

# Patient Time Burden and Sedation-Related Complications in Screening and Surveillance Colonoscopy

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## Abstract

Optical colonoscopy is the final common pathway for all other positive screening tests as well as having been recommended as a screening modality. Because of costs, it is generally considered underutilized for screening, especially among subgroups of patients who have limited resources. These costs arise as a consequence of sedation being used for screening colonoscopy – escort costs, post-colonoscopy recovery and activity restriction costs, and a low risk of sedation-related complications. A framework for consideration of the scheduled and unscheduled sedation is described to set the stage for further discussions of these sedated and unsedated alternatives.

## Narrative

The objectives of this introductory discussion are to review the components of patient time costs, to tabulate the extent and significance of sedation-related complications in screening colonoscopy, and to discuss how various options impact these events.

Colon cancer is the second leading cause of cancer deaths in the United States and worldwide. In the United States, estimated new cases and deaths from colon and rectal cancer in 2009 are as follows: new cases - 106,100 (colon); 40,870 (rectal); deaths - 49,920 (colon and rectal combined).<sup>1</sup> One out of three people diagnosed dies from colon cancer. Professional Gastroenterology, Endoscopy, and Cancer Societies have recommended colorectal cancer (CRC) screening for healthy, asymptomatic individuals. In 2004, the Center for Disease Control estimated that there were 43 million Americans eligible for CRC screening.<sup>2</sup>

Optical colonoscopy has been reported to discover 1% cancer and 9% advanced adenomas in the setting of CRC screening.<sup>3</sup> Observational studies have shown that optical colonoscopy is effective in detecting colon cancer and removal of polyps. It is the final common pathway for all patients with positive CRC screening tests such as fecal occult blood test (FOBT), fecal immunochemical testing (FIT), barium enema (BE), computerized tomographic colonoscopy (CTC), and flexible sigmoidoscopy (FS). In recent years, it has even been recommended as a first-line CRC screening tool for healthy asymptomatic individuals. Because of costs, it is generally considered underutilized for screening, especially among subgroups of patients with limited resources.<sup>4-7</sup>

The most obvious cost is due to the fact that sedation is routinely used, mandating the need for an escort, nursing staff for monitoring and recovery of the patient, and post-sedation activity restrictions. One study reported that the total time occupied by preparation, undergoing and recovering from a sedated colonoscopy amounts to 40 hours.<sup>8</sup> This subject will be covered in detail in paper by Dr. Ko in this issue.<sup>9</sup> An accounting approach to evaluate burden is micro-costing, using time and motion recording.<sup>10,11</sup> For example, a colonoscopy broken down to the individual components will reveal those related to a patient's direct and indirect costs.

Patient costs include time for bowel preparation, transport to hospital or endoscopy center, check in time, on site preparation (insert intravenous line, complete consent form, undergo induction of sedation), undergo the colonoscopy, spend time in the recovery room, receive post-procedure counseling, transport to

home, and recovery time at home before going back to normal activities. Patient costs in time and inconvenience go up when sedation is administered. For example, the post-procedure counseling done verbally with a patient immediately after sedation is a likely waste of time because of the amnesic effect of the sedation medication.<sup>12</sup> On the other hand, counseling can be done readily after an unsedated examination.

Micro-costing was applied to analyze sedated colonoscopy. Costs included \$391 for direct health care, \$288 for direct non-health care costs, and \$274 for patient time costs, when a colonoscopy was performed at one VAMC.<sup>11</sup>

Dr. Ko published a report on complications after screening or surveillance colonoscopy based on patients identified in the Clinical Outcomes Research Initiative database.<sup>13</sup> Of 21,375 patients, the incidence of sedation-related complications during colonoscopy was 12.9 per 1000 patients. The most common was respiratory depression occurring in 7.5 per 1000. Immediate cardiovascular complications including hypotension and bradycardia occurred in 4.9 per 1000. Most were self-limited. Some did require sedation reversal with atropine, flumazenil, or naloxone, occurring in 2.9 per 1000. Five were hospitalized for observation for abdominal pain or prolonged sedation.

Screening colonoscopy is offered to healthy, asymptomatic individuals between the ages of 50 and 75. Patient time costs, escort costs, and sedation complications are an integral part of the screening procedure. While these are all acceptable when a patient undergoes a diagnostic examination, some of these costs should be minimized for the healthy, asymptomatic individuals undergoing screening.

Scheduled unsedated colonoscopy is not standard practice in the US. Unscheduled, unsedated colonoscopy has been offered to the 1-2% of patients without an escort.<sup>14,15</sup> Scheduled, unsedated colonoscopy has been requested by 6-7% of colonoscopy patients at one university practice by professionals with independent knowledge of the option<sup>16</sup> as a way to reduce cost of activity restriction. Interestingly, when the colonoscopist actively presents the pros and cons of such an option, it has been consistently accepted by about one-third of the patients at one VA facility without the capability to provide on-site sedation<sup>17,18</sup> and by about one-quarter of the patients at another VA facility with the capability to provide on-site sedation.<sup>19</sup>

Even in sedated patients, there are the options of deep sedation on the one hand and minimal (less than full dose) on the other. Escort cost is unavoidable. Sedation as needed is based on assessment by the colonoscopist.<sup>20</sup> However, this may carry a risk of coercion, as assessment of patient pain at colonoscopy by nursing staff is better than by endoscopists, who tend to underestimate patient discomfort.<sup>21</sup> Escort cost is unavoidable.

Sedation on demand is requested by the patient. It is less likely to be coercive. For research studies we have proposed the following routine for on-demand sedation. To eliminate colonoscopist bias<sup>21</sup> the nurse recorded patient reported pain scores (0=none, 10=most severe) every two to three minutes. For scores  $\geq 2$ , maneuvers to minimize pain<sup>22</sup> were implemented for both methods. Immediately thereafter the nurse offered medications, which the patients could accept or decline as previously described.<sup>22</sup> Escort cost is unavoidable. Completion without sedation obviates the costs of sedation complications and costs of on-site and at-home recovery times.

**Table 1:** Attributes of scheduled options

	Sedated	Unsedated
Availability	Routine in US	Not routine in US
Risks: hypotension, hypoxia, etc.	Very small	None
Success rate	~ 90%	80 to 90%
Purge preparation	Yes	Yes
Escort	Mandatory	Not required
Drive a car after colonoscopy	Not allowed	Allowed
Discomfort reduced by medication	Likely	Not applicable
Remember discomfort	No due to amnesia	Yes
Remember discussion	No due to amnesia	Yes
Need monitoring after colonoscopy	Yes	No
Activity restriction after colonoscopy	Yes	No
May require repeat with sedation	NA	If colonoscopy is incomplete

**Table 2:** Summary of options

D E E P  S E D A T I O N	Scheduled					Unscheduled
	Conscious sedation					U N S E D A T E D
	As needed		On demand			
	S E D A T I O N	U N S E D A T E D	S E D A T I O N	U N S E D A T E D	U N S E D A T E D	U N S E D A T E D

The pros and cons of (or differences between) scheduled options with and without sedation are summarized in Table 1. If a patient completes a colonoscopy without sedation in the context of either sedation as needed or on demand, all of the benefits of no sedation are maintained except for the issue of an escort. Since the question as to which patients can complete without sedation cannot be predicted in advance, an escort is required.

To summarize, Table 2 displays the various options of sedation or no sedation. The options can be scheduled or unscheduled. The only unscheduled one is unsedated colonoscopy. This is offered to patients who drank the purge solution and arrive without an escort and do not mind having the colonoscopy done without sedation. Scheduled options include deep sedation, conscious sedation, and unsedated colonoscopy. A debate on deep sedation has been ongoing for several years. Should an anesthesiologist be involved? Obviously, if one is involved, the cost for the entire colonoscopy goes up.

Conscious sedation can be divided into as needed or on demand sedation. As needed is controlled by the colonoscopist, and on demand is controlled by the patient. In both instance, the sedation medication can be given before the start of the colonoscopy as dictated by the colonoscopist (as needed) or requested by the patient (on demand). The as needed option may suffer the drawback of coercion because data in the literature indicate the colonoscopist underestimates patient discomfort.<sup>21</sup>

Sedation on demand is based on patient request. The procedure starts without sedation, the nurse monitors the pain scores, offers the patient sedation medications when a certain level of pain is reported, the patient can accept or decline the medications. The likelihood of coercion is smaller.

In both instances a proportion of the patients will complete the colonoscopy without actually receiving medications. If the colonoscopist is motivated to complete the colonoscopy without giving the patient medications, this framework predicts a higher proportion of patient completing without sedation in the as needed option.

The scheduled unsedated option is usually requested by the patient. Studies have shown that these individuals tend to be educated professionals. The vast majority of Americans undergoing colonoscopy do receive sedation.

These proceedings assess the various options so that physicians can be more responsive to the needs of the patients. The goal is to enhance adherence to recommended screening procedures and, ultimately, to decrease morbidity and mortality related to colorectal cancers.

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