Rate of adverse events of gastroduodenal snare polypectomy for non-flat polyp is low: A prospective and multicenter study

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INTRODUCTION

Gastric polyps are found in around 3%–6% of patients undergoing upper endoscopy[1,2]. According to these sources, the most common gastric polyps are the hyperplastic and fundic gland types (70%–90%).
followed by adenomas, with a variable prevalence among countries depending on the use of proton pump inhibitor drugs (PPI) or the prevalence of *Helicobacter pylori* (*H. pylori*) infection. In western countries, where *H. pylori* infection is low and PPI use is very common, fundic gland polyps are seen more frequently.[2,3] However, two retrospective Spanish series showed that in Spain the most frequent were hyperplastic polyps (50.9%), followed by fundic gland polyps (7.4%), adenomas (3%), and adenocarcinomas (1.9%).[4,5]

Sporadic duodenal polyps are uncommon with a prevalence of 0.3% to 4.6%. [6,7] Whereas multiple, small polyps in the duodenal bulb are benign a substantial number of them located in the descending duodenum are adenomas.[8] Duodenal adenomas can occur sporadically or more commonly in patients with Familial Adenomatous Polyposis, occurring in 50% to 100%.[8] Most of gastric and duodenal polyps are asymptomatic and are incidentally found at endoscopy performed for unrelated reasons.

Gastric and duodenal polyps have a risk of malignant transformation that depends on histologic type. The risk of gastric polyps undergoing malignant transformation is near 2% for hyperplastic polyps, 5% for tubular adenoma, and up to 30% for tubulovillous adenoma.[9-11] However, polyp histology cannot be reliably distinguished by endoscopic appearance[12,13] and biopsy is not always representative of the entire polyp.[14] Therefore, polypectomy is warranted if feasible and clinically appropriate; this is supported by current guidelines.[15,16]

Endoscopic polypectomy has become standard in the management of most polyps in the gastrointestinal tract. Gastric and duodenal polyps can be safely removed with snare depending on size, location and presence of a stalk. However, bleeding is the most common adverse event (AE) of snare polypectomy, with an incidence of 6% to 7.2% in gastric polyps and up to 13.9% in duodenal polyps.[17-18] Although these figures are higher than those reported in colonic polypectomies (0.3%-6%)[19,20], the available evidence is limited by the fact that it is often based on retrospective studies performed at a single center or with a small number of patients and the nomenclature and definitions used for AEs are different. The need for standardized nomenclature and agreement on definitions for AEs was addressed by the American Society for Gastrointestinal Endoscopy (ASGE) in a workshop celebrated in 2008 and whose recommendations were published in 2010.[21] Moreover, there are few studies that specifically evaluate risk factors and the efficacy of different hemostatic techniques in the prevention and control of post-polypectomy bleeding.

The aim of this study was to estimate the incidence and risk factors of several types of AEs associated with gastroduodenal polypectomy in several Spanish hospitals using a standardized lexicon specific for endoscopic procedures.

**MATERIALS AND METHODS**

**Patients**

This is a prospective multicenter study performed at 15 Spanish hospitals. Patients with gastric and duodenal polyps that underwent endoscopic polypectomy were eligible for inclusion in the study. All patients included in the study had been previously diagnosed of gastric polyps and subsequently underwent a second endoscopy to perform the polypectomy. Therefore, when the physicians were aware that they had to perform the polypectomy, they previously asked the patient for consent to participate in the study. Inclusion criteria were: (1) protruded gastric or duodenal polyps ≥ 5 mm; and (2) polypectomy performed using an electrocautery snare. The exclusion criteria were: (1) age under 18 years; (2) prothrombin time < 50% or INR > 1.5 and platelet count < 50000 (blood test were only mandatory in patients with anticoagulation therapy or with conditions associated with coagulation disturbances); (3) aspirin intake during the previous 3 d; (4) clopidogrel intake during the previous 7 d; and (5) conditions associated with coagulation disturbances. The study protocol was approved by the Ethics Committee of each hospital and informed consent was obtained from all patients.

Three days before the procedure, oral anticoagulants were replaced by subcutaneous low-molecular weight heparin. The patients were guided to reintroduce them 24-h after the procedure (the dose depended on the value of the previous INR value). Aspirin and clopidogrel were also reintroduced at usual doses.

Snare polypectomy was performed according to the conventional method encircling the polyp with a polypectomy snare and applying electrocautery current.[22] Patients were placed in the left lateral decubitus position and sedation was administered according to the endoscopist or anaesthesiologist’s preference.

Variables were recorded in database templates. The database included demographic characteristics, medical and drug history, indication of upper endoscopy, endoscopists’ expertise (staff or fellow), morphological features and localization of polyps, technical information about the polypectomy procedure (bloc/peacemeal resection, cautery setting, hemorrhage prophylaxis technique), type of sedation, unexpected events and measures for correcting them, and patient outcome. Polyp size was determined endoscopically using an open biopsy forceps (7 mm in length, Boston Scientific Large Capacity with Needle Biopsy Forceps 2.8 mm). In cases with multiple polyps, the biggest one’s characteristics were recorded.

**Definition of AEs**

AEs were defined, following the lexicon of ASGE
Workshop\textsuperscript{[21]}, as an event that prevents completion of the polypectomy (planned procedure) and/or results in admission to hospital, prolongation of existing hospital stay, another procedure (needing sedation/anesthesia), or subsequent medical consultation. Unplanned events that did not interfere with completion of the planned procedure or changed the plan of care were classified as incidents.

Severity of AEs was graded as mild, moderate, severe and fatal according to ASGE classification. AEs were defined as mild or moderate if patients required less than 4 nights or between 4 to 10 nights of hospitalization respectively. They were classified as severe if unplanned or prolonged hospitalization was required for more than 10 nights or requiring intensive care unit admission or surgery. Finally they were graded as fatal if death occurred in relationship of the procedure.

Based on timing, AEs were defined as “intra-procedure” if they occurred during the exploration or in the recovery area, “early” if they occurred within 14 d and “late” from day 15th onward after polypectomy. 

Assessment of AEs

AEs were assessed and recorded by a physician during and after the procedure while the patient was recovering from sedation or anesthesia and up to 24 h later in those admitted for observation. At 48 h, one week and day 30 after the procedure, a telephone call was made in order to ask the patient whether they had experienced any symptoms or required medical assistance. A standard questioner was used for the evaluation of late complications. Responses were recorded and entered into a database.

The completeness of data collection was monitored every 2 wk and missing data were proactively collected by contacting the patients and/or referring physicians, as far as this was possible.

Definition of hemorrhage

Bleeding was recorded as a potential AE when it required any form of intervention, either immediately after polypectomy during the index endoscopy, or in a repeat endoscopy, regardless of obtaining hemostasis, hospital admission, blood transfusion, or surgery. Depending on its activity, bleeding was classified as spurring or oozing; depending on its timing, it was classified as immediate-onset bleeding (evident during the examination) or late-onset bleeding (evident after the examination).

Immediate postpolypectomy bleeding was graded from G1 to G4 in severity based on objective endoscopic findings based on the time and continuity of bleeding as previously described (G1: Spontaneous hemostasis within 60 s, G2: Continuous but decreased oozing over 60 seconds, G3: Continuous oozing over 60 s that needs endoscopic treatment and G4: Active spurting)\textsuperscript{[23]}. After the procedure, bleeding was defined as a drop in Hb > 2 gr/dL or clinical evidence of bleeding (melena or hematemesis).

Bleeding prophylaxis

Prophylaxis of hemorrhage was allowed in the following situations:

- Pedunculated polyps (Paris type 0-Ip): (1) Stalk ≥ 5 mm and/or head ≥ 20 mm: adrenaline injection or endoloop before or immediately after polypectomy; and (2) Visible vessel after polypectomy: adrenaline injection, endoloop or hemostatic clip.
- Sessile polyps (Paris type 0-Ia): oozing bleeding with spontaneous hemostasis in less than 30 s and polyp size > 20 mm: adrenaline injection, argon plasma coagulation (APC) or hemostatic clip\textsuperscript{[21]}. The technique was selected based on physician’s preference.

Statistical analysis

Sample size calculation was performed assuming 10% of AE from the previous data published\textsuperscript{[24,25]}. With these numbers, we calculated that a total of 300 patients were required to achieve statistical significance (α error = 0.05, β error = 0.1).

Continuous variables were expressed as mean ± SD. In cases with a multiple polypectomy, data provided correspond to the biggest one. Analysis was performed per patient and not per polyp. 95% confidence interval (CI) of AEs incidence was calculated by using standard formula. Comparisons were done using Fisher’s test for categorical variables and t test for continuous variables. The chi-squared test and the Mann-Whitney U test, or Student’s t-test were applied where appropriate for statistical analysis. In addition, a multivariate logistic regression analysis was carried out to assess the existence of predictive factors of AEs and the odds ratio (OR) was calculated to indicate the associated risk. P < 0.05 was considered statistically significant. All analyses were performed with SPSS for Windows, version 23.0 (SPSS Inc, Chicago, IL; United States).

RESULTS

From September 2012 to March 2015, a total of 326 patients with gastroduodenal polyps agreed to participate in the study. 18 patients were excluded because they did not meet inclusion criteria (polyp < 5 mm, n = 1; platelets < 50.000, n = 1; cold snare polypectomy, n = 9; Paris classification IIb or IIc polyp, n = 7). Then, 308 patients were finally included (Figure 1). Most of them were ASA I-II (n = 231, 75%) and only 36 (11.7%) were on anticoagulants. The most frequent indication was iron-deficiency anemia (n = 103, 33.4%). Characteristics of the patients are described in Table 1.

In 205 cases a single polypectomy was performed whereas in the other 103 it was multiple (mean 1.7 ± 1.3, range 1-7). Polyp mean size was 15 ± 8.9 mm.
The majority of them were located in the stomach ($n = 294, 95.4\%$). The most frequent histological type was hyperplastic ($n = 224, 72.7\%$). Characteristics of the resected polyps are described in Table 2.

Table 3 shows the technical details of the endoscopy and polypectomy. Polypectomies were performed by a staff endoscopist in 268 cases (87\%) and at university hospitals in 251 cases (81.5\%). Hemorrhage prophylaxis was performed in 219 (71.1\%) patients; the most common technique was injection of adrenaline alone or in combination with clips, endoloops and APC.

All the patients were successfully contacted. A total of 41 patients (13.3\%) presented 45 unexpected events: 30 bleeding, 10 abdominal pain, 2 respiratory desaturation, 1 spontaneous bacterial peritonitis, 1 esophageal laceration and 1 pneumothorax. However, following the ASGE lexicon, only 9 patients presented 9 (2.9%; 95%CI: 1-4.8) events that were considered AEs, and 6 of them were bleeding (5 in stomach and 1 in duodenum; 1.9%; 95%CI: 0.4-3.5). Severity and timing of these AEs are described in Table 4.

Bleeding was the most common unplanned event that occurred during the procedure ($n = 30, 9.7\%; 95%CI: 6.4-13.1\%). The majority of episodes could be managed without any change in the outcome of the endoscopy and, consequently, were considered incidents (24 out of 30, 80\%). In 13 out of 24 incidents (54.1\%) and in 5 out of 6 AE (83.3\%), different types of endoscopic treatment were performed: injection alone in 3, clips alone in 3, injection plus clips in 10 and combination of injection, clips and APC in 2. In all the cases, bleeding was adequately controlled. Figure 2 shows the relationship between the use of prophylactic measures, the presence and severity of bleeding and the use of endoscopic treatment.

There were no statistically significant differences in terms of age, gender, polyp histology and location in stomach or duodenum, technical details of polypectomy, hospital characteristics and use of prophylactic measures between patients who developed hemorrhagic episodes and those who did not. Only polyp size and endoscopist expertise were statistically significant in the univariate but not in the multivariate analysis (Table 5).

**DISCUSSION**

Bleeding is the most common adverse event of snare polypectomy in the upper gastrointestinal tract. In our study we found a 2.6\% AEs rate (1.9\% considering only bleeding) after resection of gastric and duodenal polyps which is lower than data reported in other series. To the best of our knowledge, this study is the first multicenter and prospective evaluation of AEs after gastroduodenal snare polypectomy using the lexicon recommended by the ASGE. Our results confirm the safety of gastric polypectomy when applying preventive measures and emphasize the need of using standardized systems to report AEs.

For years, polypectomy in the upper gastrointestional...
The other three (1.3%): two bleeding episodes that required hospital admission, interventional radiology or endoscopy, the rate dropped to 0.13%. Again, rates in these series were very low (0.05% and 0.65%, respectively). However, when the analysis was performed on all the cases in which a therapeutic intervention was required regardless of the need of hospitalization or transfusion. Following the ASGE lexicon definition of AEs, the rate of AEs in this study would have been of 0.98%. The retrospective design of this study limits the conclusions and it could be argued that complication rate might be higher.

Kratzsch et al. performed a retrospective study (102 patients with gastric polyps) in which the primary outcome was the occurrence of immediate or delayed bleeding episodes. Although they reported seven episodes of bleeding (6.9%), six were detected immediately after polypectomy and were adequately treated by injection. Only one episode was considered severe because it required a blood transfusion 6 days after the polypectomy and fulfilled the definition of AEs by the ASGE lexicon, decreasing the rate of hemorrhagic AEs to 0.98%. The retrospective design of this study limits the conclusions since it may underestimate complications.

Information regarding the risks of duodenal resection is even scarcer. To date, the results of the two largest retrospective series treated with snare polypectomy showed a rate of hemorrhagic AEs of 7.8%–11% which is much higher than ours. Although duodenal polypectomy is usually technically more challenging than gastric polypectomy, location in the duodenum is not significantly associated with more hemorrhagic episodes, as showed in our study. We did not include flat polyps because these should be removed with mucosectomy which is technically challenging, more difficult than standard polypectomy, and associated with more AE’s.

Polyp size has proved to be the main risk factor for significant unexpected events in colonic polypectomies. In fact, size is one factor that determines the complexity of polypectomy and as the complexity of polypectomy increases, a higher risk of complications is reported. The overall perforation and bleeding rates in these series were very low (0.05% and 0.65%, respectively). However, when the analysis was limited to bleeding requiring transfusion, unplanned hospital admission, interventional radiology or endoscopy, or surgery, the rate dropped to 0.13%. Again, the hemorrhagic events of gastroduodenal polypectomy were more challenging, more difficult than standard polypectomy, and associated with more AE’s.

Table 3  Endoscopy and polypectomy technical details

| Characteristics | n (%) |
|-----------------|-------|
| Sedation | 302 (98.1) |
| University Hospital | 251 (81.5) |
| Endoscopist Staff | 268 (87) |
| Number of polyps resected | |
| 1 | 205 (66.6) |
| 2 | 55 (17.9) |
| 3 | 20 (6.5) |
| 4 | 8 (2.6) |
| 5 | 7 (2.3) |
| >5 | 13 (4.2) |
| Cautery settings | |
| Endocut | 236 (76.6) |
| Hemorrhage prophylaxis | 219 (71.1) |
| One technique | 149 (68) |
| Two or more | 70 (32) |
| Prophylactic technique | |
| Injection alone | 119 (54.3) |
| Clips | 16 (7.3) |
| Clips + injection | 60 (27.4) |
| Endoloop | 9 (4.1) |
| Endoloop + injection | 5 (2.3) |
| APC | 5 (2.3) |
| APC + injection | 2 (0.9) |
| APC* clips + injection | 3 (1.4) |

APC: Argon plasma coagulation.

Figure 1  Study flow chart.
these results emphasize the importance of using standardized systems for reporting AEs. Because hemorrhage prophylaxis was allowed in polyps larger than 20 mm which have a high likelihood of bleeding, this fact could explain that size was not associated with a higher rate of hemorrhagic AEs in our series. Although the rate of AEs in our study is low, the number of bleeding episodes is not negligible and many of them received prophylaxis (10.5%) or were treated endoscopically (60%) with injection, APC, hemostatic clips or a combination of methods which increases health care costs. Interestingly, the combination of two or more techniques did not improve the prophylactic effect of using one technique alone against bleeding. However, one could expect a higher number and more severe bleeding episodes if we had not systematically applied prophylactic measures, with an estimated high economical impact as well.

This study has several strengths. First, it is a multicenter study performed in many hospitals (tertiary and community) with a different volume of explorations that increase the generalizability of the results. Second, preventive measures for post polypectomy bleeding were applied systematically. Third, all patients were systematically evaluated and reached three times (at 48 h, 7 and 30 d after the procedure), avoiding drop-outs that could bias the results. Fourth, we only included protruded polyps in order to avoid the use of other endoscopic resection techniques such as mucosectomy or endoscopic submucosal dissection which are more technically demanding and have a higher risk of complications. And finally, we used a standardized lexicon for endoscopic AEs.

Table 4 Type and severity of adverse events according to ASGE lexicon

| Type                      | n = 45 | Time of presentation | Severity (intraprocedural hemorrhage) | Admission or prolongation of hospitalization | Repeat endoscopy | AEs, ASGE lexicon | Severity |
|---------------------------|--------|----------------------|----------------------------------------|---------------------------------------------|-----------------|-------------------|----------|
| Hemorrhage                | 30     | Intraprocedural, n = 26 | Grade 1, n = 11<br>Grade 5, n = 14<br>Grade 4, n = 1 | Yes, n = 2 | No | 2 | Mild |
| Abdominal pain            | 10     | 24 h                 | No<br>Yes<br>Yes | Yes | No | 1 | Moderate |
| Respiratory desaturation  | 2      | Intraprocedural      | No | No | No | 1 | Moderate |
| Pneumothorax              | 1      | Intraprocedural      | Yes | No | Yes | 1 | Moderate |
| SBP                       | 1      | 7 d                  | Yes | No | Yes | 1 | Severe |
| Esophageal laceration     | 1      | Intraprocedural      | Yes | No | Yes | 1 | Mild |

SBP: Spontaneous bacterial peritonitis.

Figure 2 Relationship between the use of prophylactic measures, the presence and severity of bleeding episodes and the use of endoscopic treatment.
Finally, we used definitions of hemorrhage and criteria for prophylaxis that apply to colonic polyps because we did not find any specific definition for gastric polyps. However, we assume that the mechanism of post-polypectomy hemorrhage must be similar regardless the localization of the polyp.

In conclusion, gastroduodenal polypectomy using prophylactic measures has a rate of AEs small enough to consider this procedure a safe and effective method for polyp resection independently of the polyp size and location.

**ARTICLE HIGHLIGHTS**

**Research background**
Gastric and duodenal polypectomy is commonly performed. Although there is a theoretical increased risk of bleeding, there is scarce information regarding the potential adverse events (AEs) of polypectomy in this setting. The aim of this study was to evaluate the rate of AEs during consecutive gastric and duodenal polypectomies in several Spanish centers.

**Research motivation**
The safety of polypectomy in the upper GI tract is controversial because the reported rate in retrospective studies is higher than in colonic polypectomy but results come mainly from retrospective studies and they do not use the same standardized nomenclature and definitions for adverse events.

**Research objectives**
The aims of this study were to determine in a prospective study the rate of adverse events of gastroduodenal snare polypectomy for non-flat polyps; to evaluate the adverse events (early and late) that occur after a gastric and/or duodenal polypectomy as well as the predictive fractures for its development; to evaluate the different endoscopic techniques used in the prophylaxis of post-polypectomy hemorrhage.

**Research methods**
The research methods: (1) Multicenter, longitudinal and prospective study of all patients undergoing polypectomy of gastric or duodenal polyps ≥5 mm using an electrocautery polypectomy snare; (2) Patients with PT < 50% and

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**Table 5 Univariate analysis of bleeding risk factors n (%)**

|                        | Bleeding, n = 30 | No bleeding, n = 278 | P value |
|------------------------|-----------------|----------------------|---------|
| Age (yr), mean ± SD    | 69.5 ± 10       | 69.1 ± 12            | 0.137   |
| Gender                 |                 |                      |         |
| Male                   | 12 (40)         | 99 (35.6)            | 0.634   |
| Female                 | 18 (60)         | 179 (64.4)           |         |
| Anticoagulation\(^1\)  |                 |                      | 0.217   |
| Yes                    | 14 (46.7)       | 98 (35.2)            |         |
| No                     | 16 (53.3)       | 180 (64.7)           |         |
| ASA                    |                 |                      | 0.515   |
| I, II                  | 20 (66.7)       | 201 (72.3)           |         |
| III, IV                | 10 (33.3)       | 77 (27.7)            |         |
| Paris classification of polyps\(^1\) |                 |                      |         |
| 0-Ip                   | 17 (56.7)       | 135 (48.6)           | 0.399   |
| 0-Is                   | 13 (43.3)       | 143 (51.4)           |         |
| Polyp size\(^1\)       |                 |                      | < 0.036 |
| < 10 mm                | 7 (23)          | 120 (43.2)           |         |
| > 10 mm                | 23 (77)         | 158 (56.8)           |         |
| Location               |                 |                      | 0.557   |
| Stomach                | 28 (93.3)       | 266 (95.7)           |         |
| Duodenum               | 2 (6.7)         | 12 (4.3)             |         |
| Polyp histology\(^1\)  |                 |                      | 0.092   |
| Hyperplastic           | 18 (60)         | 206 (74.4)           |         |
| Others                 | 12 (40)         | 72 (25.6)            |         |
| Polyp with dysplasia   |                 |                      | 0.053   |
| Yes                    | 8 (26.7)        | 36 (13.4)            |         |
| No                     | 22 (73.3)       | 232 (86.6)           |         |
| Physician expertise\(^1\) |                 |                      | < 0.026 |
| Staff                  | 30 (100)        | 238 (85.6)           |         |
| Fellow                 | 0 (0)           | 40 (14.4)            |         |
| University hospital    |                 |                      | 0.207   |
| Yes                    | 27 (90)         | 224 (80.6)           |         |
| No                     | 3 (10)          | 54 (19.4)            |         |
| Number of polyps resected |             |                      | 0.989   |
| One                    | 20 (66.7)       | 185 (66.5)           |         |
| More than one          | 10 (33.3)       | 93 (33.4)            |         |
| Use of endocut\(^1\)   |                 |                      | 0.068   |
| Yes                    | 27 (90)         | 209 (75.2)           |         |
| No                     | 3 (10)          | 69 (24.8)            |         |
| Hemorrhage prophylaxis\(^1\) |             |                      | 0.479   |
| Yes                    | 23 (76.7)       | 196 (70.5)           |         |
| No                     | 7 (23.3)        | 82 (29.5)            |         |

\(^1\)Clinically relevant variables that have been included in the multivariate analysis.
platelets < 50000 or clopidogrel in the 7 d prior to endoscopy were excluded;
(3) Prophylactic measures of hemorrhage were allowed in certain predefined cases; (4) Intraprocedural hemorrhage was defined as bleeding that lasts more than 30 seconds and severity was graded from 1 to 4; (5) Late hemorrhage was defined as more than 24 h after electromechanical since discharge from endoscopy unit and up to 30 d. (6) Patients were followed during 30 d with serial phone calls; and (7) Predictive factors of complications were analyzed.

Research results
308 patients were included and a single polypectomy was performed in 205. Hemorrhage prophylaxis was performed in 219 (71.1%) patients. Nine patients presented AEs (2.5%), and 6 of them were bleeding (n = 6, 1.9%) (5 out of 6 AEs, different types of endoscopic treatment were performed). Other 24 hemorrhagic episodes could not be managed without any change in the outcome of the endoscopy and, consequently, were considered incidents. We did not find any independent risk factor of bleeding.

Research conclusions
The rate of adverse events of gastroduodenal snare polypectomy for non-flat polyp is low. However, the number of bleeding episodes is not negligible and many of them receive prophylaxis or are treated endoscopically with injection, APC, hemothastic clips or a combination of methods which increases health care costs. Prophylactic measures do not reduce the risk of hemorrhage. To our knowledge, this is the first study using the ASGE lexicon for reporting adverse events of gastro-duodenal polypectomy and shows an acceptable low rate, confirming the safety of this procedure. Because AEs of gastroduodenal polypectomies are low, there is no need of using more than one prophylactic endoscopic technique (clips, sclerosis, APC...) with the consequent reduction of costs.

Research perspectives
Gastroduodenal polypectomy using prophylactic measures has a rate of AEs small enough to consider this procedure a safe and effective method for polyp resection independently of the polyp size and location. The future research direction is to compare the use of prophylaxis or not before polypectomy in gastropolyps and the best method would be a prospective, comparative and randomized study.

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