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# Use of fully covered self-expanding metal biliary stents for managing endoscopic biliary sphincterotomy related bleeding

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## ABSTRACT

**Background and study aims** Endoscopic biliary sphincterotomy (EBS) related-bleeding is a common adverse event related to endoscopic retrograde cholangiopancreatography (ERCP). Traditionally, endoscopic modalities such as epinephrine injection, cauterization, and balloon tamponade have been used for management. Recently, use of a fully covered self-expandable metal stent (FCSEMS) to manage EBS-related bleeding has gained popularity. However, data regarding its use are limited to small case series. Therefore, we aimed to evaluate the safety and efficacy of FCSEMS placement for the treatment of EBS-related bleeding.

**Patients and methods** All patients referred to our center from October 2014 to November 2019 who had an FCSEMS placed for EBS-related bleeding were included. FCSEMS was placed either for primary control of bleeding or after failure of other traditional endoscopic hemostasis techniques at the discretion of the endoscopist. Data was collected regarding patient demographics, procedural characteristics, clinical and technical success rates of FCSEMS, as well as adverse events.

**Results** A total of 97 patients underwent placement of FCSEMS for EBS-related bleeding, of which 76.3% had immediate bleeding and 23.7% had delayed bleeding. Mean age was 67.2 years and 47.4% were males. Seven patients who had immediate EBS-related bleeding at index ERCP underwent other endoscopic therapies prior to placement of FCSEMS for rebleeding. The technical success rate for FCSEMS placement was 100% and the rebleeding rate was 6.2%. Four patients with FCSEMS placement developed pancreatitis and four had stent migration.

**Conclusions** Our findings suggest that FCSEMS is a highly effective treatment modality for managing EBS-related bleeding and has an acceptable safety profile.

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## Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) was initially developed as a diagnostic tool in the 1960s [1]. However, over the past several decades, ERCP has become mainly a therapeutic procedure. ERCP is now routinely used for the management of numerous benign and malignant pancreatobiliary diseases [2–4]. A recent report suggested that while the use of ERCP in the United States increased over the past decade, there has also been an increase in ERCP-related adverse events (AEs) [5].

ERCP-related AEs have been associated with both patient and procedural level factors. [6–8] The major AEs associated with ERCP include sedation-related cardiopulmonary events, perforation, cholangitis, post-ERCP pancreatitis, and endoscopic biliary sphincterotomy (EBS)-related bleeding [3, 6, 7, 9]. Previous reports describe various rates of post-EBS-related bleeding, ranging from as low as 1% to nearly 50%, depending on how bleeding was defined [7, 10–13]. The clinical significance of EBS-related bleeding ranges from mild hemorrhage that does not require transfusion to life-threatening bleeding, which requires transfusion of more than 5 units of red blood cells [10, 11, 14]. EBS-related bleeding can occur immediately at the time of the index ERCP (intra-procedural bleeding) or in a delayed fashion, with melena, hematemesis, or progressive anemia observed up to 1 to 21 days following sphincterotomy [9, 15].

Traditionally, EBS-related bleeding has been treated with endoscopic techniques such as sclerotherapy, epinephrine injection, cauterization, and balloon tamponade. In cases where EBS-related bleeding is refractory to endoscopic treatment, interventional radiology-guided angiographic embolization or surgery have been utilized [14, 16, 17]. In the initial series describing the angiographic approach, the most common locations for bleeding were branches of the gastroduodenal artery, located near the major papilla. [16] Surgery is generally reserved for cases refractory to endoscopic and radiological techniques [14, 17].

Over the last decade, several series and small cohort studies have reported utilizing fully covered self-expanding metal stents (FCSEMS) to achieve hemostasis in severe cases of EBS-related bleeding that were refractory to traditional management [18–23]. A recent retrospective study compared FCSEMS to traditional endoscopic modalities for the management of EBS-related bleeding after failure of traditional endoscopic modalities [20]. The authors reported lower rates of bleeding at 72 hours in the 23 patients who underwent FCSEMS placement versus the 44 patients managed with traditional endoscopic therapies [20].

While these reports have shown promising results, they have been limited due to the small sample size. While this technique is often utilized in routine clinical practice, currently there are no large studies evaluating the role of FCSEMS for management of EBS-related bleeding. Therefore, we aimed to evaluate the safety and efficacy of FCSEMS placement for the treatment of EBS-related bleeding.

## Methods

This was a retrospective, single-center study of consecutive patients who underwent ERCP with biliary sphincterotomy at our tertiary care academic medical center. All patients who had EBS-related bleeding and had FCSEMS placed for control of hemostasis from October 2014 to November 2019 were included. Exclusion criteria included patients who had FCSEMS placed for indications other than bleeding. FCSEMS were placed either for primary control of EBS-related bleeding or after other endoscopic modalities of hemostasis had failed at the discretion of the advanced endoscopist. The electronic medical record was reviewed and data were collected regarding patient demographics (age, gender, co-morbid conditions, use of anticoagulation or antithrombotic medication), procedure-related factors (indication for index ERCP, presence of periampullary diverticula, timing of EBS-related bleeding, hemodynamic compromise), outcomes (technical success of FCSEMS placement, size of FCSEMS, therapies used prior to FCSEMS, adjunctive therapy used with FCSEMS, mean time to FCSEMS removal), rates of re-bleeding, need for repeat intervention, and AEs (pancreatitis, cholecystitis or stent migration). Patients who did not have FCSEMS removal were excluded from the analysis for calculating mean time for FCSEMS removal. This study was approved by our local Institutional Review Board.

### Definitions

Immediate EBS-related bleeding was defined as bleeding at the time of sphincterotomy and/or continued bleeding at the end of the ERCP procedure. Delayed EBS-related bleeding was defined as hemorrhage after completion of index ERCP procedure (up to 21 days after the procedure), and manifested by melena, hematemesis, or hematochezia associated with a decrease in hemoglobin level.

Hemodynamic compromise was defined as a decrease in blood pressure and an increase in heart rate requiring bolus intravenous fluid resuscitation and/or the need for hemodynamic support for vasopressor medication with admission to the intensive care unit.

### Endoscopic FCSEMS placement

All FCSEMS were deployed by experienced advanced endoscopists (authors JC, TB, MS, DP) who perform ERCP at our tertiary care referral center where we perform 2000–2500 ERCP procedures per year. The decision to place FCSEMS was at the individual discretion of the endoscopist. All biliary sphincterotomies were performed using the new generation microprocessor-controlled electrosurgical generator (ERBE, ERBE United States). The FCSEMS used at our center were WallFlex Biliary Fully Covered Stents (Boston Scientific, Marlborough, Massachusetts, United States]. The sizes of stents used were either 10 mm × 60 mm, 10 mm × 40 mm or 8 mm × 60 mm. The FCSEMS were removed within 4 to 8 weeks of placement.

### Statistical analysis

Statistical analysis was performed using STATA, version 14.0 (StataCorp, College Station, Texas, United States). Continuous variables were presented as mean ± standard deviation (SD), whereas categorical variables were expressed as proportions and percentages (%). Categorical variables were compared by using chi-square test. $P<0.05$ was considered statistically significant.

## Results

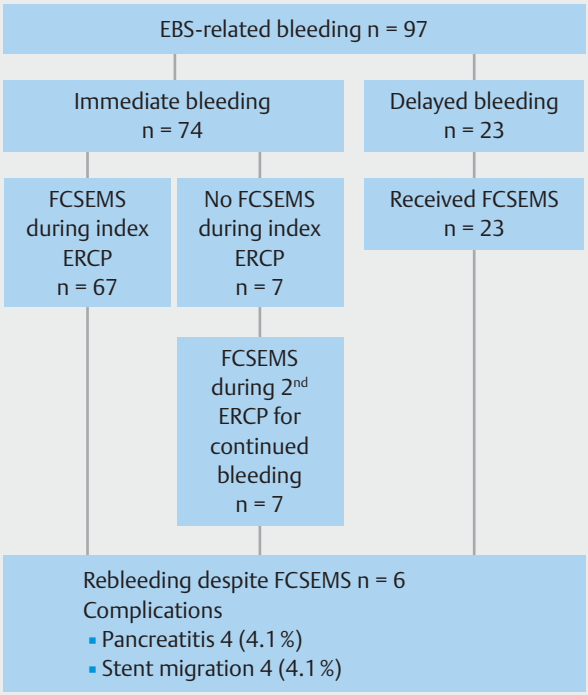
### Demographics

A total of 97 patients with EBS-related bleeding who underwent FCSEMS placement were included (▶ **Fig. 1**). Index ERCP had been performed in the inpatient setting in 77 patients (79.4%) while the remaining 20 patients (20.6%) underwent outpatient ERCP. Average age was 67.2 years (S.D. 16.4) and 51 (52.6%) were female. The most common indication for index ERCP was choledocholithiasis in 59 patients (60.8%), followed by acute cholangitis in 10 (10.3%), malignant biliary obstruction in nine (9.3%), bile leak in six (6.2%), unspecified biliary obstruction in six (6.2%), biliary stricture in three (3.1%), and other in four patients (4.1%) (▶ **Table 1**). Major comorbidities included chronic kidney disease in 12 patients (12.4%), coronary artery disease in 13 (13.4%), congestive heart failure in 12 (12.4%), history of cerebrovascular accident in five (5.2%), and cirrhosis in 10 (10.3%). Mean international normalized ratio (INR) was 1.2 and mean serum platelet count was $209.6\times10^9$/L. 30 patients (30.9%) were on aspirin, two (2.1%) were on antithrombotic medications while 18 patients (18.6%) were on anticoagulation therapy. Aspirin was continued in all patients; however, antithrombotic and anticoagulation medications were held 5 days and 48 hours prior to the procedure, respectively. Patient demographics are summarized in ▶ **Table 2**.

### Procedural information

Immediate EBS-related bleeding occurred in 74 patients (76.3%) while delayed bleeding occurred in 23 patients (23.7%). Periampullary diverticulum was present in 18 patients (18.6%). EBS-related bleeding was described as continued oozing in 70 patients (72.2%), followed by those with adherent clot in 22 (22.7%), other high-risk stigmata in four (4.1%) and pulsatile in one case (1.0%). Hemodynamic compromise occurred in six patients (6.2%).

The most common FCSEMS used was a 10 mm x 60 mm stent in 89 cases (91.7%), 10 mm × 40 mm in three cases (3.1%), and 8 mm × 60 mm in five cases (5.2%). 67 (69%) of patients had FCSEMS placement for immediate EBS-related bleeding, 23 (23.7%) had FCSEMS placement for delayed EBS-related bleeding while seven patients (7.3%) patients had FCSEMS placement as secondary therapy for rebleeding at the time of second ERCP after undergoing endoscopic therapy for immediate EBS-related bleeding on index ERCP. These alternate therapies included: epinephrine injection alone in three cases, bipolar cautery in two cases, and balloon tamponade in two cases.




▶ **Fig. 1** Flowchart showing the study inclusion process.

▶ **Table 1** Indication for index ERCP.

| | Indication | N = 97 (%) |
|---|---|---|
| 1. | Choledocholithiasis/CBD stone | 59 (60.8) |
| 2. | Acute cholangitis | 10 (10.3) |
| 3. | Malignant biliary obstruction | 9 (9.3) |
| 4. | Bile leak | 6 (6.2) |
| 5. | Biliary stricture | 3 (3.1) |
| 6. | Biliary obstruction, not otherwise specified | 6 (6.2) |
| 7. | Other | 4 (4.1) |

ERCP, endoscopic retrograde cholangiopancreatography; CBD, common bile duct

Among all patients who underwent FCSEMS placement, additional endoscopic therapy at the time of FCSEMS placement was performed in 45 patients (46.4%): epinephrine injection in 34 (35.1%), bipolar cautery in six (6.2%), balloon tamponade in two (2.1%) and hemostatic clip in three (3.1%). FCSEMS was used as monotherapy in the remaining 52 patients (53.6%).

### Outcomes

Characteristics of EBS-related bleeding and outcomes in patients who underwent FCSEMS placement are outlined in ▶ **Table 3**. Deployment of FCSEMS was technically successful in all 97 cases (100%). Immediate hemostasis was achieved in all 97 patients (100%). Following FCSEMS placement, rebleeding occurred in six patients (6.2%). Of the six patients with rebleeding

▶ **Table 2** Patient characteristics.

| | N = 97 (%) |
|---|---|
| **Comorbidities** | |
| Chronic kidney disease | 12 (12.4) |
| Coronary artery disease | 13 (13.4) |
| Congestive heart failure | 12 (12.4) |
| Cerebrovascular accidents | 5 (5.2) |
| Cirrhosis | 10 (10.3) |
| INR mean (± SD) | 1.2 (± 0.32) |
| Platelet mean (±SD) | 209.6 (± 86.8) |
| Antithrombotic medications | 2 (2.1 %) |
| Anticoagulation medications | 18 (18.6 %) |
| Aspirin use | 30 (30.9 %) |
| Presence of peri-ampullary diverticulum | 18 (18.6 %) |

INR, international normalized ratio.

▶ **Table 3** Endoscopic biliary sphincterotomy-related bleeding characteristics and management.

| | N = 97 (%) |
|---|---|
| **Timing of bleeding** | |
| ▪ Immediate bleeding | 74 (76.3 %) |
| ▪ Delayed | 23 (23.7 %) |
| Type of bleeding | |
| ▪ Pulsatile | 1 (1.0 %) |
| ▪ Oozing | 70 (72.2 %) |
| ▪ Clot | 22 (22.7 %) |
| ▪ High-risk stigmata | 4 (4.1 %) |
| Hemodynamic compromise | 6 (6.2 %) |
| FCSEMS Technical success | 97/97 (100 %) |
| FCSEMS size diameter x length | |
| ▪ 10 mm × 60 mm | 89 (91.8 %) |
| ▪ 10 mm × 40 mm | 3 (3.1 %) |
| ▪ 8 mm × 60 mm | 5 (5.2 %) |
| Immediate hemostasis with FCSEMS | 97/97 (100 %) |
| Endoscopic therapies in patients who underwent FCSEMS placement as secondary treatment modality on repeat ERCP (n = 7) | |
| ▪ Epinephrine injection alone | 4 |
| ▪ Bipolar cautery | 3 |
| ▪ Balloon tamponade | 2 |

▶ **Table 3** (Continuation)

| | N = 97 (%) |
|---|---|
| **Timing of bleeding** | |
| Additional endoscopic interventions alongside FCSEMS placement | |
| ▪ Epinephrine injection | 34 (35.1 %) |
| ▪ Bipolar cautery | 6 (6.2 %) |
| ▪ Balloon tamponade | 2 (2.1 %) |
| ▪ Endoclip placement | 3 (3.2 %) |
| ▪ FCSEMS as monotherapy | 52 (53.6 %) |
| Hospital stay duration after FCSEMS placement in days – mean (SD) | 3.3 (3.6) |
| Rebleeding after FCSEMS placement | 6/97 (6.2 %) |
| Time to rebleed (N = 6) | |
| ▪ 0 days | 1 |
| ▪ 1 days | 2 |
| ▪ 2 days | 2 |
| ▪ 3 days | 1 |
| Reintervention for rebleeding | |
| ▪ Repeat endoscopy | 3 |
| ▪ Interventional radiology treatment | 2 |
| ▪ Surgery | 1 |
| Complications | |
| ▪ Pancreatitis | 4 (4.1 %) |
| ▪ Migration of stent | 4 (4.1 %) |
| Time to FCSEMS removal in weeks – mean (SD) | 7.7 (9.3) |
| 30-day mortality | 2/97 (2.1 %) |

FCSEMS, fully covered self-expandable metal stent; ERCP, endoscopic retrograde cholangiopancreatography.

following FCSEMS, this occurred the same day in one patient (16.6 %), on post-procedure Day 1 in two patients (33.3 %), on Day 2 in two patients (33.3 %) and on Day 3 in 1 patient (16.6 %). Only one patient who had rebleeding was on aspirin, and none of the other patients were on anticoagulation or antithrombotic therapy. Detailed characteristics of the six patients who had rebleeding are summarized in ▶ **Table 4**. There was no significant difference in rebleeding rates in patients who had FCSEMS placement as monotherapy (9.6 %) versus those who had traditional endoscopic therapies in addition to FCSEMS placement (2.2 %; $P = 0.13$).

The most common intervention for rebleeding following FCSEMS was a repeat upper endoscopy/ERCP in three cases, angiographic embolization with interventional radiology in two cases and surgery in one patient. Of the patients who had repeat endoscopy, one did not have any intervention because bleeding had stopped by the time of repeat endoscopy, while two patients had epinephrine injection for hemostasis.

▶ **Table 4** Characteristics of patients who developed rebleeding.

| | Age | Indication | Comorbid conditions | Platelet count | INR | Anticoagulation or antithrombotic medications | Precut sphincterotomy |
|---|---|---|---|---|---|---|---|
| Patient 1 | 52 | Choledocholithiasis | Coronary artery disease, liver cirrhosis | 49,000 | 2.0 | None | No |
| Patient 2 | 72 | Choledocholithiasis | Coronary artery disease | 244,000 | 1.0 | Aspirin | No |
| Patient 3 | 74 | Malignant biliary obstruction | None | Not available | 1.0 | None | No |
| Patient 4 | 49 | Choledocholithiasis | None | 203,000 | 1.1 | None | Yes |
| Patient 5 | 48 | Choledocholithiasis | Cirrhosis | 70,000 | 1.3 | None | No |
| Patient 6 | 59 | Choledocholithiasis | None | 302,000 | 1.1 | None | No |

INR, international normalized ratio.

### Adverse events

AEs following FCSEMS placement included acute pancreatitis in four patients (4.1 %) and stent migration in four patients (4.1 %). Among patients who developed acute pancreatitis, one patient had pancreatic duct cannulation and pancreatogram during ERCP, while none of the patients had a precut sphincterotomy and all patients received rectal indomethacin. All patients who had stent migration had a 10 mm × 60 mm FCSEMS placed. None of the patients in our cohort developed acute cholecystitis; however, 35 patients (36 %) in our cohort had prior cholecystectomy. The mean time to discharge was 3.3 days (SD 3.6) and mean time to stent removal was 7.7 weeks (SD 9.3). FCSEMS was not removed in seven patients (1 with biliary stricture, 6 with malignant biliary obstruction). Two patients in our cohort had 30-day mortality. None of the deaths were due to EBS-related bleeding. One patient died of sepsis and multiorgan failure with malignant biliary obstruction and one died of acute on chronic liver failure due to cryptogenic liver cirrhosis.

## Discussion

To our knowledge, this is the largest study reporting outcomes in patients treated with FCSEMS for EBS-related bleeding. Previous reports have described improved hemostasis rates with FCSEMS compared to other endoscopic interventions [20–23] While our study did not have a control arm, we observed durable hemostasis in the 94 % of patients undergoing FCSEMS. In addition, seven patients who were not managed with FCSEMS placement at the time of immediate EBS-related bleeding, were successfully managed with FCSEMS on subsequent ERCP. We demonstrated technical success in all patients and clinical success with durable hemostasis was achieved in 94 % of patients. Only six patients had rebleeding after FCSEMS placement.

EBS-related bleeding continues to be a challenging AE of ERCP. Ferreira et al have previously suggested an algorithm for management of EBS-related bleeding [14]. They suggest monotherapy with endoscopic interventions as first-line for managing EBS-related bleeding. These interventions include balloon tamponade, epinephrine injection, thermal cautery or endoclip placement. If bleeding is not controlled with monotherapy, then combination therapy has been suggested. However, this algorithm does not suggest the role of FCSEMS in management of EBS-related bleeding and was published before the widespread availability of FCSEMS. In 2016, Cochrane et al examined the role of FCSEMS in managing EBS-related bleeding after primary endoscopic intervention failure [20]. The study included 67 patients with EBS-related bleeding, out of which 23 patients underwent FCSEMS placement while 44 patients were managed with traditional endoscopic interventions. The authors reported that the FCSEMS treatment group had a lower bleeding rate at 72 hours (0.66 g/dL vs 1.98 g/dL $P<0.001$). Based on their findings, the authors proposed a new algorithm for the management of EBS-related bleeding [20]. The authors suggest that patients with moderate bleeding or those at high-risk of continued bleeding should undergo FCSEMS placement as first-line therapy. In patients with mild bleeding and those at low-risk of continued bleeding, monotherapy with traditional endoscopic modalities should be the first line of therapy. If there is continued bleeding, then FCSEMS should be considered. Our study findings validate the efficacy of FCSEMS in successfully controlling EBS-related bleeding. Furthermore, in over half the patients in our cohort, FCSEMS was used as primary monotherapy for control of EBS-related bleeding. In addition, in sevedn patients who had rebleeding after treatment with traditional endoscopic modalities, FCSEMS placement resulted in successful hemostasis.

They key question that remains is precisely where FCSEMS placement should fit in the management of EBS-related bleeding. In cases of immediate bleeding, FCSEMS will generally allow for a more definitive management at the time of index ERCP and potentially decrease the procedural risks and costs associated with a repeat ERCP in case there is re-bleeding or de-

layed bleeding. A disadvantage of placement of FCSEMS purely for the purpose of hemostasis is that a follow-up ERCP is then required for stent removal. Other concerns with using FCSEMS as primary modality include the cost and potential adverse events associated with FCSEMS placement. Adverse events associated with FCSEMS include pancreatitis, cholecystitis (due to occlusion of the cystic duct), stent migration, perforation or bacteremia [24, 25]. In our report, four patients had pancreatitis and four patients had stent migration. It cannot be ascertained, however, whether the pancreatitis was due to FCSEMS placement or due to other etiologies of post-ERCP pancreatitis. Interestingly, in our study none of the patients developed acute cholecystitis following FCSEMS placement, however, it is important to note that more than one-third of our patients had prior history of cholecystectomy, so this finding is not generalizable. This could also be related to the fact that all procedures were performed with expert advanced endoscopist at a high-volume ERCP center with experienced endoscopy staff or because the majority of our patients underwent ERCP for non-malignant indications, and cholecystitis following FCSEMS placement is more common in patients with biliary stricture where the stent covers the cystic duct at the level of the stricture. Another concern with FCSEMS placement is cost effectiveness. According to one US-based randomized controlled trial, the average cost of ERCP with FCSEMS placement (including all procedural/anesthesia/facility fees) was $22,729 for patients with pancreatic adenocarcinoma [26]. When factoring in the price of index ERCP, FCSEMS placement and adverse events the total was $41,112 [26].

While our study shows that FCSEMS is effective as both a first-line monotherapy for EBS-related bleeding, as well as, for bleeding not controlled by traditional endoscopic methods, given the factors above, we agree with the algorithm suggested by Cochrane et al [20]. In patients with mild bleeding or those at low-risk of continued or delayed bleeding, it is reasonable to try traditional endoscopic interventions (epinephrine injection, balloon tamponade etc) as first-line which will prevent the need for repeat ERCP and will be more cost effective, but in patients with moderate to severe bleeding or those at high-risk of continued bleeding (patients on anti-coagulation/thrombotic medications, patients with cirrhosis, renal dysfunction, thrombocytopenia or coagulopathy), FCSEMS placement should be considered as first-line therapy.

Our study had several limitations. This was a single center retrospective study with no control group. Moreover, all ERCPs were performed by expert advanced endoscopists at a busy ERCP referral center so the results might not be generalizable. Also, decision to place FCSEMS was based on the discretion of the endoscopist and hence there might not be consistency in utilizing FCSEMS for similar type and severity of bleeding, as well as what time criteria each endoscopist used to determine persistent bleeding. However, previous reports have shown that the pattern of bleeding post EBS do not predict the risk of delayed bleeding [27]. Finally, almost half of the patients in our study had additional endoscopic interventions performed for hemostasis alongside FCSEMS placement, so that might have an impact on reducing re-bleeding rates. However, in the remaining half of patients who had FCSEMS placement as monotherapy, there was no difference in re-bleeding rates.

## Conclusions

Despite these limitations, our study is the largest to date evaluating the efficacy and safety of FCSEMS in management of EBS-related bleeding. While FCSEMS is often used for this indication in clinical practice, our study provides much needed large data to validate including FCSEMS placement in the management algorithm for EBS-related bleeding. Moreover, the placement of FCSEMS in the hands of expert endoscopist has a low rate of adverse events. However, given the paucity of literature, our findings need to be validated through multicenter prospective trials.

## Competing interests

Dr. Cohen is a consultant for Boston Scientific. Dr. Berzin is a consultant for Boston Scientific, Medtronic, and Fuji. Dr. Pleskow is a consultant for Boston Scientific, Medtronic, Olympus, and Fuji.

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