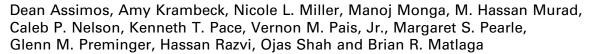
Surgical Management of Stones: American Urological Association/Endourological Society Guideline, PART I



From the American Urological Association Education and Research, Inc., Linthicum, Maryland

Purpose: This Guideline is intended to provide a clinical framework for the surgical management of patients with kidney and/or ureteral stones. The summary presented herein represents Part I of the two-part series dedicated to Surgical Management of Stones: American Urological Association/ Endourological Society Guideline. Please refer to Part II for an in-depth discussion of patients presenting with ureteral or renal stones.

Materials and Methods: A systematic review of the literature (search dates 1/1/1985 to 5/31/2015) was conducted to identify peer-reviewed studies relevant to the surgical management of stones. The review yielded an evidence base of 1,911 articles after application of inclusion/exclusion criteria. These publications were used to create the Guideline statements. Evidence-based statements of Strong, Moderate, or Conditional Recommendation were developed based on benefits and risks/burdens to patients. Additional directives are provided as Clinical Principles and Expert Opinions when insufficient evidence existed.

Results: The Panel identified 12 adult Index Patients to represent the most common cases seen in clinical practice. Three additional Index Patients were also created to describe pediatric and pregnant patients with such stones. With these patients in mind, Guideline statements were developed to aid the clinician in identifying optimal management.

Conclusions: Proper treatment selection, which is directed by patient- and stonespecific factors, remains the greatest predictor of successful treatment outcomes. This Guideline is intended for use in conjunction with the individual patient's treatment goals. In all cases, patient preferences and personal goals should be considered when choosing a management strategy.

Key Words: nephrolithiasis; ureteroscopy; nephrostomy, percutaneous

BACKGROUND

Kidney stones are a common and costly disease; it has been reported that over 8.8% of the United States population will be affected by this malady, and direct and indirect treatment costs are estimated to be several billion dollars per year in this country.¹⁻³ The surgical treatment of kidney stones is complex, as there are multiple competitive treatment modalities, and in certain cases more than one modality may be appropriate.

The surgical management of patients with various stones described

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Abbreviations and Acronyms

AUA = American Urological Association
${\sf CBC}={\sf complete}\ {\sf blood}\ {\sf count}$
CT = computerized tomography
$MET=medical\;expulsive\;therapy$
PCNL = percutaneous
nephrolithotomy
SWL = shock-wave lithotripsy
UPJ = ureteropelvic junction
URS = ureteroscopy
UTI = urinary tract infection

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herein is divided into 13 respective patient profiles (table 1). Please refer to the unabridged version of this Guideline for a complete description of each Index Patient.

METHODOLOGY

Consistent with the AUA published Guideline methodology framework,⁴ the AUA commissioned an independent group to conduct a systematic review and meta-analysis of the published literature on various options for the surgical management of stones.

The quality of individual randomized controlled trials or clinical controlled trials was assessed using the Cochrane Risk of Bias tool.⁵ The quality of case-control studies and comparative observational studies was rated using the Newcastle-Ottawa Quality Assessment Scale.⁶

The AUA categorizes body of evidence strength as Grade A, B, or C based on both individual study quality and consideration of study design, consistency of findings across studies, adequacy of sample sizes, and generalizability of samples, settings, and treatments for the purposes of the Guideline.⁴

Evidence-based statements are provided as *Strong*, *Moderate*, and *Conditional Recommendations* with additional statements provided in the form of *Clinical Principles* or *Expert Opinion* (table 2).

GUIDELINE STATEMENTS

Imaging, Preoperative Testing. 1. Clinicians should obtain a non-contrast CT scan on patients prior to performing PCNL. (Strong Recommendation; Evidence Strength: Grade C)

The use of computerized tomography for preoperative assessment in those with nephrolithiasis prior to performance of percutaneous nephrolithotomy has gained widespread acceptance as it defines stone burden and distribution and provides information regarding collecting system anatomy, position of peri-renal structures and relevant anatomic variants. It may also be used to predict

Table	1. Index	Patients
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1	Adult, <10 mm proximal ureteral stone
2	Adult, \leq 10 mm mid ureteral stone
3	Adult, <10 mm distal ureteral stone
4	Adult, >10 mm proximal ureteral stone
5	Adult, >10 mm mid ureteral stone
6	Adult, >10 mm distal ureteral stone
7	Adult, \leq 20 mm total non-lower pole renal stone burden
8	Adult, $>$ 20 mm total renal stone burden
9	Adult, ≤10 mm lower pole renal stone(s)
10	Adult, >10 mm lower pole renal stone(s)
11	Adult, with residual stone(s)
12	Adult, renal stone(s) with pain and no obstruction
13	Child, ureteral stone(s)
14	Child, renal stone(s)
15	Pregnant female, renal or ureteral stone(s)

operative outcomes and, in some instances, stone composition. $^{7,8}\!$

2. Clinicians may obtain a non-contrast CT scan to help select the best candidate for SWL versus URS. (Conditional Recommendation; Evidence Strength: Grade C)

The Panel recognizes that multiple imaging modalities may be used to preoperatively assess candidates for shock-wave lithotripsy (SWL) and ureteroscopy (URS).⁹ However, in light of the breadth of information provided by CT, the Panel feels that CT can be useful to help determine whether SWL or URS is better suited for a given patient.

3. Clinicians may obtain a functional imaging study (DTPA or MAG-3) if clinically significant loss of renal function in the involved kidney or kidneys is suspected. (Conditional Recommendation; Evidence Strength: Grade C)

If a clinician suspects compromised renal function, obtaining a functional imaging study (DTPA or MAG-3) can help guide treatment for stone disease. Nuclear renography can define the differential function of the two kidneys in addition to assessing for urinary tract obstruction. It should be noted that the ability of nuclear renography to assess obstruction may be limited in cases of moderate to severe chronic kidney disease.

4. Clinicians are required to obtain a urinalysis prior to intervention. In patients with clinical or laboratory signs of infection, urine culture should be obtained. (Strong Recommendation; Evidence Strength: Grade B)

It is critical that clinicians obtain a urinalysis prior to stone intervention in order to minimize the risks of infectious complications. A urine culture should be obtained if urinary tract infection is suspected based on the urinalysis or clinical findings. If the culture demonstrates infection, the patient should be prescribed appropriate antibiotic therapy.

5. Clinicians should obtain a CBC and platelet count on patients undergoing procedures where there is a significant risk of hemorrhage or for patients with symptoms suggesting anemia, thrombocytopenia or infection; serum electrolytes and creatinine should be obtained if there is suspicion of reduced renal function. (Expert Opinion)

The American Society of Anesthesiologists recommends selective ordering of preoperative complete blood count and serum chemistry testing.¹⁰ The Panel recommends that a CBC be obtained prior to procedures where there is a significant risk of hemorrhage or if a patient has symptoms suggesting anemia, thrombocytopenia, or infection.

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	Evidence Strength A (High Certainty)	Evidence Strength B (Moderate Certainty)	Evidence Strength C (Low Certainty)	
Strong Recommendation	Benefits > Risks/Burdens (or vice versa)	Benefits > Risks/Burdens (or vice versa)	Benefits > Risks/Burdens (or vice versa)	
	Net benefit (or net harm) is substantial	Net benefit (or net harm) is substantial	Net benefit (or net harm) appears substantia	
(Net benefit or harm substantial)	Applies to most patients in most circumstances and future research is unlikely to change confidence	Applies to most patients in most circumstances but better evidence could change confidence	Applies to most patients in most circumstances but better evidence is likely to change confidence (rarely used to support a Strong Recommendation)	
Moderate Recommendation	Benefits $>$ Risks/Burdens (or vice versa)	Benefits $>$ Risks/Burdens (or vice versa)	Benefits $>$ Risks/Burdens (or vice versa)	
(Net benefit or harm moderate)	Net benefit (or net harm) is moderate	Net benefit (or net harm) is moderate	Net benefit (or net harm) appears moderate	
	Applies to most patients in most circumstances and future research is unlikely to change confidence	Applies to most patients in most circumstances but better evidence could change confidence	Applies to most patients in most circumstances but better evidence is likely to change confidence	
Conditional Recommendation (No apparent net benefit or harm)	Benefits = Risks/Burdens	Benefits = Risks/Burdens	Balance between Benefits & Risks/Burdens unclear	
	Best action depends on individual patient circumstances	Best action appears to depend on individual patient circumstances	Alternative strategies may be equally reasonable	
	Future research unlikely to change confidence	Better evidence could change confidence	Better evidence likely to change confidence	
Clinical Principle	A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature			
Expert Opinion	A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence			

 Table 2. AUA nomenclature linking statement type to level of certainty, magnitude of benefit or risk/burden, and body of evidence strength

Evaluation of serum chemistries and renal function tests should be based upon clinical characteristics, including pertinent preoperative medications and therapies, endocrine disorders, and risk of renal dysfunction. An assessment of serum electrolytes, creatinine and BUN should be checked if reduced renal function is suspected.

6. In patients with complex stones or anatomy, clinicians may obtain additional contrast imaging if further definition of the collecting system and the ureteral anatomy is needed. (Conditional recommendation; Evidence Strength: Grade C)

Situations in which complex urinary tract anatomy may require further imaging include ectopic kidneys (e.g., horseshoe kidney, pelvic kidney, cross-fused ectopia), other congenital kidney conditions (e.g., ureteropelvic junction obstruction, duplicated collecting system, caliceal diverticulum, ureteral stricture, megaureter, ureterocele), renal transplant grafts, kidneys with prior surgery or complex stone anatomy/conditions (e.g., staghorn stones, nephrocalcinosis).

All Patients with Renal or Ureteral Stones. 23. When residual fragments are present, clinicians should offer patients endoscopic procedures to render the patients stone-free, especially if infection stones are suspected.

(Index Patient 11) (Moderate Recommendation; Evidence Strength: Grade C)

In a retrospective analysis of the natural history of residual fragments following PCNL, 43% patients experienced a stone-related event at a median of 32 months.¹¹ Similarly, in a recent report by the EDGE Research Consortium evaluating patients with residual fragments following URS, 15% of patients developed a complication requiring no intervention, and an additional 29% of patients required intervention for residual fragments.¹²

The Panel advocates for the removal of suspected infection stones or infected stone fragments to limit the possibility of further stone growth, recurrent UTI, and renal damage.

24. Stone material should be sent for analysis. (Clinical Principle)

An exception would be a patient who has had multiple recurrent stones that have been documented to be of similar stone composition and there is no clinical or radiographic evidence that stone composition has changed.

26. Open/laparoscopic/robotic surgery should not be offered as first-line therapy to most patients with stones. Exceptions include rare cases of anatomic abnormalities, with large or complex stones, or those requiring concomitant reconstruction. (Index Patients

1-15) (Strong Recommendation; Evidence Strength: Grade C)

Advances in URS and PCNL now allow endoscopic management of the vast majority of stones. In rare cases, patients may be offered open/ laparoscopic/robotic surgery as a more efficient way to remove large or complex stones, especially in patients with anatomic abnormalities of the urinary tract, particularly those that require reconstruction, as in the case of concomitant UPJ obstruction or ureteral stricture.

36. A safety guide wire should be used for most endoscopic procedures. (Index Patients 1-15) (Expert Opinion)

In general, a safety guidewire is advisable when performing URS or PCNL for stones. It can facilitate rapid re-access to the collecting system if the primary working wire is lost or displaced and can provide access to the collecting system in cases of ureteric or collecting system injury, including perforation or avulsion.

37. Antimicrobial prophylaxis should be administered prior to stone intervention and is based primarily on prior urine culture results, the local antibiogram, and in consultation with the current Best Practice Policy Statement on Urologic Surgery Antibiotic Prophylaxis. (Clinical Principle)

In the absence of a UTI, SWL does not require antimicrobial prophylaxis. Perioperative antibiotic therapy, where required, is administered within 60 minutes of the procedure and re-dosed during the procedure if the case length necessitates. Antibiotic prophylaxis is recommended for ureteroscopic stone removal, PCNL, open and laparoscopic/robotic stone surgery. A single oral or IV dose of an antibiotic that covers gram positive and negative uropathogens is recommended.¹³

38. Clinicians should abort stone removal procedures, establish appropriate drainage, continue antibiotic therapy, and obtain a urine culture if purulent urine is encountered during endoscopic intervention. (Index Patients 1-15) (Strong Recommendation; Evidence Strength: Grade C)

The presence of purulence at the time of instrumentation mandates placement of a ureteral stent or nephrostomy tube and aborting the procedure. The purulent urine should be cultured, and broad spectrum antibiotics should be continued, pending cultures. The procedure can be undertaken once the infection is appropriately treated.

41. If initial SWL fails, clinicians should offer endoscopic therapy as the next treatment option. (Index Patients 1-14) (Moderate Recommendation; Evidence Strength: Grade C) If initial SWL fails, it is important to re-evaluate the stone characteristics (e.g., size, location, density, composition) and patient characteristics (e.g., obesity, collecting system anatomy including an obstructed system) that may have contributed to the initial failure. Success may be stratified such that those who have had partial fragmentation and clearance may be considered for repeat SWL while those with no fragmentation and/or clearance may be selected specifically for endoscopic intervention. Success rates for PCNL and URS as secondary procedures after failed SWL are reported as 86-100% and 62-100%, respectively.¹⁴

42. Clinicians should use URS as first-line therapy in most patients who require stone intervention in the setting of uncorrected bleeding diatheses or who require continuous anticoagulation/antiplatelet therapy. (Index Patients 1-15) (Strong Recommendation; Evidence Strength: Grade C)

Unlike both SWL and PCNL, URS can usually be safely performed in patients with bleeding diatheses or in those who cannot interrupt anticoagulation or antiplatelet therapy. URS should be considered first-line therapy for these patients when stone treatment is mandatory. Clinicians should also consider deferred treatment to a time when antiplatelet or anticoagulation therapy can be safely interrupted or observation alone for non-obstructing, non-infected, and asymptomatic stones that do not require urgent treatment.

Pediatric Patients. 46. In pediatric patients with uncomplicated ureteral stones ≤10 mm, clinicians should offer observation with or without MET using α-blockers. (Index Patient 13) (Moderate Recommendation; Evidence Strength: Grade B)

An initial trial of observation with or without medical expulsive therapy (MET) is appropriate in children with ureteral stones because a significant proportion of children will pass their stones spontaneously, thus avoiding the need for surgical intervention. In trials of MET with α -blockers in children, stone-free rates in the observation (non-treatment) arm averaged 62% for stones under 5 mm diameter in the distal ureter, and 35% for stones >5 mm.^{15–17}

Two of these trials demonstrated that α -blockers facilitated stone passage. If MET with α -blockers is prescribed, parents should be informed that it is in an off-label setting. As in adults, the maximum time duration for a trial of MET is undefined, but it is prudent to limit the interval of conservative therapy to a maximum of six weeks from initial clinical presentation (as in adults) in order to avoid irreversible kidney injury. 47. Clinicians should offer URS or SWL for pediatric patients with ureteral stones who are unlikely to pass the stones or who failed observation and/or MET, based on patientspecific anatomy and body habitus. (Index Patient 13) (Strong Recommendation; Evidence Strength: Grade B)

Meta-analysis demonstrated that stone free rates in pediatric patients with ureteral stones <10 mm are high for both SWL (87%) and URS (95%). For larger stones (>10 mm), stone free rates are a bit lower at 73% and 78%, respectively.¹⁴

While SWL is an acceptable option for ureteral stones, the poor visualization of the ureter (particularly the mid-ureter) with ultrasound-based lithotriptors may limit use of SWL in this setting. SWL may be preferable in certain pediatric populations, such as very small children, or other patients in whom ureteroscopic access may be challenging due to their anatomy (e.g., severe scoliosis, history of ureteral reimplantation).

48. Clinicians should obtain a low-dose CT scan on pediatric patients prior to performing PCNL. (Index Patient 13) (Strong Recommendation; Evidence Strength: Grade C)

Modified protocols and equipment permit CT imaging in children that adheres to "ALARA" principles (radiation exposure kept "as low as reasonably achievable").¹⁸ Several studies have shown that in adults, low dose CT is comparable to standard CT with respect to stone diagnosis and measurement.^{19–21} Although comparative studies of low-dose CT in the pediatric population are lacking, generalization of the findings from the adult to the pediatric population seems reasonable.

49. In pediatric patients with ureteral stones, clinicians should not routinely place a stent prior to URS. (Index Patient 13) (Expert Opinion)

In pediatric patients who require endourologic intervention for a ureteral stone, access is sometimes difficult or impossible due to a narrow ureterovesical junction and/or ureter. In such cases, placement of a ureteral stent typically results in passive dilation of the ureter, thus permitting access at the time of the next attempted URS.²² However, "pre-stenting" should not be considered a routine aspect of a ureteroscopic procedure in pediatric patients, since access to the upper tract is possible on the initial attempt in a majority of children undergoing attempted URS.²³

50. In pediatric patients with a total renal stone burden ≤20 mm, clinicians may offer SWL or URS as first-line therapy. (Index Patient 14) (Moderate Recommendation; Evidence Strength: Grade C) Stone free rates following SWL are reported to be relatively high in children at 80-85% overall, and at 80% for lower pole stones.^{24,25} URS also appears to have a high success rate, with stone free rates of around 85%.²⁶ Complication rates may be somewhat higher with URS, estimated at 12.4%-20.5% in reviews compared to 8%-10% with SWL.²⁷

51. In pediatric patients with a total renal stone burden >20 mm, both PCNL and SWL are acceptable treatment options. If SWL is utilized, clinicians should place an internalized ureteral stent or nephrostomy tube. (Index Patient 14) (Expert Opinion)

SWL has been reported to have stone free rates of 73-83% in pediatric patients, while PCNL results vary by site, but recent large series have approached 90% success rates.¹⁴ Several factors must be taken into consideration when selecting which of these procedures to pursue including stone composition and attenuation, stone location, body habitus, collecting system anatomy, relation of the kidney to surrounding viscera, medical co-morbidity and parental preference. The utilization of smaller instruments for PCNL (mini-PCNL, micro-PCNL) may limit the risk of hemorrhage in this population.^{28,29}

52. In pediatric patients, except in cases of coexisting anatomic abnormalities, clinicians should not routinely perform open/ laparoscopic/robotic surgery for upper tract stones. (Index Patients 13, 14) (Expert Opinion)

Series in adults have suggested that laparoscopic approaches may compare favorably to percutaneous techniques for large or staghorn renal stones,¹⁴ but in children, these approaches should be considered secondary or tertiary options for treatment of renal or ureteral stones, since more conventional procedures including SWL, URS, and PCNL have high rates of success and lower risks of serious complications. The primary exception to this is in the pediatric patient with one or more renal or ureteral stones and a co-existing anatomic anomaly, such as UPJ obstruction.³⁰

53. In pediatric patients with asymptomatic and non-obstructing renal stones, clinicians may utilize active surveillance with periodic ultrasonography. (Index Patient 14) (Expert Opinion)

While observation of an asymptomatic, nonobstructing renal stone is an option for children, such patients should be seen regularly with routine surveillance ultrasound to monitor for increase in size or number of stones, and silent obstruction.

Pregnant Patients. 54. In pregnant patients, the clinician should coordinate pharmacological and surgical intervention with the obstetrician. (Index Patient 15) (Clinical Principal)

Stone disease during pregnancy can be a challenging condition to diagnose and treat, and investigations are complicated by the normal changes during pregnancy that can resemble obstructing calculi. The risks to the fetus of ionizing radiation, analgesics, antibiotics and anesthesia must also be considered.

55. In pregnant patients with ureteral stones and well controlled symptoms, clinicians should offer observation as first-line therapy. (Index Patient 15) (Strong recommendation; Evidence Strength: Grade B)

The spontaneous passage rates for pregnant women with ureteral stones have not been demonstrated to be different than those of a non-pregnant patient. Therefore, in a patient whose symptoms are controlled, a period of observation should be the initial therapy. The clinician should be aware that a stone event in pregnancy does carry with it an increased risk of maternal and fetal morbidity, so patients should be followed closely for recurrent or persistent symptoms.³¹ Should MET be considered for the pregnant patient, the patient should be counseled that MET has not been adequately investigated in the pregnant population, and the pharmacologic agents are being used for an "offlabel" purpose.³² Non-steroidal anti-inflammatory agents (e.g., ketorolac) are contraindicated in pregnancy.

56. In pregnant patients with ureteral stones, clinicians may offer URS to patients who fail observation. Ureteral stent and nephrostomy tube are alternative options, with frequent stent or tube changes usually being necessary. (Index Patient 15) (Strong Recommendation; Evidence Strength: Grade C)

Should a trial of observation fail for the pregnant patient with a ureteral stone, an intervention is indicated. Ureteral stent and percutaneous nephrostomy will both effectively decompress the obstructed collecting system, and thereby bring symptom relief. However, the introduction of such foreign objects into the collecting system of a pregnant woman can be a point of concern, as they tend to encrust rapidly. Therefore, frequent stent or tube exchanges are typically required. As an alternative, URS provides a definitive treatment for the pregnant patient, as it accomplishes stone clearance, obviating the need for prolonged drainage with stent or percutaneous nephrostomy.³³

FUTURE RESEARCH

There is an extreme paucity of high-quality, randomized controlled trials comparing competitive surgical interventions for stone disease, and a lack of standardization of terminology and metrics, such as stone size, stone location, stone-free status, complications, and economic outcomes, prevents reliable comparisons among studies.

Our ability to utilize imaging studies to predict treatment outcomes for differing stone interventions is limited at present. This is particularly true for SWL, where pre-treatment understanding of stone fragility is lacking.

While many patients will pass a symptomatic ureteral stone spontaneously, clinicians' ability to counsel patients on time to passage is limited and points to a need for future studies better defining the ability of MET to promote passage. Additionally, the development of agents with better efficacy and tolerability to facilitate stone passage is warranted.

The mechanical action of stone fragmentation and removal is the primary driver of intraoperative time allocation during a stone removal procedure. It is currently unknown in some cases whether URS or PCNL yields superior outcomes.

Despite recognition as a source of significant morbidity, ureteral stent placement is commonly performed following stone interventions. Future efforts should be devoted to better identifying patients in whom stent placement may be safely avoided. In addition, advances in stent technology, with a focus on identifying the nature and source of stent morbidity, may improve surgical care.

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DISCLAIMER

This document was written by the Surgical Management of Stones Guideline Panel of the American Urological Association Education and Research, Inc., which was created in 2014. The Practice Guidelines Committee of the AUA selected the committee chair. Panel members were selected by the chair. Membership of the panel included specialists in urology with specific expertise on this disorder. The mission of the panel was to develop recommendations that are analysis-based or consensus-based, depending on panel processes and available data, for optimal clinical practices in the treatment of stones.

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While these guidelines do not necessarily establish the standard of care, AUA seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.

Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ("off label") that are not approved by the FDA (Food and Drug Administration), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice statements are not intended to provide legal advice about use and misuse of these substances.

Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices. For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily experimental or investigational.

CONFLICT OF INTEREST DISCLOSURES

All panel members completed COI disclosures. Those marked with (C) indicate that compensation was received. Disclosures listed include both topic and non-topic related relationships.

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