Multimodal intervention for avoiding inappropriate cessation of aspirin prior to outpatient endoscopy

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submitted 19.7.2019
accepted after revision 14.10.2019

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DOI https://doi.org/10.1055/a-1134-4813 |
Endoscopy International Open 2020; 08: E708–E716

eISSN 2196-9736

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ABSTRACT

Background and study aims Existing guidelines recommend continuation of aspirin therapy prior to outpatient endoscopic procedures, as it reduces peri-procedural cardiovascular events and is not associated with an increased risk of bleeding. Despite this, many patients at our institution inappropriately alter their aspirin prior to endoscopy. We sought to identify why this occurs and implement an intervention that could reduce improper aspirin alteration.

Patients and methods All adult patients undergoing outpatient endoscopy at the Medical University of South Carolina were administered a survey querying demographics, aspirin use, endoscopic procedure, thromboembolic risk factors, and pre-procedural aspirin alteration, if any. An intervention involving revised written and verbal instructions as well as an automated voicemail aimed at ensuring patients adhere to guidelines was then undertaken. The same survey was administered after the intervention to assess for improved adherence.

Results A total of 240 patients from the initial survey reported daily aspirin use, of which 114 (47.5 %) inappropriately altered aspirin therapy. A total of 182 patients from the post-intervention survey reported daily aspirin use, of which 66 (36.3 %) inappropriately altered aspirin therapy. This was a statistically significant reduction ($P = 0.04$), which included adjustments for age, sex, procedure type, and thromboembolic risk.

Conclusions A high proportion of patients at our institution inappropriately alter aspirin therapy prior to outpatient endoscopy. The reasons for this behavior include patient self-direction, misguidance from staff, and instruction from other physicians. This alteration can be reduced significantly through an intervention that educates both patients and staff on continuation of aspirin therapy prior to outpatient endoscopy.

Introduction

Aspirin is one of the most commonly used medications worldwide, and is indicated for prevention or management of a variety of thromboembolic conditions [1, 2]. Initially isolated from willow bark, it functions as an anti-platelet agent by irreversibly acetylating the cyclooxygenase function of prostaglandin H synthase leading to inhibition of thromboxane A2-dependent platelet aggregation [3]. The benefits of aspirin in the prevention and management of thromboembolic conditions are clear, and the risks of hemorrhage associated with outpatient endoscopic procedures are minimal [4, 5].

Historically, aspirin has often been held prior to endoscopy due to the theoretical risk of hemorrhage [6]. More recent studies with large numbers of patients have shown that aspirin does not increase bleeding risk in patients undergoing endoscopy [4, 5]. In accordance with these findings, the American Society for Gastrointestinal Endoscopy (ASGE) has recommended against alteration in aspirin therapy prior to elective endoscopic procedures [7]. This includes both diagnostic and higher risk procedures, such as ERCP, EMR, and others [8]. Despite this, many patients, including those at high risk of peri-procedural thromboembolic events, withhold aspirin therapy prior to routine endoscopies, either at the direction of their physician, or

on their own accord. We sought to identify specific reasons for why this occurs, and developed a multimodal intervention to minimize inappropriate cessation of aspirin prior to outpatient endoscopy. We then conducted a post-intervention survey to evaluate the effects of our intervention.

Patients and methods

Patients

This prospective, interventional, single-center study was conducted after obtaining exempt status approval from the Institutional Review Board of the Medical University of South Carolina. Patient data collection and analysis was performed between September 2014 and August 2018. We estimated that an 8-week period for survey collection would be sufficient to power our study given the volume of outpatients that undergo procedures at our endoscopy center. Eligible patients included adults (≥18 years of age) presenting to the MUSC Digestive Disease Center (DDC) for outpatient endoscopic procedures who were taking aspirin. Exclusion criteria included patients less than 18 years of age and patients undergoing inpatient or emergent endoscopy. Each patient was interviewed by trained nursing staff during their routine history and examination prior to their scheduled endoscopy.

Pre-intervention phase

Initial data collection occurred over an 8-week period from September to November 2014. This involved a 10-question survey which was completed pre-procedurally via interview by the endoscopy prep nurse, and identified basic demographics, the endoscopic procedure to be performed, thrombotic risk factors, details regarding aspirin utilization prior to the planned procedure, and the rationale for discontinuing aspirin, if applicable (▶ **Supplementary Fig. 1**). The survey was designed according to current ASGE (American Society of Gastrointestinal Endoscopy) and BSG (British Society of Gastroenterology) guidelines to define procedural bleeding risk and thromboembolic risk and was reviewed for face validity by the investigators [9, 10]. Patients at high risk for thromboembolism included those with atrial fibrillation associated with valvular heart disease, mechanical mitral valve, mechanical valve and prior thromboembolic event, coronary artery stent placement within the last 12 months, and previous myocardial infarction. Patients with some increased risk for thromboembolism included those with atrial fibrillation, valvular heart disease, other prosthetic valves, congestive heart failure, hypertension, diabetes mellitus, stroke or transient ischemic attack, deep vein thrombosis, or pulmonary embolism.

Intervention

Results from the initial survey were analyzed and particular attention was paid to reasons why aspirin therapy was altered. Based on these results, three principal interventions were designed to mitigate the most commonly cited reasons for alteration. These interventions focused on improved communication and education and were implemented prior to collecting post-intervention survey data. On review of written instructions being provided to patients prior to their procedure, it was noted that recommendations regarding anticoagulants were in the middle of the instructions. The first intervention was to revise these instructions to include an explicit statement at the top of the first page of the packet instructing patients to "continue your aspirin unless otherwise instructed by your gastroenterologist." The second intervention was to include this same statement in a revised script used by schedulers when calling patients. An educational meeting was held with both our nursing staff and schedulers to emphasize the use of this statement when discussing endoscopic procedures with patients. The third intervention was to implement an automated voicemail to be left with patients one week prior to their endoscopic procedure, which again instructed patients to continue their aspirin unless otherwise instructed by their gastroenterologist.

Some logistical barriers were encountered in implementing changes in the pre-procedural written instructions that were sent to patients as well as ensuring all phone schedulers used the revised instruction script, which accounts for the lag in pre- and post-intervention surveys. Once we had ensured a full 8-week "washout" interval after full implementation of the intervention phase had occurred, we initiated the post-intervention survey over an 8-week period from June to August 2018. This was done so as to avoid collecting data from patients who had not yet been fully exposed to our multifaceted intervention.

Post-intervention phase

Post-intervention data was then collected in identical fashion over another 8-week period from June to August 2018. This included the same 10-question survey that was used during the pre-intervention phase, and was also administered by a pre-procedural nurse prior to outpatient endoscopy.

Outcomes

The primary outcomes of our study included the rate at which patients alter their aspirin therapy prior to outpatient endoscopic procedures and whether or not this outcome changed after implementing several targeted interventions. Secondary outcomes included associations with thrombotic risk, procedural bleeding risks, and a qualitative assessment of the reasons for patient alteration of aspirin therapy prior to their procedure. Reasons assessed for alteration in aspirin included: instructions from primary care provider or other non-gastroenterology physician, family or friend, preoperative written instructions sent by mail, instructions during a call from our DDC, patients deciding on their own, or other.

Statistical analyses

A comparison of demographic (age, sex) and clinical (thrombotic risk, procedure type) characteristics of patients enrolled prior to and after the intervention were performed using student t-tests (continuous variables) and chi-square tests (categorical variables) to determine if patients' pre- and post-intervention characteristics were broadly similar. The primary endpoint was cessation of aspirin use prior to endoscopy, defined as stopping aspirin at least 1 day prior to the exam. A logistic

▶ **Table 1** Patient and procedure characteristics.

Variable	Patients on ASA pre-intervention, n = 240	Patients on ASA post-intervention, n = 182	*P* value
Gender no. (%)			0.59
Male	122 (51)	97 (53)	
Female	118 (49)	85 (47)	
Age: years, mean ± SD (range)	64.7 ± 8.9 (30–88)	65.8 ± 8.9 (45–85)	0.22
Length of cessation: days, mean ± SD (range)	4.8 ± 6.1 (1–42)	5.1 ± 8.4 (1–56)	0.36
Thrombotic risk no. (%)			0.44
High risk	35 (15)	19 (10)	
Other risk	163 (68)	128 (70)	
No risk	42 (18)	35 (19)	
Procedure type (%)			
Diagnostic EGD	49 (20)	38 (21)	0.91
EGD, planned resection	8 (3)	4 (2)	0.49
Screening colonoscopy	145 (60)	109 (60)	0.91
Colonoscopy, planned resection	12 (5)	7 (4)	0.57
Enteroscopy	1 (0)	0 (0)	0.38
PEG or PEG-J tube placement	2 (1)	1 (1)	0.73
ERCP	9 (4)	11 (6)	0.27
EUS	18 (8)	19 (10)	0.22
EUS, planned FNA	4 (2)	1 (1)	0.29
Endoscopic ablation	1 (0)	4 (2)	0.09
Other	12 (5)	4 (2)	0.14

ASA, aspirin; EGD, esophagogastroduodenoscopy; PEG, percutaneous endoscopic gastrostomy; ERCP, endoscopic retrograde cholangiopancreatography; FNA, fine-needle aspiration

regression was used to generate Odds-ratios (OR) (95 % CIs) to model the likelihood of cessation as a function of the intervention. OR (95 % CIs) were also generated for multivariable models: model one was adjusted for age and sex, model two was adjusted for age, sex, thrombotic risk (none, other, high) and indication for endoscopy (screening colonoscopy vs. other). Three additional regression models were then generated to examine association between the intervention and the risk of cessation by age (< median, ≥ median), gender (male, female), and categories of risk (no, other, high). Wald tests were used to assess the P for interaction between the intervention and each of the potentially modifying variables. A sub-group analysis was performed among all patients (pre- and post-intervention) who reported cessation of aspirin therapy. Reasons for cessation in patients in the pre- and post-intervention groups were compared using a chi-square test.

Results

Patients and procedures

We identified 240 patients on aspirin therapy prior to our intervention and 182 patients on aspirin post-intervention. There were no significant differences in patient demographics and procedure characteristics when comparing the pre-intervention and post-intervention groups (▶ **Table 1**). The majority of procedures performed consisted of esophagogastroduodenoscopies (EGDs) and screening colonoscopies, accounting for 194 (80 %) and 147 (81 %) patients in the pre-intervention and post-intervention groups, respectively.

Primary outcomes

One hundred and fourteen patients (47.5 %) in the pre-intervention group and 66 patients (36.3 %) in the post-intervention group stopped aspirin prior to their procedure (▶ **Table 2**). There was a significant reduction in the unadjusted rate of aspirin cessation when comparing the pre-intervention and post-

▶ **Table 2** Impact of intervention on aspirin cessation adjusted for risk of cessation.

		Univariate[1]	Adjusted[2]	Adjusted[3]
Intervention Status	Stop taking, n (%)	OR (95 % CI)	OR (95 % CI)	OR (95 % CI)
Pre (n = 240)	114 (47.5)	1.0	1.0	1.0
Post (n = 182)	66 (36.3)	0.63 (0.42–0.93)	0.66 (0.44–0.99)	0.65 (0.43–0.98)
P value		0.02	0.04	0.04

[1] n = 422
[2] Adjusted for age, gender
[3] Adjusted for age, gender, thromboembolic risk (none, other, high), procedure type

▶ **Table 3** Impact of intervention on aspirin cessation by category of reported reason for behavior.

Reason for alteration of aspirin regimen no. (%)	Pre-intervention, n = 116	Post-intervention, n = 67	Total, n = 183	*P* value
Primary care told them to	8 (7)	4 (6)	12	0.81
Another physician told them to	4 (3)	5 (7)	9	0.23
Family member or friend told them to	1 (1)	2 (3)	3	0.28
They were told to in a letter from the DDC	15 (13)	11 (16)	26	0.52
They were told to in a call from the DDC	33 (28)	9 (13)	42	**0.02**
They decided to on their own	50 (43)	36 (53)	86	0.17
Other	8 (7)	4 (6)	12	0.81

DDC, digestive disease center

▶ **Table 4** Impact of intervention on aspirin cessation by categories of thromboembolic risk

Intervention status	No risk OR (95 % CI)	Other risk OR (95 % CI)	High risk OR (95 % CI)
Pre	1.0	1.0	1.0
Post	0.70 (0.28–1.71)	0.63 (0.39–1.02)	0.49 (0.15–1.58)
P value	0.40	0.06	0.20

intervention groups (OR, 0.63; 95 % CI 0.42–0.93), and after adjusting for age, gender, thromboembolic risk, and procedure type (OR, 0.65; 95 % CI 0.43–0.98).

Secondary outcomes

Pre-intervention survey results showed that the most common reasons for cessation of aspirin were self-direction (43 %), pre-procedural phone call instructions (28 %), and pre-procedural written instructions (13 %) (▶ **Table 3**). Post-intervention survey results demonstrated that the only group with a statistically significant reduction was patients reporting pre-procedural phone call instructions as the reason for cessation ($P = .02$) while self-direction and written instruction groups had roughly similar rates of cessation post-intervention.

When assessing whether thrombotic risk was associated with reduction of cessation of aspirin therapy from pre- to post-intervention, we found no significant differences, but there was a trend toward reduction in all categories (▶ **Table 4**).

Demographic variables associated with a reduction of cessation of aspirin therapy from pre- to post-intervention included older age (OR 0.51; 95 % CI 0.29–92) and male gender (OR 0.51; 95 % CI 0.29–0.91) (▶ **Table 5**).

Discussion

To our knowledge, this is the first study to evaluate reasons for cessation of aspirin prior to outpatient endoscopy, and implement an intervention to reduce this behavior. Despite our multi-faceted intervention, however, we were not able to entirely avoid cessation of aspirin. Recommendations to continue aspirin prior to endoscopy are relatively new, and it appears there is a pervasive belief among many patients and practitioners in our referral base that the procedural bleeding risk associated with aspirin is high; as well as, perhaps, an under-appreciation of the increased peri-procedural cardiovascular events associated with its cessation. This is likely not unique to our area, however, as a review of preparation instructions from 317 endoscopy units found that only 43.5 % recommended continuing aspirin, while 32.5 % actually recommended stopping aspirin [11]. Another study found that only 49.5 % of analyzed patients undergoing endoscopy on antiplatelet or anticoagulant therapy were managed in complete compliance with current antiplatelet/anticoagulant guidelines [12].

While we did not evaluate morbidity and mortality related to aspirin alteration in this study, other data suggest that holding

▶ **Table 5** Impact of intervention on aspirin cessation by subgroup (age, gender).

	Adjusted[1]	Adjusted[1]	Adjusted[1]	Adjusted[1]
Intervention status	Younger age[2] OR (95 % CI)	Older age[2] OR (95 % CI)	Male OR (95 % CI)	Female OR (95 % CI)
Pre	1.0	1.0	1.0	1.0
Post	0.87 (0.49–1.54)	0.51 (0.29–0.92)	0.51 (0.29–0.91)	0.85 (0.47–1.51)
P value	0.22	0.02	0.02	0.59

[1] Adjusted for age, gender, thromboembolic risk (none, other, high), procedure type
[2] Age was cut at the median (66).

aspirin monotherapy for significant periods of time in order to reduce gastrointestinal bleeding risk can increase mortality, thrombotic events, and overall adverse events [13]. With approximately 18 million endoscopies performed annually in the United States, it is concerning that potentially almost half of patients are altering their aspirin unnecessarily even when told to continue it, if other centers reflect our experience [14]. This number goes up if one includes the centers that recommend stopping aspirin prior to endoscopy. It should also be noted that the use of aspirin therapy as primary prevention is now a topic of debate and recommendations for this practice may change in the future potentially leading to fewer patients presenting to outpatient endoscopy on aspirin therapy [15].

Our intervention improved patient adherence to aspirin by 11.2 %, which was a relative risk reduction of 23.6 %. When analyzing subgroups of patients and their response to our intervention, there was interestingly no significant effect on those with an increased risk for thromboembolism. All risk profile subgroups, however, did trend towards reduction in cessation and may have been statistically significant with an increased sample size. Unexpectedly, older patients and male patients were significantly more adherent to their aspirin regimen after our intervention was implemented. The reasons for these differences are unclear.

Data from the pre-intervention survey indicate that while the most cited reason that patients held aspirin therapy was self-direction, a close second was the aggregate of written or verbal instructions from our facility. Investigation of this unexpected finding led to the realization that our instructions regarding aspirin continuation were lacking in simplicity and emphasis, potentially leading to confusion and misdirection for patients. It has been estimated that over 90 million Americans have low literacy skills, and that physicians tend to give too much information on too high of a level for many patients to understand [16]. This seems to have played a role in our experience, both for written and verbal instructions.

Data from the post-intervention survey show that our phone call instructions resulted in a significant reduction in patients discontinuing their aspirin. This may be due to alteration of the phone scripts used by our nurses, or the automated voicemail we implemented to further emphasize the need to continue aspirin therapy, or a combination of the two. Interestingly, simplifying and clarifying our written instructions provided no benefit. This is consistent with prior studies, which have found that adding written information to verbal information when communicating with patients does not necessarily improve their understanding [17]. It also may be that timing of the information delivery may have played a role: our automated calls were delivered just a week prior to the scheduled endoscopy, while the written information tended to be delivered substantially earlier than this, potentially making it easier to forget or misinterpret. What proportion of our patients read the instructions is also not known, as we did not specifically assess for this. Notably, all of these interventions have been permanently implemented and we expect no washout of our multifaceted intervention going forward.

A noteworthy finding is that patients discontinued aspirin at the same rate from pre- to post-intervention based on instructions from their non-gastroenterology providers. This finding is echoed by a previous study which showed that only 20 % of participating physicians correctly adhered to aspirin/nonsteroidal anti-inflammatory drug guidelines prior to endoscopy [18]. As our patients are referred from a wide geographic base, we could not conceive of a practical way to convey the message to all potential referring providers, but we were hopeful that our revised written and verbal instructions would be enough to ensure patients continued aspirin. This phenomenon could in part be due to patients having confidence in providers, with whom they may share a more longitudinal relationship. This observation underscores the importance of involving referring physicians in future interventions to reduce aspirin discontinuation.

A weakness of our study is that it was a single-center, tertiary care experience. Our patient population has widely varied levels of education. While we did not assess whether this variable influenced aspirin cessation, it is possible that other centers with a different average level of education may experience different results. Future studies should assess the impact and other social determinants of health.

Conclusion

Our findings indicate that many patients inappropriately discontinue aspirin prior to outpatient endoscopy, for several different reasons. While targeted interventions such as the one we used can reduce this behavior, it also seems to be the case that there is a need for wide spread education to both gastroenter-

ologists and other physicians about the benefits of continuing aspirin prior to endoscopy and the harms of discontinuing it.

Competing interests

The authors declare that they have no conflict of interest.

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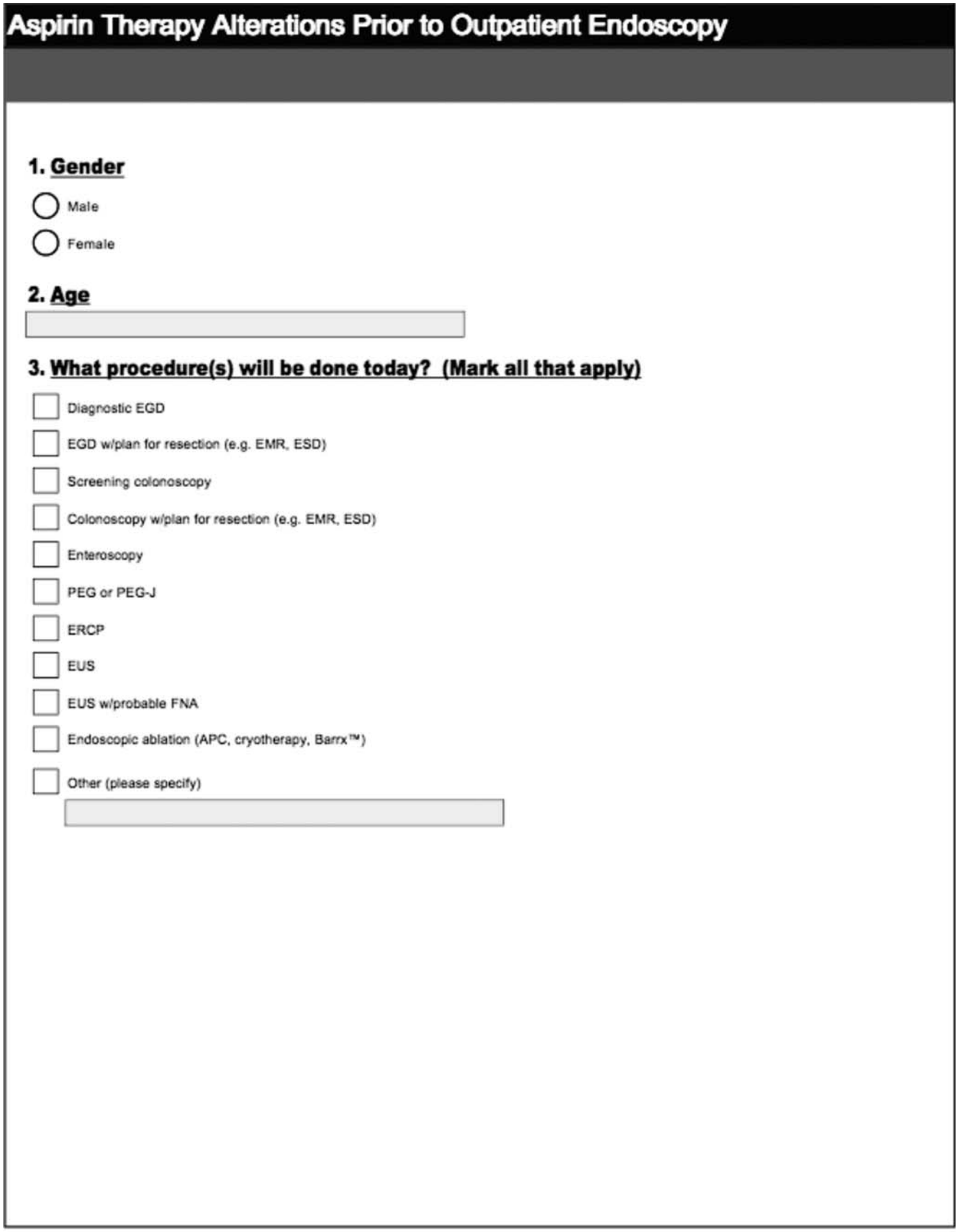

Aspirin Therapy Alterations Prior to Outpatient Endoscopy

1. Gender

Male

Female

2. Age

3. What procedure(s) will be done today? (Mark all that apply)

Diagnostic EGD

EGD w/plan for resection (e.g. EMR, ESD)

Screening colonoscopy

Colonoscopy w/plan for resection (e.g. EMR, ESD)

Enteroscopy

PEG or PEG-J

ERCP

EUS

EUS w/probable FNA

Endoscopic ablation (APC, cryotherapy, Barrx™)

Other (please specify)

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▶ **Supplementary Fig. 1** Pre-intervention and post-intervention survey.

Aspirin Therapy Alterations Prior to Outpatient Endoscopy

4. Do you have a history of any of the following? (Mark all that apply)

- ☐ A fib
- ☐ Valvular heart disease (i.e. aortic stenosis, mitral regurgitation etc.)
- ☐ Prosthetic valve
  (**Please circle type:** *bioprosthetic, mechanical*)
  (**Please circle valve location**: *aortic, mitral, pulmonic, tricuspid*)
- ☐ Congestive heart failure
- ☐ Hypertension
- ☐ Diabetes
- ☐ Stroke/TIA
- ☐ Deep vein thrombosis
- ☐ Pulmonary embolism
- ☐ Recently placed coronary stent (<1 year ago)
- ☐ Heart attack

***5. Do you normally take aspirin on a daily basis?**

- ○ Yes
- ○ No (**SURVEY FINISHED**)

6. What dose of aspirin do you normally take?

- ○ 81 mg or less
- ○ 82-324mg
- ○ 325mg
- ○ >325mg

7. Did you completely stop taking your normal dose of aspirin prior to today's visit?

- ○ Yes
- ○ No

8. Did you decrease your normal dose of aspirin prior to today's visit?

- ○ Yes
- ○ No

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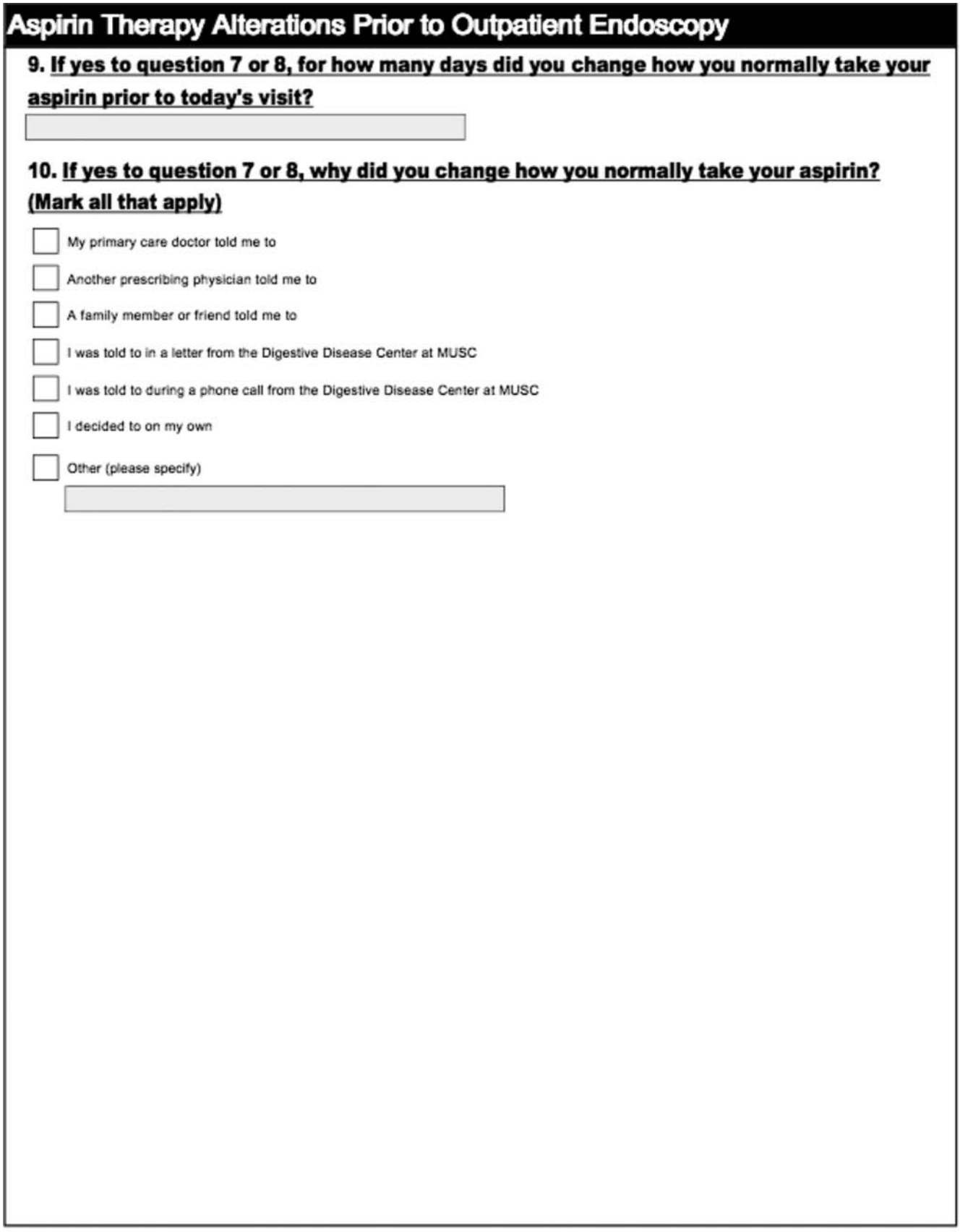
▶ **Supplementary Fig. 1** *Continuation.*



Aspirin Therapy Alterations Prior to Outpatient Endoscopy

9. If yes to question 7 or 8, for how many days did you change how you normally take your aspirin prior to today's visit?

10. If yes to question 7 or 8, why did you change how you normally take your aspirin? (Mark all that apply)

- ☐ My primary care doctor told me to
- ☐ Another prescribing physician told me to
- ☐ A family member or friend told me to
- ☐ I was told to in a letter from the Digestive Disease Center at MUSC
- ☐ I was told to during a phone call from the Digestive Disease Center at MUSC
- ☐ I decided to on my own
- ☐ Other (please specify)

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▶ **Supplementary Fig. 1** *Continuation.*