ORIGINAL ARTICLE

Safety and efficacy of the patency capsule

G. Blanco-Velasco*, J. Ramos-García, O.M. Solórzano-Pineda, C. Martínez-Camacho, E. Murcio-Pérez, O.V. Hernández-Mondragón

Servicio de Endoscopia, Hospital de Especialidades, Centro Médico Nacional Siglo XXI, Instituto Mexicano del Seguro Social, Mexico City, Mexico

Received 29 March 2021; accepted 10 June 2021
Available online 10 December 2021

KEYWORDS
Patency capsule; Capsule endoscopy; Crohn’s disease

Abstract

Introduction and aims: The patency capsule is an effective diagnostic method for preventing video capsule retention in the small bowel during capsule endoscopy. The most frequently associated complication when using the patency capsule is symptomatic retention. The aim of the present study was to evaluate the effectiveness and safety of patency capsules administered to patients at a tertiary care hospital center.

Materials and methods: A retrospective observational study was conducted that included all the patients with confirmed Crohn’s disease that were administered a patency capsule, within the time frame of January 2019 and December 2020. PC diagnostic yield, sensitivity, specificity, positive predictive value, and negative predictive value were evaluated, in relation to capsule endoscopy and double-balloon endoscopy findings. Complications associated with the patency capsule were also identified.

Results: Thirty patients were included, in whom the patency capsule had 83% sensitivity, 100% specificity, 100% positive predictive value, and 96% negative predictive value, with a diagnostic yield of 96.7%. There was one complication (3.3%) and it resolved spontaneously.

Conclusions: The patency capsule is a safe and effective method for reducing video capsule retention during capsule endoscopy in patients with Crohn’s disease.

© 2021 Asociación Mexicana de Gastroenterología. Published by Masson Doyma México S.A. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

* Corresponding author at: Av. Cuauhtémoc 330, Colonia Doctores, Alcaldía Cuauhtémoc, C.P. 06720 Mexico City, Mexico. Tel.: +52 5556276900; extension 21317 and 21318.
E-mail address: gerardoblanco@hotmail.com (G. Blanco-Velasco).

Introduction and aim

Capsule endoscopy (CE) is a noninvasive diagnostic method that enables visualization of the small bowel (SB). It is useful in different diseases of the SB, such as suspected bleeding, Crohn’s disease (CD), polyposis syndromes, celiac disease, and other inflammatory diseases, as well as in the search for tumors. Video capsule retention is the main complication of CE and is defined as the capsule remaining in the SB for more than 14 days post-ingestion or when symptoms of bowel obstruction present. Its extraction requires medical, endoscopic, or surgical management. Capsule retention rate in CE depends on the indication for the procedure and can vary from below 1% in patients suspected of SB bleeding to 21% in the context of obstruction in patients undergoing CE, enteropathy due to nonsteroidal anti-inflammatory drugs, SB tumors, SB anastomosis, and enteropathy due to radiation.

The patency capsule (PC) (Pillcam™ Given Imaging, Yoqneam, Israel) is the same size as the video capsule utilized in CE (length: 26 mm, diameter: 11 mm) and is designed to be used before CE, to detect the presence of SB strictures that could cause video capsule retention. The PC is made of a polyurethane membrane that contains lactose, barium, and a radiofrequency identification tag (3 × 13 mm) and is sealed at both ends with a wax plug. Post-ingestion, intestinal secretions degrade its content, enabling the release of the barium. The device then wrinkles, and the remaining empty membrane and radiofrequency tag pass through any stricture that is present. The PC has been shown to be effective in preventing capsule retention during CE in SB strictures, with a negative predictive value of 100%.

Despite the fact that PC ingestion is a safe test, it is not exempt from complications. Symptomatic retention is the main complication, causing bowel obstruction, even though the degradation of the PC continues, enabling its passage through the stricture and symptom relief, in the majority of cases. Very infrequently, medical treatment with steroids has been required, and surgical treatment is exceptional. Another complication is aspiration of the PC into the airway, but it is uncommon, with only a few isolated cases reported. The aim of the present work was to analyze the effectiveness and safety of PCs used in patients at a tertiary care center.

Materials and methods

Study design

A retrospective, descriptive, cross-sectional study was conducted that included all the PCs administered to patients at the Endoscopy Service of the Hospital de Especialidades, Centro Médico Nacional Siglo XXI of the Instituto Mexicano del Seguro Social, within the time frame of January 2019 and December 2020. The effectiveness and safety of PC use was analyzed.

Patient selection

All the study patients had confirmed CD and required CE to evaluate treatment response. Due to the high risk of video capsule retention, the decision was made to have the patients undergo a PC test before the CE. All the patients fasted for 8 h prior to PC ingestion. No preparation with...
laxatives or prokinetics was carried out. The patients were
given an appointment 30 h post-PC ingestion. If the PC was
expelled in a bowel movement during the 30 h period, it had
to be collected or photographed, to evaluate its physical
integrity. If that was not possible, a plain abdominal x-ray
in two positions was taken, to verify the location of the PC
in the gastrointestinal tract.

Result evaluation

Three criteria were considered PC predictive values of pos-
sible retention: 1) radiologic evidence of the PC located in
the SB, 30 h after its ingestion, 2) expulsion of the disinte-
grated PC, and/or 3) the presence of obstructive symptoms
during the passage of the PC through the SB (pain, bloating,
and/or diarrhea). If there were no PC predictive criteria
for retention, CE with a SB3 video capsule (Given Imaging,
Yogneam, Israel) was administered within 48 h. If there
were PC predictive criteria for retention, they were con-
firmed through anterograde or retrograde double-balloon
enteroscopy (DBE), depending on the location of the proba-
ble stricture site.

Statistical analysis

The quantitative variables were calculated as frequencies
and percentages and the qualitative variables as mean and
standard deviation or median and interquartile range (25th,
75th percentiles) according to their distribution. A 2 x 2
was utilized to analyze sensitivity, specificity, posi-
tive predictive value (PPV), negative predictive value (NPV),
and diagnostic yield. PC diagnostic yield was determined in
relation to the findings identified through CE or DBE. SPSS
version 25 (IBM, Chicago IL, USA) software was used for the
statistical analysis.

Ethical considerations

All study patients remained anonymous and each of them
signed written statements of informed consented. The
present study meets the current bioethics research reg-
ulations and was authorized by the Research and Ethics
Committee of the Hospital (R-2018-3601-188).

Results

The study included 30 PCs administered to the same number
of patients. Nineteen of the patients were women (63.3%) and
mean patient age was 55 years (±13.81). The PC iden-
tified predictive data of SB stricture in 5 patients. In 3 of
those cases, a plain abdominal x-ray showed PC retention
in the SB, 30 h post-ingestion, and in one case, a deformed
PC was expelled in a bowel movement, within the first 30 h.
In the remaining case, the patient went to the emergency
service 6 h post-ingestion, with signs of bowel obstruction
that were then confirmed through a plain abdominal x-ray.
Twelve hours after symptom onset, the patient expelled a
deformed capsule in a bowel movement, spontaneously
resolving the situation.

Stricture was corroborated in the 5 cases through DBE; one was identified in the jejunum and
the others were found in the terminal ileum, at least one
meter from the ileocecal valve. None of the patients had
symptoms prior to the bowel obstruction. During the DBE,
strictures were dilated in 3 patients: to 15 mm in one patient
and to 18 mm in two patients. CE was carried out in the
25 patients that met no PC retention criteria, one to two
days after PC ingestion. Only one case presented with video
capsule retention (Table 1). The stricture that caused the
retention was in the jejunum and the video capsule was
expelled in a bowel movement 27 days post-ingestion.
The patient was asymptomatic during the time the capsule
was retained. Comparing the PC predictive criteria for retention
with the findings identified by CE and DBE, sensitivity was
83%, specificity was 100%, PPV was 100%, NPV was 96%, and
PC diagnostic yield was 96.7%. There was one complication
(3.3%) in the cases, and it resolved spontaneously.

Discussion

In a study conducted in Japan, Yoshimura et al.13 admin-
istered 99 PCs in patients with CD. There were no PC-related
data suggestive of stricture in 84 patients (84.8%) that
underwent CE. Fifteen patients had PC-related data sug-
gestive of SB stricture; 10 of them underwent enteroscopy
and 2 had enterolysis; stricture was confirmed in 11 of the
cases. PC had 91.7% sensitivity, 98.8% specificity, 98.9% PPV,
and 91.7% NPV, results very similar to those of our study,
in which specificity and PPV were close to 100%.

In another study, Silva et al.14 included 54 patients diag-
nosed with CD. PC retention was identified through plain
abdominal x-ray in 20% of the cases, at 30 h post-ingestion.
Abdominal tomography scans carried out later identified
retention in only 9%. In the rest of the cases, the PC was
located in the colon. We did not perform abdominal tomog-
raphy to corroborate whether the PC that was retained in the
SB, identified through abdominal x-ray 30 h post-ingestion,
was in fact in the SB, and not in the colon. However, in the 4
cases in which PC retention was identified through abdomi-
nal x-ray, SB stricture was confirmed through enteroscopy.

Kopylov et al.15 carried out the largest multicenter study
evaluating the safety of PCs administered over a 10-year
period and included 1,615 patients. They found symptomatic
retention in only 20 cases (1.2%). One of those patients (5%)
required surgery, whereas the rest resolved spontaneously
or after treatment with corticosteroids. In the case series we
present herein, symptomatic retention was slightly higher
(3.3%), which could be due to the smaller study population,
and the fact that one case resolved spontaneously.

The PC should not be utilized in all cases prior to CE.
Its use should be reserved for cases in which there is a

Table 1 Effectiveness of the patency capsule for evaluating small bowel stricture.

<table>
<thead>
<tr>
<th>Stricture identified by CE or DBE</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stricture identified by PC</td>
<td>Positive</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>24</td>
</tr>
</tbody>
</table>

CE: Capsule endoscopy; DBE: Double-balloon endoscopy; PC: patency capsule.
high risk for retention, such as patients with confirmed CD, symptoms of obstruction, chronic use of nonsteroidal anti-inflammatory drugs, or a history of abdominal and pelvic radiation. Due to the low risk of capsule retention in CE in patients with other diseases, such as SB bleeding or suspected CD, the diagnostic yield of PC would be lower than in high-risk populations.

Among the limitations of the present study were the number of patients and the fact that it was conducted at a single tertiary care center. Another limitation was not having carried out abdominal tomography scans to corroborate the location in the SB of the retained PC. Nevertheless, the present study on PC is the largest case series reported in Latin America, and it can be concluded that PC is a safe and effective method for reducing video capsule retention during CE, in patients with confirmed CD.

Financial disclosure

All the patency capsules utilized in the study were donated by Medtronic and Endomédica.

Conflict of interest

Gerardo Blanco-Velasco is a speaker for Medtronic. The rest of the authors declare that they have no conflict of interest.

References