Post-operative complications after abdominal surgery in patients treated with oral anticoagulant therapy

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Table 1
Table 2
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Abstract

Introduction: The management of oral anticoagulant therapy preceding abdominal surgery is a clinical problem that will be more and more frequent in the coming years.

Objectives: To investigate the correlation between comorbidities (at the time of surgical treatment) and abdominal surgery post-operative complications in patients treated with OAT, in order to identify risk stratification, correct timing of surgical treatment and postoperative support requirement.

Materials and Methods: In this Prospective Observational Study all patients undergoing abdominal programmed surgery between September 1st 2009 and May 31th 2011 were enrolled. Surgical outcomes and complications were recorded (transfusion requirements, anastomotic leaks, abdominal wall collections, abdominal collections, re-interventions, infections, anemia, hospital re-admission, death).

Results: A total of 834 patients were therefore considered, 35 in OAT (Group A) and 780 not in OAT (Group B). Seven patients in Group A and 153 patients in Group B required transfusion (20.0% vs 19.6%, p= ns), with a mean of 2.71 RBC units required in Group A and 2.75 in Group B. As for fresh frozen plasma, the mean requirement was 0.57 units in Group A as compared to 0.24 units in Group B (p= ns).

Conclusions: Although bleeding in the peri-operative period was feared, hemorrhagic events were not more frequent in the OAT group as compared to the non-OAT one. On the contrary, the most serious complications, including death, were related to thrombotic episodes. A multidisciplinary evaluation is therefore fundamental for these patients, requiring the implementation of new "ad hoc" guidelines.

Introduction

The management of oral anticoagulant therapy preceding abdominal surgery is a clinical problem that will be more and more frequent in the coming years. Several clinical conditions require oral anticoagulant therapy (OAT): mitral stenosis, post-infarction apical thrombosis, significant idiopathic left ventricular dysfunction, antiphospholipid syndrome, deep vein thrombosis, pulmonary embolism, but mainly mechanical heart valve prostheses and chronic atrial fibrillation. The average age of these patients is usually high and, as it is known, advanced age itself represents a risk factor for thrombo-embolic complications in the peri-operative period [1].

Two types of oral anticoagulants are available in Italy: warfarin and acenocoumarol. Their different plasma half-life (32-46 hours and 12 hours respectively) affects the speed of induction and regression of the anticoagulant effect, which is achieved through the interference in the hepatic synthesis of K vitamin dependent coagulation factors. Cardiovascular diseases, the main cause of death in the postoperative period [2], are the most important factor in the assessment of pre-operative risks.

The American College of Physicians has published specific guidelines regarding the evaluation of the peri-operative risk before non-cardiothoracic surgery [3]: risk factors for cardiac complications and postoperative pulmonary disease (COPD, Age ≥ 60 years, ASA II, heart failure) should be assessed in all patients undergoing surgery. A better care is needed for those patients who undergo long lasting operations (> 3 hours) performed urgently and in general anesthesia. For surgery that cannot be deferred in heparin treated patients, the anticoagulant effect can be antagonized by protamine sulfate administration (i.e., push repeated doses while monitoring the aPTT value). However, there is no way to antagonize warfarin. If life-threatening bleeding complications occur during major surgery, only vitamin K and fresh frozen plasma administration is clinically acceptable [4].

In the last years, prothrombin complex concentrates (coagulation factors II, VII, IX and X) have been introduced in clinical practice. When an OAT treated patient needs urgent surgery, these concentrates can be used, since they have an immediate effect in restoring the correct INR value [5].
Methods

Objectives of the Study

The aim of the present study was to investigate the correlation between pre-existing comorbidities (at the time of surgical treatment) and abdominal surgery post-operative complications in a population of patients treated with OAT, in order to identify risk stratification, correct timing of surgical treatment and postoperative support requirement. The objective was to recognize the specific needs of patients taking OAT in order to obtain surgical outcomes similar, as close as possible, to those of patients not in anticoagulation therapy.

Materials and Methods

In this Prospective Observational Study all patients undergoing abdominal programmed surgery between September 1st 2009 and May 31th 2011 at the General Surgery Dept of the University Hospital of Modena were enrolled. A total of 834 patients were therefore considered, 35 in OAT (Group A) and 780 not in OAT (Group B). For low-risk patients [1] we proceeded as follows:

1. dicumarolic drugs were discontinued 3 to 5 days before surgery;
2. if INR was <2, i.v. heparin or s.c. low molecular weight heparin (LMWH) was given in a prophylactic dosage;
3. the time between last heparin dose and surgery depended on dose and type of heparin used (usually 12 hours);
4. 12 to 24 hours after surgery, i.v. heparin or LMWH was given; OAT was started within 24-48 hours after surgery and heparin or LMWH were discontinued when an INR >2 was reached.

For high-risk patients [1], we proceeded according to the following schedule:

1. OAT was discontinued 3 to 5 days before surgery, 6 to 7 days in the elderly;
2. if INR was <2, i.v. heparin in a therapeutic dose (in order to reach an aPTT value not lower than double the reference values) was given until 4 to 6 hours before surgery;
3. according to bleeding surgical risk, iv heparin was started after 8 to 12 hours and OAT after 24-48 hours concurrently (for 5 days), while monitoring both INR and a-PTT;
4. after the correct INR value was reached, heparin was continued for at least 48 hours;
5. alternatively, LMWHs were used, keeping in mind their longer plasma half-life and that limited possibilities are available to antagonize their anticoagulant effect. Usually, LMWHs doses are used in relation to body weight, once or twice a day, according to drug type (last dose at least 12 hours before surgery); 24 hours after surgery heparin was re-started and after further 24 hours OAT was given concurrently. LMWHs were avoided, when possible, in patients with significant renal disease.

Patients were followed for at least three months after discharge, and surgical outcomes and complications were recorded (transfusion requirements, anastomotic leaks, abdominal wall collections, abdominal collections, re-interventions, infections, anemia, hospital re-admission, death). Results were compared in the 2 Groups and the Fisher's exact test was used for statistical analysis.

Results

The characteristics of patients in Group A are reported in Table 1. The main indication to OAT was chronic AF (24/35 patients, 68.6%), followed by mechanical aortic valve (5/35 patients, 14.3%) and previous lower limbs DVT (3/35 patients, 8.6%). All 35 patients were taking medications for hypertension, while 10 of 35 patients had diabetes (28.6%); 8 malignancies (22.9%), 5 chronic ischemic heart disease (14.2%). Nine patients necessitated admission to ICU (3 gastrectomy, 2 sigmoidectomies, 2 right hemicolecotomies, 1 anterior resection of the rectum, 1 incisional hernia repair).

Table 2 shows the clinical outcomes in Group A and Group B. Seven patients in Group A and 153 patients in Group B required transfusion (20.0% vs 19.6%, p=ns), with a mean of 2.71 RBC units required in Group A as compared to 2.75 in Group B (p=ns). Considering surgical outcomes, Group A showed more anastomotic leaks, deaths, and postoperative anemia occurrence (conservatively treated without blood transfusion); the difference reached statistical significance (Table 2). The two deaths in Group A occurred due to thromboembolic complications: pulmonary thromboembolism and stroke.
Discussion

According to the International Self-Monitoring Association of oral anticoagulated Patients (ISMAAP), approximately 650,000 patients in Italy are treated with OAT [6]. OAT treated patients are complicated patients who require more support and care as compared to those not treated with warfarin when even a minor surgery is planned. Unfortunately, guidelines for OAT patients undergoing surgery are not available, and the management of such patients is based only on “personal clinical experience”.

The most feared complication of OAT is bleeding, and the risk of bleeding progressively increases with increasing levels of anticoagulation [7]. Patient’s characteristics are also an important clinical variable influencing the bleeding risk. A past medical history of gastrointestinal or urogenital bleeding, as well as kidney failure, high blood pressure or anemia, increase the frequency of peri-procedural bleeding. Several studies have shown an increased frequency of bleeding complications in elderly patients, although it is difficult to find a precise correlation between age and such complication [8]. However, CNS bleeding (hemorrhagic stroke, subdural hematoma) and major thrombotic events (massive pulmonary embolism) are more frequent in the elderly population, whose bleeding risk is directly related to the anticoagulation levels [9]. LMWHs have already been demonstrated to be able to prevent DVT, pulmonary embolism, stroke and cardiac ischemia, and furthermore their use reduces the incidence of thrombocytopenia and osteoporosis [10].

Our study showed that bleeding is not a frequent complication in OAT treated patients after surgery: in fact blood transfusion and FFP requirement were not different in the 2 examined Groups. Although OAT treated patients can “bleed more” compared to the other patients, this event does not have clinical consequences in the peri-procedural period and surgical outcomes and results are not adversely affected. Post-operative bleeding can be easily controlled and we have several available “weapons” to counter the hemorrhage. In contrast, any thrombo-embolic complication is much more fearsome since we are powerless facing thrombosis. Finally, we recall that bleeding and thrombosis are two sides of the same coin and the flip from one to the other can be almost immediate [11].

Conclusion(s)

The high incidence of postoperative complications in our patient population is mainly due to aging, not only for the degenerative processes of tissues and organs age-associated but also because of the greater susceptibility to infections in elderly patients. Moreover, concurrent diseases age-associated (atherosclerosis, diabetes, respiratory failure, renal failure, etc.) contribute to worsen the clinical picture and to facilitate the onset of acute complications, significantly worsening the prognosis [12].

Finally, great care is needed regarding their labile hemostatic profile approaching surgery and managing their peri-operative period.

As for management of OAT taking patients, the balance between risks and benefits for the single patient should be evaluated taking in account:

- The potential risk for thromboembolic events in case of OAT suspension or reduction;
- The specific bleeding risk for the operation and the possibility to control any bleeding that could occur (e.g., the different approach for the control of venous, arterial or capillary bleeding – oozing - depending on site of bleeding and surgical technique);
- The possible hypercoagulable state after OAT suspension (especially if abrupt).

The patients in our study were taking OAT because of a clear pro-thrombotic state due to the different comorbidities, especially atrial fibrillation. Although bleeding in the peri-operative period was feared, hemorrhagic events were not more frequent in the OAT group as compared to the non-OAT one. On the contrary, the most serious complications, including death, were related to thrombotic episodes. Therefore OAT suspension reverts the thrombotic risk due to the underlying comorbidities, thrombotic risk further increased by the burden of surgical stress.

A multidisciplinary evaluation is therefore fundamental for these patients, requiring the identification and specific training of different physicians, and the implementation of new “ad hoc” guidelines.

Abbreviation(s)

OAT: Oral Anticoagulant Therapy
ICU: Intensive Care Unit
References

11.http://www.fcsa.it
Illustrations

Illustration 1

Table 1: Group A characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Characteristic</th>
<th>Group A (n = 35)</th>
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<td>N</td>
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<tr>
<td>Gender</td>
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<tr>
<td>Male</td>
<td></td>
<td>23</td>
</tr>
<tr>
<td>Female</td>
<td></td>
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<tr>
<td>Comorbidites requiring OAT</td>
<td>Pulmonary thromboembolism</td>
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<td></td>
<td>Dilatative cardiomyopathy</td>
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</tr>
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<td></td>
<td>Mitral valve repair</td>
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</tr>
<tr>
<td></td>
<td>Low limbs DVT</td>
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</tr>
<tr>
<td></td>
<td>Mechanical aortic valve</td>
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</tr>
<tr>
<td></td>
<td>Chronic AF</td>
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<td>Other concurrent diseases</td>
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<td>Ischemic heart disease</td>
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Illustration 2

Table 2: Post-operative complications

<table>
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<th>A (n = 35)</th>
<th>B (n = 780)</th>
<th>P-value</th>
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<tbody>
<tr>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Transfusional requirement</td>
<td>7</td>
<td>20,0%</td>
<td>153</td>
</tr>
<tr>
<td>Partial anastomotic leak</td>
<td>3</td>
<td>8,6%</td>
<td>11</td>
</tr>
<tr>
<td>Abdominal wall collections</td>
<td>1</td>
<td>2,9%</td>
<td>3</td>
</tr>
<tr>
<td>Abdominal collections</td>
<td>0</td>
<td>0,0%</td>
<td>5</td>
</tr>
<tr>
<td>Re-operations</td>
<td>0</td>
<td>0,0%</td>
<td>3</td>
</tr>
<tr>
<td>Septic shock</td>
<td>1</td>
<td>2,9%</td>
<td>2</td>
</tr>
<tr>
<td>Anemia</td>
<td>7</td>
<td>20,0%</td>
<td>8</td>
</tr>
<tr>
<td>Deaths</td>
<td>2</td>
<td>5,7%</td>
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</tr>
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</table>
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