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# How long does it take to be an ERCP expert?

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## ABSTRACT

**Introduction:** Although many researches have been done on the success and complications of the endoscopic retrograde cholangiopancreatography (ERCP) procedure, the effects of the endoscopist's experience are still a controversial issue.

**Materials and Methods:** Between January 2016 and January 2020, 320 ERCP procedures with natural papilla performed sequentially by a single endoscopist were divided into 4 groups only in chronological order. Medical records from the hospital automation system and ERCP forms were reviewed retrospectively. The effects of experience on the ERCP procedure were investigated by comparing the success rate and complications between the groups.

**Results:** In the procedures carried out on 320 native papilla, success rate was 88.43%; the success rates of selective biliary cannulation in four groups were, respectively, 83.75, 93.75, 88.75, and 87.50%. It was determined that success rate did not increase by increasing experience (p=0.696). Cannulation period and attempts are reduced by group 1 to 4 (p<0.01), but the decrease in ERCP specific complications which are associated with cannulation time and the number of attempts was not statistically significant. On the contrary, hemorrhage complication in the syphinchteretomy line was increased from group 1 to group 4. (p=0.014).

**Conclusion:** 240 cases refer to the critical value in terms of complications. Therefore, in difficult procedures and for patient selection, this value (240 cases) should be considered. Since being an expert is a highly individual situation at ERCP, the standard number of case or definitions of experience are likely to be discussed for a longer time.

**Keywords:** Endoscopic retrograde cholangiopancreatography case volume; endoscopic retrograde cholangiopancreatography experience; endoscopic retrograde cholangiopancreatography.

## Introduction

After the endoscopic retrograde cholangiopancreatography (ERCP) procedure was first described by McCune in 1968, the first sphincterotomy has been done by Kawai in 1974; thus, ERCP became an effective method of treatment in addition to its established role as a diagnostic method for biliary and pancreatic diseases and its therapeutic gained for widespread acceptance. It is estimated that more than 200,000 ERCPs are performed annually in the United States. Diagnostic ERCP has gradually decreased with the introduction of noninvasive modalities such as magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasonography (EUS).[1-4] In the past 30 years diagnostic ERCP has increased 7 times, however therapeutic ERCP has increased 30 times.[5]

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The success of the procedure increases as a result of experience over time in all invasive procedures. While the success of the procedure is increased, naturally, a decrease in the procedure specific complications is anticipated. In the ERCP procedure, the relationship between the experience of the endoscopist and the success of the process and the complication rates has been discussed in many studies, but the data on this issue are still debated.[6]

In our literature review, we have observed that in many studies presented comparison were made between centers; thus, endoscopists and assistant health personnel were different in each of the studies. Therefore, with the current literature, examining the effects of the endoscopist's personal experience on success and complication rates is not based on objective criteria. It is not known whether the low-volume endoscopist can achieve optimal success in a high-volume center.[5]

In this submitted document, we tried to find out the effects of the experience of an endoscopist on the success and complications of the procedure by evaluating a single endoscopist performing the ERCP operations by the help of the same assistant healthcare personnel and the same tools and thus to set objective criteria about the role of the endoscopist.

Under the heading "how long does it take to be an expert" answers for secondary implications such as when the patients and situations with higher risk can be intervened, when to cancel the operation in case a risky situation is encountered during the procedure and when to consult to an expert or refer the patient to another center are looked for.

## Materials and Methods

After approval of Derince Training and Research Hospital Clinical Researches Ethics Committee/Kocaeli/Turkey on 23rd of June, 2020, with 2020/105 registration no, all patient related data (age, gender, indication) and procedure-related data (duration of cannulation, number of attempts, cannulation technique, procedure related complications) of the ERCP procedures performed in one center in a state hospital by the same doctor and same two ERCP nurse between January 2015 and January 2019 were retrospectively evaluated using records in the hospital information system.

### Inclusion Criteria

All ERCP cases whether successful or failed were evaluated. Only the ERCP procedures made on native papilla are included in the study. Only the first ERCP procedure is included into the study, if for any reason there is more than one ERCP procedure performed in the same patient.

### Exclusion Criteria

Thirteen patients who have undergone ERCP procedure but whose data cannot be retrieved from the hospital information system are excluded from the study.

All of the procedures were divided into four chronological groups of 80 cases each (Group 1, 2, 3 and 4). All of the patients had native papilla.

### ERCP Protocol

After the patients were provided tracheal intubation under general anesthesia in supine position, ERCP procedure was performed in the prone position. Standard biliary cannulation was attempted with a sphincterotome or ERCP cannula (Microtech, Chinese) with a guidewire (0.035 inch hydrophilic type; Microtech, Chinese) inside. Cut in the papilla with the standard needle knife at first sight instead of attempt to the papilla through sphincterotome or ERCP cannula was defined as early precut, whereas the cut afterward was defined as late precut. After selective common bile duct (CBD), cannulation is established cholangiography was performed using non-ionic contrast material and subsequently standard sphincterotomy was done. Ceftriaxon 2 g. was use as prophylactic antibiotic. All of the patients were admitted to inpatient ward for observations for at least 24 h after the procedure.

Two standard identical Pentax (EPM 3500) duodenoscopes were used in all procedures. Diathermy (120 watts cut; 60 watts coagulation) was applied with the pure-cut mode in the Bowa system (Bowa ARC400/Germany) when the needle-knife catheter and standard sphincterotome were used. The sphincterotomy technique was performed with an endo-cut mode, which adjusts the amount of cutting and coagulating current automatically, depending on the tissue resistance.

No patient has been given rectal indomethacin or any similar drug for prophylactic purposes to prevent post ERCP pancreatitis (PEP). When guide inserted into two or more Wirsung, channel instead pancreatic stent was applied to Wirsung.

Symptomatic patients with 3 × uln amylase 24 h after the procedure and who were required to stay in hospital more than 3 days were considered as PEP according to the cotton criteria.[7] The patients with increased amylase levels but without any complaint who stay in the hospital <3 days are considered as asymptomatic PEP.

### Background of the Endoscopist

In his 10 years of endoscopy experience, the doctor have performed around 20 000 upper gastrointestinal endoscopy + lower gastrointestinal endoscopy + upper and lower malignant gastrointestinal stenosis and self-expandable stent + endoscopic mucosal resection + endoscopic submucosal dissection procedures and then undertook a training program wherein he practiced each step of the diagnostic procedures (MRCP and EUS) and therapeutic ERCP procedure, including various standard techniques for cannulation, therapeutic trials, and management of complications. ERCP procedures were done under the supervision of an expert whose ongoing workload had been more than 750 ERCPs annually for at least 12 years. Before beginning to self-perform ERCP, endoscopist was involved in a total 6 months training program; watched 190 ERCP performed by the supervisor all procedures were therapeutic after that endoscopist performed at least 100 ERCP under the supervision of the supervisor. Subsequently, endoscopist started to self-perform ERCP at a government state hospital. All data are recent and after the training program.

### Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences program version 25. Conformity of the variables to normal distribution was assessed by histogram tables and Kolmogorov-Smirnov test. Mean, standard deviation, number, and percentage values were used for presenting descriptive analysis. Categorical variables were compared using Pearson Chi-square test. The change in successful cannulation, successful cannulation without complication and complication rates were assessed by Chi-square Trend Analysis. During inter-group comparison of variables with non-normal distribution (non-parametric) Kruskal Wallis test was used and for post hoc analysis Mann Whitney U test was used. For comparison of quantitative values with each other spearman correlation test was used. Results with P-value below 0.05 were considered as statistically as significant.

## Results

Total 463 ERCP procedures were assessed retrospectively using the records retrieved from hospital information system. 13 cases without access to the detailed information and examinations from the hospital information system were excluded from the study, although previously ERCP was performed on these cases. A total 320 procedures with natural papilla from 450 procedures were included in the study. All the patients who have undergone ERCP were above age of 18 years and had normal anatomy.

Mean age of the patients included in the study was 59.83 years (range 21–104) including 127 were male and 193 were female patients. Punch biopsy were taken in 3 patients without any cannulation attempt due to ampulla tumor, in 34 patients, cannulation could not be established despite all efforts. Cannulation was established in 283 patients in total (88.43%).

There is no significant difference between the groups in terms of age, gender, and indication distribution. The most common indication was choledocholithiasis. The indications were choledocholithiasis (246/320), hepatobiliary malignancy (28/320), cystic duct leakage after cholecystectomy (12/320), biliary pancreatitis (32/320), and rupture of the hydatid cyst into the biliary ducts (2/320), respectively (Table 1).

### Cannulation of the CBD

The rates of successful cannulation and the ones without complication increased from group 1 to group 4. Yet, no statistical significance was observed (p=0.696) (Table 2).

After observing the correlation, it is seen that there is a reverse relationship between the period of cannulation and the number of attempts and experience in all of the patients with or without complication, regardless of the groups. From group 1 to group 4, there is a significant decrease in the period of cannulation and the number of attempts (Table 3).

While ERCP cannula was preferred with 53.75% as the cannulation method in group 1, the use of ERCP cannula significantly decreased moving toward group 4 and preference of early precut method significantly increased. Likewise, preference over late precut method significantly decreased from group 1 to group 4. Early precut substantially increased after group 3. Although this resulted in general decrease in complications, increase in the rate of hemorrhage was observed. Despite all interventions,

**Table 1. Distribution of the demographic data and indications of the groups**

| | Group 1 (1-80) | | Group 2 (81-160) | | Group 3 (161-240) | | Group 4 (241-320) | | Total | | P |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Age | 62,14±20,13 | | 60,70±18,49 | | 58,83±17,48 | | 58,10±16,52 | | 59,94±18,19 | | 0,320[1] |
| Sex | | | | | | | | | | | |
| Male | 28 | (35,00) | 36 | (45,00) | 32 | (40,00) | 31 | (38,75) | 127 | (39,69) | 0,635[2] |
| Female | 52 | (65,00) | 44 | (55,00) | 48 | (60,00) | 49 | (61,25) | 193 | (60,31) | |
| Indication | | | | | | | | | | | |
| Choledocholithiasis | 63 | (78,75) | 61 | (76,25) | 62 | (77,50) | 60 | (75,00) | 246 | (76,88) | 0,636[3] |
| Malignancy | 7 | (8,75) | 9 | (11,25) | 6 | (7,50) | 6 | (7,50) | 28 | (8,75) | 0,596[3] |
| Bile leakage | 3 | (3,75) | 3 | (3,75) | 4 | (5,00) | 2 | (2,50) | 12 | (3,75) | 0,793[3] |
| Biliary pancreatitis | 6 | (7,50) | 7 | (8,75) | 7 | (8,75) | 12 | (15,00) | 32 | (10,00) | 0,134[3] |
| Hydatic cyst | 1 | (1,25) | 0 | (0,00) | 1 | (1,25) | 0 | (0,00) | 2 | (0,63) | 0,526[3] |

[1]Kruskal Wallis Test; [2]Chi-Square Test; [3]Chi-Square Trend Analysis.

**Table 2. Cannulation rates of the groups**

| | G1 | | G2 | | G3 | | G4 | | Total | | P |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % | N | % | |
| Successful cannulation | 67 | (83,75) | 75 | (93,75) | 71 | (88,75) | 70 | (87,50) | 283 | (88,43) | 0,696 |
| Successful cannulation without complication | 56 | (70,00) | 65 | (81,25) | 65 | (81,25) | 62 | (77,50) | 248 | (77,50) | 0,282 |

Chi-Square Trend Analysis.

**Table 3. Duration of cannulation and number of attempts in the patients**

| | Non-complicated (277) | | Complicated (43) | | Total (320) | |
|---|---|---|---|---|---|---|
| | R | P | R | P | R | P |
| Duration of cannulation | -0,848 | <0,001 | -0,908 | <0,001 | -0,849 | <0,001 |
| Number of attempts | -0,690 | <0,001 | -0,820 | <0,001 | -0,697 | <0,001 |

Spearman Correlation test.

failure in cannulation decreased from group 1 to group 4, but this decrease was not statistically significant. Furthermore moving from group 1 to group 4, the ratio of failed ones without any attempts of the papilla was increased and the ratio of ones without attempting significantly increased (Table 4).

### Procedure-related Adverse Events

Only PEP, perforation, hemorrhage and their combinations were considered as complications specific to ERCP. No complication related to anesthesia was observed.

Perforation which is considered as the most hazardous complication has occurred in 2 cases in group 1, one case in group 1 and one case in group 2 as perforation + PEP combination, and one in group 2 as hemorrhage + PEP combination. All perforation cases were treated with conservative treatment methods without the need for operation. Perforation has not been observed in group 3 and beyond. However, this difference was not also statistically significant (p=0.116)

PEP was the most frequent procedure-related complication with total 8 cases with non-symptomatic (5%) and with total 8 cases symptomatic groups (5%). From group 1 to 4 as experience increases PEP incidence has decreased toward group 4, but this difference was also not statistically significant (p=0.264)

Except hemorrhage, all complications decreased from group 1 to group 4. Yet, this was not statistically significant. Hemorrhage on the other hand, substantially increased (Table 5).

Moving toward group 4 the mean cannulation time and the mean number of attempts to the papilla decreased. In the intra- and inter-group comparisons:

There was no-statistical significant difference between group 1 and group 2 patients with and without complications in terms of cannulation period and number of attempts. Yet, following group 3 average duration of the cannulation and number of attempts have substantially decreased. This is applicable for non-complicated patients as well. It is important to note that there is decrease in the duration of cannulation with complications between group 1 and group 2 while there is a significant decrease between group 2 and group 3.

Given intra-group comparisons, duration of cannulation and number of attempts are significantly higher in complicated cases until we reach to group 4. Since there is no statistical difference within group 4, the complications that occur in those groups are not related to duration of cannulation and number of attempts (Table 6).

## Discussion

Effectiveness of ERCP depends on high success and low complication rate. ERCP is one of the technically difficult procedures in gastrointestinal endoscopy with a relatively high complication rate that varies between 3% and 15%.[8] Expert ERCP endoscopists are expected to be able to clean the main bile duct in 85% of the cases with balloon or basket after the sphincterotomy.[9]

Although the skill of the endoscopist is a very personal case, as experience increases, success is expected to increase and complications to decrease. Masci et al. indicated that the only factor expressly related to the success and complication rates is the number of cases operated by the endoscopist.[10] However, there are many different results in the literature in terms of annual number of the cases. The results show that those who perform more than 150 ERCP/year are overtly more successful than those who perform <50. This finding is consistent with some other studies,[11-13] and it has been determined that even better results will be achieved when more than 200 procedures are done annually. Freeman et al. have shown that endo-

**Table 4. Cannulation Methods According to Groups**

| | 1 | | 2 | | 3 | | 4 | | P |
|---|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % | |
| Failed without any attempts of the papilla | 0 | (,00) | 1 | (1,25) | 3 | (3,75) | 4 | (5,00) | 0,025 |
| Cannula | 43 | (53,75) | 12 | (15,00) | 10 | (12,50) | 20 | (25,00) | <0,001 |
| Sphincterotomy | 3 | (3,75) | 31 | (38,75) | 36 | (45,00) | 16 | (20,00) | 0,013 |
| Early precut | 1 | (1,25) | 7 | (8,75) | 6 | (7,50) | 30 | (37,50) | <0,001 |
| Late precut | 20 | (25,00) | 25 | (31,25) | 19 | (23,75) | 4 | (5,00) | 0,001 |
| Failed in spite of all interventions | 13 | (16,25) | 4 | (5,00) | 6 | (7,50) | 6 | (7,50) | 0,099 |

Chi-Square Trend Analysis.

**Table 5. Complication Rates According to Groups**

| | Group 1 | | Group 2 | | Group 3 | | Group 4 | | P |
|---|---|---|---|---|---|---|---|---|---|
| Asymptomatic PEP | 7 | (8,75%) | 4 | (5%) | 3 | (3,75%) | 2 | (2,5%) | 0,264 |
| Symptomatic PEP | 5 | (6,25%) | 4 | (5%) | 3 | (3,75%) | 4 | (5%) | 0,603 |
| Perforation | 2 | (2,5%) | 0 | (0%) | 0 | (0%) | 0 | (0%) | 0,116 |
| Hemorrhage | 0 | (0%) | 1 | (1,25%) | 2 | (2,5%) | 3 | (3,75%) | 0,014 |
| Perforation + PEP | 1 | (1,25%) | 1 | (1,25%) | 0 | (0%) | 0 | (0%) | 0,344 |
| Hemorrhage + PEP | 0 | (0%) | 1 | (1,25%) | 0 | (0%) | 0 | (0%) | 0,823 |

Chi-square trend analysis.

**Table 6. Duration of Cannulation and Number Of Attempts According To The Groups**

| | Group 1 | Group 2 | Group 3 | Group 4 | Total | P[1] |
|---|---|---|---|---|---|---|
| Duration of cannulation | 27,66±16,74 | 19,10±10,18 | 7,65±2,94 | 4,84±1,66 | 14,81±13,48 | <0,001 |
| Duration of cannulation in cases without complication | 23,82±16,09 | 16,93±8,92 | 7,49±3,03 | 4,73±1,63 | 12,96±11,81 | <0,001 |
| Duration of cannulation in complicated cases | 44,33±5,63 | 32,73±6,47 | 9,12±1,25 | 5,67±1,80 | 26,72±17,19 | <0,001 |
| P[2] | <0,001 | <0,001 | 0,044 | 0,059 | <0,001 | |
| Number of attempts | 11,35±5,61 | 9,58±4,41 | 5,96±2,60 | 3,56±1,60 | 7,61±4,92 | <0,001 |
| Number of attempts in cases without complication | 9,68±4,77 | 8,52±3,49 | 5,64±2,28 | 3,44±1,52 | 6,74±4,02 | <0,001 |
| Number of attempts in complicated case | 18,60±2,03 | 16,18±3,92 | 8,88±3,52 | 4,56±1,94 | 13,23±6,34 | <0,001 |
| P[2] | <0,001 | <0,001 | 0,004 | 0,063 | <0,001 | |

[1]Kruskal Wallis Test/ [2]Mann Whitney U Test (complicated-non-complicated comparison has been done).

scopists with more than 50 cases of sphincterotomy annually are more successful and serious complications are lower.[14] Similarly, in a single-centered study from Germany, it was concluded that if the endoscopist performs ERCP <40/year, a high complication rate will ensue. The difference is more prominent if the case load annually increases over 100. Experience, even as a sole factor, has a tendency to lower complication rates.[15] In their systemic research review, Keswani et al., assessed ERCP success rates in four studies according to the volume of the endoscopist.[11,12,16,17] In the analysis, success rates of high volume endoscopists found to be 60% more than low volume endoscopists.[5] However, this finding is not consistent with others.[18,19]

Complication rate of high volume endoscopists are 31% less than low volume endoscopists and endoscopists who perform <40 sphincterotomy/year tend to cause more complications.[5,20] In terms of success and low rate complications, the number of ERCP performed annually by the endoscopist alone is not enough. Continuity of lifetime acquired experience year by year is also important. Therefore, solely annual 50 cases as a threshold value does not seem to be a satisfactory definition to be an expert but continuous experience is equally important.[8] In our results, it was observed that after a total of 160 cases duration of cannulation and the number of attempts declines significantly and upon reaching 240 cases number of attempts in the complications and duration of cannulation becomes negligible.

ERCP-specific complications are assessed by ASGE under three main headings: (1) patient-related risks, (2) procedural risks, and (3) endoscopist-related risks.[21] Common considerations have occurred partly in literature for patient-related and procedural risks; however, factors such as duration of cannulation and number of attempts which are considered as procedural risks are indeed associated with the experience of the endoscopists. As its shown in this document, duration of cannulation and number of attempts decrease as the experience of the endoscopist increases. Therefore, this decrease is expected to reduce the ratio of complications.

It has been shown that the rate of cannulation of the desired duct is higher among endoscopists with more than 50 ERCP/year and the mean complication rates are lower.[11] With the experience obtained over time, the rate of PEP development due to unintentional Wirsung cannulation is expected to decrease. However, the results about this

issue are mixed. There are studies revealing prominent difference with experience of the endoscopist,[14,15,22,23] but there are also some publications that don't confirm it.[16,24-27] Freeman et al. have found unexpectedly higher pancreatitis rate rather than a lower rate in cases operated by high volume endoscopists compared to low volume endoscopists.[16] Williams et al. stratified the annual case numbers as <50, 50–100, 100–150, 150–200 and >200 and didn't find any differences in terms of PEP.[26]

Difficult cannulation is a clear risk for PEP. The rate of PEP is 4.3% in patients who have undergone simple cannulation but the rate reaches up to 12.5% in difficult cannulation.[16] Pancreatic cannulation and contrast material injection are determined to be independent risk factors for PEP development in numerous previous publications.[14,16,22,23,25,28-31] Difficult cannulation has been shown to be an independent risk factor solely for pancreatitis and may occur without any apparent pancreatic duct instrumentation.[14,16,24,32] This suggests that trauma to the papilla and pancreatic sphincter with impaired pancreatic drainage may be important in the pathogenesis of pancreatitis. Although there is an association with the number of times the papilla was manipulated, the cutoff numbers vary widely and increasing number of attempts at cannulating Water's papilla was the riskiest factor for post-ERCP pancreatitis.

Being an expert on the procedure affects positively the general performance of the ERCP process, including successful cannulation, the risk of bleeding and perforation, but it appears that it cannot totally prevent pancreatitis which seems to be associated with patient related conditions rather than technical skills. Mean pancreatitis rate does not differ between high and low volume centers.[31] A possible explanation for this is that: as Freeman et al. have determined the number of cases couldn't reach 300–500/year which is the point where PEP rate decrease is expected to occur.[16]

Most authorities recommend that a precut be used only for therapeutic indications by experts because precut incision is a risk for perforation.[7,14,22,33-42] A meta-analysis has shown that precut incision does not carry a higher risk when applied by expert endoscopists, and it is shown in a prospective study that, compared to standard canulation methods comparable successful canulation rate and mean complication rate are achieved by difficult canulation and PEP rate was significantly lower.[3,43,44] As shown in the results of this study, use of early precut and the ratio of complications decreased towards group 4. Yet, this is not statistically significant.

However, Akaraviputh et al.[45] reported that the success rate did not significantly change with the endoscopist's experience over time, and complication rates reached a plateau despite increasing experience.

Endoscopists performing <50 ERCPs/year, must carefully make their prospective plans and make a decision to stop to perform this procedure or not in the light of scientific data by comparing their own data with the literature. Maybe it will be a healthy decision to stop performing ERCP for some endoscopists.[20]

After the papilla was appeared in group 1, attempt cannulation was implemented in all patients. Yet, the procedure was declared failed without any attempts toward the group 4. The ratio of complications was decreased as the ratio of experience increased. Insistence on risky procedures such as ERCP could result in mortal complications. Instead, it would better that the procedure is interrupted and patient is referred to an expert.

Individual skills of trainees and educators to be selected for ERCP education are the most important factors during the selection. To educate new endoscopists and to provide relative standardization to improve community health, more studies assessing the individual data of the endoscopists are needed rather than comparing the performance of the centers.

Our study has several limitations. Firstly, it was examined retrospectively and some failed ERCP procedures were treated in an-other tertiary hospital. Secondly, ERCP procedure cannot rely on objective criteria as it is mainly affected by individual factors. Finally, the data cannot be compared in the absence of second endoscopist working in the same hospital.

## Conclusion

The number of cases that the endoscopist has observed and applied under the supervision of a supervisor, the number of cases that the endoscopist has performed by his/her own and the number of ERCP/year are important factors for the procedure to be successfully carried out without complication. Experience and skill of the endoscopist still constitute a very important factor that still preserves its value. 100 cases to be performed under the supervision of an expert is considered to be sufficient for

gaining the ability to perform CBD cannulation. However, since the complication rate of an endoscopist decreases significantly after 240 cases, we advise that high-risk ERCP procedures and the procedures to be performed on high-risk patients should be done after this stage.

### Disclosures

**Ethichs Committee Approval:** The study was approved by the Derince Training and Research Hospital Clinical Researches Ethics Committee/Kocaeli/Turkey on 23rd of June, 2020, with 2020/105.

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**Conflict of Interest:** None declared.

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