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Robot-assisted cholecystectomy is a safe but costly approach: A national database review

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ABSTRACT

Background: This study sought to evaluate surgical outcomes, cost, and opiate utilization of patients who underwent laparoscopic (LC) or robotic cholecystectomy (RC).
Methods: The Vizient database was queried for patients admitted with mild to moderate severity of illness (SOI) scores who underwent LC or RC from January 2015 through December 2017. Rates of overall complications, postoperative infection, mortality, LOS, cost, and opiate utilization were compared between groups using IBM SPSS v.25.0, $\alpha = 0.05$.
Results: 91,849 patients (LC:N = 89,878; RC:N = 1,971) met the inclusion criteria. Robotic approach was associated with more complications (LC:0.9%, RC:1.7%; $p < 0.001$), postoperative infections (LC:0.2%, RC:0.4%; $p = 0.033$) and a higher direct cost (LC:\$6782 ± 3421, RC:\$9354 ± 5497; $p < 0.001$). Opiates were prescribed more frequently in the laparoscopic group (LC:98.3%, RC:97.2%; $p = 0.002$).
Conclusion: The direct cost of RC is significantly higher than LC with no added benefit. Routine use of the robotic platform for cholecystectomy should be discouraged until costs are reduced.

1. Introduction

Over half a million cholecystectomies are performed annually in the United States, with the vast majority being successfully completed via a minimally invasive approach.[1] Minimally invasive surgery encompasses both laparoscopic and robotic-assisted approaches which offer patients several benefits including decreased pain, faster recovery, less blood loss, and lower morbidity and mortality compared to an open approach.[2,3] Laparoscopy is currently considered the standard of care for elective cholecystectomy, however, use of the robotic-platform is increasing in popularity.[4]

Use of the robotic platform is now widely adopted in urologic and gynecologic surgery as it has been deemed a safe and effective alternative to the laparoscopic approach.[5] Many surgeons credit improved visualization, better ergonomic design, and other technical advantages for the success of robotic platforms.[6] Additionally, research has shown that complex laparoscopic tasks are more easily accomplished when the surgeon uses a robotic platform.[7] Despite technical advantages, robotic surgery remains costlier than the laparoscopic approach. Existing data addressing the surgical value of robotic cholecystectomy remains inconclusive.[1] Consensus among the established literature also suggests that use of the robotic platform is associated with significantly longer operative times compared to laparoscopic alternatives, however, some experts speculate that longer set-up and docking times are attributable to the learning curve associated with the implementation of new technology.[8]

Within the field of general surgery, robotic cholecystectomy (RC) has previously been shown to have similar 30-day outcomes when compared to the laparoscopic approach. Existing studies indicated that laparoscopic cholecystectomy (LC) and RC have similar complication rates, estimated blood loss, and postoperative pain scores, while also finding that the robotic group to have superior overall patient satisfaction ratings ($p < 0.001$).[1] There is limited data regarding long term outcomes, but RC has been proven safe at three year follow-up.[1] The majority of existing literature describing intra- and postoperative outcomes of RC originates from

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single-surgeon or single-center data.[9] While these initial findings provide valuable insight regarding the potential use of the robotic platform for cholecystectomy, single-surgeon or single center data cannot be generalized to all populations. National databases are particularly valuable for this reason as they provide a more robust and inclusive patient cohort. Therefore, the aim of this study was to evaluate clinical outcomes including postoperative complications, length of stay (LOS), cost, and opiate utilization of patients who underwent a LC or RC using a national database.

2. Methods

2.1. Database description

The Vizient Clinical Database (CDB) is an aggregate of clinical outcomes-based measures, procedure-based supply utilization and cost information. Vizient hospital membership is diverse, including 97% of academic medical centers and affiliated hospitals, greater than 230 community hospitals, nonprofit research facilities, integrated health care delivery systems, and non-acute healthcare providers.[10] Comparisons can be made within hospital systems or on a national level. Patient demographics, postoperative complications, mortality, length of stay (LOS), readmission rates, and direct costs are recorded. A list of Vizient-specific postoperative complications such as aspiration pneumonia, postoperative infection, gastrointestinal hemorrhage, etc. is maintained. The Vizient database is de-identified to ensure patient privacy rights are respected. Since this study utilized an administrative database and was not classified as human subjects research, IRB approval was not required.

The Vizient clinical database resource manager (CDB/RM) is a health analytics platform that uses a validated clinical algorithm to assess patient demographics, major diagnoses, and presence or absence of twenty-nine comorbidities to assign each individual a severity of illness (SOI) score. Based on the SOI, patients are classified into minor, moderate, major, or extreme severity groups. Ratio of cost-to-charge (RCC) methodology is applied to estimate the cost of patient care along service lines. Logistic regression models are used for risk adjustment outcomes. The methodology for data collection and commuting for this database was previously described by Armijo et al.[10]

2.2. Study design

The CDB/RM was queried for patients who underwent LC and RC from January 2015–December 2017. The database was queried for adult patients (>18 years old) with ICD-9-CM or ICD-10 CM diagnosis codes for cholelithiasis, cholecystitis, and choledocholithiasis ICD-9(5750, 5751, 57510, 57511, 57512, 5740, 57400, 574, 57401, 5741, 57410, 57411, 57420, 5742, 57421, 5743, 57440, 5744, 57431, 57430, 57441, 57450, 5745, 57451, 5746, 57460, 57461, 5747, 57470, 57471, 5748, 57480, 57481, 5749, 57490, 57491), ICD-10(K800, K8000, K8001, K801, K8010, K8011, K8012, K8013, K8019, K8018, K802, K8020, K8021, K804, K8040, K8041, K8042, K8043, K8044, K8045, K8046, K8047, K805, K8050, K8051, K806, K8060, K8061, K8062, K8063, K8064, K8065, K8066, K8067, K807, K8070, K8071, K81, K810, K811, K812, K819) who underwent either laparoscopic (CholeLAP9(5123, 5124), CholeLAP10(0FB44ZX, 0FB44ZZ, 0FT44ZZ, 0FB43ZX, 0FB43ZZ, 0FD43ZX, 0FD44ZX, 0F543ZZ, 0F544ZZ, 0F548ZZ) or robotic-assisted (ICD-9(174, 1742, 1743, 1744, 1745, 1749), ICD-10(8E0W3CZ, 8E0W4CZ, 8E0W8CZ, 8E0WXCZ), used in association with a laparoscopic code) cholecystectomy. In order to standardize our cohorts, only adult patients classified as minor or moderate SOI on admission were included in this study.

2.3. Outcomes measured

Data regarding patient demographics, including age, gender, race and BMI were collected. Intraoperative data included LOS, direct cost, and intra-hospital opiate utilization. Defined Daily Dose (DDD) is the assumed average maintenance dose per day for a drug used for its primary indication in adults. United Health Care (UHC) takes into account route of administration and patient age when using this methodology to calculate doses and estimate pharmacy costs. The total number of units for a selected resource billed in each group is reported as the "total resource units used." The estimated average normalized drug cost per individual resource and average days of resource used, per case, is available in Vizient using DDD. The approach and limitations of data collection in regards to narcotic utilization and its corresponding cost, was previously described by Armijo et al.[10]

The overall 30-day postoperative complication rate encompasses the total number of cases of hospital-acquired conditions captured under the heading of "Vizient complications." The established list of conditions is comprised of six obstetric and thirteen medical-surgical complications which include stroke, aspiration pneumonia, gastrointestinal hemorrhage, myocardial infarction, adverse events due to anesthesia, plus four classifications of post-operative infections and four indications for hospital readmission.

2.4. Statistical analysis

Clinical outcomes of interest were compared between minimally invasive approaches, LC and RC. Categorical data was expressed as frequency, with 95% confidence interval. Continuous data was reported as mean ± standard deviation (SD), or median, interquartile range (IQR) according to normality of distribution. Kruskal-Wallis H test, one-way ANOVA with Tukey's HSD Post Hoc Test, Fischer's exact and Pearson's chi-squared test with Bonferroni correction were applied where appropriate. Statistical analysis was performed using IBM SPSS v.25.0, with a level of significance of $\alpha = 0.05$.

3. Results

A total of 91,849 patients underwent minimally invasive cholecystectomy from January 2015 through December 2017 and met the inclusion criteria for the study (LC: N = 89,878; RC: N = 1,971). A majority of patients were over 30 years old in both groups, however, the RC group had a greater percentage of patients over 51 years old (LC:47%; RC: 53.6%; $p < 0.001$). Over half of patients were female (LC:66.4%; RC:66.5%) and Caucasian (LC: 65.2%; RC:67.9%) [Table 1].

Table 2 summarizes our postoperative findings. The RC group had a higher rate of complications ($p < 0.001$), and post-op infections ($p = 0.033$) than the LC group. Length of stay was 3.10 ± 2.22 days for LC and 3.27 ± 2.72 days for the RC approach ($p < 0.001$). Mortality rates were similarly low in each group.

Opiate agonist utilization is detailed in Table 3. A significantly higher percentage of patients were prescribed opiate agonists in the LC group (LC: 98.3%; RC:97.2%; $p = 0.002$). No additional statistical analysis was performed to compare opiate utilization between approaches as SD was not provided.

A subgroup analysis was performed to investigate outcomes of patients with obesity (BMI>40) undergoing LC or RC [Table 4]. Postoperative outcomes including complications, infection, readmission rates, and mortality were not significantly different between groups. As expected, the direct cost was significantly higher in the RC group for patients with a BMI>40 (LC:$6782 ± 3421;

Table 1
Cholecystectomy patient demographics by surgical approach.

	Lap N = 89,878		Robot N = 1,971		p-value
Age					
18–30 Years	16,144	17.9%	215	10.9%	**<.001**
31–50 Years	31,553	35.1%	699	35.5%	.715
51–64 Years	21,084	23.4%	531	26.9%	**.001**
≥ 65 years	21,197	23.6%	526	26.7%	**<.001**
Gender					
Female	59,780	66.4%	1,311	66.5%	.946
Male	30,194	33.6%	660	33.5%	
Race					
White	56,553	65.2%	1,317	67.9%	**<.001**
Black	10,906	12.6%	334	17.2%	
Other	19,306	22.3%	288	14.9%	

LAP Laparoscopic *ROBOT* Robotic-assisted.

Table 2
Cholecystectomy outcomes by surgical approach.

	Lap		Robot		P-value
	N = 89,878		N = 1,971		
Overall Complications N (%)	851	0.9%	34	1.7%	**<.001**
Post-op Infection N (%)	133	0.2%	7	0.4%	**.033**
Post-op Sepsis N (%)	53	0.1%	3	0.2%	.120
7-day Readmission N (%)	998	1.0%	16	0.8%	.399
14-day Readmission N (%)	1415	1.6%	26	1.3%	.354
30-day Readmission N (%)	1749	2.0%	37	1.9%	.805
Mortality N (%)	40	<.001%	1	0.1%	.589
LOS – days (mean, SD)	3.10 ± 2.22		3.27 ± 2.72		**<.001**

LAP Laparoscopic *ROBOT* Robotic-assisted *POST-OP* Post-operative.

RC:$9354 ± 5497; p < 0.001).

One of the most unique aspects of the Vizient database is the availability of mean direct costs classified by service groups [Table 5]. Total overall cost was significantly higher for RC compared to LC (8,620 ± 5,055 vs 6,503 ± 3,706; p=<.001). The raw data revealed a higher cost of surgical supplies in the robotic group (RC $2,470 vs LC $992). There was also a trend towards higher costs for surgical services including the anesthesia (RC:$332 vs LC:$238), operating room (RC:$2,652 vs LC:$1,728), and recovery room (RC:$261 vs LC:$255). Cost of accommodations was similar between groups (LC $1,375 vs RC $1,360). Again, we were not able to further analyze differences in mean service line cost data between approaches given the lack of information regarding SD.

4. Discussion

Benefits of the robotic platform for foregut operations has previously been demonstrated with improved lymphadenectomy and shorter LOS for gastrectomy, lower anastomotic leak rates for bariatrics, and improved retrohepatic dissection for hepatectomy.[11] In 2014, an estimated 570,000 da Vinci robotic procedures were performed worldwide, which correlates to a 178% increase compared to 2009.[12] The robotic platform offers magnified, three-dimensional visualization, elimination of natural tremor, wristed instrumentation offering increased dexterity, and ergonomic positioning enhanced by sitting at the robotic console.[13] Articulating robotic instruments provide range of motion at the tip of the instrument unlike traditional rigid laparoscopic instruments.[12] For cholecystectomies in particular, the surgeon's control over third robotic arm for dynamic or static retraction of the gallbladder and/or segment IV simplifies the procedure as there is no dependency on the assistant.[14]

Initial studies comparing the use of LC versus RC mainly focused on routine, elective cases in the setting of cholelithiasis.[1] Acute cholecystitis was considered a risk factor for conversion to open approach, therefore, more patients underwent LC rather than RC.[20] Many investigators specifically chose to exclude acute cholecystitis cases when comparing outcomes between minimally invasive techniques.[11,15] The possibility of expanding the application of robotic-assisted technology is gradually being explored, however. Several studies now suggest that using the robotic platform in the setting of acute disease with inflammation is a safe approach.[14,16,17]

For patients with obesity, laparoscopy can become technically difficult due to increased intra- and extra-abdominal fat that limits instrument mobility and visualization. Obesity has been reported as an independent risk factor for conversion to laparotomy in several publications.[18] In an attempt to investigate this theory, we performed a subgroup analysis comparing outcomes of LC and RC for patients with obesity (which we defined as a BMI >40. Our results showed no difference in the rate of overall complications, postoperative infection, sepsis, readmission, or mortality. Both groups also had similar mean LOS. The higher direct cost of RC remained statistically significant, as expected. Our findings are consistent with a propensity-matched analysis performed by Main et al. that reported no difference in post-operative outcomes or mortality but significantly increased operative times and cost for the robotic group.[18]

Numerous studies have shown that RC is associated with longer

Table 4
Cholecystectomy outcomes for patients with obesity (BMI >40) by surgical approach.

	Lap		Robot		P-value
	N = 8,905		N = 426		
Overall Complications N (%)	87	1.0%	4	0.9%	1.000
Post-op Infection N (%)	22	0.3%	1	0.2%	1.000
Post-op Sepsis N (%)	3	<.001%	0	N/A	1.000
7-day Readmission N (%)	69	0.8%	2	0.5%	.773
14-day Readmission N (%)	106	1.2%	3	0.7%	.490
30-day Readmission N (%)	133	1.5%	3	0.7%	.218
Mortality N (%)	2	<.001%	0	N/A	1.000
LOS – days (mean, SD)	2.8 ± 1.94		2.83 ± 2.53		.7589
Direct Cost - $ (mean, SD)	6,782 ± 3,421		9,354 ± 5,497		**<.001**

LAP Laparoscopic *ROBOT* Robotic-assisted *POST-OP* Post-operative.

Table 3
Post-cholecystectomy opiate agonist utilization by surgical approach.

	Lap N = 53,028	Robot N = 1,314
Patients who were prescribed opiates (%)*	98.3%	97.2%
Mean Resource Units Used/Case (Units)[a]	11.9	16.1
Mean Days of Resource Units Used/Case (Days)[a]	2.5	2.4
Normalized Opiate Cost/case ($)[a]	19	18

LAP Laparoscopic *ROBOT* Robotic-assisted.
Resource units: opiate agonists.
*$p = 0.002$ laparoscopic versus robotic-assisted.
[a] No statistical analysis was performed due to lack of information on SD or IQR.

Table 5
Mean direct cost breakdown for cholecystectomy by surgical approach.

	Lap N = 53,028	Robot N = 1,314
Accommodations - General Routine Care ($)[a]	1,375	1,360
Medical Surgical Supplies ($)[a]	992	2,470
Surgical Services ($)[a]		
Anesthesia	238	332
Operating Room	1,728	2,652
Recovery Room	255	261
Total Cost - $ (mean, SD)*	6,503 ± 3,706	8,620 ± 5,055

LAP Laparoscopic *ROBOT* Robotic-assisted.
*$p = < .001$ laparoscopic versus robotic-assisted.
[a] No statistical analysis was performed due to lack of information on SD or IQR.

operative times.[1,9,11,15,19] As surgeons gain more experience with the robotic platform, operating time may be less of a deciding factor in cost which can explain the reason for decreased costs between 2010 and 2011.[20] Additional factors contribute to decreased set-up time including training patient-side assist in a robotics lab, continuous and simultaneous training of team members for docking, and staff surgeon with the ability to rapidly troubleshoot any emergent robotic system problems.[14] A case series of 51 patients reported a significant reduction in operative time after 16–32 procedures.[21] In the future, it would be extremely beneficial for Vizient to capture this outcome measure in order to make further comparisons.

Interestingly, the robotic approach was found to have an overall complication rate of 1.7% which is significantly higher than the 0.9% reported within the laparoscopic group (p=<.001). Unfortunately, it is difficult to determine the clinical relevance of this statistic given that the overall complication rate reported within Vizient reflects a total aggregate number of tracked hospital-acquired conditions occurring within the 30-day postoperative period. In the setting of cholecystectomy, however, bile duct injury is certainly the most feared complication as it is associated with significantly higher rates of reoperation, morbidity, and mortality. Integration of ICG technology with the robotic platform may help reduce to reduce rates of iatrogenic biliary injury by allowing for real-time toggling between near-infrared fluorescent cholangiography (NIFC) and bright-light illumination throughout the case.[22] In fact, a recent study published by Gangemi et al. found a significantly reduced rate of minor biliary injuries in cases where ICG-RC was performed.[17] In the future, it would be beneficial to capture and isolate procedure-specific complications such as biliary injury, while also tracking the use adjunctive measures such as use of immunofluorescence technology.

Another important surgical quality metric and procedure-specific complication is the rate of postoperative infection. In this study, we found that 0.4% of patients in the RC group developed an infection within the 30-day postoperative period, which was double the rate of the LC group (p = 0.033). We suspect the significantly higher rate of infectious complications to be associated with a progression towards single-incision surgical technique that is facilitated by use of robotic platform.[13] Compared to laparoscopic approach, single-incision RC (SIRC) is associated with a higher rate of wound infection (3.9 vs 1.1%; p = 0.037) and incisional hernia (6.5 vs 19%; p = 0.006).[25] Another retrospective review found that the robotic group had a trocar-site infection rate of 13.5%.[26] SIRC is also associated with a higher incidence of gallbladder rupture which is attributed to increased technical difficulty due to inadequate length of the non-wristed robotic instruments.[27] Currently, the general acceptance of single-incision cholecystectomy remains limited because of the expected increase risk of bile duct injuries.[23] Unfortunately, the distinction between single-incision and conventional multi-port techniques cannot be elicited from the Vizient database in order to perform a sub-group analysis.

Our duration of hospital stay was surprisingly long but similar between groups with a mean LOS of 3.10 ± 2.22 days for LC and 3.27 ± 2.72 days for RC (Table 2). Given that many cholecystectomies are performed on an outpatient or elective basis with a typical LOS of 0–1 days, our data appears to be skewed towards a prolonged hospital course regardless of which minimally invasive surgical approach was used. Although the Vizient platform is being used in ambulatory centers, the database may have a higher capture rate for inpatient cases with longer average LOS, resulting in this unanticipated finding. While reported average durations of hospital stay vary throughout the existing literature, there does appear to be a consensus that no significant difference in LOS exists when comparing by surgical approach within each study.[9,11,12,15,20,23,28] Of note, our cost breakdown indicated that the mean cost of accommodations were very similar between LC and RC ($1,375 vs $1,360, respectively). The comparable costs between groups further reinforces that the minute difference in LOS elicited in this study carries no clinical significance.

98.3% of patients who underwent LC were prescribed opiates for postoperative pain compared to 97.2% for RC. Although the difference in opiate utilization determined to be statistically significant, it is unlikely to be clinically relevant. Mean duration of opiate use was 2.4 and 2.5 days for LC and RC, respectively. A prospective randomized double-blind trial comparing short-term outcomes between SIRC and conventional four-port LC (CLC) published by Pietrabissa et al. also noted no reduction in postoperative pain for the robotic group. The study suggested that the cosmetic advantage of SIRC should be balanced against the increased risk of incisional hernias and higher costs. The authors also proposed that the amount of pain after LC is already so minimal that the hope of further reduction with technical refinement is unlikely.[29]

Surgical value is defined as the outcome divided by cost.[30] As we develop and implement new surgical technology, we must ensure that we continue to assess its benefits within the framework of surgical value.[30] Unfortunately, it is difficult to achieve this objective given that cost estimates are not very granular at the procedural level and they more often tend to be hospital charge data, which is difficult to compare across healthcare systems. Vizient does provide mean cost data with breakdown across service groups and service lines. For minimally invasive cholecystectomy, total cost associated with robotic approach was significantly higher than laparoscopy (8,620 ± 5,055 vs 6,503 ± 3,706; p=<.001). These costs are within previous estimates reporting additional costs for RAS range from $600-$4,000.[31]

As expected, our cost breakdown also reflected a higher cost for surgical supplies in the RC group (RC $2,470 vs LC $992. A cost analysis performed by Higgins et al. investigated the difference in cost of consumables in elective robotic versus laparoscopic general surgery cases. In this study, the total supply cost (mean) for the robot was $1,699 (SD 844.1) vs $631.1 (SD 281.1) for laparoscopy

($p < 0.01$). Total cost for robotic instruments (mean excluding outliers) RC $665.9 (SD 393.5) and mean total number of robotic instruments per case = 4.3 (SD 1.3).[12] It is important to recognize that robotic instrument cost is typically not corrected for actual number of uses which can be less than the recommended number. The decrease in intended use can drastically increase the item purchase cost for robotic cases.[30] With increased efficiency and use of the robotic platform, the overhead costs associated with purchasing and maintenance is further distributed and the hospital's single procedure costs decrease.[17] In terms of cost by service line, we found that RC costs were higher for all surgical services including anesthesia (RC $332 vs LC $238), operating room ($2,652 vs $1,728), and recovery room ($261 vs $255).

There is an argument to be made that increased costs of the robotic platform should be considered as a cultural investment for institutions, physicians, nurses, and administrators whose support of technological advances shapes the future of our healthcare system.[24] With preliminary data suggesting that robotic surgery may require a different skill set than laparoscopy, there is a need to train surgeons to operate and troubleshoot a complex machine.[13] Given that cholecystectomy is a common procedure, it is believed that the technical aspects do not distract from the robotic platform. A consensus statement from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) identifies RC as an opportunity for surgeons to acquire the operative skills necessary to perform larger operations robotically.[11] With use of the robotic-platform becoming increasingly popular, there is also a need for strategies to integrate this minimally invasive technique into surgical education.[13] Existing studies show that trainees can perform robotic cholecystectomy without adverse effects on patient outcomes.[13,28]

Use of the Vizient database allows us to analyze national trends in surgical outcomes, mean direct costs, and opiate use in both public and private sectors. Even as its adoption increases nationally, it remains an evolving administrative database with several inherent limitations. The maintenance of the database is dependent on coding strategy, accuracy of data input, and use of comprehensive guidelines with consistency of clinical documentation. There is significant potential for variance among participating institutions. Failing to appropriately flag conversions or document secondary diagnoses could lead to imprecise or incomplete data. The implementation of ICD-10 codes during our study period also could have resulted in coding discrepancies. Currently, however, Vizient is designated as a validated database with a <0.1% reported rate of coding errors.[10]

As we are able to increase efficiency and standardization of case reviews, we hope to increase the scope of data capture. For this study, we would have been interested in determining the frequency of single-incision surgery for both robotic and laparoscopic approach. Certain data points are reported as mean averages and lack information regarding standard deviation or normality of distribution. In the case of LOS, the database does offer an algorithm to exclude outliers as a standard restriction but this option is not available for other data points.

To our knowledge, this is the largest study of a national database comparing outcomes and cost between LC and RC performed in both the inpatient and outpatient setting. Overall, we found similar outcomes between minimally invasive approaches with a slightly higher rate of overall complications and postoperative infections associated with use of the robotic platform. Existing literature suggests that the robotic-assistance can be particularly useful for difficult dissections in the setting of increased inflammation often encountered in cases of acute cholecystitis. We suspect that increased complication and infection rates demonstrated in this study could relate to increased use of single-incision technique in the robotic group. Cost of RC remains significantly higher than LC. Given the overall similar clinical outcomes between groups, however, implementation of randomized controlled trials should be feasible to further delineate differences in outcomes between these approaches.

Disclosures

Dr. Dmitry Oleynikov declares an Equity Interest – Virtual Incision Corporation; Founder, Board Member, Officer. The other authors have nothing to disclose.

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