

# Questionable benefit of being in hospital after procedure for patients without immediate adverse events in EUS-guided drainage of pancreatic pseudocysts

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## Abstract

**Introduction:** There is no consensus about if patients with EUS-guided drainage (EUS-GD) of pancreatic pseudocyst (PPC) could be discharged the same day or if the patient must stay at least one night in hospital. The aim was to report adverse events rate in the first 24 h after the procedure of patients with PPC treated by EUS-GD. **Materials and Methods:** A retrospective analysis of data obtained prospectively was conducted. Patients with PPC were included in the study. EUS-GD was using two double pigtail plastic stents (7F and 4 cm). **Results:** A total of 31 procedures in 29 patients with PPC were analyzed. There were 16 (55.2%) men with a mean  $\pm$  SD age of  $42.5 \pm 14.5$  years. The endoscopic drainage was performed through transgastric in 23/29 (79.3%) patients and transduodenal in 6/29 (17.2%) patients. Technical success was 100%, clinical success was 27/29 (93.1%), and three (10.3%) patients had recurrence. In total, 5/31 (16.1%) procedures have adverse events. One patient had stent migration after 24-month follow-up, two patients had infection of PPC after the punctuation (at day 4 and 5 after procedure), and two patients who bled during endoscopic drainage (one of them was successfully treated endoscopically with clips and the second required surgery). **Conclusion:** There is not a clear reason because patients with PPC and EUS-GD need for staying one night in hospital if was not any adverse event during the procedure.

**Key words:** México. EUS-guided drainage. Pancreatic pseudocyst.

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Fecha de recepción: 01-09-2018

Fecha de aceptación: 20-11-2018

DOI: 10.24875/END.M19000001

Disponible en internet: 05-02-2019

Endoscopia. 2019;31:34-39

www.endoscopia-ameg.com

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## Beneficio cuestionable de estar en el hospital después del procedimiento para pacientes sin eventos adversos inmediatos en el drenaje guiado por USE de pseudoquistes pancreáticos

### Resumen

**Introducción:** No hay consenso acerca de si los pacientes con pseudoquiste pancreático (PQP) con drenaje guiado por EUS (EUS-GD) podrían ser dados de alta el mismo día o si el paciente debe permanecer al menos una noche en el hospital. El objetivo fue informar la tasa de eventos adversos en las primeras 24 horas después del procedimiento.

**Material y métodos:** Se realizó un análisis retrospectivo de datos obtenidos prospectivamente. Se incluyeron pacientes con PQP. Los EUS-GD utilizaron dos endoprótesis de plástico de doble cola de cochino (7F X 4 cm). **Resultados:** se analizaron un total de 31 procedimientos en 29 pacientes con PQP. Se incluyeron 16 (55.2%) hombres con una media  $\pm$  DE de edad  $42.5 \pm 14.5$  años. El drenaje se realizó por vía transgástrica en 23/29 pacientes (79,3%) y transduodenal en 6/29 pacientes (17,2%). El éxito técnico fue del 100%, el éxito clínico fue de 27/29 (93,1%) y 3 (10,3%) pacientes tuvieron recurrencia. En total, 5/31 (16.1%) procedimientos tuvieron eventos adversos. Un paciente tuvo una migración del stent después de 24 meses de seguimiento, dos pacientes tuvieron una infección del PQP después de la punción (en los días 4 y 5 después del procedimiento) y dos pacientes con hemorragia durante el drenaje endoscópico (uno de ellos se trató con éxito con endoscopia con clips y el segundo requirió cirugía). En **conclusión**, no hay una razón clara por la cual los pacientes con EUS-GD de PQP necesitan quedarse hospitalizados si no hubo ningún evento adverso durante el procedimiento.

**Palabras clave:** México. Drenaje guiado por ultrasonido endoscópico. Pseudoquiste pancreático.

### Introduction

Endoscopic ultrasound-guided drainage (EUS-GD) is replacing surgical treatment of pancreatic pseudocysts (PPC)<sup>1</sup> regardless that now there is agreement that endoscopic treatment must be the first line therapy for PPC<sup>2-5</sup>, there are some unanswered questions. There is no consensus about if patients with EUS-GD of PPC could be discharged the same day or if the patient must stay at least one night in hospital. Many endosonographers leave patients in hospital, regardless, they are asymptomatic after procedure and others prefer to discharge the patient the same day of the procedure. In an email survey made by one of the authors (free-trade agreements [FTA]) with six top endosonographers around the world (France, the United States, Canada, and Brazil), four of six endosonographers prefer to discharge the patient to home the day after the procedure, regardless, they are asymptomatic. Two of the endosonographers consulted also recommend that antibiotics should be given up to 7 days after drainage. This is an important topic because space in the third level hospitals and costs. The aim was to report adverse events rate in the first 24 h after procedure of patients with PPC treated by EUS-GD with focus in the question about if to stay for one night in hospital could represent some benefit to patients.

### Materials and methods

A retrospective analysis of data obtained prospectively was conducted. Patients were seen from 2008 to

2014 at the National Institute of Medical Sciences and Nutrition Salvador Zubirán at Mexico City, Mexico. PPC was defined as a fluid collection in the pancreatic/peripancreatic area that had a well-defined wall and contained no solid debris or recognizable parenchymal necrosis<sup>6</sup>. All patients gave their written informed consent before the procedure and all were evaluated routinely with a contrast-enhanced computed tomography (CT) scan before the procedure. Patients were intubated and received prophylactic antibiotics before the procedure (1 g I.V. of ceftazidime 30 min before). A convex linear array echoendoscope was used and once the PPC was identified, it was accessed using a 19-gauge needle (Echo-Tip, Wilson-Cook Medical, Inc., Winston Salem, North Carolina, USA) and a 0.035-inch guidewire was inserted through the needle into the pseudocyst with fluoroscopic guidance. After removal of the needle, we used a needle knife inserted over the guidewire to create a bigger fistula. Finally, the gastric wall was dilated up to 12-15 mm and two double pigtail plastic stents (7F and 4 cm) were deployed for drainage. The procedure was performed in both inpatients and outpatients. In those outpatients, they were observed at least every 4 h and discharged once they were awake and asymptomatic. Decision about if one particular patient was discharged the same day of procedure or if the patient stayed one night in hospital was based on criteria of the treating physician.

We consider complications as follows: perforation was diagnosed when pneumoperitoneum was evident

on imaging studies associated with peritoneal signs. Bleeding was defined as any hemorrhagic event that required endotherapy, blood product transfusion, or inpatient observation. Infection was considered if any septic event occurred after the initial endoscopic drainage and was caused by contamination of PPC, proven by new-onset fever, positive blood cultures, or by positive fluid cultures obtained at endoscopic revision<sup>5,7</sup>. Stent migration was defined as the need to retrieve a stent from within the pseudocyst or the enteral lumen<sup>8</sup>. 8 weeks after the drainage, an endoscopic retrograde pancreatography or magnetic resonance cholangiopancreatography was performed. Partial ductal disruption was defined as extravasation of contrast from the main pancreatic duct (MPD) with opacification of PD proximal to the disruption<sup>9,10</sup>. An abrupt cutoff of MPD with or without contrast extravasation, or an inability to traverse this disconnection with a guidewire, was diagnostic of disconnected pancreatic duct syndrome<sup>11</sup>.

Clinical success was defined as complete resolution or a decrease in size of the PPC to 2 cm or smaller on CT associated with the resolution of symptoms at the 8-week outpatient follow-up evaluation<sup>2</sup>. Recurrence was defined as PPC found on CT associated with symptoms after an initial resolution<sup>2</sup>. Reintervention was defined as the need for repeat surgery or endoscopy due to persistent symptoms in association with a residual pseudocyst that was not <50% of the original size on follow-up imaging<sup>2</sup>.

### Statistical analysis

Continuous variables were expressed as means and SD. Categorical data were expressed as absolute numbers and percentages. Differences between groups were analyzed for categorical variables with the Chi-square test, except where the frequency was <5, in which Fisher's exact test was used. For continuous variables, analysis with Mann-Whitney *U*-test was done. We considered  $p < 0.05$  as statistically significant. Statistical analysis was performed with SPSS version 20.0 for Mac (SPSS Inc., Chicago, EEUU).

### Results

A total of 31 procedures in 29 patients with PPC were analyzed. There were 16 (55.2%) men and 13 (44.8%) women with a mean  $\pm$  SD age of  $42.5 \pm 14.5$  years. Gallstones were the most common etiology of pancreatitis with 15/29 (51.7%) cases. The average diameter of

**Table 1.** Baseline clinical characteristics of patients included in the study

Characteristic	n = 29 (%)
Male	16 (55.2)
Age, years	42.5 $\pm$ 14.5
BMI	24.2 $\pm$ 4.1
Comorbidities	16 (55.2)
Cause of pancreatitis	
Gallstones	15 (51.7)
Alcohol	6 (20.7)
Hypertriglyceridemia	2 (6.9)
Idiopathic	1 (3.4)
Unspecified	5 (17.2)

BMI: body mass index calculated by dividing the patient's body weight by the square of their height expressed as kg/m<sup>2</sup>, PPC: pancreatic pseudocyst.

PPC was 9.6 cm (range 4.5-33 cm). Table 1 summarizes the baseline clinical characteristics of patients.

The endoscopic drainage with EUS guidance was performed through transgastric in 23/29 (79.3%) patients and transduodenal in 6/29 (17.2%) patients. The mean number of stents used was 2 (1-4). 12 (41.3%) patients required a nasocystic catheter because of infected PPC. In one patient, a metallic stent was used. The location of PPC in the 29 patients was the pancreatic body in 9 (31%), body-tail in 8 (27.6%), head in 5 (17.2%), tail in 2 (6.9%), uncinate region in 2 (6.9%), and head-body in 2 (6.9%). In one patient, PPC location was not specified. Technical success was 100%, clinical success was 27/29 (93.1%), and three (10.3%) patients had recurrence. In total, 5/31 (16.1%) procedures have adverse events (Table 2).

### STENT MIGRATION

One patient had stent migration after 24-month follow-up; in this case, PPC resolved, and in CT, one stent was detected in the small bowel at ileum. Due to intermittent abdominal pain, a double-balloon enteroscopy was performed; this found the stent 30 cm from the ileocecal valve and enabled retrieval of them with a polypectomy loop, with improvement on follow-up.

### INFECTION

The first patient was a male of 36 years old with PPC of 15 cm in the head of the pancreas who back to the emergency department because chills and fever at day

**Table 2.** Patients with adverse events related to EUS-GD of PPC

Patient	Sex/age	Complication	Size of PPC, cm	Time from procedure	Need for hospitalization	Need for surgery	Days of follow-up	Outcome	Reintervention
1	F/46	Bleed	13	During procedure	Yes	Yes	760	Alive	No
2	F/74	Migration of stent	8	2 years	No	No	730	Alive	Yes*
3	M/44	Infection	15		Yes	No	1825	Alive	Yes**
4	F/33	Bleed	16	During procedure	Yes†	No	720	Alive	No
5	M/36	Infection	15	5 days	Yes	No	670	Alive	Yes**

\*Need for enteroscopy for to get the prosthesis.

\*\*Need for new EUS procedure.

†Patient was discharged the next day without another adverse event.

**Table 3.** Complications reported in previous studies of EUS-guided drainage of pancreatic pseudocysts

Author/year	N	Complications n, (%)	Type complication	Time after procedure	Treatment
Krüger 2006	35	11 (31)	Cyst infection (4) Stent occlusion (4) Limited stent drainage (3)	–	Endoscopy
Varadarajulu 2008	20	0	–	–	–
Itoi 2008 <sup>15</sup>	13	0	–	–	–
Yasuda 2009	26	0	–	–	–
Varadarajulu 2011	20	0	–	–	–
Sadik 2011 <sup>16</sup>	16	1 (6)	Perforation	2 days	Surgery
Varadarajulu 2011	148	8 (5.4)	Perforation (2) Bleeding (1) Stent migration (1) Infection (4)	<24 h (3) not specified (4) 1 week (1)	Surgery (5) Endoscopy (3)
Puri 2012 <sup>17</sup>	40	3 (7.5)	Bleeding (1) Infection (1) Perforation (1)	Inmediatly (2) 40 h (1)	Surgery (1) Conservative (2)
Seewald 2012* <sup>18</sup>	80	21 (26)	Bleeding (12) Perforation (7) Portal air-embolis (1) Ogilvie Syndrome (1)	Inmediatly (19) Not specified (2)	Surgery (4) Conservative (5) Self-limited (11) Endoscopy (1)
Wen 2014	118	23 (19.5)	Bleeding Infection Migration	–	–
Siddiqui 2013	87	11 (12)	Bleeding (5) Pain (3) Fever (1) Stent migration (2)	Inmediatly (5) (bleeding) 48-72 h (4) 1 month (2)	Embolization by radiology (1) Self-limited (8) Endoscopically (2)
Kwon 2013 <sup>19</sup>	12	5 (41)	Fever (3) Stent migration (2)	2 months (1 stent) 8 months (1 stent) 4-6 weeks (2 fever)	Pancreatic stent (2) Stent replacemente (1) Nothing (2 stent migration)
Shah 2015	33	5 (15)	Pain (3) Stent migration (1) Infection (1)	–	–

(Continue)

**Table 3.** Complications reported in previous studies of EUS-guided drainage of pancreatic pseudocysts (*Continued*)

Author/year	N	Complications n, (%)	Type complication	Time after procedure	Treatment
Kokosis 2015	65	11 (17)	Infection (4) Perforation (5) Stent migration (1) Bleeding (1)	24 h (1) Immediately (5) Not specified (5)	Surgery (3) Self-limited (1) Conservative (6) Radiology (1)
Kokosis 2015	65	11 (17)	Infection (4) Perforation (5) Stent migration (1) Bleeding (1)	24 h (1) Immediately (5) Not specified (5)	Surgery (3) Self-limited (1) Conservative (6) Radiology (1)

WEN ◊ in chinese, only abstract is available in English \*WON and PQP

4 after procedure. The second patient was a male of 44 years old with PPC of 15 cm who presented with abdominal pain and fever after 5 days of the drainage. The two patients with infectious adverse events were treated with a second EUS-GD using a nasocystic catheter with irrigation of 1000 mL/day of saline solution for 5 days with clinical and radiological resolution. The infection presented after the first procedure, regardless, both patients received prophylactic antibiotics.

### BLEEDING

About the two patients who bled during endoscopic drainage, one of them was successfully treated endoscopically with clips and the second required surgery. No deaths related to endoscopic treatment were documented.

### Discussion

According to our data staying one night in hospital, if were not any adverse events during the procedure, does not make a difference. If there is an adverse event, it happens immediately (bleeding and perforation) or days later (infection).

According to our results, in a previous retrospective analysis, only 32% of patients with EUS-GD required hospitalization<sup>12</sup>. Another study with 30 patients did not found any immediate adverse event procedure related, but four secondary infections were reported<sup>13</sup>. Siddiqui *et al.* reported a complication rate of 10.3% ( $n = 9$ ), they had 5 intra-procedural bleeding, three post-procedure pain, and one patient fever of uncertain etiology<sup>14</sup>. One RCT (2) with 20 patients with EUS-GD of PPC reported none adverse events in concordance to another study that compares EUS versus EGD<sup>7</sup>. In Table 3, complications reported in previous studies of EUS-GD of PPC are shown, as it can

be seen in that table, of 15 studies reported, 2-23% of the total of complications are during the procedure or < 24 h later and the rest appears after more than 3 days.

The complication rate in our study was 16.1% and is according with previous reports<sup>2,7,15-21</sup>. For us, bleeding was the more important complication and we think that the use of needle knife to create a bigger fistula could explain this. Other authors recommend the use of a cystostome 6F after initial puncture; however, unfortunately, this is not widely available in our country. We have two patients with infection of PPC after the initial drainage. The occurrence of post-puncture infections has been attempted to prevent with the use of prophylactic antibiotics; however, these are not 100% effective. It is currently recommended that patients with pseudocysts with viscous debris-laden fluid the use of a nasocystic drain for the purpose of performing either "in bolus" or continuous lavage<sup>14</sup>. At this moment, there is no information on how long after drainage, the nasocystic drain must be in place or if there is any difference between doing them continuously or "in bolus." According to our experience, when PPCs are large (> 15 cm) and the contents are clearly purulent, it is more appropriate to perform the washing through the nasoabscess catheter "in bolus" and not continuously, because at least in our experience, it causes a higher frequency of patients with systemic inflammatory response.

There are some limitations of our study; first, the retrospective design. However, for our knowledge, there is a lack of studies specifically focus on complications of EUS-guided PPC drainage<sup>21</sup>. Our data could be important for future study designs and reviews.

### Conclusion

There is not a clear reason because patients with PPC and EUS-GD need for staying one night in hospital if was not any adverse event during the procedure.

Disclosure: All authors disclosed no financial relationship relevant to this publication.

## Authors' Contributions

Félix I. Téllez-Ávila design the study; Félix I. Téllez-Ávila and Miguel A. Ramírez-Luna were attending doctors and performed endoscopies; Félix I. Téllez-Ávila, Luis Eduardo Casasola-Sánchez, Angela Saul, Carlos Chan, Jorge Hernández-Calleros and Luis Uscanga-Domínguez organized the report; and Félix I. Téllez-Ávila, Luis Eduardo Casasola-Sánchez, Angela Saul, Carlos Chan, Jorge Hernández-Calleros and Luis Uscanga-Domínguez wrote the paper.

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