

## BRIEF REPORT

# Absorption of apixaban following metabolic and bariatric surgery: is reluctance still warranted?

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## Abstract

**Background:** Absorption of apixaban, a direct oral anticoagulant (DOAC), may be impaired after metabolic and bariatric surgery (MBS). The Dutch guideline advises switching to vitamin K antagonists (VKA), while patients prefer the use of DOACs. Apixaban is not regularly prescribed after MBS due to a lack of evidence regarding its efficacy and safety.

**Objectives:** This study aimed to evaluate the efficacy and safety of apixaban after MBS.

**Methods:** In this retrospective cohort study, chronic DOAC users who received pre-operative and postoperative consultation and used apixaban (5 mg twice daily) after MBS with available anti-Xa levels were included. The outcomes were incidence rate of postoperative bleeding and thromboembolic events, number of patients switching to VKA, and percentage of anti-Xa peak levels within the expected on-therapy range up to 1 year postoperatively.

**Results:** Of the 97 included patients, 63.9% were female, median age was 57 years (range, 51-61 years), and median preoperative body mass index was 43.2 kg/m<sup>2</sup> (range, 39.5-46.8 kg/m<sup>2</sup>), DOAC use was mostly indicated because of atrial fibrillation (59.8%), and 71.1% underwent Roux-en-Y gastric bypass. No thromboembolic events or major bleeds occurred, and 1 clinically relevant non-major bleeding was observed (incidence rate, 0.61; 95% CI, 0.02-3.38 per 100 patient-years). One patient switched to VKA, and 91.1% of patients had postoperative anti-Xa peak levels within expected on-therapy range.

**Conclusion:** In this population of chronic DOAC users, apixaban with consultation including regular anti-Xa peak level measurements seems safe and effective after MBS. However, future prospective research in a larger population with longer follow-up is needed to confirm these results.

## KEYWORDS

atrial fibrillation, bariatric surgery, factor Xa inhibitors, obesity, thrombosis

## 1 | INTRODUCTION

Obesity is a known risk factor for developing venous thromboembolism and atrial fibrillation [1–3]. Metabolic and bariatric surgery (MBS) is an effective treatment for obesity [4]. For the treatment of venous thromboembolism and the prevention of stroke in patients with atrial fibrillation, direct oral anticoagulants (DOACs) and vitamin K antagonists (VKAs) are commonly used. However, there may be a substantial risk of DOAC malabsorption after MBS, as a part of the gastrointestinal tract where DOACs are absorbed is removed or bypassed after MBS [5]. Currently, the International Society on Thrombosis and Haemostasis (ISTH) advises obtaining a trough drug level if DOACs are prescribed after MBS, to assess adequate absorption [6]. Since this DOAC drug level can only be measured in 2 laboratories in the Netherlands, the Dutch guideline advises switching to a VKA after MBS, as VKAs can be monitored using international normalized ratios, while patients prefer the use of DOAC [7–11].

As an alternative to measuring DOAC drug levels, anti-Xa peak levels can be used, as these exhibit a close direct linear relation with the corresponding DOAC plasma concentrations. Assays of anti-Xa levels are more commonly available in laboratories in the Netherlands and most other countries [12]. Previous research in relatively small study populations ( $n = 18$ –57) found that anti-Xa peak levels of apixaban are mostly within expected on-therapy range, while those of rivaroxaban tend to be below this range after MBS [13–15]. Therefore, this study aimed to evaluate the efficacy and safety of apixaban in a larger population, by evaluating clinical outcomes with the corresponding anti-Xa peak levels in patients who underwent MBS.

## 2 | METHODS

### 2.1 | Study design and population

This was a retrospective cohort study in patients who underwent MBS at Rijnstate hospital (the Netherlands) between November 2018 and October 2023 and with postoperative anti-Xa peak levels available. Patients who chronically used a DOAC before MBS received preoperative and postoperative consultation with a vascular medicine specialist as part of standard care. Patients were informed about the lack of evidence regarding the efficacy and safety of DOAC after MBS, and the advice to switch to a VKA. If patients preferred using a DOAC after MBS, they were allowed to use apixaban, providing that their anti-Xa peak levels were measured and remained within the expected on-therapy range. If the anti-Xa peak level was repeatedly below this range, patients were switched to VKA.

Potential patients for enrollment were identified using CTcue (IQVIA, v4.10.1). Exclusion criteria were the use of another DOAC or dose than apixaban 5 mg twice daily, and not chronically using a DOAC. This study was approved by the local ethical committee of Rijnstate hospital (reference number: 2020-1637).

### 2.2 | Data collection

The following preoperative characteristics were collected from electronic patient records; age, sex, body weight, height, body mass index, estimated glomerular filtration rate, obesity-related comorbidities (ie, hypertension, dyslipidemia, diabetes mellitus type 2, and obstructive sleep apnea), indication for DOAC use, type and dose of DOAC, date and type of MBS (eg, Roux-en-Y gastric bypass [RYGB], sleeve gastrectomy [SG], distal bypass, and revisional surgery).

Primary outcomes were postoperative bleeding and thromboembolic events, expressed as incidence rates per 100 patient-years. For this purpose, the number of events and the follow-up time per patient were collected with a maximum follow-up of 5 years, reflecting standard postoperative follow-up. All electronic patient records were manually reviewed for thromboembolic and bleeding events, including all follow-up consults in bariatric surgery, vascular medicine, and other medical specialties—both inpatient and outpatient—within Rijnstate hospital. Bleeding events were classified as major bleeding or clinically relevant non-major bleeding (CRNMB), using ISTH guidelines [16,17].

Secondary outcomes were the number of patients switching to VKAs and anti-Xa peak level below, within, and above expected on-therapy range (59–302 ng/mL) [12]. Anti-Xa peak levels were measured preoperatively and at 2 weeks, 2 months, and 12 months after MBS, per institutional protocol. Patients were instructed to have blood drawn 2 to 4 hours after ingestion of apixaban to obtain a peak level. Each postoperative anti-Xa peak level measurement was evaluated during a vascular medicine consult. For this study, all levels up to 1 year postoperatively were manually collected from the electronic patient records. For each measurement, the following data were collected: anti-Xa peak level (ng/mL), date and time of blood collection, time since last apixaban intake, use of comedication, and if apixaban was changed to a VKA, including the reason. Trough anti-Xa levels were excluded for analysis. For the preoperative level, the most recent level before surgery was used.

### 2.3 | Anti-Xa assays

Apixaban anti-Xa peak levels from blood samples were determined using an anticoagulation testing system (ACL-Top-350-CTS, Instrumentation Laboratory) at the Department of Clinical Chemistry of the Radboud University Medical Center (Nijmegen, the Netherlands).

### 2.4 | Statistical analysis

Continuous data were expressed as median with (25th percentile [quartile 1]–75th percentile [quartile 3]), and categorical data as frequencies (percentage). For thromboembolic and bleeding events, the incidence rate per 100 patient-years with a 95% CI was calculated using the Poisson distribution. Proportions were used to

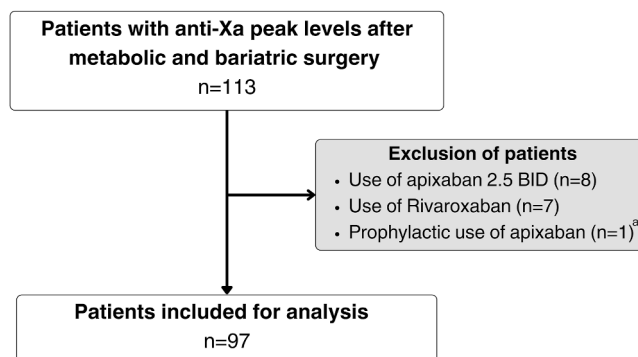


FIGURE 1 Flowchart of exclusion and subsequent inclusion for analysis. <sup>a</sup>This patient used apixaban 5 mg twice daily as postoperative prophylaxis for thromboembolic events, due to an allergy for nadroparin (standard postoperative prophylaxis).

describe postoperative switches to VKA and anti-Xa peak levels (categorized in frequency below, within, or above expected on-therapy range). The anti-Xa peak levels were displayed as boxplots, clustered into time categories (preoperatively, 0-1, 1-6, and 6-12 months). All data were analyzed using IBM SPSS Statistics (version 29.0).

### 3 | RESULTS AND DISCUSSION

After exclusion, 97 patients were included for data analysis (Figure 1). The majority was female (63.9%), with a median age of 57 years [51-61 years], and a preoperative body mass index of 43.2 kg/m<sup>2</sup> [39.5-46.8 kg/m<sup>2</sup>] (Table 1).

#### 3.1 | Bleeding and thromboembolic events

The median postoperative follow-up was 1.4 years [0.9-2.4 years] per patient. No thromboembolic events and 1 CRNMB were observed over 165 patient-years, resulting in an incidence of 0.61 (95% CI, 0.02-3.38) per 100 patient-years. This patient experienced new-onset heavy menstrual bleeding that began during the first menses after RYGB, for which she was treated with tranexamic acid. Her postoperative anti-Xa peak levels were within expected on-therapy range (240 ng/mL at 2 weeks; 262 ng/mL at 5 months postoperatively), and she continued using apixaban.

#### 3.2 | Therapy switches

One patient switched to VKA, 10 months after RYGB, because of a low trough anti-Xa level (20 ng/mL), which was measured in another hospital and was not part of the postoperative consultation. In the remaining 96 patients, there was no reason to switch to VKA and apixaban was continued.

TABLE 1 Patient characteristics of apixaban users before metabolic and bariatric surgery.

Characteristic	Value (N = 97)
Female	62 (63.9)
Age (y)	57 [51-61]
Body weight (kg)	134.0 [117.1-144.6]
BMI (kg/m <sup>2</sup> )	43.2 [39.5-46.8]
eGFR (mL/min/1.73 m <sup>2</sup> ) <sup>a</sup>	88.0 [74.8-90.0]
Indication DOAC	
AF	58 (59.8)
VTE	30 (30.9)
AF and VTE	5 (5.2)
Other <sup>b</sup>	4 (4.1)
Type of surgery	
RYGB	69 (71.1)
SG	22 (22.7)
Other <sup>c</sup>	6 (6.2)
Obesity-related comorbidities	
Hypertension	60 (61.9)
Dyslipidemia	24 (24.7)
Diabetes mellitus type 2	27 (27.8)
Obstructive sleep apnea <sup>d</sup>	42 (43.3)

Data are presented as n (%) or median [quartile 1-quartile 3].

AF, atrial fibrillation; BMI, body mass index; DOAC, direct oral anticoagulant; eGFR, estimated glomerular filtration rate; RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; VTE, venous thromboembolism.

<sup>a</sup> n = 62.

<sup>b</sup> Other indication: atrial flutter (n = 2) transposition of the great vessels (n = 1), cerebrovascular accident in a patient with patent foramen ovale (n = 1).

<sup>c</sup> Other type of surgery: distal gastric bypass (n = 2); single anastomosis duodenal-ileal bypass (n = 1), redo surgery gastric sleeve to RYGB (n = 2), and mason gastric bypass to RYGB (n = 1).

<sup>d</sup> Patients were not routinely tested for obstructive sleep apnea.

**TABLE 2** Categorization of apixaban anti-Xa peak levels in 97 patients as below, within, or above expected on-therapy range (59–302 ng/mL).

Category	Total anti-Xa peak levels	Patients
Preoperative		
Missing	18 (18.6)	18 (18.6)
Below range	1 (1.3)	1 (1.3)
Within range	76 (96.2)	76 (96.2)
Above range	2 (2.5)	2 (2.5)
Postoperative		
Below range	1 (0.5)	0 (0.0)
Below and within range		1 (1.0) <sup>a</sup>
Within range	192 (94.1)	87 (89.7) <sup>b</sup>
Above and within range		6 (6.2) <sup>c</sup>
Above range	11 (5.4)	3 (3.1) <sup>d</sup>

Data are presented as *n* (%).

RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy.

<sup>a</sup> RYGB, *n* = 1.

<sup>b</sup> RYGB, *n* = 63; SG, *n* = 19; distal gastric bypass, *n* = 2; redo surgery of gastric sleeve to RYGB, *n* = 2; single anastomosis duodenal-ileal bypass, *n* = 1.

<sup>c</sup> RYGB, *n* = 4; SG, *n* = 1; redo surgery of mason to RYGB, *n* = 1.

<sup>d</sup> SG, *n* = 2; RYGB, *n* = 1.

### 3.3 | Anti-Xa peak levels before and after MBS

A total of 79 preoperative and 204 postoperative anti-Xa peak levels were available, with a median of 3 [2–4] postoperative levels per patient. The majority of patients (89.7%, *n* = 87) had all their postoperative levels within the expected on-therapy range, 6 patients both above and within, and 3 patients only had levels above range (Table 2). One patient had a single postoperative level below the range (5 months after RYGB; 58 ng/mL); this patient's preoperative level was also below the range (40 ng/mL), the other postoperative levels were within range (216 ng/mL at 1 month and 160 ng/mL at 6 months, postoperatively). This patient continued apixaban therapy.

Deviating anti-Xa peak levels were not related to use of comedication. The median anti-Xa peak levels remained within expected on-therapy range up to 1 year postoperatively (Figure 2). During the first 6 months following MBS, the median anti-Xa peak level slightly increased from 140 ng/mL (preoperatively) to 182 ng/mL (1–6 months postoperatively), after which it returned to 145 ng/mL (6–12 months postoperatively).

This study aimed to evaluate the efficacy and safety of apixaban in patients after MBS, by evaluating clinical outcomes with the corresponding anti-Xa peak levels. We found no thromboembolic or major bleeding events and only 1 CNRMB. Additionally, only 1 postoperative anti-Xa level was temporarily below the expected on-therapy range, in a patient whose preoperative level was also below the range.

In our study, the bleeding incidence with apixaban was 0.61 (95% CI, 0.02–3.38) per 100 patient-years. In previous studies with patients

using DOACs after MBS, the bleeding incidences varied between 3.4 and 17.1 per 100 patient-years [5,8,18]. However, these rates cannot be directly compared, as they were based on pooled data for all DOACs, and absorption may differ between individual DOACs after MBS [13,15].

Our results are comparable with a retrospective study that reported an incidence of 2.4% CRNMB (1.0% in our study) and no major bleeding or venous thromboembolic events in 42 apixaban users after MBS [19]. Moreover, a similar incidence rate was found in a large retrospective cohort of apixaban and rivaroxaban users in the general population (*n* = 15 254), where apixaban users had 0.8% thromboembolic and 1.7% bleeding events [20].

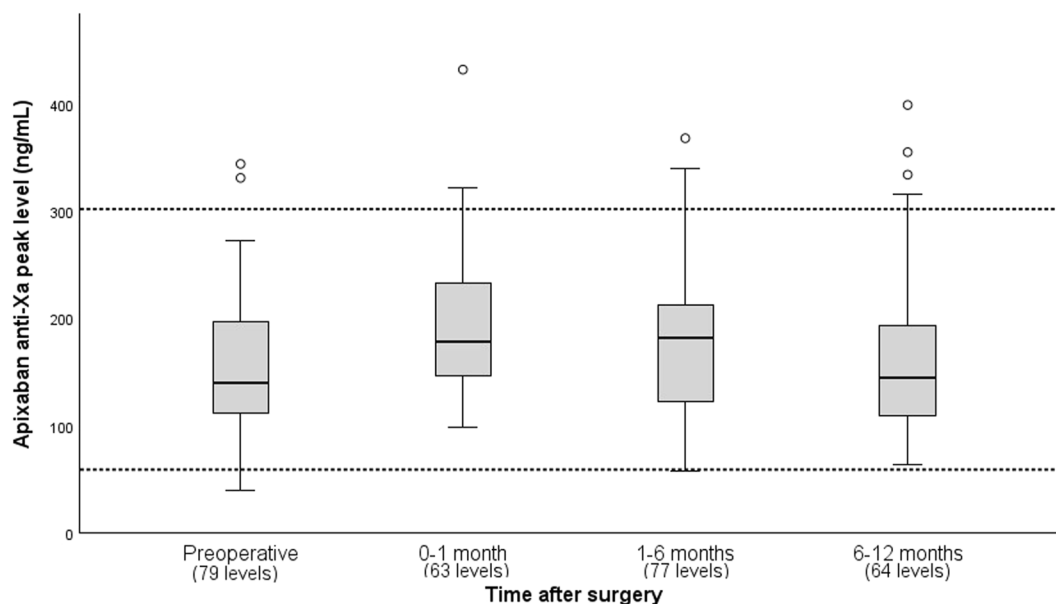
The percentage of patients with (at least 1) anti-Xa peak levels within the expected on-therapy range (96.9%) in our study aligns with a cross-sectional matched cohort study, in which 100% of apixaban users had levels within the expected on-therapy range [13]. The proportion of anti-Xa peak levels below expected on-therapy range in our study was lower (0.5%) than in another retrospective cohort (4.8%) [14]. This difference may be explained by the small study population (*n* = 21 vs *n* = 97 in our study) and the limited number of measurement (*n* = 1 vs *n* = 3 in our study). Notably, in our study, the only sample that was initially below the expected on-therapy range returned within range when reassessed.

We found that anti-Xa peak levels temporarily increased during the first months after MBS. This is in line with a single dose clinical trial in apixaban users after MBS, which found a decrease in factor X activity (which is inversely proportional to anti-Xa levels) and an increase of apixaban drug exposure in the first month after MBS [21].

As mentioned earlier, the current Dutch guideline advises DOAC users to switch to a VKA after MBS. However, a systematic review comparing DOACs and warfarin after MBS found no significant differences in pooled thromboembolic events (4.9% vs 1.5%; *P* = .18) or bleeding events (3.9% vs 11.3%; *P* = .23) [22]. This was confirmed by 3 subsequently published studies, which also found no difference in thromboembolic and bleeding events between patients using VKAs or DOACs after MBS [8,23,24]. It must be noted that the timing of events was not clearly described in these studies. Therefore, it remains unclear whether any of these events occurred in the acute postoperative phase after MBS, during which the ISTH guideline advises against the use DOACs. Despite this limitation, the results of the aforementioned studies combined with higher patient satisfaction among DOAC users, and the findings of this study indicate that apixaban should have a role in patient care after MBS [11].

A strength of this study is the use of real-world data, allowing the evaluation of apixaban within a protocol applicable in daily clinical practice. A second strength is that anti-Xa peak levels were measured serially, enabling assessment of changes over time.

However, some limitations need to be acknowledged. First, the retrospective design may have resulted in incomplete reporting of thromboembolic and/or bleeding events. Second, there is a potential for selection bias, as our cohort consisted of patients who were chronically using a DOAC before MBS, potentially excluding patients who had experienced bleeding or thromboembolic events while on a



**FIGURE 2** Boxplot with median anti-Xa peak levels in 97 patients using apixaban after metabolic and bariatric surgery. Dotted lines are upper (302 ng/mL) and lower (59 ng/mL) limits of the expected on-therapy range of apixaban 5 mg twice daily.

DOAC and subsequently switched to another anticoagulant. Third, we used anti-Xa levels instead of drug levels, although the ISTH guideline advises measuring drug levels. This reflects standard practice in the Netherlands, where anti-Xa levels are more commonly measured. Although there is a strong linear relation between apixaban plasma concentrations and anti-Xa peak levels, no association between subtherapeutic anti-Xa peak levels and decreased efficacy has been established yet. Fourth, this study is probably underpowered—in both number of patients and duration of follow-up—to assess the true incidence of thromboembolic and bleeding events. Nevertheless, this is the largest retrospective cohort study to date evaluating apixaban after MBS with both clinical outcomes and anti-Xa peak levels.

In conclusion, in this population of 97 chronic DOAC users, apixaban—when combined with consultation and regular anti-Xa peak level monitoring—seems safe and effective after MBS, and malabsorption appears limited. However, future prospective research in a larger population with longer follow-up is needed to confirm these results.

#### AUTHOR CONTRIBUTIONS

C.B., C.L., L.H., M.H., and H.M. participated in the conception and design of the study. H.M. and C.B. participated in the acquisition of data. C.B. performed data analysis. All authors contributed to the interpretation of data. C.B. drafted the manuscript and all authors participated in critically revising the manuscript. All authors approved the final version of the manuscript.

#### ETHICS STATEMENT

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional

and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was waived because of the retrospective nature of this cohort study.

#### DECLARATION OF COMPETING INTERESTS

There are no competing interests to disclose.

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