surgery (5.4% vs. 14.9%, p =0.103) and treatment failure (26.7% vs. 34.5%, p =0.395).

Conclusion: Our results suggest a benefit of TDM in achieving higher rates of mucosal healing The higher rates of treatment discontinuation suggest that TDM improves drug selection as patients switched unhelpful treatment earlier.

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Utilisation of indocyanine green fluorescence imaging for Crohn's disease following intestinal resection

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Background: Growing evidences have shown that there are important advantages related to the utilisation of indocyanine green fluorescence imaging (ICG-FI) to reduce the risk of postoperative anastomotic leakage (AL) in colorectal surgery. However, the impact of ICG-FI on postoperative AL of Crohn's disease (CD) following intestinal resection has not been investigated.

Methods: This is a retrospective study of consecutive CD patients who were treated with intestinal resection and anastomosis at a single institution between January 2017 and August 2019. The cohort was divided into 2 groups, those with ICG-FI compared with those without ICG-FI for intestinal resection. ICG was administered intravenously with a bolus of 5 mg, and the intestinal perfusion was evaluated by a SPY Elite system. Their baseline characteristics and perioperative outcomes were further analysed.

Results: No adverse reactions were recorded. Of the 88 CD patients who underwent intestinal resection, 36 patients underwent ICG-FI during intestinal resection, while 52 CD patients who underwent routine intestinal resection were from a prospectively maintained database. The 2 groups were similar in terms of patient demographics, immunosuppressive medication use, and the procedural factors. In patients with ICG-FI, poor perfusion of the bowel judged by ICG-FI led to additional intestinal resection in 25% (9/36). ICG-FI reduces the AL rate from 13.5% (7 leaks) of non-ICF-FI group to 8.3% (3 leaks) in ICG-FI group (p = 0.456). Forty-four (50%) patients had previous intestinal resection. Overall, 10 anastomotic leaks were identified (11.4% leak rate). There were 2 leaks (4.5%) detected in patients with no previous intestinal resection, compared with 8 leaks (18.2%) identified in patients with a history of previous intestinal resection (p = 0.044). The number of previous resections correlated with increasing risk for AL (correlation coefficient = 0.998). In univariate analysis, steroid use, CRP level and preoperative weight loss >10% in 6 months were independently associated with AL.

Conclusion: ICG-FI is applicable to intestinal resection for CD and may play a role in perfusion-related AL. A large prospective randomised trial should be warranted.

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Post-marketing evaluation of reported adverse events of a multi-strain probiotic product confirms that change in manufacturing site had no impact on safety profile

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Background: In 2016, the manufacturing site of the multi-strain probiotic product VSL#3 changed. The present work is aimed at verifying if this change had an impact on the safety profile of the product.

Methods: The safety reports from post-marketing surveillance in the USA received by Alfasigma in the years 2014–2015 were compared with those received in the years 2017–2018. 2016 was not considered, because the product on the market during this year could likely come from both manufacturing sites. VSL#3 is sold in the US market as a medical food. Most of the reports were from consumers and were not medically confirmed. However, this happened in both periods, so no bias is introduced in the comparison. Each single safety report contained one or more adverse events (AEs), coded with MedDRA. The comparison between the two periods concerned primarily the number of safety reports in relation to the number of units sold. Given the similarity of trends between the total number of safety reports and sales in the two periods, the frequencies of the AEs and serious AEs were also compared at the System Organ Class (SOC) and Preferred Term (PT) level.

Results: More than 70% of subjects reporting an AE were women in both periods under comparison; mean age was 58; phone was the most frequent means (overall 76%). Table 1 summarises the main results. Sales and number of safety reports were higher in the second than in the first period. However, the ratio between number of reports and sales was higher in the 2014–2015 period compared with the 2017–2018 period: 3.5 vs. 2.9 reports per 10,000 units sold, respectively. Similar results were obtained when stratifying the described ratios by formulation. The percentages of reports with at least one serious AE were respectively 3.2% in the first period and 2.5% in the second. The two periods appeared to be similar even with respect to the percentages of AEs and serious AEs by SOC and PT, being the AEs under the Gastrointestinal SOC the most frequently reported, as expected.

Table 1. Safety reports and sales of VSL#3 products(*) by period.

	2014–2015	2017–2018
Total sales (units)	1,242,714	1,767,498
Capsules	862,613	1,414,560
Sachets 450	147,709	146,632
Sachets DS	232,392	206,306
Total number of safety reports	433	514
Capsules	257	375
Sachets 450	105	68
Sachets DS	46	36
Formulation not known	25	35
Safety reports/Sales ratio per 10,000 units sold	3.5	2.9
Capsules	3.0	2.7
Sachets 450	7.1	4.6
Sachets DS	2.0	1.7

*One package was considered one unit; sales of VSL#3 Junior, i.e. sachets of 250 billion CFU, on the market only in the first period, were divided by 2 and then combined with Sachet 450.

Conclusion: The analyzed data show that the manufacturing site change had no impact on the safety profile of VSL#3.

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