Scheduled, Unsedated Colonoscopy Provides Access to Colonoscopy in a VA Setting With Unexpected, Unplanned Discoveries

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Abstract

When a nursing shortage necessitated discontinuation of our conscious sedation program for colonoscopy, scheduled, unsedated colonoscopy was offered to restore local access to colonoscopy. The option was accepted by one-third of the patients after the pros and cons of unsedated and sedated colonoscopy were explained. Interest in communication with the colonoscopist and lack of an escort were the most frequently cited reason for acceptance of the unsedated option. Initial cecal intubation rate was <80%, limited by discomfort. A search of the literature for methods to minimize discomfort led to the discovery of several water-related techniques. Based on these techniques, a water infusion in lieu of air insufflation (water method) for aiding colonoscope insertion was developed. In a consecutive group non-randomized observational study, the water method significant improved cecal intubation rate to 97%.

Narrative

This essay chronicles the evolution of a scheduled, unsedated colonoscopy program at one VA ambulatory care facility. At each step, the issues that challenged the clinician investigator, the approaches adopted to deal with these issues, the results, and the lessons learned are described. The emphasis is on providing feasibility data to support the use of scheduled, unsedated colonoscopy to provide access to colonoscopy without the need for registered nurse support and with minimal discomfort.¹⁻²

In 2002 a nursing shortage at the Veterans Affairs Greater Los Angeles Healthcare System (VAGLAHS) led to discontinuation of sedated colonoscopy practice at the VA Sepulveda Ambulatory Care Center. At patients' requests to have an alternative to being sent to another facility, the literature was reviewed. The result of the review established the feasibility of the option of scheduled, unsedated colonoscopy. With institutional approval, we offered scheduled, unsedated colonoscopy as an option to restore local access to colonoscopy¹ with emphasis on patient-centered care.² During a pre-colonoscopy clinic visit, the pros and cons (based initially on literature review) of the scheduled, unsedated option were reviewed with each patient.

The features of no escort requirement and the possibility of communication with the colonoscopist during the examination were the two most common reasons (Table 1)³ motivating veterans to choose the scheduled, unsedated option. From 2002

Table 1: The stated reasons why this group of patients (N=123) chose to undergo unsedated colonoscopy -- answers given immediately prior to examination.

Reasons* for choosing unsedated	n (% total)
Able to communicate	107 (87%)
No escort	98 (80%)
Familiarity with doctors	84 (68%)
Short distance to facility	84 (68%)
Able to return to work on the same day	41 (33%)

^{*} Patients can check more than one reason.

to 2009, consistently $\sim 1/3$ (n = 50 to 60 per year) of the veterans embraced the option. Eight patients examined in 2002 to 2003 and eligible for three-year surveillance completed repeat unsedated surveillance examination in 2006 - 2007.³ The patient-centered nature of the option has been quite convincingly dramatized by the veterans who pointed out that the scheduled, unsedated option (without escort requirement) enabled them to participate in screening.⁴

In order to minimize coercion, an agreement was made with each patient that the unsedated examination should stop if there was excessive discomfort. During unsedated colonoscopy the colonoscopist implemented maneuvers (minimal air insufflation, removal of looping) to diminish discomfort. The next challenge for the clinician investigator was the recognition that discomfort was indeed the major factor limiting the success of cecal intubation in over 20% of the patients. The cecal intubation rate of almost 80%, 1,3 though comparable to the success rate reported overseas, was far below the 90 to 95% recommended for quality performance.

To overcome this problem, another review of the literature was undertaken to identify ways to decrease colonoscopy discomfort. The literature survey led to the discovery of several water-related techniques, which we summarized in one review.8 These techniques, as adjuncts to air insufflation, facilitated passage through difficult segments with severe diverticulosis or spasm, minimized discomfort without reducing the dose of sedation medication, and decreased discomfort in unsedated patients. Since air insufflation can elongate the colon, accentuate angulations at the flexures, and increase the difficulty of cecal intubation in the unsedated patients, we decided to omit air insufflation altogether during insertion of the colonoscope. Based on information in the literature and subsequent "trial and error" attempts to modify or "perfect" the techniques to minimize colonoscopy discomfort, the water method (water infusion in lieu of air insufflation method)8-11 was developed. Details of this method are described in other articles in this issue of the Journal. 11,12

The data in an observational study¹⁰ comparing the air and water method in scheduled, unsedated patients are described below. In a consecutive group observational study, 62 patients were examined with the air method; a subsequent group was examined with the water method. The water method significantly improved cecal intubation rate from 76% to 97% and the proportion of patients who reported willingness to repeat from 69% to 90%. Failure due to poor bowel prep was 13% in the air group but only 1.5% in the water group. Similarly, failure due to abdominal discomfort was 13% in the air group but only 1.6% in the water group. A numerically higher adenoma detection rate in the water group -37% vs. 26% -was also observed. The finding of a numerically higher adenoma detection rate prompted us to perform a review of an endoscopic database to evaluate the impact of the water method on polyp detection.¹¹ Indeed, the water method appeared to have increased the proportion of patients with at least one polyp of any size.

Discussion

The importance of the data or the importance of the concept of unsedated colonoscopy in the US is as follows: In the US, unsedated colonoscopy has been offered to 1-2% of patients who present for colonoscopy without escorts after purging themselves. 13,14 Unsedated colonoscopy has also been requested by 7% of patients who are educated professionals with independent knowledge of the option. 15 When we actively discussed the option with the patients about one third accepted the option, a rate that is much higher than any previous reports in the US. The data suggest there are patients who will accept the unsedated option if it is actively discussed and offered. We speculate that when endoscopists make the assumption that most patients in the US want sedation and, therefore, omit the mention of the unsedated option, the result is a low rate of unsedated colonoscopy in this country. An alternative explanation is that most colonoscopists in the US have not received formal training in performing unsedated colonoscopy and do not offer what they have not been trained to do. A recent survey¹⁶ (28% response rate) in Germany, a country where unsedated colonoscopy has been common, reported an increasing proportion of colonoscopies there were performed with sedation, including use of propofol. To proponents of sedation this indicates that when individuals are given the option of sedation vs. no sedation, they choose sedation; and since sedation has become an option in Germany, the proportion of individuals willing to undergo screening colonoscopy has increased. An alternative interpretation is that, even in places where unsedated colonoscopy is acceptable, there is a real need to develop methods to minimize the discomfort of the unsedated procedure. Unsedated colonoscopy is not a concept. It is real practice and can be uncomfortable. The importance of our work has been in developing a less uncomfortable way to perform unsedated colonoscopy by using water infusion in lieu of air insufflation.

More studies in this area are warranted, because the data we reported have significant limitations. The studies reporting beneficial effects of the water method have been small and limited to evaluations of elderly, male veterans. Whether the results are applicable to non-veterans or other practice settings is not known. Studies in community practice, university medical practice, and health maintenance organizations will be important to determine whether the unsedated colonoscopy performed with the aid of the water method has a place in these settings. Other settings, such as rural or inner city communities where screening colonoscopy is not available in part due to lack of resources to support sedation, are appropriate for evaluating the unsedated option performed with the aid of the water method. If practitioners in these settings can learn to apply the techniques described in the articles in this issue of the Journal, then screening colonoscopy can potentially be available where there has been obvious disparity in colonoscopy service.

A number of potential patient-centered benefits deserves mention. With scheduled, unsedated colonoscopy aided by the water method achieving a successful cecal intubation rate of over 95%, patients participating in screening can be assured a qual-

ity cecal intubation rate. There is no need to bring an escort. As soon as the examination is completed, they can almost immediately resume usual activities. There is no need to spend time on site or at home to recover from the effects of sedation medications. The very small risk of sedation medication-related complications can be obviated.

The answer to the question whether unsedated colonoscopy performed with the water method would improve access to an important cancer-screening tool is unknown but deserves to be sought in formal studies. The limited experience that we have derived from the veterans who do not possess escort resources suggested that the answer to this question is "yes." Veterans have informed us that had it not been for the unsedated option (without escort requirement), they would not have participated in screening.

The documentation we have provided is focused on demonstrating the restoration of access to colonoscopy service by using the option of unsedated colonoscopy when nursing shortage curtailed the continued provision of the original sedation-based colonoscopy program. There was no intention to demonstrate any savings or a less costly approach. If readers would recognize that the unsedated option, by obviating the need for registered nurses (required if conscious sedation is administered) and the patients can avoid recovery time cost, escort cost, side effects, and complications of medications, then they can pass value judgment as to whether the approach is less costly or not than the one relying on sedation.

Physicians in primary care and family medicine in the US have long embraced the practice of unsedated extended flexible sigmoidoscopy. Gastroenterologists have reported a higher cecal intubation rate with extended flexible sigmoidoscopy. It is conceivable that with proper training of the water method, even endoscopists in primary care and family medicine practice can achieve a higher cecal intubation rate with less discomfort experienced by the patients. This is a priority for those interested in clinical research in this area. Practically, an extended flexible sigmoidoscopy is the same as an unsedated colonoscopy. The former has a better appeal because any portion of the colon examined proximal to the splenic flexure, even without achieving cecal intubation, provides added yield. In the latter, not reaching the cecum is a failed unsedated colonoscopy.

Finally, a RCT published in the Lancet recently²⁰ shows that flexible sigmoidoscopy is a safe and practical test and, when offered only once between ages 55 and 64 years, confers a substantial and long- lasting benefit. The control group had 113,195 people assigned to it, and 57,237 were assigned to the intervention group, of whom 112,939 and 57,099, respectively, were included in the final analyses. Seventy-one percent, or 40,674 people, underwent flexible sigmoidoscopy. During screening and median follow-up of 11·2 years (IQR 10·7-11·9), 2524 participants were diagnosed with colorectal cancer (1818 in control group vs 706 in intervention group) and 20,543 died (13,768 vs 6775; 727 certified from colorectal cancer [538 vs 189]). In intention-to-treat analyses, colorectal cancer inci-

dence in the intervention group was reduced by 23% (hazard ratio 0.77, 95% CI 0.70-0.84) and mortality by 31% (0.69, 0.59-0.82). In per-protocol analyses, adjusting for self-selection bias in the intervention group, incidence of colorectal cancer in people attending screening was reduced by 33% (0.67, 0.60-0.76) and mortality by 43% (0.57, 0.45-0.72). Incidence of distal colorectal cancer (rectum and sigmoid colon) was reduced by 50% (0.50, 0.42-0.59; secondary outcome). The numbers needed to be screened to prevent one colorectal cancer diagnosis or death by the end of the study period were 191 (95% CI 145-277) and 489 (343-852), respectively.

Conclusion

To meet the challenge of finding a less burdensome approach for patients in colorectal cancer screening, scheduled, unsedated colonoscopy (or extended flexible sigmoidoscopy) is an option. The option avoids all sedation-related complications, which are relevant in preventive screening for healthy asymptomatic individuals. The water method enhances success of cecal intubation and willingness to repeat. Whether the approach can enhance utilization of screening in patients with limited resources (e.g., no escort) in settings other than a VA ambulatory care facility experiencing a nursing shortage remains to be confirmed.

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