ORIGINAL RESEARCH

Rajesh Hirallal¹ MD
Gordon Guyatt² MD, MSc
Mohit Bhandari³ MD, MSc
Deborah Cook² MD, MSc
Otavio Berwanger⁴ PhD
Justin de Beer⁵ MD
Claudio Cina⁶ MD, MSc
Norm Buckley⁷ MD
Juan Carlos Villar⁸ MD, PhD
Victor Montori⁹ MD, MSc
Michael Marcaccio⁵ MD
James Paul⁷ MD, MSc
Laura Whiteacre⁶ MD
PJ Devereaux² MD, PhD

¹ Department of Medicine, McMaster University, Hamilton, Ontario

² Departments of Medicine and Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario

³ Departments of Surgery and Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario

⁴ Research Institute (IEP-HCor) Hospital do Coracao in São Paulo, Brazil

⁵ Department of Surgery, McMaster University, Hamilton, Ontario

⁶ Department of Surgery, University of Toronto, Toronto, Ontario

⁷ Department of Anaesthesia, McMaster University, Hamilton, Ontario

⁸ Department of Medicine, Universidad Autónoma de Bucaramanga, Bucaramanga, Colombia

⁹ Knowledge and Encounter Research Unit, Department of Medicine, Mayo Clinic, Rochester, Minnesota, USA

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A survey evaluating surgeons' perioperative usage of acetyl-salicylic acid (ASA) and their willingness to enroll their patients in a perioperative ASA randomized controlled trial

Abstract

Purpose: Major cardiovascular complications associated with noncardiac surgery represent a substantial population health problem for which there are no established efficacious and safe prophylactic interventions. Acetyl-salicylic acid (ASA) represents a promising intervention. The objective of this study was to determine surgeons' perioperative usage of ASA, and if they would enroll their patients in a perioperative ASA randomized controlled trial (RCT).

Methods: Cross-sectional survey of all practicing Canadian general, orthopedic, and vascular surgeons. Our mailed, self-administered survey asked surgeons to consider only their patients who were at risk of a major perioperative cardiovascular complication.

Results: The response rate was 906/1854 (49%). For patients taking ASA chronically, there was marked variability regarding ASA continuation prior to surgery amongst the general and orthopedic surgeons, whereas 76% of vascular surgeons continued ASA in 81-100% of their patients. For patients *not* taking ASA chronically, approaches to starting ASA prior to surgery were variable amongst the vascular surgeons, whereas 70% of general and 82% of orthopaedic surgeons did not start ASA. For patients taking ASA chronically, 73% of general surgeons, 70% of orthopaedic surgeons, and 36% of vascular surgeons would allow at least 40% of their patients to participate in a perioperative RCT comparing stopping versus continuing ASA. For patients *not* taking ASA chronically, most general (76%), orthopaedic (67%), and vascular (51%) surgeons would allow at least 40% of their patients to participate in a perioperative RCT comparing starting ASA versus placebo.

Conclusion: This national survey demonstrates that perioperative ASA usage as reported by surgeons is variable, identifying the need for, and community interest in, a large perioperative ASA trial.

Correspondence to:

Dr. P.J. Devereaux,
McMaster University Health Sciences Centre
Room 2C8, 1200 Main Street West,
Hamilton, Ontario, Canada, L8N 3Z5
E-mail: philipj@mcmaster.ca

Among the 200 million adults worldwide who undergo major noncardiac surgery annually, several million will suffer a major perioperative vascular complication (vascular death, nonfatal myocardial infarction, nonfatal cardiac arrest, or nonfatal stroke) [1,2]. We recently completed the PeriOperative ISchemic Evaluation (POISE-1) Trial that randomized 8351 patients in 190 centres in 23 countries to extended-release metoprolol succinate (metoprolol CR) or placebo around the time of noncardiac surgery [3]. The POISE-1 Trial demonstrated that metoprolol CR prevented myocardial infarctions but increased the risk of stroke and death. These negative consequences of perioperative beta-blockers were unsuspected prior to POISE-1, highlighting the importance and need for large randomized controlled trials (RCTs) in the perioperative setting.

In the non-operative setting, acetyl-salicylic acid (ASA) reduces nonfatal myocardial infarction by one third, nonfatal stroke by one quarter, and vascular mortality by one sixth in patients with, or at risk of, atherosclerotic disease [4]. Immediately after noncardiac surgery, patients experience a rise in circulating platelet release products [5]. Platelet surface catalyzing coagulation reactions facilitate thrombin generation and these events may promote thrombus formation and lead to arterial occlusion in the perioperative setting [6]. Acute withdrawal of chronic ASA results in a pro-thrombotic state (i.e., increased thromboxane A2 and decreased fibrinolysis) [7,8]. Given these physiological changes, ASA initiation or, for chronic users, ASA continuation - and the associated inhibition of platelet aggregation - may prevent major perioperative vascular events [9].

Despite the compelling physiological arguments for the use of ASA therapy in patients undergoing noncardiac surgery, the RCT evidence is limited and conflicting. A systematic review of antiplatelet therapy versus placebo in patients undergoing infrainguinal bypass surgery identified 10 RCTs, of which six evaluated the effects of ASA [10]. This review included a total of 168 vascular events (i.e., vascular death, nonfatal myocardial infarction, or nonfatal stroke) among 1765 patients and demonstrated a trend towards fewer events with ASA (OR=0.76; 95% CI 0.54 to 1.05). In contrast, a hip fracture surgery trial, the Pulmonary Embolism Prevention (PEP) Trial, reported 105 ischemic cardiac events (i.e., death due to ischemic heart disease or nonfatal myocardial infarction) among the 6677 patients randomized to ASA and 79 ischemic cardiac events among the 6677 patients randomized to placebo (HR=1.33; 95% CI 1.00 to 1.78) [11]. ASA did, however, prevent pulmonary emboli (HR=0.43; 95% CI 0.18 to 0.60).

ASA therapy in patients undergoing noncardiac surgery is associated with a higher risk of bleeding, but the magnitude of this risk is uncertain. In the PEP Trial, there were 197 postoperative bleeding episodes requiring a transfusion in the ASA group in comparison with 157 such events in the placebo group (RRI=24%; 95% CI 1 to 53%) [11]. In the Antiplatelet Trialists overview of RCTs in surgical patients (ASA was the intervention in 1/3 of these trials), there were 28 nonfatal bleeding episodes requiring a transfusion among the 3798 patients randomized to antiplatelet therapy and 15 among the 3808 patients randomized to control (p=0.04) [12].

The clear evidence that ASA prevents cardiovascular events in the non-perioperative setting, the physiological rationale for the use of ASA in patients undergoing noncardiac surgery, the conflicting RCT evidence surrounding the impact of ASA on perioperative cardiovascular events, and the imprecision regarding the increased risk of bleeding associated with perioperative ASA, together argue for a large definitive RCT of ASA therapy in patients undergoing noncardiac surgery. Prior to undertaking such a trial, it is important to establish feasibility: the feasibility of a perioperative ASA trial is dependent upon surgeons' willingness to allow their patients to participate. To inform this issue, we undertook a survey of surgeons' current practice patterns of perioperative ASA, and their interest in having their patients participate in a perioperative ASA RCT.

Methods

Study Design and Eligibility

A self-administered mail survey was conducted with Canadian surgeons. Given that 84% of the patients in the POISE-1 Trial underwent general, orthopedic, or vascular surgery, the survey was restricted to these surgeons. All members of the Canadian Association of General Surgeons, Canadian Orthopaedic Association, and the Canadian Society of Vascular Surgeons were eligible to participate in our survey. The surgeons' mailing addresses were obtained from these organizations.

Survey Development

The survey was designed to elicit surgeons' self-reported current use of perioperative ASA, and their willingness to have their patients participate in a perioperative ASA RCT. Research team members, comprised of two surgeons, two internists and one cardiologist, generated items for the survey, discussed format and response options, and reviewed multiple iterations of the survey.

Respondent characteristics were recorded. Surgeons were asked to only consider their patients who were ≥ 45 years of age, with, or at risk of, atherosclerotic disease, and undergoing non-cardiac surgery requiring a general or regional anaesthetic and an overnight hospital stay. These patients represent the eligibility criteria that would be used in a large trial. Surgeons were asked a series of questions related to their patients who were already taking chronic ASA and a series of questions related to their patients who were *not* taking chronic ASA. Our survey was one page long, as research demonstrates that higher physician response rates are associated with shorter surveys [13]. The final survey is given in the Appendix.

Survey Testing

Four general surgeons, nine orthopedic surgeons, and six vascular surgeons assessed the clinical sensibility of our survey instrument using a five point Likert scale, with responses ranging from 1 (negative), 3 (positive), to 5 (extremely positive). Median scores for the six domains evaluated were: face validity (4), content validity (3), clarity (4), utility (4), redundancy (5), and discriminability (3). The survey was pretested prior to administration.

Survey Administration

The survey was mailed to eligible surgeons and was resent to non-responders at four, eight, and 12 weeks after the first mail

out. Test-retest reliability of the survey was evaluated by 54 surgeons at eight weeks (range of kappa values 0.49-0.93).

Data Analyses

The surgeon response rate was determined. For each survey item, the proportion of surgeon respondents who selected each response was calculated. *A priori* a large perioperative ASA trial was deemed to be feasible if surgeons indicated that they would allow $\geq 41\%$ of their patients to participate in that trial. A survey response rate $\geq 45\%$, which would represent at least 834 respondents, was required to adequately inform the feasibility of a large ASA trial. This was based upon the assumption that general, orthopedic, and vascular surgeons would have at least one patient per week (a conservative estimate based on our research) with or at risk of atherosclerotic disease upon whom they perform major noncardiac surgery. If surgeons allowed at least 41-60% (i.e., an average of 50%) of their patients to participate in a perioperative ASA trial, and if 50% of these patients consented, 208 patients could be recruited per week. Even if only 50% of these centres participated in the trial, 104 patients could still be recruited per week. Given that there are at least 42 weeks in a year for recruiting patients, 10,000 patients could be recruited in Canada within a 2.4-year period (i.e., a feasible period of time).

The survey data were analyzed using the Statistical Package for the Social Science (SPSS) version 10.0 software.

TABLE 1. Response rate and respondent characteristics

	General surgeons (N= 900)	Orthopaedic surgeons (N=757)	Vascular surgeons (N=197)	Total surgeons (N=1854)
Number of respondents (%)	442 (49%)	347 (46%)	117 (59%)	906 (49%)
Median number of years in practice	13	15	13	14
Type of Practice (%)				
Community hospital	42%	43%	15%	40%
University affiliated hospital	25%	27%	37%	27%
University hospital	33%	30%	48%	27%

TABLE 2. Surgeons knowledge of patients ASA usage prior to surgery

Proportion of patients for whom a surgeon knew about their ASA usage prior to surgery	Percentage of general surgeons providing various responses	Percentage of orthopaedic surgeons providing various responses	Percentage of vascular surgeons providing various responses
0	0%	2%	0%
1-20	12%	29%	0%
21-40	14%	20%	1%
41-60	11%	9%	5%
61-80	14%	13%	17%
81-100	49%	27%	77%

TABLE 3. Patients taking chronic ASA – proportion of patients that surgeons had continue their ASA prior to surgery and for patients who surgeons had stop their ASA prior to surgery the day ASA was stopped

Proportion of patients for whom surgeons continued ASA before surgery	Percentage of general surgeons providing various responses	Percentage of orthopaedic surgeons providing various responses	Percentage of vascular surgeons providing various responses
0	17%	20%	3%
1-20	43%	44%	4%
21-40	9%	9%	1%
41-60	7%	8%	2%
61-80	8%	7%	14%
81-100	16%	13%	76%

Patients who had ASA discontinued prior to surgery

Day(s) before surgery ASA was typically discontinued			
Day of surgery	1%	3%	4%
1-3	3%	3%	1%
4-7	49%	36%	24%
8-10	39%	43%	19%
> 10	3%	9%	2%
No patients discontinued	6%	5%	50%

TABLE 4. Patients taking chronic ASA – proportion of patients that surgeons had restart their ASA after surgery and the day ASA was restarted after surgery

Proportion of patients for whom surgeons restarted ASA after surgery	Percentage of general surgeons providing various responses	Percentage of orthopaedic surgeons providing various responses	Percentage of vascular surgeons providing various responses
0	1%	3%	0%
1-20	8%	13%	0%
21-40	3%	5%	0%
41-60	3%	5%	3%
61-80	17%	14%	11%
81-100	67%	59%	86%

Patients who had ASA restarted after surgery

Day(s) after surgery ASA was typically restarted			
1	33%	38%	73%
2	21%	11%	9%
3	12%	5%	4%
4-7	20%	13%	9%
8-10	9%	15%	1%
>10	3%	14%	0%
No patients restarted	2%	2%	4%

TABLE 5. Patients *not* taking chronic ASA – proportion of patients that surgeons had start ASA prior to surgery and timing of when ASA was started prior to surgery

Proportion of patients for whom surgeons started ASA before surgery	Percentage of general surgeons providing various responses	Percentage of orthopaedic surgeons providing various responses	Percentage of vascular surgeons providing various responses
0	71%	82%	13%
1-20	23%	16%	11%
21-40	4%	1%	5%
41-60	1%	1%	5%
61-80	1%	1%	19%
81-100	1%	0%	48%
Patients who had ASA started prior to surgery			
Day(s) before surgery ASA was typically started			
Day of surgery	2%	2%	13%
1-3	6%	5%	10%
4-7	6%	4%	5%
8-10	4%	2%	4%
> 10	13%	5%	48%
No patients started	70%	82%	20%

Research Ethics

Permission to contact members via mailing lists was obtained from the Canadian Association of General Surgeons, Canadian Orthopaedic Association, and the Canadian Society of Vascular Surgeons. Participation was voluntary. Data were maintained in password protected files, and kept confidential in locked research offices. This survey was approved by the Hamilton Health Sciences Research Ethics Board.

Results

Response Rates, Surgeon Characteristics, and Knowledge about Patient ASA Use

Table 1 reports the response rate and respondent characteristics. A total of 1854 surgeons were surveyed and 906 completed and returned the survey, a response rate of 49%. A majority of respondents (i.e., 60%) worked in a university or university-affiliated hospital. Table 2 reports surgeons' knowledge of their patients' ASA usage prior to surgery. A majority of general and vascular surgeons reported awareness of whether 50% or more of their patients were or were not taking ASA prior to surgery. Over half of the orthopedic surgeons reported awareness of use of ASA prior to surgery in 40% or less of their patients. Two orthopedic surgeons did not know about ASA usage in any of their patients

prior to surgery; these surgeons were only able to provide data on their willingness to allow their patients to participate in an ASA trial.

Practice Patterns Relating to Patients Taking ASA Chronically

Respondents were asked four questions about their practice regarding their patients who were taking ASA chronically. A majority of general surgeons (69%) and orthopedic surgeons (73%) had less than 40% of their patients continue ASA prior to surgery, whereas a majority of vascular surgeons (76%) continued $\geq$ 81% of their patients on ASA prior to surgery (Table 3). Of respondents who had patients stop ASA, the majority did so $\geq$ 4 days prior to surgery. For patients taking ASA chronically prior to surgery, a majority of general (67%), orthopedic (59%), and vascular (86%) surgeons had their patients restart ASA after surgery (Table 4). For patients who had ASA restarted after surgery, a majority of vascular surgeons (73%) restarted on day one after surgery, whereas 43% of orthopedic surgeons had patients restart ASA $\geq$ 4 days after surgery.

Practice Patterns Relating to Patients Not Taking ASA Chronically

A majority of general surgeons (70%) and orthopedic surgeons (82%) had none of their patients start ASA prior to surgery,

TABLE 6. Patients *not* taking chronic ASA – proportion of patients that surgeons had start ASA after surgery and the day ASA was started after surgery

Proportion of patients for whom surgeons started ASA after surgery	Percentage of general surgeons providing various responses	Percentage of orthopaedic surgeons providing various responses	Percentage of vascular surgeons providing various responses
0	48%	60%	6%
1-20	39%	29%	15%
21-40	6%	4%	4%
41-60	4%	1%	6%
61-80	2%	3%	16%
81-100	2%	3%	52%
Patients who had ASA started after surgery			
Day(s) after surgery ASA was typically started			
1	11%	13%	65%
2	11%	6%	13%
3	7%	4%	6%
4-7	16%	9%	7%
8-10	7%	7%	3%
>10	6%	6%	0%
No patients started	42%	54%	6%

TABLE 7. Proportion of patients that surgeons would allow to participate in a perioperative ASA randomized controlled trial

Proportion of patients surgeons would allow to participate in a RCT	Percentage of general surgeons providing various responses	Percentage of orthopaedic surgeons providing various responses	Percentage of vascular surgeons providing various responses
RCT to evaluate stopping versus continuing ASA in patients taking ASA chronically prior to surgery			
0	15%	19%	53%
1-20	7%	8%	5%
21-40	5%	3%	6%
41-60	11%	13%	11%
61-80	14%	12%	3%
81-100	48%	45%	22%
RCT to evaluate starting ASA versus placebo in patients <i>not</i> taking ASA chronically prior to surgery			
0	14%	22%	39%
1-20	6%	7%	5%
21-40	5%	4%	5%
41-60	12%	10%	9%
61-80	12%	8%	7%
81-100	52%	50%	35%

whereas a minority of vascular surgeons (13%) had none of their patients start ASA prior to surgery (Table 5). Respondents reported widely variable approaches as to when they had patients start ASA prior to surgery (Table 5). For patients *not* taking ASA chronically prior to surgery, a majority of vascular surgeons (52%) had $\geq 81\%$ of their patients start ASA after surgery, whereas a minority of general surgeons (2%) and orthopedic surgeons (3%) had $\geq 81\%$ of their patients start ASA after surgery (Table 6). There was substantial variation as to when respondents had patients start ASA after surgery (Table 6).

Willingness to Allow Their Patients to Participate in a Perioperative ASA Trial

Considering patients taking ASA chronically, 73% of the general surgeons, 70% of the orthopaedic surgeons, and 36% of the vascular surgeons would allow $\geq 41\%$ of their patients to participate in a perioperative RCT comparing continuing versus stopping ASA, Table 7. Considering patients *not* taking ASA chronically, 76% of the general surgeons, 67% of the orthopaedic surgeons, and 51% of the vascular surgeons would allow $\geq 41\%$ of their patients to participate in a perioperative RCT comparing starting ASA versus placebo.

Discussion

Statement of Principle Findings

All Canadian general, orthopedic, and vascular surgeons (total sample 1854 surgeons) were surveyed to ascertain their perioperative usage of ASA and willingness to have their patients participate in a perioperative ASA trial; 906 (49%) surgeons completed our survey. Surgeons reported substantial practice pattern variation regarding their perioperative management of ASA. A majority of surgeons were willing to allow $\geq 41\%$ of their patients to participate in a perioperative ASA RCT.

Strengths and Weakness of This Study

Strengths of our study include the national perspective obtained by surveying all Canadian general, orthopedic, and vascular surgeons about a topical, potentially effective, and available intervention that could impact favourably on perioperative morbidity and mortality. Rigorous survey methods were used [14]. Our survey instrument demonstrated good clinical sensibility on testing in six domains (face validity, content validity, clarity, utility, redundancy, and discriminability); and the test-retest reliability of the survey among 54 surgeons at eight weeks was satisfactory. Limitations include the response rate of only 49%. This response rate did, however, provide enough respondents to assess

the feasibility of a large perioperative ASA trial using our *a priori* criteria. Furthermore, our response rate is similar to most physician-mailed surveys [15]. Many surgeons – especially orthopedic surgeons – did not know about their patients' usage of ASA prior to surgery. To limit the response burden and maximize response rates, we elected not to explore how surgeons' responses vary based upon the specific type of surgery they perform (e.g., carotid endarterectomy versus aortic aneurysm repair). Surgeons' responses to our survey questions may not reflect exactly what they do in their clinical practice; however, high test-retest reliability demonstrated that surgeons were consistent when telling us what they felt they were doing in their clinical practice.

Our Study in Relation to Other Studies

A survey of vascular surgeons in the United Kingdom published in 2001 suggested similar results to our vascular surgeons regarding discontinuation rates of ASA prior to vascular surgery [16], but also found that vascular surgeons varied in their responses based upon the type of vascular surgery. UK vascular surgeons reported discontinuing ASA more often prior to aortic aneurysm surgery (22%) compared to carotid endarterectomies and infrainguinal bypass (both 8%) or varicose vein surgeries (7%).

Meaning of Our Study

Based on the results of this study, surgeons in Canada report no uniform approach to ASA use prior to noncardiac surgery. When surgeons were asked to consider patients who were taking ASA chronically, there was wide variation in practice patterns related to stopping ASA amongst the general and orthopaedic surgeons, whereas the majority of vascular surgeons continued ASA preoperatively. In addition, there was no consensus on which preoperative day to discontinue ASA. A majority of surgeons (i.e., general 67%, orthopedic 59%, vascular 86%) restarted ASA after surgery in $\geq 81\%$ of their patients who had a history of taking ASA chronically. Variability was marked regarding when ASA was restarted except among vascular surgeons among whom 73% started on day one after surgery.

When focusing on patients *not* taking ASA prior to surgery who are at risk for a perioperative cardiovascular events, the majority of general (70%) and orthopaedic (82%) surgeons would not start ASA prior to surgery, whereas vascular surgeons demonstrated marked variability in their responses. There was substantial variability regarding the proportion of patients the various surgical groups would restart ASA in after surgery and the timing of starting ASA prior to and after surgery.

Combining surgeon responses across all surgical groups and for all patients (including those both taking and *not* taking ASA

chronically) indicates that $\geq 41\%$ of surgeons would allow their patients to participate in a perioperative ASA trial. This suggests that a 10,000 patient RCT is feasible within a reasonable time frame (2.4 years).

Conclusion

This national survey of surgeons' self-reported attitudes and practice patterns shows variable perioperative ASA usage. Until clear evidence from a large high-quality RCT is available these marked variations in practice patterns are likely to persist. Our survey identifies the need for, and interest in, a large randomized trial of perioperative ASA among patients undergoing noncardiac surgery.

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Conflict of Interest

Dr. Devereaux has received an in-kind grant from Bayer Schering Pharma AG that is supplying ASA for a large perioperative ASA trial.

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Appendix: Perioperative ASA Survey

PLEASE CHECK THE BOX NEXT TO THE MOST APPROPRIATE RESPONSE

1. What is your surgical specialty: ☐ General ☐ Orthopedic ☐ Vascular
2. Number of years in practice _____
3. Work environment: ☐ Community hospital ☐ Hospital with university affiliation ☐ University hospital

For all of the questions below only consider your patients who fulfill the following criteria: age ≥ 45 , known atherosclerotic disease or at risk of atherosclerotic disease, undergoing non-cardiac surgery requiring overnight hospital admission and a general or regional anaesthetic.

4. What percentage of your patients who fulfill the criteria above do you know whether they are taking ASA therapy or not prior to their non-cardiac surgery?
☐ 0% ☐ 1-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%

Section I: Patients taking chronic ASA therapy

5. Considering your last 100 patients whom you knew fulfilled the criteria above and were taking chronic ASA therapy, how many continued their ASA therapy prior to noncardiac surgery?

☐ 0 ☐ 1-20 ☐ 21-40 ☐ 41-60 ☐ 61-80 ☐ 81-100

6. Considering your last 100 patients whom you knew fulfilled the criteria above and were taking chronic ASA therapy, how many continued their ASA therapy post noncardiac surgery?

☐ 0 ☐ 1-20 ☐ 21-40 ☐ 41-60 ☐ 61-80 ☐ 81-100

7. In those who discontinued ASA, how many days preoperatively was ASA typically discontinued?

☐ day of surgery ☐ 1-3 days ☐ 4-7 days ☐ 8-10 days ☐ > 10 days ☐ no patients had ASA discontinued

8. In those who continued ASA post surgery, how many days post surgery was ASA typically started?

☐ 1 day ☐ 2 days ☐ 3 days ☐ 4-7 days ☐ 8-10 days ☐ > 10 days ☐ no patients had ASA started

9. What percentage of your patients who fulfill the criteria above and who take chronic ASA would you let participate in a perioperative RCT comparing stopping versus continuing ASA?

☐ 0% ☐ 1-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%

Section II: Patients not taking chronic ASA therapy

10. Considering your last 100 patients whom you knew fulfilled the criteria above and were not taking chronic ASA therapy, how many were started on ASA therapy prior to noncardiac surgery?

☐ 0 ☐ 1-20 ☐ 21-40 ☐ 41-60 ☐ 61-80 ☐ 81-100

11. Considering your last 100 patients whom you knew fulfilled the criteria above and were not taking chronic ASA therapy, how many were started on ASA therapy post noncardiac surgery?

☐ 0 ☐ 1-20 ☐ 21-40 ☐ 41-60 ☐ 61-80 ☐ 81-100

12. In those who started ASA pre-operatively, how many days preoperatively was ASA typically started?

☐ day of surgery ☐ 1-3 days ☐ 4-7 days ☐ 8-10 days ☐ > 10 days ☐ no patients had ASA started

13. In those who started ASA post surgery, how many days post surgery was ASA typically started?

☐ 1 day ☐ 2 days ☐ 3 days ☐ 4-7 days ☐ 8-10 days ☐ > 10 days ☐ no patients had ASA started

14. What percentage of your patients who fulfill the criteria above and who do not take chronic ASA would you let participate in a perioperative RCT comparing starting aspirin versus placebo?

☐ 0% ☐ 1-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%