Risk Stratification and Prophylaxis of Venous Thromboembolic Events in Obstetrics

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Abstract

Objective: To identify the risk factors for perioperative venous thromboembolism, and the possible consequences of pharmacologic thromboprophylaxis used with cesarean delivery.

Study design: An Enterprise Data Warehouse (EDW) of a multi-hospital system was queried to obtain the incidence of and risk factors for perioperative venous thromboembolism (VTE) and the use of pharmacologic thromboprophylaxis (PTP).

Results: Of 337,174 surgical patients over the course of 2010-2013, Cesarean Delivery (CD) occurred 24,608 times, with pharmacologic VTE prophylaxis (PTP) being provided 931 times (4% of the time) and 23,677 times without such prophylaxis. Hemorrhagic complications were recorded 0.08% of the time (0.3% when PTP was provided, and 0.08% without it). As this was found to be statistically significant (p=0.02), this warrants our concern, regarding the appropriateness of using PTP for all cesarean deliveries.

Conclusion: Pharmacologic thromboprophylaxis may have the risk of associated hemorrhage with its use, and it may be worthwhile to use risk stratification to decide whether or not to use it for surgical prophylaxis in particular cesarean cases.

Keywords: VTE prophylaxis; VTE risk; Antithrombotic therapy; VTE; Hemorrhage

Introduction

Venous thromboembolic episodes (VTEs) have caused recognizable morbidity and mortality in the specialty of Obstetrics and Gynecology, as well as in other medical specialties. For example, one VTE may occur per approximately 1000 pregnancies and per 200 cesarean deliveries during the puerperium [1]. Efforts have been directed towards creating Clinical Decision Support (CDS) tools so as to promote the use of prophylaxis, including pharmacologic and mechanical modalities, in standard clinical practice, possibly resulting in its recent lessened incidence [2,3]. Acknowledgement of the lessons of our clinical data collection can result in the reliance on risk stratification strategies for these continued efforts [4].

The American College of Obstetrics and Gynecology (ACOG) has long advanced risk stratification for determining the level of optimal VTE prophylaxis [1]. It may now be worthwhile to invest in those logical strategies that can lead to the most optimal results. With regard to the risks and benefits of VTE prophylaxis, one may need to consider the possible bleeding consequences of pharmacologic prophylaxis, [5-8] as well as the sometimes limited effectiveness or compliance of using the mechanical modality of Sequential Compression Devices (SCDs) [9]. The potential impact of any standardized use of a VTE prophylaxis measure in obstetric/gynecologic practice needs to be considered [10-12]. Specifically for cesarean deliveries, we may need to emphasize VTE pharmacologic prophylaxis for particular risk factors.

It is the intent of this report to describe the incidence of VTE following cesareans, its associated risk factors, and the risks and benefits of pharmacologic prophylaxis in obstetric practice, as measured in a health system.

Method

For this low-incident phenomenon, we queried the Enterprise Data Warehouse (EDW) of a Chicago metropolitan healthcare system of hospitals for the incidence of post-operative VTE among all patients having been consecutively admitted for any surgical procedure. The number of surgical cases performed, the number of cesareans performed, the methods of prophylaxis provided, associated medical co-morbidities, and bleeding complications encountered post-operatively, for the time period of 2010 through 2013 were collected. The clinical data collected in this query was initially entered at the time of care using the Cerner Millennium system, universally employed within the network of hospitals. The data was analyzed using an Excel spreadsheet, tabulating the surgical results.

The individual co-morbidities sought within the collected obstetric cases performed in the system of hospitals for this time period were identified from ICD-9 codes (used at the time of the EDW query), corresponding to personal history of thrombosis or pulmonary embolism, and personal history of all carcinomatous neoplasms. Hemorrhagic complications included postoperative and intraoperative and unspecified hemorrhagic complications, pelvic hematoma, hematoma of broad ligament, and other and unspecified intracranial/intracerebral hemorrhage. Additionally, specific codes were identified as indicating the use of specific anticoagulation medications typically

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Received: September 29, 2015; Accepted: October 31 2015; Published: November 07, 2015


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used for pharmacologic prophylaxis (e.g. enoxaparin and direct thrombin inhibitors at any dosage).

Chi Square Statistical analysis was performed for all of the discrete elements examined, and this investigation was approved by the appropriate Investigational Review Board, as all patient protections were observed for this retrospective study.

Results

A description of the demographics of the study population can be seen in Table 1. The specific International Classification of Disease (ICD) codes that were included in the query conducted for this investigation are listed in Table 2. The large dataset examined included a total of 337,174 surgical cases. Of these, 24,608 were cesareans, of which pharmacologic thromboprophylaxis (PTP) was ordered for 948 (4%) (see Table 3). Of those provided PTP, 21 cases had documented VTE (2.2%), while 2 cases of VTE occurred among the 23,660 patients who did not receive PTP (0.008%). What may be equal in importance, postoperative hemorrhage occurred in 3 Cesarean patients (of 948 who received pharmacologic prophylaxis) compared to 20 (of 23,660 who did not), 0.3% versus 0.08 (p=0.02). It is understood from internal and external data reporting that mechanical VTE prophylaxis (e.g. Sequential Compression Devices, or SCDs) were universally employed and external data reporting that mechanical VTE prophylaxis (e.g. Sequential Compression Devices, or SCDs) were universally employed when determining the incidence of hemorrhagic complications as a consequence.

The increased risk of VTE with malignancy as well as with prior history of VTE was also confirmed by analysis of this larger dataset, as opposed to the smaller cesarean population alone. It can be noted that a significant level of perioperative bleeding also occurred in the large dataset, as well as that seen among just the cesarean cases. It can be mentioned that among the patients not given peri-operative PTP, the incidence of VTE was approximately equivalent to the incidence of bleeding complications seen in the total cesarean population.

Discussion

According to our results, the risk of hemorrhagic complications may be equivalent to the risk of VTE when anticoagulant therapy is provided for VTE prophylaxis. While there may be particular risk factors for VTE associated with cesarean delivery (e.g. past history of VTE, malignancy, thrombophilia and obesity), this investigation did not adequately measure this. However, this suggests that there may indeed be an important place for risk stratification in this regard. Various publications have shown bleeding risk to be of concern in this setting, and Cundiff emphasized this [5]. Mechanical VTE prophylaxis with SCDs, has little risk of bleeding associated with its use, which has shown its value for preventing VTE, along with early mobilization after surgery, for procedures with low or moderate risk of VTE [13]. Assessing a patient’s VTE risk for any surgical procedure may help direct the choice of prophylaxis modality to be used (i.e., mechanical versus pharmacologic prophylaxis), perhaps minimizing its unwelcome consequences.

While it may appear from the collected clinical data that providing PTP may increase the likelihood of VTE occurring, it is much more likely that a clinician simply chooses to use PTP for the perceived VTE risk, and that the clinician was indeed correct in that clinical assessment, with VTE occurring more commonly among those given the PTP. In order to determine the difference in outcome between providing PTP or not, one would need to conduct a randomized trial, and that is an unlikely investigation anytime in the near future. Looking at the large clinical dataset, almost 2% of the surgical patients had a history of prior VTE, yet only less than 1% of them had a current VTE. Of course, the common current use of mechanical VTE prophylaxis may be a contributor to this, along with the selective use of PTP. Given that other factors may significantly contribute to the risk of VTE for cesarean delivery, and given that hemorrhagic complications may accompany the use of PTP, a strong argument can be made that risk stratification should always be employed to determine the ideal VTE prophylactic methodology to employ.

The primary weakness of this investigation is that from the query of the EDW, a distinction between the therapeutic and prophylactic anticoagulant medication administration was not made. Nonetheless, when determining the incidence of hemorrhagic complications as a result of use of these medications, the dosage that was used may not need to be determined, if any hemorrhagic circumstances were at all seen associated with their use. The query of the EDW, however, did collect all cases admitted even after the index surgery identified by the

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>ICDs</th>
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<tbody>
<tr>
<td>Personal History of VTE</td>
<td>V12.51, V12.55</td>
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<tr>
<td>Hemorrhagic conditions</td>
<td>459.0, 620.7, 624.5, 665.71-74, 997.02, 998.11-12</td>
</tr>
<tr>
<td>VTE</td>
<td>415.11, 415.12, 415.13, 451.0, 451.1, 451.81-89, 453.40-42, 453.6, 453.81-89, 453.9, 673.0-64</td>
</tr>
</tbody>
</table>

Table 1: International classification of diseases (ICD) codes used.

<table>
<thead>
<tr>
<th>Age</th>
<th>Total #</th>
</tr>
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<tbody>
<tr>
<td>18-51</td>
<td>19,285</td>
</tr>
<tr>
<td>36-51</td>
<td>5,029</td>
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Table 2: Demographics of study population.

<table>
<thead>
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<th>Payer</th>
<th>Total #</th>
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<tbody>
<tr>
<td>Private</td>
<td>14,737</td>
</tr>
<tr>
<td>Medicare</td>
<td>9,347</td>
</tr>
<tr>
<td>Medicaid</td>
<td>8,774</td>
</tr>
</tbody>
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Table 3: VTE results (24,608 Cesarean deliveries, 2010-2013, across all hospitals in network).
Medical Record Number. This would allow for those instances of a post-surgical VTE diagnosis at an admission separate from the index surgery. However, a postsurgical VTE case admitted to an outside institution would not have been recorded in this dataset.

Since pharmacologic prophylaxis is being considered as a measure of quality performance, [14] there should be caution applied before it becomes a standard practice, especially when mechanical prophylaxis may be a better option for many patients, with its low cost and low side effect profile. We must be cognizant of the few important risk factors for the occurrence of post-cesarean VTE (e.g., age, obesity, malignancy, immobilization and past history of VTE), [15,16] so we can offer the best prophylaxis for it, rather than always providing pharmacologic prophylaxis, considering its possibly associated perioperative bleeding risk. Perhaps a future investigation can look at the effectiveness of various tools used for risk stratification to identify appropriate VTE prophylaxis methodology.

References
14. The Joint Commission. Surgical Care Improvement Project core measure set effective for discharges.