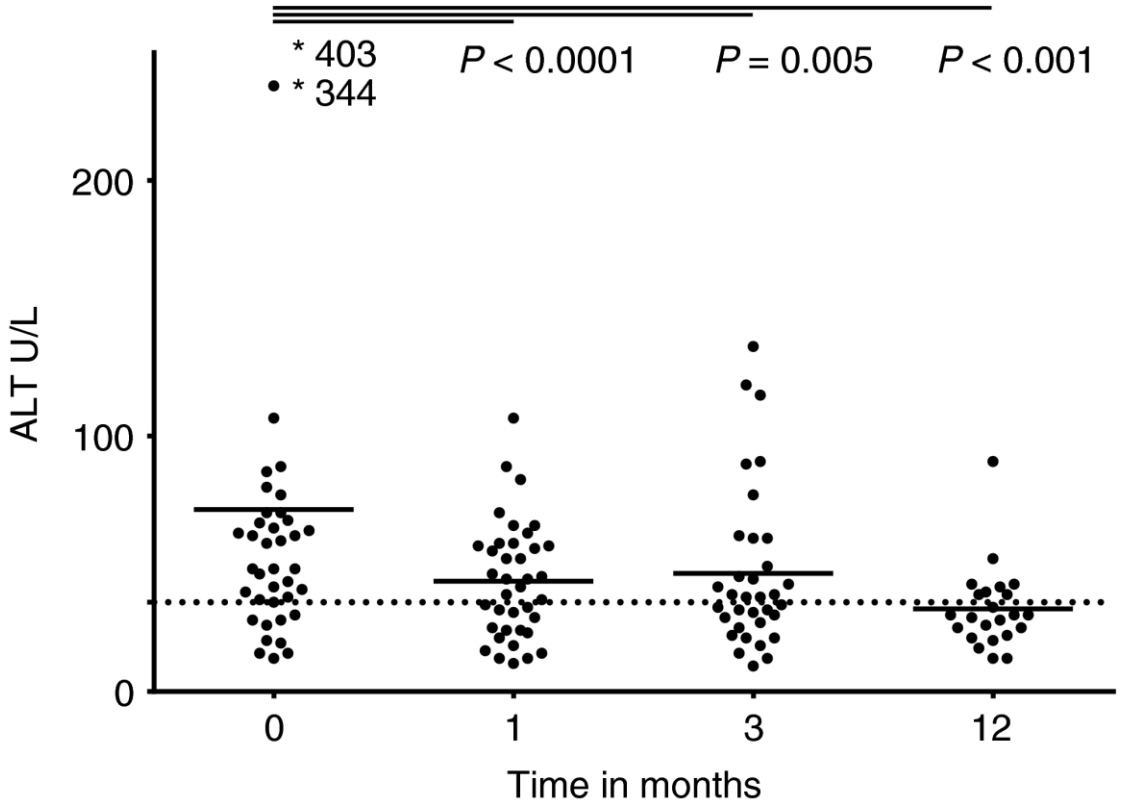
HAI : efficacité de TG en cas d'intolérance à AZA ou MP n=33
Patients tolérants la TG n=26 79%



26 patients en per protocole

- Rémission complète n=22 85%
- Rémission incomplète n=3 11%
- Pas de réponse n=1 4%

6 patients sous TG pour inefficacité AZA : 4 succès, 2 intolérances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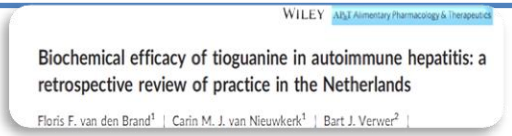
Réponse rapide

		Tioguanine therapy		Biochemical response		
Months of treatment	Follow-up n	Stopped n	Ongoing n	Incomplete n (%)	Complete n (%)	*P*-value[a]
Baseline	39	0	39	—	9 (23)	
1	38	0	38	19 (50)	19 (50)	0.002
3	36	2	34	15 (44)	19 (56)	<0.001

[a]Compared with complete biochemical response at baseline.

Epargne cortisonique : 56 % des patients

Dosage de 6 TGN n=30 patients, médiane 746 pM/8*10^8 GR, 1 patient non observant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1

- Peu de données disponibles sur l'efficacité et la sécurité de la TG chez les patients atteints d'HAI et en échec par défaut de réponse ou de tolérance à AZA /6MP

2

- Chez les patients intolérants à AZA/6MP, sous réserve de son caractère rétrospectif, l'étude est en faveur d'une **bonne tolérance de la TG** avec disparition des EI de l'AZA dans 80 % des cas
- Pas d'HNR signalée dans cette étude (faible dose de TG ?)
- **La TG induit une fréquemment une réponse** (85 % des cas quand il est toléré), MMF dans cette situation mais dans d'autres populations = réponse 43 à 75%

3

- La TG constitue une **option thérapeutique** chez les patients en échec d'AZA/6MP notamment en cas d'intolérance

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OFFICIAL JOURNAL OF THE AGA INSTITUTE

Gastroenterology

Volume 155, Issue 3, September 2018, Pages 752-759.e5

Original Research

Full Report: Clinical—Biliary

No Superiority of Stents vs Balloon Dilatation for Dominant Strictures in Patients With Primary Sclerosing Cholangitis

Cyriel Y. Ponsioen [1], Urban Arnelo [2], Annika Bergquist [2], Erik A. Rauws [1], Vemund Paulsen [3], Paolo Cantú [4], Ilaria Parzanese [4], Elisabeth M. De Vries [1], Kim N. van Munster [1], Karouk Said [2], Olivier Chazouillères [5], Benoit Desaint [5], Astrid Kemgang [5], Martti Färkkilä [6], Schalk Van der Merwe [7], Werner Van Steenbergen [7], Hanns-Ulrich Marschall [8], Per-Ove Stotzer [8], Douglas Thorburn [9], Stephen P. Pereira [9], Lars Aabakken [3]

1 Department of Gastroenterology & Hepatology, Amsterdam UMC, University of Amsterdam, the Netherlands

2 Department of Gastroenterology & Hepatology, Karolinska University Hospital, Huddinge, Karolinska Institutet, Sweden

3 Department of Gastroenterology & Hepatology, Rikshospitalet, Oslo, Norway

4 Gastroenterology and Endoscopy Unit, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Department of Pathophysiology and Transplantation, Università degli Studi di Milano, Milan, Italy

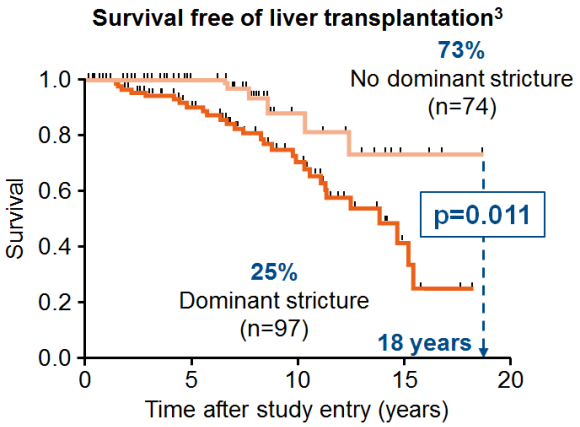
5 Department of Hepatology, Hôpital Saint Antoine, Paris, France

6 Department of Gastroenterology & Hepatology, Helsinki University Hospital, Helsinki, Finland

7 Department of Gastroenterology & Hepatology, Universiteitsziekenhuis Leuven, Leuven, Belgium

8 Department of Hepatology, Sahlgrenska University, Gothenburg, Sweden

9 Institute of Liver & Digestive Health, University College London and Sheila Sherlock Liver Centre, Royal Free Hospital, London, United Kingdom



Clinical Practice Guidelines

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EASL European Association for the Study of the Liver

ESGE

Role of endoscopy in primary sclerosing cholangitis: European Society of Gastrointestinal Endoscopy (ESGE) and European Association for the Study of the Liver (EASL) Clinical Guideline☆

European Society of Gastrointestinal Endoscopy, European Association for the Study of the Liver*

Sténose serrée ≈ 50 % des patients

Recommendations

A dominant stricture at ERCP should be defined as a stenosis with a diameter of ≤1.5 mm in the common bile duct and/or ≤1.0 mm in a hepatic duct within 2 cm of the main hepatic confluence	Weak	Low

Recommendations

ERCP and ductal sampling should be considered in confirmed PSC in the case of: • Clinically relevant or worsening symptoms • Rapid increase of cholestatic enzyme levels • New dominant stricture or progression of existing dominant strictures identified at MRC in appropriate clinical context	Weak	Low

Recommendations		
Endoscopic treatment with concomitant ductal sampling of suspected dominant strictures **is suggested in patients presenting with symptoms likely to improve following endoscopic treatment**	Strong	Low

Recommendation

8. ESGE/EASL suggest that the choice between stenting and balloon dilation should be left to the endoscopist's discretion.
Weak recommendation, low quality evidence.

MENU AJG The American Journal of GASTROENTEROLOGY

Original Contribution | Published: 01 September 1999

Four years experience with short term stenting in primary sclerosing cholangitis

C Y Ponsioen MD, K Lam, A W M van Milligen de Wit MD, PhD, K Huibregtse MD, PhD & G N J Tytgat MD, PhD

American Journal of Gastroenterology **94**, 2403–2407 (1999) | Download Citation

- 32 patients
- Prothèse transitoire 11 j en moyenne
- Bons résultats cliniques et biologiques

Etude DILSTENT randomisée multicentrique de supériorité, hypothèse d'une survie sans récidive de 60 % avec prothèse vs 30 % avec dilatation, analyse intermédiaire au 3ème mois de suivi de 50 % de la cohorte

Patients inclus : CSP selon les critères EASL 2009, pas de CCA et au moins 1 critère :

1/ bili > 3N
2/ dleur HCD, prurit, fièvre, ↑ bili ou PAL par angiocholite
3/ ↑ de 20 % de bili ou PAL dans les 4 mois + sténose serrée
4/ signes d'angiocholite et Bili ou PAL ≥ 1,2 N + sténose serrée
5/ Amsterdam Cholestatic Complaints score ≥ 3 + critères 4

Critère d'évaluation principal: survie sans récidive symptomatique de la sténose serrée traitée, en ITT
Critères secondaires : complications, évolution clinique et biologique, QDV

CPRE : standardisation autant que possible, sauf pour la SE, prothèse de 10F ou 2 prothèses 7F 7 jours, dilatation ballonnet 4 à 6 mm


No Superiority of Stents vs Balloon Dilatation for Dominant Strictures in Patients With Primary Sclerosing Cholangitis

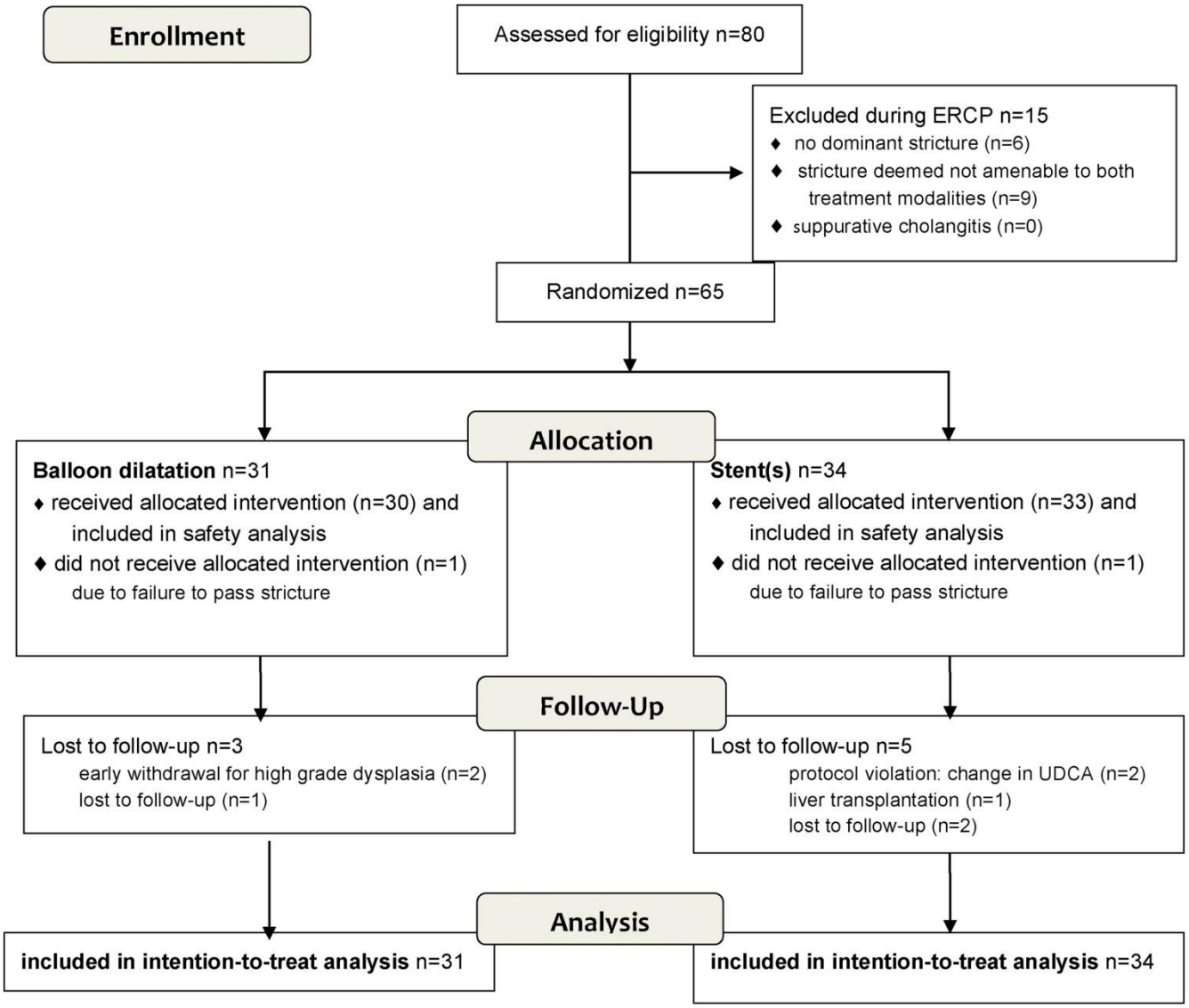

Table 1. Baseline Characteristics

Characteristics	Balloon dilatation (n = 31)	Short-term stenting (n = 34)
Mean age, *y* ± SD	40 ± 14	40 ± 11
Male, n (%)	22 (71)	23 (68)
Disease duration, *y*, median (IQR)	7 (3–10)	4 (2–8)
Concurrent IBD, n (%)	25/31 (80)	25/33 (76)*
UC	23 (74)	19 (58)
Crohn	1 (3)	5 (15)
IBD-U	1 (3)	1 (3)
Previous EPT, n (%)	15 (48)	10 (29)
UDCA use, n (%)	21 (68)	26 (76)
Anti-pruritic medication, n (%)	3 (10)	5 (15)
Bilirubin,[a] *μmol/L*, median (IQR)	38 (15–108)*	24 (12–57)[d]
ALP,[b] *U/L*, median (IQR)	312 (259–470)*	302 (214–475)[e]
AST,[c] *U/L*, median (IQR)	110 (48–170)**	70 (41–111)[f]

p = 0,12

Pas de différence significative dans la procédure de CPRE entre les 2 groupes

Table 2. Changes in Bilirubin, ALP, and AST Levels and Cholestatic Symptoms at Baseline and 3 Months and Changes Thereof Between Groups

	Balloon Group				Stent Group				
Measure	Baseline (t_0)	3 months (t_3)	Δ ($t_0 \geq t_3$)	Relative change	Baseline (t_0)	3 months (t_3)	Δ ($t_0 \geq t_3$)	Relative change	*P* value
Bili, *μmol/L*, median (IQR)	39 (16–108) n = 30	14 (11–58) n = 28	−10 (0 to −45) n = 28	—	24 (12–57) n = 33	14 (9–24) n = 28	−3 (−1 to −33) n = 28	—	.35[a]
($Bili_0$ − $Bili_{3mo}$) / $Bili_0$, median (IQR)	—	—	—	0.30 (0–0.67) n = 28	—	—	—	0.22 (0–0.53) n = 27	.54[a]
ALP, *U/L*, median (IQR)	312 (259–470) n = 30	306 (153–446) n = 29	−31 (47 to −115) n = 29	—	302 (215–475) n = 33	280 (157–390) n = 27	−35 (21 to −133) n = 26	—	.67[a]
(ALP_0 − ALP_{3mo}) / ALP_0, median (IQR)	—	—	—	0.09 (−0.17 to 0.41) n = 29	—	—	—	0.10 (−0.12 to 0.36) n = 26	.97[a]
AST, *U/L*, median (IQR)	110 (48–171) n = 29	64 (43–175) n = 29	−12 (5 to −55) n = 28	—	70 (41–111) n = 31	44 (32–83) n = 27	−15 (−2 to −39) n = 25	—	.73[a]
(AST_0 − AST_{3mo}) / AST_0, median (IQR)	—	—	—	0.14 (−0.11 to 0.49) n = 28	—	—	—	0.25 (0.06–0.43) n = 25	.32[a]
Pruritus, median (IQR)	1.5 (0–2) n = 30	0.0 (0–1) n =	−1.0 (0 to −2) n = 28	—	1.0 (0–3) n = 33	0.5 (0–1) n = 28	0.0 (0 to −2) n = 27	—	.70[a]
Fatigue, median (IQR)	1.0 (0–2) n = 30	0.5 (0–1) n = 28	−1.0 (0 to −1) n = 28	—	1.0 (0–2) n = 33	0.0 (0–2) n = 27	0.0 (0 to −1) n = 26	—	.60[a]
Fever, n (%)	1 (3) n = 30	2 (7) n = 28	—	—	4 (12) n = 33	1 (3) n = 28	—	—	1.0[b]
RUPQ, median (IQR)	1.0 (0–1) n = 30	0.0 (0–1) n = 28	0.0 (0 to −1) n = 28	—	0.0 (0–2) n = 33	0 (0–0) n = 28	0.0 (0 to −1) n = 27	—	.68[a]
ACCS, median (IQR)	4.0 (2–4) n = 30	1.0 (0–3.5) n = 28	−1.5 (−0.25 to −3) n = 28	—	4.0 (2–5) n = 33	1.0 (0–3) n = 27	−2.0 (−1 to −3) n = 27	—	.61[a]
SF-36 MCS, mean (SD)	43.2 (10.3) n = 29	49.4 (8.5) n = 20	6.5 (11.4) n = 20	—	41.7 (11.4) n = 28	49.5 (8.3) n = 16	6.5 (8.1) n = 14	—	.99[c]
SF-36 PCS, mean (SD)	46.4 (8.5) n = 29	51.4 (5.0) n = 16	4.7 (8.3) n = 20	—	47.2 (8.7) n = 28	49.4 (8.9) n = 16	0.9 (9.4) n = 14	—	.23[c]

NOTE. Analyses were performed in the per protocol population.
AST, aspartate aminotransferase; Bili, bilirubin level; IQR, interquartile range; MCS, mental component score; PCS, physical component score; SD, standard deviation.
[a]Mann-Whitney *U* test.
[b]Fisher[1]s exact test.
[c]Independent samples T-test.

	Durée médiane sans récidive	Echec initial
Dilatation	26 semaines	52 %
Prothèse	34 semaines	44 %

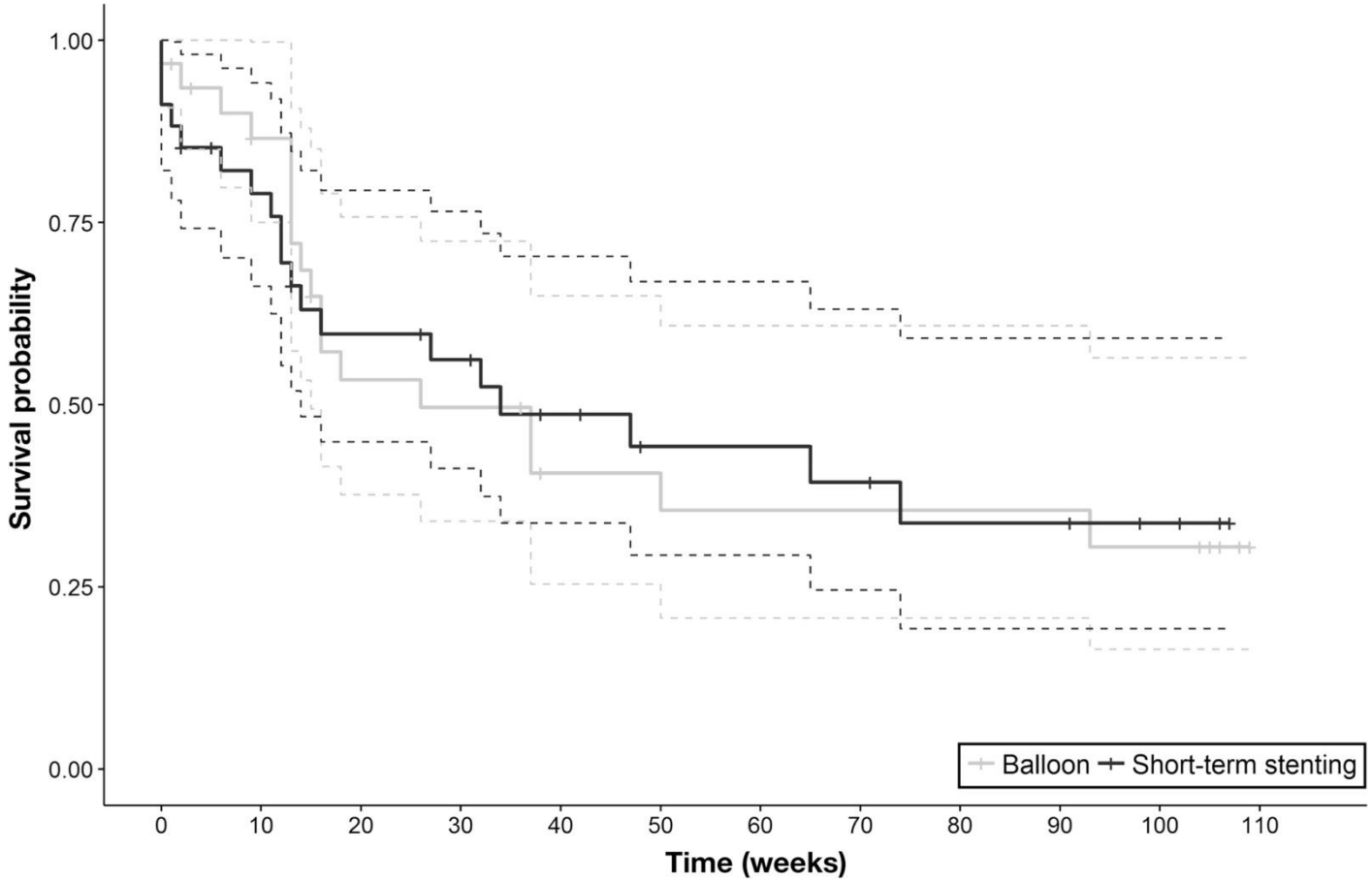

Table 3. Procedure-Related SAEs

Procedure	Balloon dilatation n = 30[a]	Short-term stenting n = 33[a]	OR (95% CI)	*P* value
All cause, n (%)	2 (6.7)	15 (45.4)	11.7 (2.4–57.2)	.001
Cholangitis/cholecystitis, n (%)	1 (3.3)	4 (12)	4.0 (0.42–38.0)	.36
Post-ERCP pancreatitis, n (%)	1 (3.3)	8 (24)	9.3 (1.1–79.4)	.03
Postprocedural pain, n (%)	0	2 (4.5)	n.a.	—
Ascites	0	1 (3)	n.a.	—

*6,8

Table 4. Univariate Analysis for Risk Factors of Procedure-Related Serious Adverse Events

Risk factor	Univariate analysis, OR	95% CI	*P* value
Age	1.0	0.9–1.03	.42
Sex	1.2	0.4–4.0	.71
Disease duration	1.0	0.9–1.1	.83
Randomization	11.2	2.4–57.2	.002
Center	0.8	0.6–1.1	.16
Previous sphincterotomy	0.6	0.2–2.0	.39
Baseline serum biluribin	1.0	0.99–1.01	.43
Procedure time	1.0	0.99–1.02	.79
NSAID prophylaxis	1.0	0.3–3.1	.99
Sphincterotomy	0.7	0.2–2.15	.48

Aucune différence significative entre les groupes pour les critères secondaires :

- Δ bilirubine, PAL
- Δ prurit, symptômes, douleurs biliaires
- Δ critères QDV

Supplementary Table 6. Univariate and Multivariate Analysis of Risk Factors for Post-ERCP Pancreatitis

Risk Factors	Univariate analysis, OR	95% CI	*P* value	Multivariate analysis, OR	95% CI	*P* value
Age	1.0	0.92–1.04	.45	—	—	—
Sex	1.1	0.24–4.90	.91	—	—	—
Disease duration	0.8	0.62–1.02	.07	—	—	—
Randomization	9.3	1.1–79.4	.04	7.5	0.9–66.1	.07
Center	0.9	0.6–1.3	.65	—	—	—
Previous sphincterotomy	0.2	0.02–1.40	.10	0.2	0.03–21.00	.19
Baseline serum biluribin	1.0	0.99–1.01	.44	—	—	—
Procedure time	1.0	0.98–1.02	.80	—	—	—
NSAID	0.7	0.15–3.00	.60	—	—	—
Sphincterotomy	0.8	0.2–3.8	.80	—	—	—

NSAID, nonsteroidal anti-inflammatory drug; OR, odds ratio.

Pancréatites hospitalisées	Bras Dilatation	Bras prothèse	Total
SE antérieure n = 25	0 /15	1 /10	1/25 (4 %)
Pas de SE antérieure n = 40	1 /16	7/24	8/40 (20 %)

OR 0,17
95% IC, 0,02-1,4
p=0,1


No Superiority of Stents vs Balloon Dilatation for Dominant Strictures in Patients With Primary Sclerosing Cholangitis

1

- La survenue d'une sténose serrée symptomatique est fréquente au cours de la CSP et les modalités endoscopiques de son traitement sont débattues

2

- Le traitement endoscopique améliore les symptômes des patients toutes modalités de traitement endoscopique confondues
- Cette étude randomisée échoue à démontrer une supériorité de la pose de prothèse sur la dilatation au ballonnet pour éviter la récidive symptomatique de la sténose traitée
- La pose de prothèse est associée à un taux de complication **près de 7 fois supérieur** à la dilatation au ballonnet avec des PA graves notamment en cas de papille intacte

3

- La dilatation au ballonnet des sténoses serrées au cours de la CSP semble constituer le **traitement initial préférable**, notamment chez les patients indemnes de sphinctérotomie