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DEEP SEDATION IS ASSOCIATED WITH INCREASED ADENOMA DETECTION RATE IN SCREENING COLONOSCOPIES: A SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

Background and aims: The cornerstone of colon cancer prevention is high-quality examination of the entire colonic mucosa performed with sedation. Deep sedation (DS) has been correlated to greater patient satisfaction, shorter procedures, and faster recoveries. However, disagreement exists on whether DS correlates to an increase in adenoma detection rate (ADR), a surrogate marker of colonic visualization. The aim of this meta-analysis was to evaluate the previously published research on the association between DS versus moderate sedation (MS) and ADR in colon cancer screening colonoscopies. ***Methods:*** We performed a comprehensive literature search in PubMed, PubMed Central, Embase, and ScienceDirect databases from inception through May 2019, to identify all studies that evaluated the association between DS with propofol versus MS and the ADR. We included studies that presented an odds ratio (OR) with a 95% confidence interval (CI) or presented the data sufficient to calculate the OR with a 95% CI. Statistical analysis was performed using the Comprehensive Meta-Analysis (CMA), Version 3 software. ***Results:*** Five studies with a total of 112,008 patients undergoing screening colonoscopies were included in this study, 6,476 of which received DS with propofol (5.8%). The pooled OR for ADR is 1.137 (95% CI: 1.019 – 1.269, $P<0.05$, $I^2 = 17\%$) in patients who underwent DS with propofol compared to MS. No publication bias was found using Egger's regression test. ***Conclusions:*** Our results indicate that patients receiving DS with propofol are 14 percent more likely to have an adenoma detected during a screening colonoscopy than those who receive MS. To our knowledge, this study represents the largest meta-analysis to assess this association. Future prospective randomized research is needed to confirm this association and suggest changes in the standard practices of sedation during screening colonoscopies.

KEY WORDS: Sedation, propofol, adenoma, cancer, colonoscopy.

INTRODUCTION

Nearly 95,000 new cases of colon cancer and 40,000 cases of rectal cancer are annually diagnosed in the United States.[1] Approximately 4.6 percent of men (1 in 22) and 4.2 percent of women (1 in 24) will be diagnosed with colon cancer in their lifetime, and approximately 50 thousand will die each year.[1] The cornerstone of colon cancer prevention is high-quality examination of the entire colonic mucosa during colonoscopy performed with sedation.[2,3] The colonoscopy allows for both the diagnosis and removal of lesions suspected to have malignant potential. Colon cancer incidence has generally decreased since the 1980s, predominantly due to screening colonoscopies allowing for the detection and removal of precancerous polyps.[4]

Ensuring the patient's pain is adequately managed is essential for all gastrointestinal (GI) endoscopic procedures. Appropriate pain management increases rates of completion of the procedure, improves patient safety, and increases likelihood for patient compliance with the treatment plan and future follow-up appointments. There are four levels of sedation, two of which are often used when completing GI procedures: moderate (conscious) sedation (MS) and deep sedation (DS).[5] MS involves the depression of consciousness of the patient undergoing the procedure. They are able to respond to verbal commands and no interventions are required to ensure spontaneous ventilation or airway patency. During DS, patients undergo drug-induced depression of consciousness. They are usually unable to

be aroused and may require assistance in maintaining airway and spontaneous ventilation.

MS was historically used to generate an amnestic and analgesic effect through the combined use of opioids, usually fentanyl or meperidine, and a benzodiazepine, often midazolam.[6] Rarely, this combination has been shown to increase risk of oxygen desaturation, cardiorespiratory complications, and residual effects on psychomotor function.[7-9] More recently, DS provided by an anesthesiologist using propofol has become more popular.[10,11] There are two likely reasons for this trend. First, propofol has a favorable pharmacokinetic profile that allows for a deeper sedation with less movement and awareness. Second, anesthesiologist-delivered DS frees the endoscopist from sedation-related decisions and enables him or her to focus on the exam. Like most general anesthetics, the mechanism of action of propofol is poorly understood, though it is thought to produce its sedative, amnestic, and hypnotic effects by its positive modulation of the inhibitory function of the neurotransmitter GABA through the ligand-gated $GABA_A$ receptors.[12]

DS has recently been correlated to shorter procedures, faster recoveries, quicker discharges, and greater patient satisfaction.[13] Patients under DS have had better scores on tests reflective of learning, memory, working memory span, and mental speed.[13] However, disagreement exists on whether DS correlates to an increase in adenoma detection rate (ADR), a surrogate marker of colonic visualization.[13,14] Some studies have found that the overall risk of complications after colonoscopy increases when patients undergo DS.[15] While patient safety and improved outcomes are most important, DS increased the total cost of the procedure.[16] The aim of this meta-analysis is to evaluate the previously published research and determine whether anesthesiologist-monitored use of propofol was associated with increased ADR compared to MS. Evidence of this hypothesis would support the higher financial burden of monitoring the use of propofol during screening colonoscopies.

METHODS AND MATERIALS

Search Strategy and Selection Criteria

We performed a comprehensive literature search in PubMed, PubMed Central, Embase, and ScienceDirect databases from inception through May 2019 to identify all the studies that evaluated the association between DS with propofol versus MS with fentanyl and midazolam and the ADR. Keywords used in our search included: "colonoscopy", "quality", "adenoma(s)", "anesthesia", "sedation", "fentanyl", "midazolam", "Demerol", "propofol" combined with adenoma detection rate. The search was limited to human studies with no restrictions placed on region, publication type, or language.

Data Extraction and Quality Assessment

To be included, studies were required to meet the following criteria: 1) Implemented a well-defined case-control or cohort design; and 2) Either presented an odds ratio (OR) for our main outcome with a 95% confidence interval (CI) or presented sufficient data to calculate the OR with a 95% CI. Studies were excluded for the following reasons: 1) Were letters to authors, case reports, case series, or review articles; or 2) Provided insufficient information to calculate the OR for our main outcome. The authors independently performed the literature review. The data from the included studies were input into a standardized table for analysis. Data were reviewed for accuracy prior to analysis.

The methodological quality of observational studies was assessed by 2 authors independently (M.A. and L.A.) using the Newcastle–Ottawa scale. In this scale, observational studies were scored across 3 categories: selection (4 questions) and comparability (2 questions) of study groups, and ascertainment of the outcome of interest (3 questions); all questions had a score of 1 except for comparability of study groups, in which separate points were awarded for controlling age and/or sex (maximum of 2 points). Studies with a cumulative score $\geq$7 were considered high quality. In our analysis, all included studies were of high quality.

Statistical Analysis

Statistical analysis was performed using the Comprehensive Meta-Analysis (CMA), Version 3 software (BioStat, Inc., Englewood, NJ). Effect estimates from the individual studies were extracted and combined using the random-effect, generic inverse variance method of DerSimonian and Laird.[17] A random effect model was used as a high probability of between-study variance was suspected due to variation in study population and methodology. A pooled OR was calculated. A Cochran's Q-test and an I^2 statistic were used to evaluate heterogeneity and quantify variation across the selected studies.[18] A funnel plot was then created to evaluate for publication and other reporting biases and then the plot was examined visually for asymmetry. Afterwards, an Egger test for asymmetry of a funnel plot was conducted.

RESULTS

Search Results

Our initial comprehensive search yielded multiple citations. All citations underwent a title and abstract review, with the majority being excluded for being letters to editor, case reports, or case series. Of our initial yield, 48 citations underwent a full-length article review, and 43 were excluded as they did not include controls, were review articles, or did not provide sufficient information to calculate the OR for our main outcome. A flow diagram illustrates the selection process, Figure 1.

Consequently, a total of five retrospective studies met our inclusion criteria and were included in the meta-analysis. Baseline characteristics of the included studies and patients are summarized in Table 1 and Table 2, respectively.

Characteristics of Included Studies

The characteristics of the studies used in the meta-analysis are shown in Table 1.[19-23] Wang et al., is a 2010 retrospective cohort study performed using the Clinical Outcomes Research Initiative (CORI) database to examine average risk screening colonoscopies performed between 2000 and 2005.[19] The paper reviewed 104,868 patients who underwent screening colonoscopies; 97% were performed with MS. Metwally et al., is a retrospective case study conducted in 2011 at two hospital-based endoscopy units in the United States (U.S.) between 2008 and 2009.[20] They reviewed 3,252 outpatient colonoscopies performed by five endoscopists. Nakshabendia et al., is a 2016 retrospective analysis conducted between 2012 and 2013.[21] They reviewed 699 patients who underwent inpatient screening colonoscopies at an academic inpatient center in the U.S. Thirumurthi et al., is a retrospective chart review of 2,604 screening colonoscopies performed at MD Anderson Cancer Center from 2010 to 2013 and published in 2017.[22] One-third of the exams were done with propofol, n = 874. Turse et al., is a 2019 retrospective study of 585 patients who underwent screening colonoscopies at a tertiary-care outpatient center in the U.S. between 2015 and 2016.[23] Forty-two percent of the screening colonoscopies were performed with propofol, n=247.

Meta-analysis results

Five studies met our inclusion criteria and were included in the meta-analysis.[19-23] These studies include a total of 112,008 patients. Of these patients, 6,476 received DS with propofol (5.8%). All five retrospective studies were conducted in U.S. hospitals and/or tertiary care centers. Our findings indicate a significant increase in ADR in patients who underwent DS with propofol with a pooled OR of 1.137 (95% CI: 928 – 1.269, P<0.05, I^2 = 17%) compared to patients who underwent a colonoscopy during MS, Figure 2A.

Evaluation for Publication Bias

A Funnel plot was generated to evaluate whether patients receiving DS with propofol are more likely to have adenoma detected during a screening colonoscopy, Figure 2B. The plot is symmetric and does not suggest the presence of publication bias. Egger's regression asymmetry testing was also done to demonstrate no evidence of publication bias (P>0.05).

Sensitivity Analysis

To review sensitivity, we excluded one study at a time to observe its individual effect on the pooled OR. The pooled effect estimates from this analysis remained approximately the same. A subgroup analysis including only the studies that evaluated advanced adenoma was performed separately. It included 3 studies: Wang et al, Thirumurthi et al, and Turse et al.[19,22,23] The pooled OR for Advanced ADR was 1.119 (95% CI: 1.019 – 1.348, p=0.239, I^2 = 37%) in patients who underwent DS with propofol compared to MS (i.e., conscious sedation). Figure 3.

Table 1: Summary of the studies used in meta-analysis.

Study	Design	Location	Setting	Time period	Total no. of subjects	No. of DS cases	Study Quality		
							Selection (Randomized)	Comparability (Double-blind)	Exposure (Withdrawals)
Wang et al[19]	retro-spective cohort study	U.S.	population-based	2000-2005	104,868	3,501	****	***	**
Metwally et al[20]	retro-spective study	U.S.	population-based	2008-2009	3,252	1456	****	**	**
Nakshabendia et al[21]	retro-spective analysis	U.S.	population-based	2012-2013	699	398	****	**	**
Thirumurthi et al[22]	retro-spective chart review	U.S.	population-based	2010-2013	2,604	874	****	**	**
Turse et al[23]	retro-spective study	U.S.	population-based	2015-2016	585	247	***	**	**

U.S. = United States, DS = Deep Sedation, * = point awarded in one of the three Newcastle–Ottawa scale categories

Table 2: Patients' characteristics.

Study	Age, years (sd)		Sex, male (%)		Adenoma detection rate, ADR (%)	
	Case	Control	Case	Control	Case	Control
Wang et al[19]	60.8 (8.8)	61.3 (8.7)	1,788 (51.1)	55,390 (54.6)	*advanced adenoma:* 251 (7.2) *any polyp:* 1,194 (34.1)	*advanced adenoma:* 6,109 (6.0) *any polyp:* 38,190 (37.7)
Metwally et al[20]	61.0 (10.3)	60.2 (9.9)	787 (54.1)	936 (52.2)	409 (28.1)	487 (27.1)
Nakshabendia et al[21]	57.5 (7.4)	58.3 (7.5)	120 (39)	166 (42.5)	109 (35.4)	122 (31.2)
Thirumurthi et al[22]	56.7 (5.9)	55.4 (5.3)	326 (35.3)	597 (64.7)	*advanced adenoma:* 95 (10.4) *sessile serrated adenoma:* 54 (5.9)	*advanced adenoma:* 134 (7.8) *sessile serrated adenoma:* 106 (6.1)
Turse et al[23]	7.04 (6.12)	56.43 (6.0)	105 (42.5)	146 (43.2)	*advanced adenoma:* 95 (38.5) *any polyp:* 167 (67.6)	*advanced adenoma:* 149 (44.1) *any polyp:* 243 (71.9)

SD = standard deviation

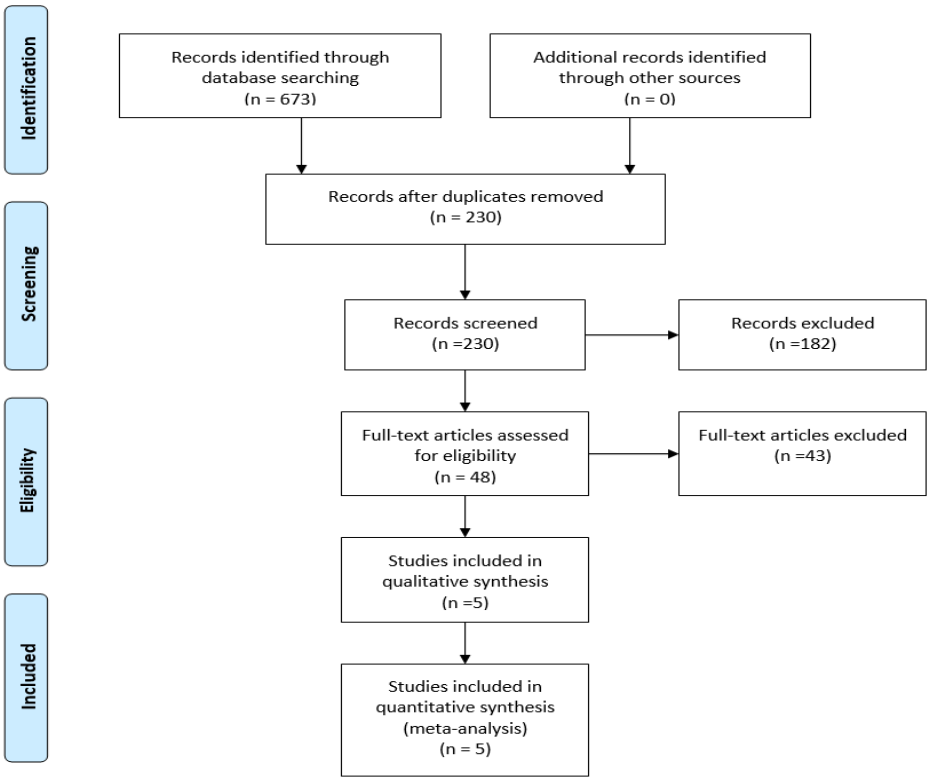

Figure 1: Flow diagram illustrating the selection process.

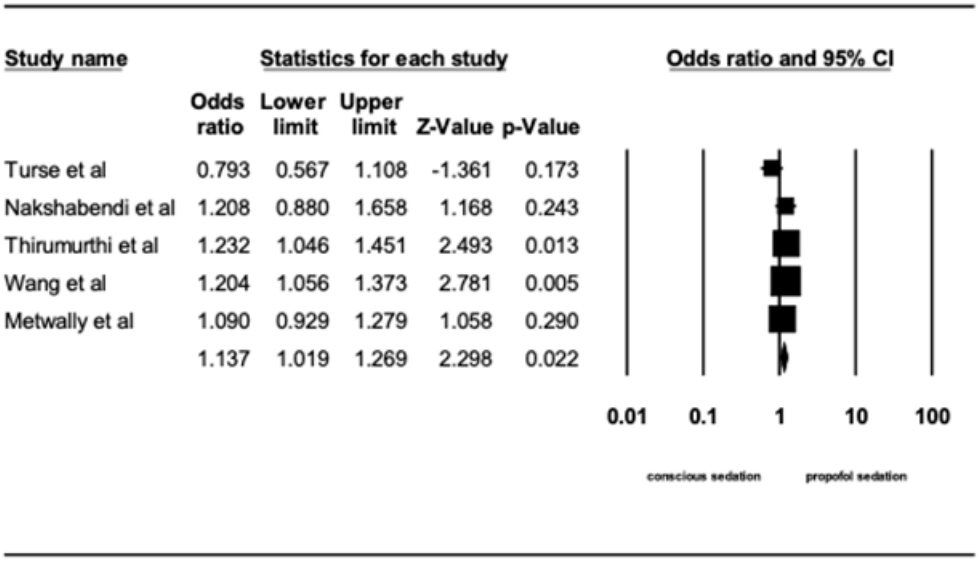

Figure 2A: Summary of odd ratios assessing the adenoma detection rates (ADR) in moderate sedation (MS) versus deep sedation (DS).
CI: Confidence interval

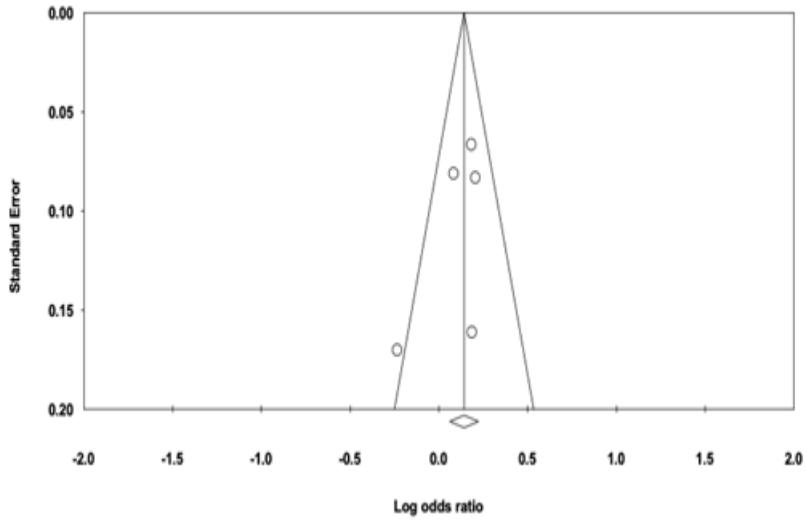

Figure 2B: Funnel plot of standard error by log odds ratio.

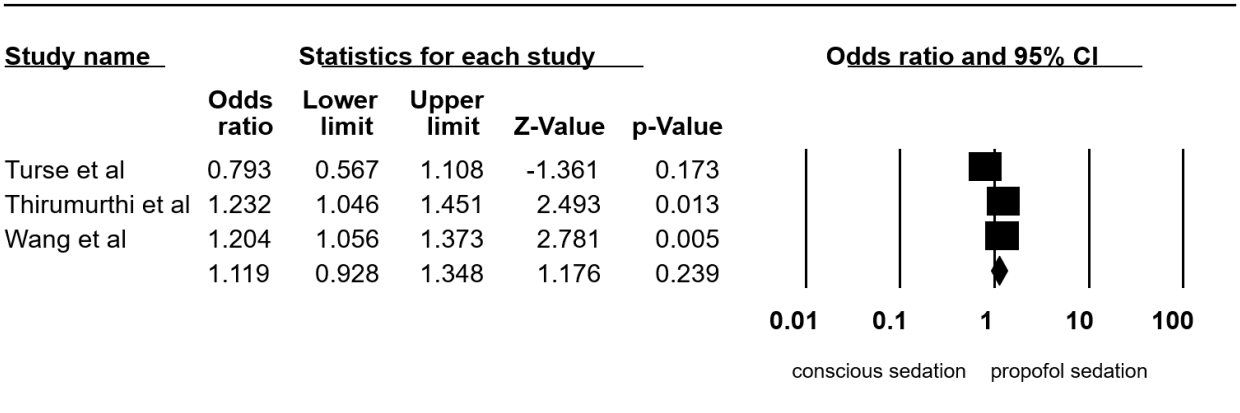

Figure 3. Pooled odd ratios assessing the advanced adenoma detection rates (ADR) in moderate sedation (MS) versus deep sedation (DS).

DISCUSSION

Numerous studies have established the benefits of having anesthesiologist-monitored propofol sedation when screening colonoscopies are performed.[13,24,25] This method allows for the endoscopist to fully direct his or her attention at the procedure being performed, it allows for shorter patient recovery times, and it is associated with higher patient satisfaction and endoscopist satisfaction.[24,26]

A considerable but variable body of research has been put forward to evaluate the association between DS and ADR. ADR is inversely associated with increased risk for cancer; and for this reason, recommendations for screening colonoscopies include an overall ADR, ADR in men and ADR in women over 25%, 30%, and 20%, respectively.[27,28] Some studies have suggested that DS patients are less likely to feel pain and allow the endoscopist more time to inspect the mucosa. Additionally, researchers have argued that colonoscopies performed with MS are associated with lower cecal intubation rates, and thus, with increased risk of post-colonoscopy colon cancers.[29,30]

Despite these theories that anesthesiologist-monitored propofol sedation would be associated with a significant difference in ADR compared to MS patients, previous studies have failed to consistently demonstrate the advantage of propofol sedation on ADR. Those demonstrating no significant difference argue that DS patients allow for a larger volume of insufflated air as the patient is unable to report pain.[21] The increased volume decreases detection of flat polyps by the endoscopist. Others have also suggested that MS allows for easier patient position change during withdrawal, which improves ADR.[31]

Because of this disagreement, the present meta-analysis aimed to examine the previously published studies on this association. By its nature, a meta-analysis can better control for the many factors that often affect ADR in small cohort studies: the quality of preparation, individual polyp size, use of optical enhancements, time spent examining the colonic mucosa during the withdrawal of the instrument, higher risk patients with positive family history, and older populations. Any one of these confounders is able to alter results in smaller retrospective studies. In our current investigation, we found that patients receiving DS with propofol are 14 percent more likely to have adenoma detected during a screening colonoscopy than in those who undergo MS.

Our analysis included five studies with a total of 112,008 patients undergoing screening colonoscopies, 6,476 of which received DS with propofol (5.8%). All five included studies were conducted in the U.S., two at academic inpatient centers, one at a tertiary-care outpatient center, one at a hospital-based endoscopy unit, and one at a combination of practices from 26 states, mostly community/HMO sites. The diverse study population incorporated into this meta-analysis allows for the results to be generalized to the U.S. population undergoing screening colonoscopies. However, we caution readers in interpreting and using our findings as support for widespread use of DS for all average-risk colonoscopies.

Over 90 percent of the data included in this meta-analysis comes from Wang et al., a 2010 retrospective study of colonoscopies conducted at 72 practices sites from 26 states.[19] The study used CORI to collect data that demonstrated that DS was associated with a 25% higher likelihood of performing a colonoscopy that identified a polyp >9 mm or suspected malignant tumor. While their data are statistically significant, Wang et al., conclude that the difference is not clinically meaningful, citing their number needed to screen to detect one additional advanced lesion as 141. For Wang et al., the clinical gain was not large enough to justify the additional costs. This is a common concern among researchers, as colonoscopies under DS with propofol cost 20 percent more than MS, an approximate $600 – $2,000 increase in cost.[32]

Metwally et al., provided the second largest dataset in our meta-analysis, followed by Thirumurthi et al.[20,22] Metwally et al., a 2011 retrospective study conducted at two hospital-based endoscopy units in the U.S., concluded that ADR is not increased by the use of anesthesiologist-monitored propofol sedation compared to endoscopist-monitored sedation with midazolam and fentanyl. Thirumurthi et al., along with the other two studies included in our meta-analysis, Turse et al., and Nakshabendia et al., similarly concluded that DS with propofol for screening colonoscopies did not significantly improve ADR.[21,23]

Our results suggest that while gastroenterologists prefer DS, and while propofol use in colonoscopies is increasing, the reason for this change is complicated and involves more than the perceived diagnostic benefit. While the difference reported in our meta-analysis is significant, like Wang et al., we question whether the clinical meaningfulness of the difference is driving the change in sedation habits. More likely, endoscopists prefer propofol as it leads to faster recovery, increases unit efficiency, and is more financially lucrative.[33-35] The increased popularity of DS is also likely due to increased patient satisfaction. Some clinicians argue that by easing the negative impression of getting a screening colonoscopy, DS may justify the increased cost. More research is needed to make a definitive conclusion.

Limitations of our meta-analysis include the inability to control for possible confounding variables included in the individual studies. These include the inconsistent use of high-definition technology, the variation in which patients with a predominantly increased risk of colonic neoplasia were enrolled in the individual studies, the experience-level of the individual endoscopists in the

study, and the variation in quality of preparation. While a meta-analysis is well-suited for limiting the effects of these confounders, all are capable of altering our analysis.

In conclusion, our results indicate that patients receiving DS with propofol are 14 percent more likely to have an adenoma detected during a screening colonoscopy than in those who undergo MS. To our knowledge, this study represents the largest meta-analysis to assess this association. Future prospective randomized research is needed to confirm this association before suggesting any changes to the standard practices of sedation during screening colonoscopies.

Author Contributions

MA, PT and MS contributed conception and design of the study; LA, MA, MTS collected data and organized the database; LA, MA, MTS, and HB analyzed and interpreted the data; HB and MA wrote the first draft of the manuscript. All authors contributed to manuscript revision and approved the submitted version.

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