Bariatric surgery: studies on its consequences with emphasis on thrombotic and bleeding complications
Çelik, F.

Citation for published version (APA):
Çelik, F. (2014). Bariatric surgery: studies on its consequences with emphasis on thrombotic and bleeding complications

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The impact of surgical complications as a main risk factor for venous thromboembolism: a multicenter study


ABSTRACT

Background:
Studies suggest that postoperative complications are a risk factor for venous thromboembolism (VTE) after bariatric surgery. Knowledge of factors associated with a higher risk of VTE after bariatric surgery may be essential to select patients who may benefit from either prolonged or intensified thrombosis prophylaxis. The aim of this study is to determine the relationship between postoperative complications and VTE after bariatric surgery and other classical risk factors.

Methods:
A retrospective multicenter case-control study was performed in patients who had bariatric surgery between January 2008 and September 2011. VTE until 6 months after surgery was registered, and patients were contacted to ascertain the results. For every case of VTE after surgery, 6 control patients were selected who were matched for gender, age, participating center and type of surgery. Risk factors for VTE before and after surgery and postoperative complications were registered.

Results:
A total of 2064 surgeries were included. In 12 patients, VTE occurred within 6 months after bariatric surgery (incidence 0.58%, 95% confidence interval (CI) 0.25 – 0.93). There was a strong association of complications after surgery (cases 91.7%, controls 15.3%, odds ratio (OR) 61.0; 95% CI 7.1 – 521.3) or intensive care admission (cases 50.0%, controls 11.1%, OR 8.0; 95% CI 2.1 – 30.8) with VTE. The majority of postoperative complications were anastomotic leak, abdominal abscess, and infection. We could not detect an association between classical thrombosis risk factors and postoperative VTE.

Conclusions:
The incidence of VTE is low after bariatric surgery using thrombosis prophylaxis. However, there is a strong association between postoperative complications and VTE. These patients may benefit from more intensive thrombosis prophylaxis.
INTRODUCTION

Obese patients undergoing bariatric surgery have an increased risk of venous thromboembolism (VTE), an important cause of morbidity and mortality [1–3]. Even with thrombosis prophylaxis, the overall incidence of VTE after bariatric surgery ranges from 0 [4] to 3.5% [5], with a mortality rate of 0 [6] to 1.9% [7]. There are indications that VTE after surgery is associated with postoperative complications [5,8,9]. A more accurate analysis of the relation between postoperative complications and VTE and knowledge of the factors associated with a higher risk of VTE after bariatric surgery may be essential to select patients with a higher VTE risk who may benefit from either prolonged or intensified thrombosis prophylaxis. In this report, a multicenter retrospective study is described which investigated whether postoperative complications and other classical factors were associated with VTE after bariatric surgery.

METHODS

Study design and population
In this study, a retrospective, multicenter case control study was performed on patients who have undergone bariatric surgery at five centers in the Netherlands: Slotervaart Hospital, Rode Kruis Hospital, Sint Lucas Andreas Hospital, Maxima Medical Center, and Rijnstate Hospital. A total of 2000 patients who had bariatric surgery at least 6 months before inclusion were selected. All types of laparoscopic or open bariatric surgery were included: gastric bypass (GBP), laparoscopic adjustable gastric banding (LAGB), sleeve gastrectomy (SG), biliopancreatic diversion with duodenal switch (DS), Scopinaro (Sc), and revisional procedure (redo). Operations with only removal of a gastric band were excluded. This study received approval from the local medical ethics review committees of each participating study center.

Data collection
Digital and paper medical patient files were used to collect follow-up data from each patient. All patients were called to ascertain the results. For each case with VTE after surgery, six control patients were chosen. The selection process was performed according to strict criteria in order to prevent selection bias. These control patients were matched for gender, age (within a range of +10 and −10 years), participating center, and type of operation by selecting three matches before and three matches after the specific date of surgery.
of the case. In those cases where not enough controls could be found with the same surgery type, GBP surgery was chosen as the control. The matching was also performed for open procedures as much as possible. In case of a reported VTE, data were collected from the case and selected controls using a case report form.

**Data definitions**

VTE was defined as reported and objectively confirmed deep venous thrombosis (DVT) of the leg, pulmonary embolism (PE), and DVT on other location. The diagnosis had to be confirmed by CT scan, duplex ultrasonography, ventilation/perfusion scan, or obduction. The definition for VTE in the past was based on the documentation of the diagnosed condition in the medical record. Complication was defined as any surgery-related complication after surgery and was divided in categories: anastomotic leak, abdominal abscess, iatrogenic injury, other infections, significant bleeding (bleeding that necessitated blood transfusion or bleeding causing a decrease in hemoglobin concentration of >1.24 mmol L−1 [10], or any symptomatic gastrointestinal bleeding), and others (platzbauch or trocar site bowel herniation). Immobility was only noted if there was specific documentation about mobility limitations or being bedridden (defined as bed rest >3 days before the development of VTE).

**Statistical analysis and power considerations**

The aim of the study was to determine the relationship between postoperative complications and VTE after bariatric surgery. We planned to include a minimum of 2000 patients. We hypothesized that the incidence of VTE would be 1% (n=20) and the complication rate around 5% for the controls and 30% for the cases. In order to have a power of above 80%, we needed at least six control patients per case. Baseline characteristics of the patients were summarized using descriptive statistics. Data were first tested for normal distribution using the Kolmogorov-Smirnov and the Shapiro-Wilk tests of normality. Univariate logistic regression analysis was used for the computation of odds ratios and 95% confidence interval (CI). All tests were two-tailed, and a p value <0.05 was considered statistically significant. Statistical analyses were performed using SPSS software package (version 19).
RESULTS

Study population
A total of 2064 surgeries, performed between January 15, 2007 and September 30, 2011 at five different medical centers, were included. The majority of the surgeries consisted of GBP (60.6%), followed by LAGB (22.1%), redo (8.1%), and SG (7.4%). A minority (1.8%) consisted of ring-banded/distal/modified GBP, Sc, and DS. Seventy-six patients (3.7%) had undergone more than one procedure (usually GBP after removal of the gastric band). Overall, the majority of the procedures (>95%) were performed using the laparoscopic approach. Fourteen patients (0.68%) died in the follow-up period. Four of these (0.2%) were related to the complications after bariatric surgery. The response rate of the telephone calls for checking data was 62% (1276 of the 2064 procedures) and was comparable in each center.

Incidence of VTE, characteristics of patients with VTE and control patients
VTE was diagnosed in 12 patients (0.58% (95% CI 0.25 – 0.93) during the first 6 months after bariatric surgery. Eleven of these were detected with data searching and one by a telephone call. This one episode of VTE “by phone” was confirmed by clinical records. In 1272 of the 1273 patients reached by telephone (99.9%), the manually checked data were confirmed. Seven patients developed PE (0.34%), one of these was fatal. Three patients had DVT (0.15%). One patient had a jugular vein and subclavian thrombosis secondary to insertion of a central venous catheter. One patient had a portal vein thrombosis after splenectomy because of a bleeding complication during bariatric surgery.

We selected 84 control patients, six matched patients for each case from the same center. The mean age of the study population was 44.9 ± 10.5 years and 63 were female (75%). Mean age was not different between the cases and the controls (46.0 ± 11.1 vs 44.8 ± 10.4 years, respectively, p=0.720). The majority of the patients (72.6%) underwent a GBP. For 8 cases who had a GBP, 48 control patients were selected who had the same surgery type (matching of 100%). For 3 patients who had a redo, 16 control patients with redo were selected and 2 patients with GBP (matching of 89%). Finally, there was one patient who had an SG. For this patient, three control patients were selected who had an SG and three with a GBP (matching of 50%). Two cases with VTE had an open surgery, while there were 11 cases for the controls (matching of 92%). Duration of surgery did not differ between cases and controls (108.5 ± 38.2 vs 98.0 ± 38.6 min, respectively, p=0.927). Additional characteristics of the patients are shown in Table 1.
Table 1. Patient characteristics of patients who experienced venous thromboembolism (VTE) after bariatric surgery (cases) and the matched (control) patients.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Cases n=12</th>
<th>Controls n=72</th>
</tr>
</thead>
<tbody>
<tr>
<td>gender (women)</td>
<td>9 (75.0)</td>
<td>54 (75.0)</td>
</tr>
<tr>
<td>age (yrs)</td>
<td>46.0 ± 11.1</td>
<td>44.8 ± 10.4</td>
</tr>
<tr>
<td>diabetes</td>
<td>4 (33.3)</td>
<td>21 (29.2)</td>
</tr>
<tr>
<td>hypertension</td>
<td>4 (33.3)</td>
<td>28 (38.9)</td>
</tr>
<tr>
<td>dyslipidemia</td>
<td>3 (25.0)</td>
<td>18 (25.0)</td>
</tr>
<tr>
<td>sleep apnea</td>
<td>4 (33.3)</td>
<td>17 (23.6)</td>
</tr>
<tr>
<td>heart failure</td>
<td>0 (0)</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td>renal insufficiency</td>
<td>2 (16.7)</td>
<td>2 (2.8)</td>
</tr>
<tr>
<td>smoking</td>
<td>1 (8.3)</td>
<td>17 (23.6)</td>
</tr>
<tr>
<td>previous smoking</td>
<td>3 (25.0)</td>
<td>19 (26.4)</td>
</tr>
<tr>
<td>length (m)</td>
<td>1.73 ± 0.09</td>
<td>1.71 ± 0.08</td>
</tr>
<tr>
<td>weight (kg)</td>
<td>134.9 ± 28.9</td>
<td>129.8 ± 24.8</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>44.7 ± 7.6</td>
<td>44.4 ± 6.0</td>
</tr>
<tr>
<td>WC (cm)</td>
<td>133.4 ± 10.3</td>
<td>133.5 ± 15.6</td>
</tr>
<tr>
<td>GBP</td>
<td>8 (66.6)</td>
<td>53 (73.6)</td>
</tr>
<tr>
<td>SG</td>
<td>1 (8.3)</td>
<td>3 (4.2)</td>
</tr>
<tr>
<td>Redo</td>
<td>3 (25.0)</td>
<td>16 (22.2)</td>
</tr>
<tr>
<td>laparoscopic</td>
<td>10 (83.3)</td>
<td>61 (84.7)</td>
</tr>
<tr>
<td>duration surgery (min)</td>
<td>108.5 ± 38.2</td>
<td>98.0 ± 38.6</td>
</tr>
<tr>
<td>mortality</td>
<td>1 (8.3)</td>
<td>1 (1.4)</td>
</tr>
</tbody>
</table>

Data are presented as mean ± standard deviation, or number of patients (%).
Abbreviations: BMI=body mass index; WC=waist circumference; GBP=gastric bypass; SG=sleeve gastrectomy; Redo= revisional procedure.

In-hospital rate of VTE was 0.05%. Four cases (33%) occurred in the first month (Fig. 1). The median time between operation and the development of VTE was 58 days (range 6 – 133). Every center used low molecular weight heparin as thromboprophylaxis. However, the type of low molecular weight heparin regimen varied (enoxaparin 40 mg twice daily during 14 days, nadroparin 2850 IU once daily during admission, nadroparin 5700 IU once daily during 4 weeks, nadroparin 5700 IU once daily during 6 weeks, and dalteparin 5000 IU once daily during 10 days), and mechanic prophylaxis was not part of every regimen. In 73% of all surgeries, low molecular weight heparin was continued for at least 10 days, while 4 of the 12 VTE cases (33%) only had low molecular weight heparin during their admission (median 3 days, range 2 – 66) or had stopped it earlier than planned after discharge. Eleven of the 12 cases (91.7%) developed VTE after cessation of thromboprophylaxis.
The impact of surgical complications as a main risk factor for venous thromboembolism

There was a strong association between complications after surgery and the development of VTE (cases 91.7%, controls 15.3%, odds ratio (OR) 61.0; 95% CI 7.1 – 521.3). Anastomotic leak and infection were observed more frequently in cases (Table 2). When we focused on non-bleeding complications (anastomotic leak, infection, and iatrogenic injury), the OR was 35.0 (95% CI 6.6 – 186.1). No differences were noted in bleeding complications. We also observed associations with the complication-related variables, readmission for complication and admission to the intensive care. We could not detect an association between classical risk factors and postoperative VTE (Table 2).
Table 2. Predictive factors for venous thromboembolism risk in cases and control patients.

<table>
<thead>
<tr>
<th>Variables</th>
<th>cases</th>
<th>controls</th>
<th>p-value</th>
<th>univariate OR 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>any complication</td>
<td>11 (91.7)</td>
<td>11 (15.3)</td>
<td>&lt;0.001</td>
<td>61.0 7.1 - 521.3</td>
</tr>
<tr>
<td>anastomotic leak/iatrogenic/infection</td>
<td>10 (83.3)</td>
<td>9 (12.5)</td>
<td>&lt;0.001</td>
<td>35.0 6.6 - 186.1</td>
</tr>
<tr>
<td>anastomotic leak</td>
<td>7 (58.3)</td>
<td>3 (4.2)</td>
<td>&lt;0.001</td>
<td>32.2 6.3 - 164.2</td>
</tr>
<tr>
<td>anastomotic leak/iatrogenic</td>
<td>7 (58.3)</td>
<td>4 (5.6)</td>
<td>&lt;0.001</td>
<td>23.8 5.2 - 109.7</td>
</tr>
<tr>
<td>infection</td>
<td>9 (75.0)</td>
<td>6 (8.3)</td>
<td>&lt;0.001</td>
<td>33.0 6.9 - 155.6</td>
</tr>
<tr>
<td>bleeding</td>
<td>2 (16.7)</td>
<td>4 (5.6)</td>
<td>0.188</td>
<td>3.4 0.5 - 21.0</td>
</tr>
<tr>
<td>other complication</td>
<td>2 (16.7)</td>
<td>2 (2.8)</td>
<td>0.065</td>
<td>7.0 0.9 - 55.4</td>
</tr>
<tr>
<td>central venous catheter</td>
<td>5 (41.7)</td>
<td>1 (1.4)</td>
<td>0.001</td>
<td>50.7 5.2 - 497.4</td>
</tr>
<tr>
<td>immobility</td>
<td>2 (16.7)</td>
<td>0 (0)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>hospital stay, days</td>
<td>5 (2-55)</td>
<td>3 (1-66)</td>
<td>0.018</td>
<td>1.1 1.0 - 1.1</td>
</tr>
<tr>
<td>readmission</td>
<td>10 (83.3)</td>
<td>12 (16.7)</td>
<td>&lt;0.001</td>
<td>25.0 4.9 - 128.9</td>
</tr>
<tr>
<td>intensive care admission</td>
<td>6 (50.0)</td>
<td>8 (11.1)</td>
<td>0.003</td>
<td>8.0 2.1 - 30.8</td>
</tr>
<tr>
<td>obstructive lung disease</td>
<td>2 (16.7)</td>
<td>9 (12.5)</td>
<td>0.693</td>
<td>1.4 0.3 - 7.4</td>
</tr>
<tr>
<td>previous malignancy</td>
<td>1 (8.3)</td>
<td>4 (5.6)</td>
<td>0.708</td>
<td>1.5 0.2 - 15.1</td>
</tr>
<tr>
<td>venous insufficiency/varicosis</td>
<td>2 (16.7)</td>
<td>5 (6.9)</td>
<td>0.275</td>
<td>2.7 0.5 - 15.7</td>
</tr>
<tr>
<td>previous venous thromboembolism</td>
<td>1 (8.3)</td>
<td>2 (2.8)</td>
<td>0.361</td>
<td>3.2 0.3 - 38.1</td>
</tr>
<tr>
<td>oral contraceptives</td>
<td>2 (16.7)</td>
<td>11 (15.3)</td>
<td>0.902</td>
<td>1.1 0.2 - 5.8</td>
</tr>
<tr>
<td>trauma</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>thrombophilia</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>pregnancy</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

Data are presented as number of patients (%) or median (range). Controls are matched for age, gender, and type of surgery. Univariate logistic regression analysis was used. OR=odds ratio. CI=confidence interval. NA= not applicable. Other complication; platzbauch or trocar-site bowel herniation.
DISCUSSION

This study shows that, with thromboprophylaxis, the incidence of VTE after bariatric surgery is low. However, there is a very strong association between postoperative complications and VTE. No relation was detected for other traditional risk factors of VTE.

The low incidence of VTE in our study is in line with the previous studies [4,9,11–15]. A systematic review showed a 0.5% incidence of postoperative PE [16]. However, the incidence of VTE in the literature varies. Gonzalez et al. [5] showed a prevalence of postoperative VTE of 3.5%. Also, Steele et al. [17] found a cumulative incidence of 2.99% 6 months after bariatric surgery. Many studies showed a lower prevalence of postoperative VTE than observed in this study, however, with a shorter follow-up time [9,13–15]. The reason for this wide variation in incidence of VTE may be related to heterogeneity of the studies in sample size, distribution of the type of bariatric surgery, open or laparoscopic procedure, different methods to define VTE and to follow up patients, the use of different inclusion and exclusion criteria, the use of different schemes of thromboprophylaxis, and varying follow-up time of the study. In many (large) population studies, the follow-up time is usually limited to in-hospital [1,7,14,18–20] or 30 days after surgery or discharge [9,21–27]. Another possible reason for the varying incidence, even in large studies, is the utilization of ICD-9 CM codes [1,7,13,17,18,20] or an insurance claims database [17] for detecting VTE cases with the potential for errors and bias in diagnostic and procedural coding. Surgeon volume, which is also a well recognized predictor of outcome, could give as well an explanation for this varying incidence of post surgical VTE [22].

In this study, complications after surgery were found to be predictive of higher risk for VTE. There are few studies that identified complications as a VTE risk. Finks et al. [9] showed that when anastomotic leak was included in the regression model, it proved to be a highly significant predictor of VTE, with an OR of 8.84 (95% CI 3.59 – 21.73). Also, in the study of Carmody et al. [8], gastrointestinal leak was identified by univariate analysis as a predictor of PE before 1992, but this correlation disappeared during the more recent era of routine anticoagulation prophylaxis. Gonzalez et al. [5] showed with multivariate analysis that postsurgical anastomotic leak was associated with an increased likelihood of developing postoperative VTE.
How do the observed ORs translate in terms of absolute VTE risk? When we speculate that the rate of complications during 6 months after surgery was 15% in all 2064 surgeries, based on the rate among 72 control patients, the absolute risk of developing a VTE was 3.6% in patients with a complication versus 0.06% in patients without a complication.

We did not investigate the underlying mechanism explaining the relation between complications and VTE. However, most complications are related to a strong inflammatory response, immobilization, interventions, dehydration, a high hematocrit level, or combinations of these. All these elements are proven VTE risk factors. One could argue that the pathogenesis of portal vein thrombosis is different. However, exclusion of this case yielded similar results (data not shown). There are indications that a prolonged operative time might contribute to an increased risk of postoperative VTE [9,19,28]. This might be related to the complexity of the surgery that can contribute to the complication risk and therefore the development of VTE. There is little data on variability in VTE risk among the different bariatric surgery procedures, although a wider range was reported after open bariatric surgery [5,7,13,29] and revisional procedures [5,27]. From our study, we cannot conclude that a specific type of surgery is a risk for VTE because of the matching procedure. In addition, the study was not powered to compare VTE incidence between different procedures. Given the higher surgical complication rate after redo, one would expect a higher incidence of VTE in this group. We did not detect a clear difference in duration of surgery between cases and controls.

Previous studies on risk factors for VTE after bariatric surgery suggested male gender [1,7,9,17,30], older age [1,5,9,17,30–32], ethnic difference [1,30], VTE in the past [5,9,17,30,33], chronic renal failure [7], congestive heart failure [7], chronic lung disease [7], obesity hypoventilation syndrome [8,34,35], venous insufficiency [8,35,36], smoking [5,17,31], alcohol abuse [7], high BMI [8,9,27,30,35], type of bariatric procedure (revisional procedures) [5,27], open surgery [5,7,13,29,30], duration of surgery [9,19,28], a longer hospital stay [7,17], and immobility [24] as potential risk factors. The fact that the combination of factors per study differs might be due to the heterogeneity of studies. We could not detect an association between other classical thrombosis risk factors and postoperative VTE, but the study was underpowered to detect more subtle differences. A risk factor known in studies as a strong predictor of development of a VTE postsurgery is a history of VTE [5,9,17,30,33]. In this study, the cases had a higher percentage of a previous VTE than the controls (8.3 vs 3.6%), respectively, which was not statistically significant different, given the low numbers. Age and gender could not be analyzed as risk factors for VTE
because of the matching procedure. However, the percentage of women and mean age was comparable with the total study population.

The reported incidence of VTE is reduced since the use of thromboprophylaxis. However, there is still no consensus about the best prophylaxis regimen [37,38]. The current guidelines issued by the ACCP recommend routine pharmacologic prophylaxis combined with mechanical prophylaxis [39]. A notable finding in this study is that most VTE developed after cessation of thromboprophylaxis. This is in line with other studies [27,31]. However, we do not think that we have to extend the postoperative chemoprophylaxis in all patients after bariatric surgery. The observed incidence of VTE is too low, in those without a surgical complication even very low. Extending chemoprophylaxis in all patients would mean an overtreatment for many patients, with additional costs and potential harm. Moreover, there is no clear evidence for the efficacy of extending chemoprophylaxis. The time of development and duration of postoperative complications are heterogeneous. Complications may present or may not be solved when the routine thromboprophylaxis is stopped. The question arises therefore whether these specific high risk patients need a more aggressive or extended scheme of thromboprophylaxis. Especially patients with a (nonbleeding) complication more than a week after surgery may benefit from a higher than the usually prescribed low dose of anticoagulant therapy. Whether a low molecular weight heparin at 50% or at 80% from therapeutic dose is better needs to be investigated in a prospective clinical trial.

The use of routine duplex ultrasonography to detect VTE has been suggested. Based on our findings in this study, we cannot recommend routine use of repeat duplex ultrasound in patients with complicated outcomes in order to detect DVT. The efficacy of this must be proven in further prospective trials. The problem is that this strategy probably leads to asymptomatic DVT cases, a well-known problem in the orthopedic surgery trials in which repeat ultrasound is used as an “intermediate” endpoint. There is no consensus in the literature on how to treat these patients, and the majority of these subclinical thromboses do not lead to clinical symptoms without treatment.

Theoretically, an inferior vena cava (IVC) filter may prevent pulmonary emboli in patients after bariatric surgery. However, there is no evidence for the use of IVC filters in this setting with a too low VTE incidence. The guidelines of the American Chest Physicians state clearly that IVC should not be used for primary VTE prevention. However, an IVC filter can be
used in patients with a high VTE risk in combination with a high bleeding risk, for instance, a patient with a previous VTE and a severe bleeding complication.

There are limitations of this study. Although the way we conducted this research by searching medical records was extensively and carefully, data can be missed for the analysis of other possible traditional risk factors because of the retrospective design of the study. The strengths of this study are that the design of the study for risk analysis is new and that we have confirmed the results with additional searches and telephone calls to the majority of the patients, which makes the results more reliable and the chance that we have missed VTE cases low. The fact that the differences in the distribution of type of surgery, mortality, VTE rate, response rate, and the follow-up of patients between centers were small is important. The follow-up time of this study was adequate to register the VTE cases in comparison with other studies. We checked all types of bariatric surgery, all forms of VTE, traditional risk factors, did not maintain exclusion criteria, in a multicenter study. This design adds to the generalizability of the study.

In conclusion, this study identified postoperative complications as an important risk factor for the development of VTE after bariatric surgery despite the low incidence of VTE under widespread use of prophylactic therapy and the trend toward less-invasive surgical procedures. Patients with postoperative complications may benefit from intensified thromboprophylaxis. This should be evaluated in a prospective clinical trial.

ACKNOWLEDGEMENTS

The authors wish to thank Mark Tenhagen, Karin Hartog, Kemal Dogan, Parweez Koehestanie, Jan Blokzijl, and Vanessa Pen for their support of controlling the logistics of looking up data.

CONFLICT OF INTEREST

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.
REFERENCE LIST


