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ORIGINAL ARTICLE

Bleeding and thrombotic risk after direct oral anticoagulant interruption for urological surgery

Riesgo de sangrado y trombosis luego de la interrupción de anticoagulantes orales en cirugías urológicas

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Abstract

Objective: *The aim of this study was to establish the incidence of post-operative bleeding and thrombotic complications after common urological procedures in patients taking a regularly prescribed direct oral anticoagulant (DOAC).* **Method:** *An ambidirectional cohort study of patients on DOACs undergoing urological surgery was undertaken from 2017 to 2019 in a single center. Data were collected on bleeding complications according to the Clavien-Dindo classification, and thrombotic events within 30 days of DOAC interruption.* **Results:** *One hundred and nine patients (99 males, 10 females, mean age 75.7) taking a regular DOAC had urological surgery from 2017 to 2019. Procedures included transurethral resection of bladder tumor (TURBT) (20), TURP (11), holmium laser enucleation of the prostate (HoLEP) (12), ureteroscopy (10), prostate biopsies (19), and others (37). The DOAC was stopped on average 49.7 h before surgery. The median time for restarting the DOAC was 3 days after surgery, mean 4.6 days, IQR 4.5 days. Bleeding complications were noted in four patients (3.66%). Of the patients who had bleeding complications: two patients (following TURP and bladder biopsy) were Clavien-Dindo Grade I; one patient (following HoLEP) was Clavien-Dindo II requiring a blood transfusion; and one patient (following TURBT) was Clavien-Dindo IIIb returning to theatre for bladder washout and cystodiathermy. There were no thrombotic complications within 30 days of stopping DOACs in any patient.* **Conclusion:** *Bleeding complications after perioperatively interrupting DOAC prescription for patients undergoing common endourological procedures are infrequent (< 4%). The risk of blood transfusion and risk of return to theater is < 1%, with no thrombotic complications seen within 1 month of surgery.*

Keywords: *Anticoagulants. Post-operative hemorrhage. Urology. Apixaban. Rivaroxaban. Dabigatran.*

Resumen

Objetivo: *Determinar la incidencia de sangrado postoperatorio y complicaciones trombóticas luego de procedimientos urológicos comunes en pacientes que toman un anticoagulante oral directo (ACOD) regularmente.* **Método:** *Se realizó un estudio de cohorte ambidireccional en pacientes que tomaban ACOD sometidos a cirugías urológicas entre 2017 y 2019 en un solo centro. Se recogieron datos sobre complicaciones hemorrágicas según la clasificación de Clavien-Dindo y eventos trombóticos dentro de los 30 días posteriores a la interrupción del ACOD.* **Resultados:** *En total 109 pacientes (99 hombres, 10 mujeres; edad media 75,7) que tomaban un ACOD regularmente se sometieron a procedimientos urológicos entre 2017*

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y 2019. Los procedimientos incluyeron resección transuretral de tumor de vejiga (RTUV) (20), resección transuretral de próstata (RTUP) (11), enucleación de próstata con láser de holmio (HoLEP) (12), ureteroscopia (10), biopsias de próstata (19) y otros (37). El ACOD se interrumpió en promedio 49,7 horas antes de la cirugía. El tiempo medio para reiniciar el ACOD fue de tres días después de la cirugía, media 4,6 días (RIQ 4,5 días). Se observaron complicaciones hemorrágicas en cuatro pacientes (3,66%). De los pacientes que tuvieron complicaciones hemorrágicas: dos (después de RTUP y biopsia de vejiga) fueron Clavien-Dindo grado I, uno (después de HoLEP) fue Clavien-Dindo II y requirió una transfusión de sangre, y uno (después de una RTUV) fue Clavien-Dindo IIIb y volvió al quirófano para lavado vesical y coagulación. No hubo complicaciones trombóticas dentro de los 30 días posteriores a la interrupción de los ACOD. **Conclusión:** *Las complicaciones hemorrágicas después de la interrupción perioperatoria de los ACOD en pacientes sometidos a procedimientos endourológicos comunes son poco frecuentes (< 4%). El riesgo de transfusión sanguínea y de volver al quirófano es < 1%, sin complicaciones trombóticas observadas dentro del mes posterior a la cirugía.*

Palabras clave: *Anticoagulantes. Sangrado postoperatorio. Urología. Apixabán. Rivaroxabán. Dabigatrán.*

Introduction

Direct oral anticoagulants (DOACs) have been in use for nearly 15 years and have become the most prescribed oral anticoagulants (74% DOACs in the UK in 2019)[1]. DOAC use has gained popularity over warfarin mainly due to more favorable and predictable pharmacokinetics. There is no need for International Normalization Ratio blood test monitoring, and DOACs have fewer interactions with other drugs as well as a faster onset and offset of action. Although the overall "major" bleeding risk is similar for both warfarin and DOACs, the risk of intracerebral hemorrhage is 52% less with DOACs[2]. The four DOACs licensed in the UK are as follows: Rivaroxaban, apixaban, and edoxaban which are direct inhibitors of factor Xa; and Dabigatran – an inhibitor of factor IIa (thrombin). Renal elimination is responsible for 80% of dabigatran clearance, 50% for edoxoban, 35% for rivaroxaban, and 27% for apixaban[3].

At present, guidance for perioperative management of DOACs in urology is variable. The European Association of Urology (EAU) guidelines recommend stopping DOACs between 1-3 days before surgery and restarting "when bleeding is no longer a serious risk – typically 4 days post-surgery"[4]. The EAU guideline is focused on uro-oncological procedures rather than endourological procedures. In other sources, Kanthabalan advised stopping DOACs 24-48 h before surgery, depending on renal function; and advised restarting 24 h post operatively in low bleeding risk procedures or 72 h postoperatively in high to moderate bleeding risk procedures[5]. Lai et al.'s guidelines recommend stopping DOACs 24 h before low bleeding risk surgery, and 48 h before high bleeding risk surgery. Lai et al.'s guidelines state that DOACs should be restarted 24 h postoperatively in low bleeding risk surgery or 48-72 h postoperatively in high bleeding risk surgery[6].

The recent PAUSE study demonstrated a reduced rate of major bleeding (< 2%), and a low rate of arterial thromboembolism (< 1%) when omitting the DOAC for 1 day before and after a low bleeding risk procedure, and for 2 days before and after a high bleeding risk procedure[7]. It should be noted, however, that the PAUSE study population underwent various surgical procedures and interventions, only included patients who took a DOAC for atrial fibrillation (AF), and very few patients were on edoxaban. The EMIT-AF/venous thromboembolism (VTE) observational study reported low major bleeding rates (0.4%) and thromboembolic (0.6%) event rates for patients stopping edoxaban (taken for both AF and VTE). Again, these patients were not having urological procedures specifically. The median pre-operative interruption was 2 days, and restart of edoxaban 3 days postoperatively[8]. There are little data on the safety or otherwise of interrupting DOACs for urological surgery specifically. That said, the PAUSE study indicated that for most patients, a total 2-5-day peri-operative DOAC omission was reasonable.

There is then a lack of consensus on the timing of stopping or restarting these drugs before and after urological surgery. This study aims to highlight a gap in the literature on this subject and begin to address this issue by determining:

- Real-time average safe period of DOAC cessation pre-urological surgery
- Real-time average safe window to restart DOACs after urological surgery
- The bleeding complication rate and outcomes
- The thrombotic complication rate and outcomes
- A comparison with data from non-anti-coagulated patients.

Finally, guidelines for perioperative management of DOACs are outlined which have been adapted from the PAUSE study and presented in this paper.

Method

Data were collected in an ambidirectional manner on consecutive patients on DOACs having urological surgery at Colchester Hospital (East Suffolk North Essex Foundation Trust) during a 2-year period from December 2017 to November 2019. All patients undergoing elective urological surgery who are regularly prescribed a DOAC long-term (either apixaban, rivaroxaban, dabigatran, or edoxaban) were eligible. Flexible cystoscopies were excluded from the study. The cohort was comprised 58 patients with data collected retrospectively from December 2017 to November 2018 and 51 patients with data collected prospectively from December 2018 to November 2019. Hospital healthcare records were used to determine the age, sex, procedure, type of DOAC, indication for DOAC, date of stopping and restarting the DOAC, and use of bridging agents. Bleeding complications were assessed by measuring: the presence of post-operative bleeding in those readmitted; the presence of any hemoglobin drop > 30 g/L; the need for three-way catheterization, blood transfusion, or re-operation. Any post-operative bleeding was accordingly classified with Clavien-Dindo. Community healthcare records were utilized to collect data on any thrombotic events within 30 days of DOAC interruption in this group of patients.

Results

The cohort consisted 109 patients (99 males and 10 females), with mean age 75.7 and IQR 13 years. Seventy-five patients (68.8%) were on apixaban; 22 (20.2%) on rivaroxaban, 10 (9.2%) on dabigatran, and 2 patients (1.8%) on edoxaban. The indications for the DOAC were as follows: 61 patients taking a DOAC due to AF (56%), 13 for pulmonary embolism (11.9%), 5 for deep vein thrombosis (4.6%), and 1 (0.9%) each for aortic valve replacement, stroke, transient ischemic attack, and portal vein thrombosis. Twenty-six patients did not have a clearly documented indication (23.9%).

The following procedures were included as can be seen in table 1: TURBT (20), prostate biopsies (19), HoLEP (12), TURP (11), ureteroscopy (10), cystoscopy and biopsy (6); cystoscopy (6); stent exchange (5); suprapubic catheter insertion (4); UroLift (3); cystolitholapaxy (3); percutaneous nephrolithotomy (PCNL) (2); and one each of the following procedures; circumcision, scrotal exploration, cystoscopy and botulinum toxin injection, laparoscopic nephrectomy, glans penis biopsy, segmental resection of proximal ureter, laparoscopic pyeloplasty, and open nephroureterectomy.

Table 1. Urology procedures included

Urological procedure	Number included
TURBT	20
Prostate biopsy	19
HoLEP	12
TURP	11
Ureteroscopy	10
Cystoscopy	6
Stent exchange	5
Suprapubic catheter insertion	4
UroLift	3
Cystolitholapaxy	3
PCNL	2
Other	8

The DOAC was discontinued on average (mean) 49.7 h before surgery. The median time to restart the DOAC was 3 days after surgery (mean 4.6 days, IQR 4.5 days). Bleeding complications were noted in four patients (3.66%). Three of the patients were on apixaban, and one on rivaroxaban. There was incomplete documentation for 37 patients on the timing of DOAC restart after surgery.

Of the patients who had bleeding complications: two patients (following TURP and bladder biopsy) were Clavien-Dindo Grade I, one patient (following HoLEP) was Clavien-Dindo II requiring a blood transfusion, and one patient (following TURBT) was Clavien-Dindo IIIb requiring bladder washout and cystodiathermy. Two of the four patients with hemorrhagic complications had their DOACs restarted more than 3 days after the operation, as per the surgeon's discretion. The patient who required re-operation following TURBT recommenced his DOAC after 7 days. There were no thromboembolic complications within 30 days of stopping DOACs in any patient.

Discussion

None of the patients who stopped their DOAC in the perioperative period had any thrombotic complications within 30 days of DOAC cessation. Whilst it is encouraging that the perioperative management did not produce any thrombotic complications, the expected rate

of thromboembolic complications is generally accepted to be low (0.4% after TURP)[4].

About 3.66% patients had bleeding complications despite holding their DOAC prescription before urological surgery. About 0.9% required re-operation to stop the bleeding. The transfusion rate was < 1%. This transfusion rate is less than that seen in established TURP case series (3%), in patients not taking DOACs[9]. This is therefore a less than expected rate of transfusion.

What follows is a discussion of bleeding risks by procedure, referencing the available literature and the data from this study.

TURBT

TURBT was the most commonly performed operation (20) in this study, but there are only a few small studies in the literature reporting on the impact of oral anticoagulation on the outcome of TURBT. As far as the authors are aware, all those studies to date have collectively grouped oral anticoagulants with antiplatelet drugs. Konishi et al. conducted a retrospective study on 37 patients who either had their antithrombotic drugs interrupted or continued during their TURBT and found that patients in the continuation group had a clot retention rate of 21% compared to 5% of controls[10]. In another retrospective review Ghali et al. found that non-aspirin anticoagulation increased the rate of hematuria-related unplanned hospital return from 13% to 22% which was statistically significant[11]. In our series of 20 TURBT procedures, there was a 5% risk of clot retention, and 5% risk of unplanned hospital return. These are similar rates to those seen with Konishi's anti-thrombosis interruption cohort, but a more powerful comparison would require larger sample sizes.

HoLEP

HoLEP in the context of DOACs has been studied more extensively. Deuker et al. studied a cohort of 268 HoLEP patients, of whom 22 were treated with a DOAC. The DOAC cohort was too small to conduct subgroup analysis on, but anticoagulation therapy as a whole was not associated with complication rates on regression analysis[12]. Zheng's systematic review of HoLEP in the context of anticoagulation did not make a distinction between DOACs and other forms of anticoagulation. They found that anticoagulation increased the risk of clot retention (RR 2.3), blood transfusion (RR 5.4), and acute urinary retention (RR 2.3)[13]. Becker et al. carried out a retrospective cohort study of 2178 patients undergoing HoLEP where 94 patients were prescribed a DOAC. On cessation of anticoagulation, all these patients were "bridged" with low-molecular-weight heparin (LMWH) perioperatively. The patients on a DOAC had a longer post-operative stay, higher rate of clot retention, and returning to theatre to stop bleeding. There was not a significantly greater drop in hemoglobin compared to the control group who were not on any anticoagulation[14]. Gild et al. have demonstrated, in their retrospective cohort study of HoLEP patients, that anticoagulation therapy bridged with LMWH was associated with an increased hemoglobin drop, a higher blood transfusion rate, and a higher rate of Clavien-Dindo Grade 3b or greater complications[15]. However, neither Becker's nor Gild's study reflect current practice. Bridging with LMWH was standard practice in the management of peri-procedural warfarin interruption. However, the BRIDGE study showed that peri-procedural "bridging" with LMWH in patients taking warfarin for atrial fibrillation produced higher rates of bleeding, with no reduction in thrombotic risk[16]. As a corollary, the practice of routinely "bridging" anti-coagulated patients with LMWH is no longer recommended in the EAU guidelines[3].

Twelve patients who had a HoLEP were included in our own study. The DOAC was restarted on average 5.6 days postoperatively; a slightly later restart compared to the other procedures. One patient had two readmissions with visible hematuria requiring catheterization and a two unit blood transfusion (hemoglobin of 66g/L compared to 113g/L preoperatively). Our data indicates that there may be an increased rate of bleeding complications when performing a HoLEP on patients taking a DOAC, even when stopped 2-3 days before the procedure. Surgeons should consider this when planning HoLEP for anti-coagulated patients.

TURP

While several studies have investigated bleeding risks of TURP in patients taking warfarin, there are no studies that the authors are aware of that have included DOACs. The rate of bleeding complications has been found to be increased in formerly anti-coagulated patients undergoing TURP; additionally, there is an increased risk of thromboembolic complications when anticoagulation is interrupted for the perioperative period[17-19]. Taylor et al. found a bleeding complication rate of 26.3% in anti-coagulated patients having TURP compared with

9.8% in the non-anticoagulated[17]. In a review comparing TURP across different eras, Rassweiler et al. found that in recent studies (2000-2005), the transfusion rate was 3% in patients with unspecified anticoagulation status[9]. Of 11 patients who had TURP included in our study, one had a bleeding complication and required re-admission for three-way catheterization and bladder irrigation. No patients required transfusion. From our data set, it would seem that the bleeding complication rate for patients interrupting DOAC treatment to undergo TURP is similar to that seen in patients that are not regularly prescribed a DOAC, our small sample size acknowledged.

Ureteroscopy

The rate of bleeding complications from ureteroscopy is known to be increased with anticoagulation. Sharaf et al. conducted a systematic review on patients having ureteroscopy on anticoagulation and found that the rate of bleeding complications was significantly increased from 0.42% to 2.5%[20]. No patients on DOACs were included in that systematic review. A retrospective review by Westerman et al. found that in patients who continued anticoagulation during ureteroscopy, the rate of significant bleeding was 33% on DOACs and 7% on warfarin. However, due to the small patient numbers in that subgroup analysis, the authors did not show any statistical significance[21]. Our own study had ten ureteroscopy patients who had been on DOACs before surgery. There were no bleeding complications in our small group.

Transperineal biopsy of the prostate

Transperineal biopsy of the prostate is a procedure with a low risk of bleeding complications, and evidence suggests that it may be safe to continue anticoagulants during the perioperative period. Saito et al. performed a cohort study on patients having transperineal prostate biopsies who were on antiplatelets or anticoagulants. These medications were not stopped before or after the procedure. They reported higher rates of hematuria and clot retention but no complications of Clavien-Dindo Grade 3 and above. However, the authors only included nine patients who were on DOACs[22]. There are 19 patients that had prostate biopsies which were included in our study. All interrupted their DOACs in the perioperative period and there were no bleeding complications.

Table 2. East Suffolk North Essex NHS Foundation Trust guidance on peri-operative management of direct oral anticoagulants (DOACs)

Pre-procedural Management of DOACs			
Rivaroxaban	**Apixaban**	**Edoxaban**	**Dabigatran**
OMIT 2 days pre-procedure			If eGFR ≥ 50: OMIT 2 days pre-procedure. If eGFR < 50: OMIT 4 days pre-procedure.
Pre-procedural Bridging is NOT required after DOAC interruption			
Post-procedural Management of DOACs			
HIGH bleeding risk procedure	Resume DOAC 3 days post-procedure		
All other procedures (non-high bleeding risk)	Resume DOAC 2 days post-procedure		

Major laparoscopic or open surgery

Pose et al. conducted a retrospective cohort study of 321 patients who had radical prostatectomy. The DOAC cohort (107 patients) had their DOAC stopped 2-3 days before surgery, and received LMWH until restarting the DOAC on the 3rd post-operative day[23]. Patients who had DOACs did not have any significant increase in thromboembolic or bleeding complications. Kubota et al. undertook a retrospective study of 20 patients who continued their DOAC throughout the perioperative period for robot-assisted radical prostatectomy (RARP) and did not find any difference in the rates of bleeding or thrombotic complications[24]. This indicates that interrupting the DOAC may not actually be necessary for a RARP in some patient groups. Only four major open or laparoscopic cases were included in our study: laparoscopic nephrectomy, segmental resection of proximal ureter, laparoscopic pyeloplasty, and open nephroureterectomy. With DOAC prescription held perioperatively, there were no bleeding complications in this group.

Conclusion

Our study is limited by the lack of a control cohort for the purpose of comparison, and by the inclusion of relatively small numbers of different operations, making

it difficult to demonstrate statistical significance. There are very few publications studying DOACs in the context of urological surgery, and this study starts to plug the existing gap in the literature. To the best of our knowledge, this is the largest cohort of patients on DOACs having urological surgery in the literature to date.

Bleeding complications after stopping and restarting DOACs for patients undergoing urological procedures appear to be low (< 4%). In our study of 109 patients, there were no thrombotic complications within 30 days of DOAC discontinuation. The rate of either transfusion or return to theatre was 0.9%.

Given our data above, the key findings of the PAUSE study (2019), and drawing on existing local guidelines[4-6,25], we have updated our guidance (Table 2).

Kanthabalan et al. produced guidelines which also involved a categorization of procedures into low or high risk of bleeding; and similarly, a second distinction between high and low risk of thrombosis[5]. Kanthabalan's guidelines focus on patient based risk factors for thrombosis, whereas our guidelines consider primarily the bleeding risk of the procedure. In reality, both patient and procedure thrombotic risk factors must be taken into account. As previously discussed, the current EAU guidelines are non-specific, suggesting stopping a DOAC 1-3 days before surgery and restarting when the DOAC when there is a low risk of bleeding[4]; we feel our updated guidance offers a greater degree of precision.

Our guidelines have been simplified for practical use and so eGFR is used instead of creatinine clearance. As further studies emerge outlining the hemorrhagic and thrombotic risks of different procedures and patient groups, the guidelines can be refined.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of humans and animals. The authors declare that no experiments involving humans or animals were conducted for this research.

Confidentiality, informed consent, and ethical approval. The study does not involve patient personal data nor requires ethical approval. The SAGER guidelines do not apply.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing of this manuscript.

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