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Are real-world data studies on bowel preparation for colonoscopy necessary? Aren't RCTs enough?

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Real-world studies in many fields of medicine are becoming quite popular. They usually represent manuscripts with obvious shortcomings, including retrospective character, historical/not randomized comparison groups or lack of them, large amounts of missing data or various definitions of important aspects of the study. But they also have multiple advantages, including less "sterile" populations studied as compared to those in well-defined typical randomized controlled trials (RCTs), which is seen in inclusion/exclusion criteria that are much less strict and exclusive in real-world studies. Altogether, clinical scenarios in real-world studies much more closely resemble what is going on in existing health care systems. Therefore, some experts claim that real-world studies may be regarded as the ones verifying recommendations and also presenting data that can become hypothesis-generating.

In this recent issue of EIO, the paper by Jose Esteban and colleagues [1] on bowel preparation for colonoscopy represents a real-world data study with typical shortcomings and advantages. The study was based on medical records from 10 centers (8 in Spain and 2 in Portugal). Patients were adults and used 1 L PEG plus ascorbic acid. Adequate bowel prep was assessed using the standard Boston Bowel Preparation Scale (BPPS) system. The main outcome measures were: adequate cleansing in the whole large bowel, high-quality cleansing in the right colon, and frequency of adverse events (AEs). Fortunately, all critical data defined as mandatory were available (sex, age, indication, dosing regimen, BPPS and number of polyps in each segment) and those not-mandatory, not surprisingly, were missing (e. g. body mass index) in roughly 50% to 90% of cases.

The interesting aspects of this study are multiple but I want to focus on two of them. First, two main regimens were used in participating centers: overnight split-dose regimen and same-day regimen (the morning of the colonoscopy). Interestingly, despite current recommendations, split dosing was used infrequently (in only 32.8% of participants). It appears that there is a notion that split dosing in participating countries may lead to low adherence due for cultural and social reasons [2]. Specifically in Portugal, centers adopted the same-day regimen predominately due to the fact that colonoscopies are frequently performed in the afternoon. In this context, it has to be stressed that the overall adequate bowel preparation as well as high quality in the right colon were statistically significantly higher for split dosing than for same-day. And it confirms what we have known for a long time. Therefore, it needs to be considered in real practice in those two countries. The authors claim that the worse bowel prep with the same-day regimen was due to the interval between dosing and the start of colonoscopy, which was longer than 5 hours. Whatever the reason, it should corrected for the sake of Spanish/Portuguese patients.

Another aspect of this real-world study was a bit shocking. This was the lack of information in the medical documentation

about whether complete cecal intubation was achieved – in as high a proportion of colonoscopies as 50%. Lack of this information may happen occasionally, but not in such a high percentage. This is alarming, and in my view, publication of this real-study and appropriate action by Spanish/Portuguese endoscopic bodies to correct this finding may provide great benefits to society and patients.

It is also worth drawing attention to confounding aspects of the study, which are unfortunately present in most of papers dealing with bowel preparation for colonoscopy. First, scoring of the quality of bowel preparation is very subjective. This is usually expressed by high interobserver and intraobserver variability observed in other studies. A very interesting finding is that high-detector endoscopists (achieving high adenoma detection rates [ADRs]) usually report lower scores for bowel preparation quality [3]. This goes with the fact that perfectionist endoscopists (high detectors) are not so easily satisfied with imperfect bowel prep. They want to have a perfect view because they usually have higher expectations than the average endoscopist. That is why it is quite difficult to prove that the better bowel prep, the higher ADR and polyp detection rate. Such a finding, which is logical, was confirmed in only a small fraction of studies. Second, authors of this study and frequently other authors of papers dealing with the so-called "low-volume preparation" do not report the volumes of plain water that was drunk by participants as supplementary hydration. That supplementary hydration is recommended in Product Characteristics and in Instructions for Patients but then disregarded in analyses. It is understandable that the expression "low-volume" applies to volume of "unpleasant or special taste" liquid, but for the sake of critical comparisons, such data should be available. But this was a real-world study, so lack of that data is understandable.

In summary, I would like to thank the authors for their effort in performing this study and providing data thanks to which the real-world situation in endoscopy may hopefully improve. Let us call for more high-quality, real-world studies honestly performed like this one.

Conflict of Interest

The authors declare that they have no conflict of interest.

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