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Abstract

TITLE: Systematic versus endoscopy-driven treatment with azathioprine to prevent postoperative ileal Crohn's disease recurrence: interim results from a randomized, multicenter trial

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ABSTRACT BODY: Background & Aims: Preventing postoperative Crohn's disease (CD) recurrence remains challenging. Prophylactic therapy with azathioprine (AZA) has been shown efficacious, but it is unknown whether it should be started immediately after surgery in all patients. Therefore, we compared systematic versus endoscopy-driven therapy with AZA in preventing CD recurrence at 24 months.

Methods: Patients with CD undergoing curative ileal resection with ileocolonic anastomosis and at high risk of recurrence (smoker, perforating disease, age <30 years, previous resections, or recent use of anti-TNF agents) were included in this prospective, multicentre, IOIBD sponsored trial. Patients were randomized to systematic AZA initiated ≤2 weeks from surgery (SYS-AZA), or endoscopy-driven AZA (ED-AZA). Patients in the ED-AZA arm underwent ileocolonoscopy at 6 and 12 months, and AZA was initiated at a standard dose of 2.0-2.5mg/kg in case of endoscopic recurrence (≥i2). The primary endpoint was the proportion of patients with endoscopic remission at 24 months, defined as a post-operative endoscopic recurrence score of i0 or i1. Secondary endpoints included the proportion of patients with i0, and the proportion of patients in clinical remission (CDAI<150) at 24 months. We estimated that 100 patients were required in each group to show superiority of SYS-AZA for the primary endpoint (power 80%, alpha 5%). Only patients in whom the primary endpoint was accessible or who developed clinical recurrence within 24 months, were included in the per-protocol (PP) analysis.

Results: Due to slow recruitment, only 59 patients (26 male, median age 36.5 years) were randomized between 2005-2011 and included in the intention-to-treat (ITT) analysis. Baseline characteristics are shown in Table 1. Eighteen of the 59 patients withdrew prematurely from the study (7 clinical recurrence, 5 adverse events due to AZA, 6 patient's preference). Of the 30 patients included in the ED-AZA group, 10 and 4 patients initiated AZA at months 6 and 12, respectively. Both ITT and PP analyses revealed no

difference in primary and secondary endpoints between the SYS-AZA and ED-AZA group (Table 2). In the ITT analysis, endoscopic remission was achieved by 52% in the SYS-AZA and 43% in the ED-AZA group (p=0.519).

Conclusions: Although this study was underpowered, we could not observe a benefit of systematic post-operative prophylactic therapy with AZA in patients at high risk of post-operative CD recurrence. Early post-operative endoscopic evaluation to guide further therapy seems most appropriate, but more studies are warranted.

Table 1: Baseline patient's characteristics

	Intention-to-treat analysis			Per-protocol analysis		
	SYS-AZA (n=29)	ED-AZA (n=30)	p-value	SYS-AZA (N=23)	ED-AZA (n=25)	p-value
Male (%)	11 (38)	15 (50)	0.351	7 (30)	15 (60)	0.040
Age (years, IQR)	37.4 (30.7-49.8)	34.3 (28.5-42.8)	0.458	40.1 (33.3-49.9)	32.6 (27.8-43.0)	0.190
Duration of disease (years, IQR)	4.5 (1.1-10.7)	6.5 (2.0-15.4)	0.413	6.1 (1.3-13.7)	7.5 (2.1-15.5)	0.910
Disease Location (%) L1 L2 L3	13 (45) 0 (0) 16 (55)	18 (60) 0 (0) 12 (40)	0.243	11 (48) 0 (0) 12 (52)	15 (60) 0 (0) 10 (40)	0.398
Disease Behaviour (%) B1 B2 B3	1 (4) 14 (48) 14 (48)	2 (6) 17 (57) 11 (37)	0.617	1 (4) 12 (52) 10 (44)	2 (8) 12 (48) 11 (44)	0.862
Previous resection (%)	5 (17)	7 (23)	0.561	5 (22)	5 (20)	0.882
Active smoking (%)	14 (48)	8 (27)	0.086	10 (44)	7 (28)	0.263

IQR: interquartile range

Table 2. Study outcome

	Intention-to-treat analysis			Per-protocol analysis		
	SYS-AZA (n=29)	ED-AZA (n=30)	p-value	SYS-AZA (N=23)	ED-AZA (n=25)	p-value
i0 at m24 (%)	7 (24)	9 (30)	0.613	7 (30)	9 (36)	0.683
i0/i1 at m24 (%)	15 (52)	13 (43)	0.519	15 (65)	13 (52)	0.353
i0/i1/i2 at m24 (%)	17 (59)	17 (57)	0.879	17 (74)	17 (68)	0.653
CDAI<150 at m24 (%)	19 (66)	17 (57)	0.486	19 (83)	17 (68)	0.324
CDAI<150 till m24 (%)	15 (52)	13 (43)	0.519	15 (65)	13 (52)	0.353
Radiology normal m24 (%)	13/18 (72)	16/19 (84)	0.447	13/17 (77)	16/19 (84)	0.684

m24: month 24

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Disclosure Status

The following authors have completed their 2014 DDW disclosure: Marc Ferrante: Disclosure completed | Konstantinos Papamichael: Disclosure completed | Dana. Duricova: Disclosure completed | Geert D'Haens: No Answer. | Severine Vermeire: Disclosure completed | Emmanuel Archavlis: Disclosure completed | Paul Rutgeerts: No Answer. | Martin Bortlik: No Answer. | Gerassimos Mantzaris: Disclosure completed | Gert Van Assche: Disclosure completed

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