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DDW Highlights: Endoscopic ultrasonography

T. B. Gardner

Section of Gastroenterology and Hepatology, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, USA

Introduction

The 2012 Digestive Disease Week (DDW; 19–22 May 2012, San Diego, California, USA) featured exciting research from the field of endoscopic ultrasonography (EUS). The research highlights continued to focus on tissue acquisition and interventional EUS. Although overall there were fewer novel EUS applications presented, the quality of research, as evidenced by more prospective randomized trials, was generally higher than in previous years. In this review, the top 20 EUS abstracts from DDW 2012 are identified and key aspects are discussed.

Tissue sampling and staging

EUS-based tissue sampling continued to be a major focus of interest at DDW 2012. With the advent of different needle platforms such as the ProCore (Cook Medical Inc., Bloomington, Indiana, USA) and classic sampling needles (Expect; Boston Scientific, Inc., Natick, Massachusetts, USA), there continued to be several studies evaluating various-sized needles for sampling pancreaticobiliary, mediastinal, and rectal malignancies. Although, none of these studies was particularly novel, some practical insights were gained on basic EUS technique. For example, Wani et al. presented a prospective single-blinded randomized trial evaluating the diagnostic yield of malignancy during EUS-guided fine-needle aspiration (EUS-FNA) of solid lesions with and without a stylet [1]. The primary aims of the study were the diagnostic yield of malignancy, and the degree of cellularity, specimen adequacy, contamination, and amount of blood. Over the course of 11 months, all patients ($n = 100$) who were referred to the center for EUS-FNA of solid lesions were assigned to receive an equal number of needle passes in a randomized sequence with and without a stylet. The sites for EUS-FNA were: pancreas ($n = 58$), lymph node ($n = 25$), liver/adrenal/subepithelial lesions/others ($n = 17$). Overall diagnosis was malignancy ($n = 56$), benign ($n = 30$), suspicious/atypical ($n = 7$), and inadequate specimen ($n = 7$) lesions. There were 550 total passes made; 275 each with and without a stylet. There was no difference between the two groups in diagnostic yield of malignancy (34.2% vs. 40.0%; $P = 0.2$), proportion of inadequate specimens (20.7% vs. 23.3%; $P = 0.2$), cellularity ($P = 0.83$), contamination ($P = 0.31$), number of cells ($P = 0.25$), and amount of blood ($P = 0.6$). Similar results were noted in a subgroup analysis based on lesion site (pancreas, lymph node, others). The authors concluded that there was no difference in the diagnostic yield of malignancy, proportion of

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Corresponding author: T. B. Gardner, MD, Pancreatic Disorders, Dartmouth-Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03756, Fax: +1-603-650-5225, timothy.b.gardner@hitchcock.org.

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inadequate specimens or characteristics of samples using validated criteria between passes with and without a stylet and that the use of a stylet does not confer any advantage during EUS–FNA.

A revealing study was performed to evaluate the role of linear vs. radial EUS for detecting pancreatic lesions by performing tandem EUS in prospectively screened asymptomatic high-risk individuals (HRIs) as part of the American Cancer of the Pancreas Screening (CAPS 3) Consortium study [2]. EUS was performed by expert endosonographers. A total of 54 HRIs had only one radial or linear EUS, and 224 HRIs had tandem radial and linear EUS in a randomized order. Using a per-patient analysis, the prevalence of >1 pancreatic lesions was 43.2% (120/278). In HRIs who had one EUS exam, linear EUS detected more pancreatic lesions than radial EUS (65.4% vs. 39.5%; $P = 0.01$). In those who had two EUS exams in tandem, 16/224 (7.1%) HRIs had lesions missed during the initial EUS. Of these 16 HRIs with missed lesions, 11 (9.8%) had radial followed by linear (radial/linear) EUS and 5 (4.5%) had linear followed by radial (linear/radial) EUS ($P = 0.03$). In HRIs who had tandem radial/linear EUS, the first radial EUS yielded 73/109 lesions (67.0%) and the second linear EUS yielded an additional 36 lesions. In the linear/radial group, the first linear EUS detected 99/120 lesions (82.5%) and the second radial EUS yielded an additional 21 lesions. Hence, the incremental detection rate for a pancreatic lesions during a second examination with linear EUS was significantly higher than that for radial EUS (33.0% vs. 17.5%; $P = 0.007$). The authors concluded that linear EUS detected more pancreatic lesions than radial EUS and that there was a “second-pass effect” with additional lesions detected with the second examination for both radial and linear EUS.

A representative study evaluating the optimal tissue acquisition technique for the ProCore needle was reported [3]. Fine-needle biopsy (FNB) using the 22-G ProCore needle was performed on fresh porcine pancreas ex vivo using three techniques: 1) stylet rapidly removed before 30 seconds of half suction (5 mL) was applied followed by five to-and-fro thrusts of the needle before withdrawal; 2) similar to the first technique but with full suction (10 mL) being applied; and 3) capillary aspiration without suction, whereby the stylet was slowly removed over 40 seconds as the needle was moved to-and-fro. Three expert endoscopists performed two FNBs using each of the three techniques. Specimens were recovered and fixed in formalin. A single expert pancreatic pathologist who was blinded to the FNB method used scored each specimen on size and number of tissue fragments. The authors found that the capillary FNB method provided significantly higher tissue adequacy scores compared with half or full suction methods, with this improved yield primarily due to increased number of tissue fragments obtained with each pass.

One area of tissue sampling that has previously not received a great deal of attention has been the diagnosis of intra-abdominal lymph nodes; specifically, the role of EUS–FNA to evaluate intra-abdominal lymphadenopathy has not been well-defined. Pausawasdi et al. performed a retrospective, single-center evaluation of patients evaluated for isolated intra-abdominal lymphadenopathy (LAD) of unknown cause [4]. Patients with undiagnosed intra-abdominal LAD who underwent EUS–FNA from 2003–2010 were identified using the Center’s EUS database, with EUS–FNA having been performed using a 22-G needle. A total of 36 patients (mean age 51.5 years; 64% male) were included in the study, and the final diagnoses based on the cytopathology, histology, immunohistochemistry, and/or clinical response to treatment included metastatic malignancy ($n = 13$), lymphoma ($n = 8$), tuberculosis ($n = 8$), reactive change ($n = 6$), and amyloidosis ($n = 1$). EUS–FNA provided adequate specimens in 34 patients (94%), and cytopathological diagnosis could be made in all patients. The overall sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of EUS–FNA were 86.7%, 83.3%, 96.3%, and 55.6%, respectively (area under the receiver-operating characteristic curve = 0.850). The diagnostic accuracy for

lymphoma was 100% based on cytology and immunohistochemistry results. The authors concluded that EUS–FNA provides a high diagnostic accuracy of undiagnosed intra-abdominal LAD, particularly in lymphoma and tuberculosis.

Focusing attention on omental masses, Rao et al. reported a single-center experience comparing EUS–FNA with noninvasive imaging (computed tomography [CT] or magnetic resonance imaging [MRI]) for the detection of metastases in patients with omental thickening [5]. In a selected cohort of patients who underwent EUS with FNA of omental thickening, the authors compared the detection rate of metastases by noninvasive imaging with that by EUS to determine the impact on resectability status. A total of 59 patients underwent EUS with omental FNA for cancer staging (n = 50) or restaging (n = 9) between June 2006 and October 2011. Primary sites of malignancy included pancreas (n = 38), bile duct (n = 8), gallbladder (n = 2), stomach (n = 1), and duodenum (n = 1). All patients underwent pre-EUS noninvasive imaging with either CT (n = 57) or MRI (n = 2). The test characteristics for CT and EUS, respectively, to detect omental metastases in all malignancies was as follows: sensitivity 29% vs. 100%, specificity 87% vs. 67%, PPV 86% vs. 89%, NPV 31% vs. 100%. Positive omental EUS–FNA cytology converted 8 out of 10 patients (80%) undergoing initial staging from resectable to unresectable disease. The authors concluded that EUS with FNA is a safe modality for the detection of omental metastases that may be missed by noninvasive imaging alone, thereby significantly impacting the clinical staging and management.

Contrast-enhanced harmonic EUS

Enhanced EUS imaging techniques to better identify malignant and nonmalignant diseases were again highlighted at this year's DDW, with the most focus on contrast-enhanced harmonic EUS (CEH–EUS). There were not as many reports presented on endoscopic elastography as at past DDW meetings, although an important abstract comparing elastography and CEH–EUS was presented (see below).

Fukasawa et al. reported their prospective study, which aimed to evaluate the value of software-aided quantitative analysis of CEH–EUS for diagnosis of pancreatic solid lesions [6]. A total of 94 patients presenting with solid pancreatic lesions were prospectively enrolled and all patients had conventional B mode and CEH–EUS with a second-generation contrast agent. Time-intensity curves (TIC) were obtained for all examinations in two regions of interest (ROI) within the lesion and within the normal pancreatic tissue. Images were processed using DAS-RS1 software (Aloka System Engineering, Tokyo, Japan), and the following parameters were obtained: baseline intensity, maximum intensity, intensity at 1 minute, and time-to-peak. Histological analysis revealed 55 pancreatic ductal adenocarcinomas (PDACs), 15 autoimmune pancreatitis (AIP), 11 chronic pancreatitis, and 13 pancreatic neuroendocrine tumors (PNETs). The peak ratio of the lesion to the normal tissue was significantly lower in PDACs (0.60 ± 0.24) and higher in PNETs (1.20 ± 0.22) compared with AIP (0.97 ± 0.13) and chronic pancreatitis (0.96 ± 0.04) ($P < 0.01$). The sensitivity, specificity, PPV, NPV, and accuracy of the low peak ratio for diagnosing PDAC were 91%, 95%, 96%, 88%, and 92%. The authors concluded that in most cases of PDAC, CEH–EUS exhibits hypoperfusion pattern compared with the adjacent normal pancreatic tissue, whereas AIP/chronic pancreatitis exhibits iso-perfusion and PNET exhibits a hyper-perfusion pattern.

Iglesias-Garcia et al. compared CEH–EUS and quantitative-elastography endoscopic ultrasound (QE–EUS) for their ability to differentiate between benign and malignant pancreatic lesions [7]. The study evaluated 62 consecutive patients who underwent both

CEH-EUS and QE-EUS, with the final diagnosis based on surgical histopathology or imaging assessment and clinical follow-up.

The final diagnoses were pancreatic adenocarcinoma (n = 47), neuroendocrine tumor (NET) (n = 3), inflammatory mass of chronic pancreatitis (n = 10), pancreatic metastasis (n = 1), and autoimmune pancreatitis (n = 1). The overall diagnostic accuracy of QE-EUS was superior to CEH-EUS based on sensitivity (96% vs. 90%), specificity (91% vs. 82%), and accuracy (95% vs. 89%). The authors concluded that the diagnostic accuracy of QE-EUS in pancreatic masses is superior to CEH-EUS and furthermore, that the addition of CEH-EUS does not significantly increase the diagnostic accuracy of QE-EUS.

Interventional EUS

Interventional EUS remains one of the major areas of focus for new research, and this year's DDW featured many exciting new developments in the field. One of the compelling abstracts was an interim analysis of a prospective randomized trial comparing EUS-guided transgastric ureteral internal drainage vs. percutaneous nephrostomy in patients with advanced bladder cancer and renal failure [8]. The authors aimed to compare the safety and effectiveness of EUS-guided antegrade double-pigtail stent placement and percutaneous nephrostomy in patients in whom previous retrograde stent placement had failed. Between March 2008 and October 2011, 21 patients with advanced bladder cancer and dilated left ureter were selected for the study. EUS-guided access and drainage was attempted in 10 cases, with successful drainage being achieved in nine. Percutaneous nephrostomy with antegrade placement of pigtail stents was attempted in nine cases, with a successful stent placement in seven (78%). There was no significant difference in the diameter of the ureter pre-procedure, duration of the procedure, and postprocedure creatinine levels, and there were more complications in the percutaneous group. The authors concluded that given both techniques showed similar success rates with low complications, EUS-guided transgastric antegrade ureteral stenting was an effective alternative to percutaneous drainage.

Another exciting investigational trial featuring a novel application of interventional EUS was a prospective multicenter study evaluating EUS-guided therapy of gastric varices [9]. Under the hypothesis that EUS-guided injection into the feeding gastric veins may offer some benefits over cyanoacrylate (CYA) injection (such as independence of the endoscopic view, lower volume of glue, possibly lower risk of complications, avoidance of gastric wall injection, and visualization of successful thrombosis), the authors aimed to determine the feasibility, safety, and efficacy of EUS-guided therapy of gastric varices using CYA injection or coil deployment. Between May 2005 and September 2011, 35 patients entered the multicenter study and were randomized to either the coil group (if there was EUS accessibility of the feeding vessel) or to the EUS-guided CYA group.

Initial gastric variceal obliteration was achieved in 34/35 patients (97%). Coil deployment required fewer sessions for obliteration (n = 19) when compared with CYA (n = 37), although CYA injection was technically less demanding. Nine out of 35 patients (26%) experienced severe complications. Patients in the coil group experienced significantly fewer complications (n = 2: one gastric varices recurrent bleeding, successfully treated with CYA, one esophageal variceal bleeding) compared with incidents in the CYA group (n = 7: six asymptomatic pulmonary glue embolisms, one esophageal variceal bleeding). The authors concluded that EUS-guided therapy for gastric varices using CYA injection or coil deployment seems to be effective. Coil deployment, although only thought to be easily achievable in 37% of patients, required fewer endoscopies and had significantly fewer complications when compared with CYA injection.

Another novel EUS application, using an EUS-guided radiofrequency ablation (RFA) probe to ablate both lymph nodes and the pancreas, was evaluated in two porcine feasibility studies [10,11]. In the first study, which evaluated lymph nodes [10], EUS-guided RFA of targeted mediastinal lymph nodes was performed in six pigs using a 19-G needle and an EUS-adapted probe (EUS RFA; EMcision, London, UK), which was inserted through the core of the needle. RFA was performed with the ERBE Vario generator (ERBE, Tuttingen, Germany) with bipolar settings of 10 watts, effect 2 for 2 minutes. During the procedure, echogenic visualization of the probe was possible in all six cases. Echogenic tissue effect during RFA was seen in 3/6 procedures. No evidence of ablation effect in the surrounding tissue or at the needle puncture site was seen on gross examination and a direct correlation was seen between probe length and length and diameter of necrosis. In the pancreas ablation study [11], five Yucatan pigs underwent EUS-guided RFA of the head of the pancreas using an EUS needle. RFA was applied with 6 mm of the probe exposed at 4 watts for 5 minutes, 5 watts for 0.9 minutes, and 6 watts for 0.2 minutes. Then, with 10 mm of the probe exposed in the pancreas, RFA was performed at 4 watts for 4.3 minutes, 5 watts for 1.4 minutes, and 6 watts for 0.8 minutes. At autopsy, only one pig showed moderate levels of pancreatitis, with involvement of 20% of the proximal pancreatic tissue. The other animals showed much lower areas of tissue damage. The authors concluded that EUS-guided RFA of the pancreatic head with the monopolar probe through a 19-G needle was well tolerated with a minimal amount of pancreatitis.

An important abstract on interventional EUS complications was presented by Tarantino et al. who performed a prospective multicenter evaluation of complications from interventional EUS procedures [12]. They reported that 1118 patients underwent interventional EUS procedures: 1044 FNA (214 on cystic lesions), 43 celiac plexus neurolysis (CPN), 23 pseudocyst drainage, and 8 biliary drainage. The overall complication rate was 1.9%. Complications were: seven fever, four diarrhea (all in CPN), three intracystic hemorrhages, three mild pancreatitis (all in FNA), two gastric bleeding (both in FNA), one epigastric pain (in FNA), and one desaturation. This study represents the first prospective multicenter assessment of complication rates after interventional EUS procedures and confirms their overall general safety when performed by expert hands.

EUS-guided pancreaticobiliary access

EUS-guided pancreaticobiliary access, as at past DDWs, continues to be an area of intense interest. One highlight was the reporting of a randomized prospective trial evaluating EUS-guided choledochoduodenostomy vs. surgical drainage in patients with unresectable malignant biliary obstruction [13]. The authors enrolled 20 patients with distal malignant biliary obstruction from May 2009 to October 2011. All patients had a previously failed endoscopic retrograde cholangiopancreatography (ERCP) and were randomized to undergo either placement of a metal biliary stent at EUS (Group I) or hepaticojejunostomy with or without gastrojejunostomy (Group II). There was no significant difference in the technical and clinical outcomes in the two groups. Cost analysis demonstrated a significantly increased cost per patient in the surgical group (\$9878 vs. \$6238; $P = 0.039$) with higher complications ($P = 0.041$). There was one case of self-limiting bleeding in Group I and one case each of wound abscess, abdominal abscess, internal fistula, and pneumonia in Group II.

Another study evaluated the efficacy, morbidity, and costs of EUS-guided biliary rendezvous techniques by comparing the intra- and extrahepatic routes [14]. A total of 35 patients were analyzed (17 intrahepatic, 18 extrahepatic). There was no difference in the technical success among the two groups. However, the intrahepatic group had a higher incidence of postprocedure pain, bile leak, and air under the diaphragm ($P = 0.045$). All of the bile leaks were small and were managed conservatively. The authors concluded that

EUS-guided rendezvous procedures had similar success rates by the intrahepatic or extrahepatic routes, but the intrahepatic route had significantly higher postprocedure pain, bile leak, and duration of hospitalization. The authors recommended that the extrahepatic route should be preferred for EUS rendezvous procedures in patients with distal common bile duct obstruction.

The effectiveness of combining EUS with ERCP as a means of reducing ERCP-related complications in pregnant patients with suspected choledocholithiasis was the subject of another exciting abstract [15]. Patients at a single center underwent EUS and only those patients with confirmed choledocholithiasis subsequently underwent ERCP with sphincterotomy and stone extraction. A total of 10 pregnant women were included in the study, with the mean gestational age of 24 weeks. Four patients had no evidence of stones at EUS and were managed conservatively (no ERCP) with uneventful outcomes. Five patients with choledocholithiasis and one patient with a pancreatic duct stone at EUS went on to same-session ERCP. In 4/5 patients, the number of stones extracted matched the number of stones seen at EUS. No fluoroscopy was used in five patients, and a 1-second fluoroscopic image without radiograph was required in the patient with a pancreatic duct stone to confirm wire position prior to stent insertion. The average endoscopy time was 43 minutes for the ERCP group compared with 11 minutes for the EUS group ($P < 0.01$). There were no complications in any of the cases. The authors concluded that EUS prior to ERCP eliminated the need for ERCP and its attendant risks in 4 of 10 pregnant patients with suspected choledocholithiasis and recommended that when available, same-session EUS should precede ERCP.

Lutzak et al. presented an abstract of their experience with EUS rendezvous procedures of the pancreatic duct [16]. Results were reported for 19 patients with a history of pancreatitis and an obstructed pancreatic duct in whom pancreatic duct cannulation had failed on initial ERCP and who went on to have EUS-guided rendezvous ERCP over a 3-year period (2009–2011). Pancreatic duct access via EUS with both contrast and wire was successfully achieved in 16 of 19 patients. Completion of the rendezvous procedure with ERCP access to the pancreatic duct occurred in 5 of the 19 patients. Causes for failure included inability to direct the wire past downstream strictures and complete ductal obstruction. Pancreatic duct size did not seem to influence successful wire advancement. Complications were limited to a single patient who developed a retroperitoneal hematoma and a self-limiting leak from the pancreatic duct. The authors concluded that EUS-guided rendezvous for ERCP intervention in the pancreatic duct can be achieved safely and successfully, although further innovations in echoendoscopes and guide wires would likely allow current difficulties with wire advancement to be overcome.

Pancreatic cyst lesions

Although there were not as many abstracts on EUS management of pancreatic cystic lesions presented at this year's DDW, there were some of importance. The clinical dilemma of the incidental pancreatic cyst continues to receive a great deal of attention. Lee et al. evaluated the outcomes and costs in 60 consecutive patients referred for EUS evaluation of an incidental pancreatic cyst [17]. Of the 60 patients referred, 53 cysts (88.3%) were found incidentally on abdominal CT, 1.7% on chest CT, 5% on MRI, and 5% on transabdominal ultrasound. Overall, 71.7% of patients had greater than one imaging test before EUS, with a mean of 2.8 tests per patient (range 1–9). EUS–FNA cytology was obtained in 71.7% of patients: 8 nondiagnostic, 23 negative, 5 suspicious for mucinous neoplasm, 3 neuroendocrine tumor, and 1 adenocarcinoma. Of the 60 patients, 11 patients eventually underwent surgery, 40 patients were followed with surveillance imaging, 6 were recommended for no follow-up, 3 were lost to follow-up, and 2 had infections, which were

treated with antibiotics. Only 16 patients (26.7%) had a definitive diagnosis by cytology or surgical pathology. Importantly, the mean cost of evaluation per person for an incidental pancreatic cyst was \$17 606 (range \$11 669–\$32 457).

A study to evaluate the long-term treatment response in patients with incidental pancreatic cysts treated with EUS-guided ethanol ablation found the procedure to be safe, with 40% of patients having complete resolution after 12 months [18]. A total of 37 patients were enrolled and after the procedure three patients had fever without documented bacteremia, 6 patients had mild abdominal pains, and only 2 patients had mild pancreatitis. Presumed diagnoses were mucinous cystic neoplasm in 2 patients, intraductal papillary mucinous neoplasm (IPMN) in 2 patients, pseudocyst in 2 patients, serous cystadenoma in 10 patients, and indeterminate cyst in 21 patients.

A cost-effectiveness analysis, comparing management of incidental pancreatic cystic neoplasm (PCN) guided by molecular analysis vs. carcino-embryonic antigen (CEA) and cyst fluid cytology was reported by Das et al. [19]. Using a third-party-payer perspective Markov decision analysis model, four mutually exclusive strategies were examined: I) natural history of PCN was followed without any intervention; II) an aggressive surgical approach was considered; all patients were considered for resection without initial EUS-based evaluation; III) EUS-FNA for cyst fluid analysis with cytology/CEA estimation was performed, and only patients with mucinous cysts (CEA >192 ng/mL) were considered for resection; IV) risk-stratification was performed with molecular analysis using the PathFinderTG assay. In baseline analysis, strategy IV was the dominant strategy, yielded the highest quality-adjusted life-years, and was also the cheapest intervention.

Miscellaneous

Finally, and very importantly, the issue of minimal competence for training in EUS was addressed in an abstract of a study that was designed to measure competence and define learning curves in EUS among advanced endoscopy trainees (AETs) [20]. In this prospective multicenter study, AETs with no prior experience in EUS were supervised by expert endosonographers. AETs were evaluated by supervising endosonographers at the 25th and for every subsequent 10 upper EUS examinations, during a 12-month training period. A standardized data collection form was used to grade EUS examination of anatomic stations, and when applicable, lesions of interest, accurate uTNM staging, wall layer origin of subepithelial lesions, and technical success with FNA. A 5-point scoring system was used: 1 – no assistance needed; 2 – one verbal instruction needed; 3 – multiple verbal instructions needed; 4 – hands-on assistance needed; and 5 – unable to achieve. Competency was defined by a sum average score of 1. Cumulative sum (CUSUM) analysis, a statistical process control chart that displays the performance of a series of consecutive observations, was applied to produce a learning curve for each trainee not only for overall performance using the median score across stations, but also for each station. Acceptable and unacceptable failure rates of 10% and 20%, respectively, were used. Competency was also assessed by the number of cases required to achieve three consecutive scores of 1 for all stations. Four AETs from three centers were included with a total of 1138 EUS exams. Overall, learning curves demonstrated substantial variability: 1 AET crossed the threshold for acceptable performance at the 24th evaluation (case no 255); two AETs showed a trend towards acceptable performance after 225 and 196 cases but needed ongoing observation; and 1 AET demonstrated need for ongoing training and observation after 402 cases. These pilot data suggest substantial variability in the achievement of competency and a consistent need for more supervision than the 150 cases currently recommended in guidelines issued by the American Society for Gastrointestinal Endoscopy. Future studies should focus on standardization of trainee performance and definition of competency.

Conclusion

This year's DDW featured exciting new research, focusing in particular on the interventional aspects of EUS and continued refinements of EUS pancreaticobiliary access. Looking forward, I would expect further refinements to existing indications and expansion of therapeutic applications in the coming years.

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