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Perioperative Platelet Inhibition in Elective Inguinal Hernia Surgery—Increased Rate of Postoperative Bleeding and Hematomas?

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In patients on oral antiplatelet therapy secondary to critical vascular diseases, the risk of interrupting antiplatelet therapy has to be weighed against the risk of postoperative hematoma or bleeding when surgery is planned. The goal of this study was to determine the risk of postoperative hematoma and postoperative bleeding in elective inguinal hernia surgery during continuous platelet inhibition. Patients receiving either elective total extraperitoneal hernioplasty or Lichtenstein repair for inguinal hernia were included. Patients with mere suture repair, emergency hernia repair, combination of different simultaneous operations, and patients under therapeutic anticoagulation with heparin were excluded. Postoperative bleeding/hematoma was determined by physical examination and graded according to the Clavien-Dindo classification. Between January 2006 and December 2013, 561 patients with elective surgical repair of an inguinal hernia were included. A total of 29 patients were under continuous perioperative platelet inhibition (PI) with either aspirin or clopidogrel in addition to perioperative antithrombotic prophylaxis with subcutaneous dalteparin injections (PI group). A total of 532 patients received perioperative antithrombotic prophylaxis only (control group). The number of patients under antiplatelet therapy increased from 1.3% (Jan. 2006–Dec. 2009) to 10.0% (Jan. 2010–Dec. 2013; $P < 0.0001$). Postoperative hematoma/bleeding occurred in 5 PI patients (17.2%) versus 38 control patients (7.1%, $P = 0.062$). Rate of postoperative bleeding or hematoma is not higher under mono antiplatelet therapy for elective inguinal hernia repair. Since the majority of hematomas

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can be treated conservatively, it seems unnecessary to stop mono platelet inhibition perioperatively.

Key words: Medical inhibition of platelet function – Aspirin – Clopidogrel – Postoperative complication – Inguinal hernia surgery

Dual antiplatelet therapy with aspirin and a $P2Y_{12}$ inhibitor such as clopidogrel for at least 1 year after percutaneous coronary intervention (PCI) is highly recommended in order to prevent post-PCI stent thrombosis or cardiovascular events.[1] Thereafter, these patients as well as many other patients with cardiovascular comorbidities or risks require at least mono antiplatelet therapy for the rest of their lives. These patients may also develop symptomatic inguinal hernia with a clear indication for surgical repair. Yet, what is the surgeon to do with the antiplatelet therapy? Currently, general surgeons do not have any evidence-based perioperative bridging guidelines at hand.[2] Unsurprisingly, many patients under continuous mono antiplatelet therapy (i.e., aspirin or clopidogrel) undergo inguinal hernia repair without any preoperative risk estimation of postoperative bleeding and hematoma. Thus, the aim of our study was to analyze the postoperative rate for hematomas and bleeding after elective inguinal hernia surgery under mono antiplatelet therapy combined with antithrombotic prophylaxis with subcutaneous low molecular weight heparin (LMWH) injections compared to antithrombotic prophylaxis with LMWH alone.

Patients and Methods

Patients

Patients undergoing elective total extraperitoneal hernioplasty (TEP) or Lichtenstein hernioplasty for inguinal hernia at the Surgical Department I of Charité Campus Benjamin Franklin in Berlin were included in this study. Exclusion criteria were any other types of hernia repair, emergency repair, perioperative low molecular weight heparin (LMWH) or high molecular weight heparin (HMWH) therapy in therapeutic dosages and double antiplatelet therapy. The administration of mono antiplatelet therapy as well as LMWH and HMWH in prophylactic dosage was closely monitored. Mono antiplatelet therapy consisted of either 100 mg aspirin or 75 mg clopidogrel orally continuously on a daily basis. Thrombotic prophylaxis had been dalteparin 5000 IU as subcutaneous injections once daily. Every patient was monitored daily for bleeding or hematoma and underwent a final physical examination for any early postoperative complication by a surgeon before discharge.

Procedures

Lichtenstein hernioplasty and TEP had been each performed in standardized manner as described elsewhere.[3] Intravenous cefuroxime 1.5 g (Fresenius Kabi, Frankfurt Main, Germany) was routinely administered 30 minutes prior skin incision for Lichtenstein hernioplasty. As for TEP, no antibiotic prophylaxis was administered. Both techniques required the tension-free implantation of a 15×12 cm polypropylene-poliglecaprone mesh (Ultrapro, Ethicon, Norderstedt, Germany). As for Lichtenstein repairs, 37.6% were done by the head of the department or an attending surgeon, 14.0% by fellows and 48.4% by residents. As for TEP repairs, 77.7% were done by the head of the department or an attending surgeon, 14.5% by fellows and 7.8% by residents.

The subcutaneous suture was a running Vicryl 2.0 (Ethicon, Norderstedt, Germany). No subcutaneous or subfascial drain was used. The skin closure was a running suture with Prolene 4.0 in Lichtenstein repair and an interrupted suture with Ethilon 5.0 in TEP repair (Ethicon).

Outcome parameters

Primary endpoints were hematoma (defined as a collection of blood subcutaneously of at least 3 cm diameter and swelling) and postoperative bleeding requiring intervention (Clavien-Dindo classification grade 1-3b).[4] Age, sex, length of hospital stay, classification of hernia, training level of surgeon, and surgical procedure were also evaluated. The hernias were classified according to Nyhus classification (Table 1) and between inguinal and scrotal hernias. The frequency of patients receiving platelet inhibition was evaluated and compared between the years 2006 and 2009, and 2010 and 2013.

Table 1 Nyhus classification of inguinal hernias

Nyhus I: Indirect sac, normal internal ring
Nyhus II: Indirect sac, dilated internal ring
Nyhus IIIa: Direct hernia
Nyhus IIIb: Combined indirect and direct inguinal hernia
Nyhus IIIc: Femoral hernia
Nyhus Iva: Recurrent hernia, direct recurrence
Nyhus IVb: Recurrent hernia, indirect recurrence
Nyhus IVc: recurrent hernia, femoral recurrence
Nyhus IVd: Recurrent hernia, combined recurrence

Statistical analysis

Statistical analysis was done with statistical software (IBM SPSS Statistics 21, IBM Corp, Armonk, New York). Descriptive analyses include absolute and relative frequencies for categorical variables, mean, and standard deviation for quantitative measurements. Sex of covariates, surgeon's training level, type of surgical intervention, type of hernia, and platelet inhibition were analyzed univariately on their influence on the occurrence of a postoperative hematoma/bleeding. Multiple logistic regression analysis was performed for the binary outcome "complications" coded 0/1. Covariate ages ($\leq$55 versus >55 years), platelet inhibition and recurrent hernia were included forward stepwise.

Analysis of primary and secondary endpoints was done by χ^2 test or—in case of more than 25% of cells having expected frequency less than 5—Fisher's exact test for group comparisons concerning categorical variables. Group differences concerning numeric variables were analyzed by the Mann-Whitney *U* test. Values of $P \leq 0.05$ (two-sided) were considered significant; no Bonferroni adjustment was performed.

Results

Patient characteristics

Table 2 gives an overview of patient characteristics. A total of 561 patients with elective inguinal hernia surgery between January 2006 and December 2013 were included: 518 males (92.3%) and 43 females (7.7%). A total of 29 patients received perioperative antiplatelet therapy (aspirin 100 mg or clopidogrel 75 mg) combined with prophylactic LMWH (dalteparin 5000 IU); 532 patients received prophylactic LMWH alone. Patients in the platelet inhibition (PI) group were older (68 versus 60 years; $P < 0.001$) and received more often Lichtenstein hernioplasty: 86.2% versus 49.2% in the control group ($P = 0.0001$).

Hematoma/postoperative bleeding: PI versus control group

Five PI patients (17.2%) and 38 control patients (7.1%) developed postoperative hematoma or bleeding ($P = 0.062$). Three PI patients (10.3%) and 32 control patients (6.0%) with postoperative hematoma did not require any surgical intervention ($P = 0.129$). Two PI (6.9%) and two control patients (0.4%) did require bedside intervention (Clavien-Dindo

Table 2 Patient and surgical baseline characteristics: PI in combination with LMWH antithrombotic prophylaxis versus LMWH alone (control)

	Platelet inhibition (aspirin or clopidogrel) and prophylactic LMWH (PI group)	Prophylactic LMWH alone (control group)	*P* value
Patients, n	29	532	
Age, y; median	68	60	0.001
Preoperative hospital stay, d; median	0	0	0.846
Postoperative hospital stay, d; median	4	4	0.622
Type of hernia			
Nyhus 1, n	0	0	–
Nyhus 2, n	14	251	0.691
Nyhus 3a, n	5	115	0.546
Nyhus 3b, n	7	95	0.409
Nyhus 3c, n	0	6	1.00[a]
Nyhus 4a, n	1	23	1.00[a]
Nyhus 4b, n	1	31	1.00[a]
Nyhus 4c, n	0	0	–
Nyhus 4d, n	1	11	0.475[a]
Scrotal hernia, n	3	34	0.429[a]
TEP, n	4	270	< 0.001
Lichtenstein, n	25	262	< 0.001

[a]Fisher's exact test.

Table 3 Hematomas/postoperative bleeding and treatment in patients with PI and prophylactic LMWH (PI group) versus prophylactic LMWH (control group)

	Platelet inhibition (aspirin or clopidogrel) and prophylactic LMWH (PI group)	Prophylactic LMWH alone (control group)	*P* value
Patients, n (%)	29 (5.2%)	532 (94.8%)	
Hematomas/postoperative bleeding, n (%)	5 (17.2%)	38 (7.1%)[b]	0.062[a]
Odds for hematomas/postoperative bleeding	2.71 (CI 0.98–7.5)	0.37 (CI 0.13–1.02)	
Conservative therapy	3 (10.3%)	32 (6.0%)	0.129[a]
Intervention on ward	2 (6.9%)	2 (0.4%)	0.007[a]
Reoperation in general anesthesia	0	3 (0.6%)	1.00[a]

CI, confidence interval.

[a]Fisher's exact test.

[b]One patient had missing data regarding therapeutic intervention.

Grade I; $P = 0.007$). No PI patient had to be taken to the operating room for wound revision under general anesthesia. One control patient showed missing data regarding therapeutic intervention and three control patients underwent surgical wound revision under general anesthesia (Clavien-Dindo Grade IIIb; $P = 1.0$). None of the patients in either group received a blood transfusion.

Frequency of platelet inhibition

The number of patients with elective inguinal hernia repair under antiplatelet therapy increased within the duration of the study: from 4 patients (1.3%: Jan. 2006–Dec. 2009) to 25 patients (10.0%: Jan. 2010–Dec. 2013; $P < 0.0001$; Table 4).

Univariate analysis

Univariate analysis did not show any influence of sex, type of surgical intervention, surgeon's experience (resident, fellow, attending surgeon/head of department); type of hernia; or platelet inhibition on incidence of postoperative hematoma/bleeding (Table 5). Postoperative hematomas/bleeding were more frequent in patients aged older than 55 years compared with patients who were younger (9.6% versus 4.6%; $P = 0.03$) and more postoperative hematomas/bleeding in patients with recurrent hernia vs. those with primary hernia repair (15.3% versus 6.3%; $P = 0.007$). Since platelet inhibition showed a trend toward more postoperative bleeding/hematoma ($P = 0.062$), this aspect was analyzed in more detail by multivariate analysis.

Multivariate analysis

Postoperative hematoma/bleeding was not associated with the initial regression variables age ($P = 0.052$) and platelet inhibition ($P = 0.052$) in multiple logistic regression analysis. A correlation between hematoma/bleeding was observed for recurrent hernia ($P = 0.005$; Table 5).

Discussion

Patients with acute coronary syndrome often require revascularization by means of PCI.[5] Approximately 90% develop restenosis, consequently leading to the implantation of bare metal stents or drug eluting stents. The American College of Cardiology, the American Heart Association, and the European Society of Cardiology highly recommend dual antiplatelet therapy (aspirin, $P2Y_{12}$ inhibitor) for at least 12 months followed by lifelong treatment with

Table 4 Number of patients with elective inguinal hernia repair under PI and prophylactic LMWH and under LMWH alone from Jan. 2006 to Dec. 2013

	Platelet inhibition (aspirin or clopidogrel) and prophylactic LMWH (PI group)	Prophylactic LMWH alone (control group)	*P* value
Jan. 2006–Dec. 2009	4 (1.3%)	306 (98.7%)	<0.001
Jan. 2010–Dec. 2013	25 (10.0%)	226 (90.0%)	

Table 5 Univariate and multivariate analysis of potential risk factors for postoperative bleeding/hematoma

	Postoperative bleeding/ hematoma, n (%)	No postoperative bleeding/ hematoma, n (%)	*P* value, univariate analysis	OR (95% CI univariate analysis)	*P* value, logistic regression
Sex					
Female	2 (4.7)	41 (95.3)	0.76[a]	0.57 (0.13–2.43)	/
Male	41 (7.9)	477 (92.1)		1	
Surgical intervention					
Lichtenstein	22 (7.7)	265 (92.3)	1.0	1.0002 (0.54–1.86)	/
TEP	21 (7.7)	253 (92.3)		1	
Surgeon's training level					
Resident	12 (7.7)	144 (92.3)	1.0	1.007 (0.49–2.07)	/
Fellow	6 (7.7)	72 (92.3)		1.007 (0.40–2.55)	
Unknown	1 (7.7)	12 (92.3)		1.007 (0.13–8.08)	
Consultant/head of department	24 (7.6)	290 (92.4)		1	
Hernia type					
Scrotal hernia	5 (13.5)	32 (86.5)	0.191[a]	2.0 (0.74–5.42)	/
Inguinal hernia	38 (7.3)	486 (92.7)		1	
Age, y					
55	10 (4.6)	207 (95.4)	0.03	0.46 (0.22–0.94)	0.052
≥55	33 (9.6)	311 (90.4)		1	
Platelet inhibition					
Yes	5 (17.2)	24 (82.8)	0.062[a]	2.71 (0.98–7.5)	0.052
No	38 (7.1)	494 (92.9)		1	
Occurrence of hernia					
Recurrent hernia	13 (15.3)	72 (84.7)	0.007	2.68 (1.34–5.39)	0.005
Primary hernia	30 (6.3)	446 (93.7)		1	

[a]Fisher's exact test.

aspirin.[6] In the United States 4% to 7% of stented patients require noncardiac surgery.[7–9] In these cases, the perioperative risk for stent thrombosis due to both a surgery-induced prothrombotic state and antiplatelet therapy interruption has to be weighed against a potentially increased risk of postoperative hematoma or bleeding. The risk for stent thrombosis is highest 6 weeks after bare metal stent and 6 months after drug eluting stent implantation.[10,11] A lack of evidence exists for perioperative bridging therapy in case of permanent antiplatelet therapy.[2] Many patients with continuous mono antiplatelet therapy (aspirin or $P2Y_{12}$ inhibitor such as clopidogrel) undergo inguinal hernia repair without knowing the risk for postoperative hematoma or bleeding. To our knowledge, this is the first analysis evaluating the risk of postoperative hematoma and bleeding in elective inguinal hernia surgery under continuous medical platelet inhibition.

Risk of postoperative hematoma/postoperative bleeding

The number of patients with elective inguinal hernia surgery under continuous antiplatelet therapy rose significantly from 1.3% (Jan. 2006–Dec. 2009) to 10% (Jan. 2010–Dec. 2013) reflecting the widely accepted standard lifetime mono antiplatelet therapy post-PCI and the higher rate of patients requiring antiplatelet therapy due to other cardiovascular and cerebrovascular diseases.[6] With increased aging of our population, we anticipate that this percentage will further rise in the near future. Preoperative withdrawal of ASS as antiplatelet agent in patients with stable coronary artery disease was identified as an independent risk factor for myocardial infarction[12] and accounts for 10% of all postoperative vascular events.[13] Therefore, it became readily common practice in our institution, not to discontinue the antiplatelet therapy pre- and perioperatively in elective inguinal hernia surgery.

The rate of postoperative hematoma/postoperative bleeding was 7.7%. El-Dhuwaib *et al*[14] reported a postoperative hematoma rate of merely 0.8% for laparoscopic and 1% for open repair of inguinal hernia. However, their analysis did not consider the influence of any antiplatelet therapy. Wakasugi *et al*[15] reported not a single postoperative hematoma after TEP procedure when either warfarin had been stopped for 3 days or antiplatelet therapy for 7 days prior surgery. On the other hand, the meta-analysis by Schmedt *et al*,[16] which also did not consider the effect of antiplatelet therapy, revealed a postopera-

tive hematoma rate after inguinal hernia repair between 13.1% and 16%. None of the aforementioned authors stated an exact definition for postoperative hematoma. Imprecise definition possibly explains great variation in postoperative hematoma rates. Furthermore, our fairly broad definition of hematoma probably explains the relatively high rate of detected hematomas at 7.7%. We did not insert any wound drains as Peiper *et al*[17] could show their ineffectiveness to significantly reduce the occurrence of postoperative hematoma in elective inguinal hernia repair.

Postoperative hematoma/bleeding: univariate analysis

Univariate analyses showed no significant influence of surgical technique, training status of the surgeon, type of hernia and especially platelet inhibition on postoperative bleeding. The randomized trial by Andersson *et al*[18] that defined postoperative hematoma as one of the secondary endpoints and the above mentioned meta-analysis by Schmedt *et al*[16] reported more hematomas in the open group compared with endoscopic repair. A trial focusing on postoperative hematomas as primary endpoint failed to determine the favorable surgical technique in order to successfully prevent postoperative hematomas.[19] Both minimal invasive and open repair techniques with mesh can be performed with a comparable and acceptable risk of postoperative hematoma.

Training status of the surgeon was not associated with a higher risk of bleeding complications in our trial. In line with our results, Raval *et al*[20] also found no significant difference in surgical outcomes based on resident involvement in inguinal hernia surgery. Both open and minimal invasive elective inguinal hernia surgery can be done by residents under qualified supervision without increasing the risk of bleeding complications.

Postoperative hematoma/bleeding: multivariate analysis

Our multivariate analysis results did not show a higher risk of bleeding complications for patients older than 55 years. Similarly, Kurzer *et al*[21] also did not show any differences in the occurrence of hematomas between patients aged older than 70 and younger than 50 years who received elective inguinal hernia repair. However, multivariate analysis in our trial was close to statistical significance and the univariate analysis showed a higher proportion of bleeding complications in the elder age group. These older patients might have had unknown valvular diseases, blood abnormalities, or vascular diseases leading to an increased risk for postoperative hematoma or bleeding, which could not have been properly incorporated into our multivariate analysis.

Our multivariate analysis results did show a higher risk of postoperative bleeding episodes in patients with recurrent hernia (15.3%; $P = 0.005$). Smoot *et al*[18] could not detect recurrent hernia repair as a risk factor for postoperative bleeding complications. However, common sense implies the increased difficulty of repairing recurrent hernias without the given regular surgical planes during the primary operation, thus potentially leading to more complications.

The rate of postoperative hematomas and postoperative bleeding under platelet inhibition reached more than 17% but none of these patients had to be reoperated under general anesthesia and no blood transfusions had to be administered. Although there was no significantly higher rate of postoperative hematomas under platelet inhibition, we detected a trend toward more postoperative hematomas under aspirin or clopidogrel in multivariate analysis ($P = 0.052$) and more patients received an intervention on the ward due to postoperative bleeding complications with platelet inhibition ($P = 0.007$).

Burger *et al*[13] described an increased bleeding risk (factor 1.5) for surgical and diagnostic procedures under aspirin therapy, yet without increasing the severity of bleeding complications except for intracranial surgery and transurethral prostatectomy. This systematic review neither detected any trials concerning inguinal surgery nor defined a current guideline for general surgery. In a small pilot study with 52 patients dealing with perioperative use of low-dose aspirin in cholecystectomy, inguinal hernia surgery and colorectal surgery, the risk of severe bleeding was not increased[22] while postoperative hematomas were not evaluated.

As for mono antiplatelet therapy with clopidogrel, Ozao-Choy *et al*[24] could show for patients who took their last dose of clopidogrel within 1 week of surgery required more often blood transfusions intraoperatively. However, there were no significant differences between the groups in postoperative blood transfusions, decreases in hematocrit, hospital stay, intensive care unit stay, late complications, or mortality.[23] Still, the significance of this trial was limited by the fact that it only involved 50 patients and included about 20 different surgical procedures. What is more, the two groups were not well

balanced with more emergency procedures in the clopidogrel group. In surgery of hip fractures, patients receiving aspirin or clopidogrel perioperatively had an increased intraoperative blood loss without increased mortality.[23] In a small retrospective trial with 46 patients with inguinal hernia repair comparing clopidogrel cessation less than 7 days to clopidogrel cessation more than 7 days preoperatively, no differences were seen with respect to blood loss and postoperative bleeding complications. Only 5% of patients under clopidogrel developed a postoperative hematoma.[24]

In line with the majority of studies, we were unable to detect an increased risk of bleeding complications under mono antiplatelet therapy. The majority of complications could be treated conservatively. Still, our study has some limitations. It is a retrospective trial and the number of patients taking antiplatelet agents was quite low.

Summary and Conclusion

Looking at the crude data our study shows that patients with single platelet inhibition (aspirin or clopidogrel) and prophylactic LMWH have a 2.7-fold higher chance of developing a postoperative hematoma or bleeding compared with patients with prophylactic LMWH alone. Though this difference did not prove to be of statistical significance and the majority of these bleeding events had been managed conservatively, clinical relevance and patient comfort cannot be completely dismissed. If withdrawal of platelet inhibition is associated with an increased risk of cardiac events, aspirin or clopidogrel should be continued peri- and postoperatively, otherwise antiplatelet agents should be paused. If inguinal hernia surgery is performed under continuous platelet inhibition especially in recurrent hernia, special caution should be paid to hemostasis and a meticulous operation technique is mandatory.

To our knowledge, this is the evaluation with the greatest number of patients evaluating bleeding complications in inguinal hernia surgery during medical platelet inhibition. Therefore, this trial may help surgeons to assess patients' risk for these complications in this increasingly frequent condition.

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