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Research Report

PROJECT TITLE & AUTHORS

Project Title:	Efficacy of currently recommended enoxaparin dosing titration for therapeutic use in neonates	
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PROPOSAL CHECKLIST

Completed (Y)	Checklist item
Y	Project title is clear and concise.
Y	Names and emails for project advisor(s) and up to five students per group are provided.
Y	Abstract is no more than 250 words and retains headings
Y	Introduction provides a definition of the topic under study, importance of the topic, and the issue addressed by the study and is no more than one single-spaced page.
Y	There is NO literature review section
Y	Purpose of project is clearly and concisely stated
Y	Methods section uses headings and represents a summary of the methods used. (Actual methods used should be described if they were modified from the proposal.)
Y	Data analysis described is appropriate and responds to the purpose.
Y	Appropriate tables are included in the results section.
Y	Text of results section interprets the findings reported in the tables, not repeating them.

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Y	The discussion section includes a description of the most important findings, and relates findings to the literature.
Y	The final section of the discussion is the limitations section.
Y	The conclusions respond to the purpose statement.
Y	Reference list is complete and contains appropriate references, and reference style is applied correctly and consistently.
Y	Data collection/recording form(s) and/or questionnaire(s) are included in the appendix.
Y	Information is placed in the appropriate section—introduction, methods, results, etc.
Y	Template structure is maintained and all required sections are included. Red text instructions/examples are removed. Proposal is written in Times New Roman 12-point font and does not exceed 10 single-spaced pages (excluding appendices). Proposal has been spell-checked and grammar-checked.

ABSTRACT

Specific Aims: To determine if current published enoxaparin dose titration recommendations are effective in achieving therapeutic anti-FXa concentrations on the first dose titration in neonates.

Methods: Retrospective chart review included neonates (< 28 days old) who received therapeutic enoxaparin between 09/01/2018 to 09/01/2021. Patients on mechanical circulatory support (MCS) or renal replacement therapy (RRT) during or within 48 hours of enoxaparin therapy, or had a creatinine clearance (CrCl) < 30 ml/min/m^2 were excluded. Primary objective analyzed correlation between age (preterm < 37 weeks gestation and term ≥ 37 weeks gestation) and anti-FXa concentrations after the first enoxaparin dose titration when following published titration guidelines in neonates. Secondary objective determined the frequency of anti-FXa concentration achievement after first enoxaparin dose titration.

Results: Twenty-six patients were included for analysis, with 76.9% being full term infants. Between age and anti-FXa concentrations after the first dose titration, preterm correlation coefficient of -0.71 and 0.29 for term. Fifty percent of the subjects were not at a therapeutic anti-FXa concentration on their first draw. Of those, 62% reached therapeutic concentrations after their initial enoxaparin dose titration in accordance with the published guidelines.

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Conclusions:

Due to the small sample size, it is unclear whether current enoxaparin dosing titration recommendations are adequate to achieve therapeutic anti-FXa concentrations after the first dose titration in neonates. Further studies should be conducted with larger sample sizes.

INTRODUCTION

Inpatient pediatric patients are at risk for venous thromboembolic (VTE) events. In response, neonates may be given therapeutic enoxaparin, a low molecular weight heparin (LMWH), to treat the hospital-acquired VTE (HA-VTE). According to a review from 2017, there has been an estimated increase from 5.3 HA-VTE events per 10,000 pediatric hospital admissions up to 30-58 events per 10,000 from the early 1990s to 2017.[1] VTE is typically diagnosed as a secondary complication from a primary underlying disease such as sepsis, use of central venous lines, or malignancies, and has an estimated mortality rate of 2.2%.[1,2] The disease process begins by the formation of a blood clot in a larger vein where it can become more severe if the clot breaks off and lodges itself resulting in an occlusion.[3] The coagulation cascade evolves with age, where the majority of development occurs within the first six months, although not all proteins reach normal adult levels until adolescent years.[4] Literature shows that neonates require larger weight-based doses of enoxaparin compared to older pediatrics. There has been an increase in enoxaparin use in the pediatric population due to an increase in pediatric thrombosis and its predictable pharmacokinetic profile.[5] Enoxaparin works by binding to antithrombin, enhancing its activity, which then binds to and inactivates Factor Xa (FXa) in the coagulation cascade. The effect of enoxaparin is measured by the lab measurement of anti-FXa concentrations.[5]

Currently, few data exist showing the efficacy of published dose titration recommendations corresponding to the achievement of therapeutic anti-FXa concentrations. The purpose of this study is to investigate how often anti-FXa concentrations reach therapeutic concentrations when following the published titration guidelines.

METHODS

Design

This study was a retrospective chart review and was approved by the Phoenix Children's Hospital (PCH) Institutional Review Board (IRB).

Subjects

Patients were included if the subject was admitted to PCH between 09/01/2018 and 09/01/2021, was a neonate; defined as less than 28 days old and received at least one therapeutic dose of

enoxaparin and at least one anti-FXa concentration measured within 4-6 hours of receiving the enoxaparin dose. Patients were excluded if the subject was receiving prophylactic enoxaparin doses of ≤ 1 mg/kg subcutaneously every 12 hours, those with creatinine clearance (CrCl) < 30 ml/min/m^2 (calculated via the bedside Schwartz equation), and those who were actively receiving mechanical circulatory support (MCS) or renal replacement therapy (RRT) at the time of the enoxaparin treatment or had received it within 48 hours of treatment. However, patients were not excluded if they met inclusion criteria and transitioned from prophylaxis to treatment dosing.

Measures

Data was collected directly from the patient's electronic health record (EHR). The data collection sheet provided below (see Appendices: Data Collection Form) was used to guide information collected for each patient. Demographic data collected included date of birth, preterm vs. term, sex, and ethnicity. The data collection sheet was used to document enoxaparin doses received accompanied by the time and date given, anti-FXa concentrations accompanied by the time and date given, as well as patient's serum creatinine, creatinine clearance, urine output, prothrombin time, INR, platelet count, if the patient was on MCS/RRT, or had any bleeding complications that correlated with the enoxaparin dosing.

Data Collection

Data collection was conducted by accessing patient charts to extract the information on the a priori data collection sheet (see Appendices: Data Collection Form). In order to determine eligible subjects, patient age, date of therapeutic enoxaparin dose given and corresponding anti-FXa concentration was collected from the EHR. In addition, SCr, treatment indication, MCS/RRT status and duration was also collected. Such data was stored on a secure server within the PCH VPN encrypted with password access where only the advisor and students had access to.

Data Analysis

Based on the strict inclusion and exclusion criteria in a niche population, our sample size was smaller than expected and had inadequate power. Therefore, data analysis was conducted using descriptive statistics. Due to the lack of a normal distribution, continuous data were summarized using medians and interquartile ranges (IQRs) to accommodate for extreme or outlying values.

RESULTS

From a total of 717 enoxaparin orders, 650 orders did not meet inclusion criteria. Of the remaining 67 orders, an additional 41 orders were excluded due to being either duplicate orders or continuation of therapy from included order. This left a total of 26 patients for data analysis (Figure 1). Patients were excluded due to enoxaparin doses given when patients were > 28 days

old, CrCl < 30 mL/min during all anti-FXa concentrations, orders that were a continuation of therapy from already included patients, and duplicate patient orders. Patient demographics of the participants can be found in Table 1. The majority of the participants were full term (76.9%) and males (62%), with equal prevalence of White vs. Hispanic ethnicity.

Of the 6 subjects who were preterm, 33% reached a therapeutic anti-FXa concentration after their first enoxaparin dose with a median initial dose of 1.78 mg/kg. The remaining 67% of preterm participants who were not therapeutic after the first enoxaparin dose had a median initial dose of 1.96 mg/kg. Of the 20 subjects who were full term, 55% reached a therapeutic anti-FXa concentration after their first enoxaparin dose with a median initial dose of 1.73 mg/kg. The remaining 45% of full term participants who were not therapeutic after the first enoxaparin dose had a median initial dose of 1.67 mg/kg (Figure 3). No correlation was found between preterm age and initial anti-FXa concentrations with a correlation coefficient (r) = -0.52. There was a negative correlation found between preterm neonates and initial post-titration anti-FXa concentration with (r) = -0.71 (Figure 2.1). There was found to be no correlation between term neonates' age and their initial and post-titration anti-FXa concentrations with r-values of 0.21 and 0.29 respectively (Figure 2.2).

Of the 26 subjects included in the data analysis, 13 subjects (50%) achieved therapeutic anti-FXa concentrations after their initial enoxaparin dose. The remaining 13 subjects underwent appropriate enoxaparin dose titration according to the published guidelines (Appendix: Enoxaparin Dose Titration). Following the recommended dose titration in these 13 subjects, 62% of the participants reached a therapeutic anti-FXa concentration after their first enoxaparin dose titration (Figure 4). Ten patients (77%) fell into the "increase by 10%" recommendation category while three patients (23%) fell into the "increase by 25%" recommendation category (Figure 5).

DISCUSSION

The primary objective was to analyze the correlation between age (preterm vs. term) and anti-FXa concentrations after the first enoxaparin dose titration. Unfortunately, no correlation was found between preterm neonates' and their initial anti-FXa concentrations. However, a negative correlation was found between preterm neonates and their initial post-titration anti-FXa concentration (Figure 2.1). This value may not truly be significant as it only includes data from two subjects. Moreover. There was no correlation between term neonates' age and their initial and post-titration anti-FXa concentrations (Figure 2.2).

Current literature suggests a higher initial enoxaparin dose in preterm infants vs. term which was appropriately followed. However, based on the results, when following the PCH protocol of initial enoxaparin dosing of 2 mg/kg for preterm and 1.7 mg/kg for term, there was a higher percentage of preterm patients who had subtherapeutic anti-FXa concentrations with a median initial dose of 1.96 mg/kg vs. those achieving a therapeutic anti-FXa concentration with a lower initial median dose of 1.78 mg/kg. The higher percentage of preterm participants (67%) who did not readily achieve therapeutic concentration after the initial dose may be due to the developmental differences of the coagulation cascade compared to full term neonates. This

finding also aligns with current literature which suggests that a reduction in specific coagulation proteins in preterm vs. term neonates significantly affects the clinical management of thrombolytic therapy.[6] In contrast to preterm neonates, there was a higher percentage of term patients who achieved therapeutic anti-FXa concentrations when their initial dose more closely resembled the PCH protocol of 1.7 mg/kg. The median dose for term neonates that resulted in therapeutic anti-FXa concentrations was 1.73 mg/kg, whereas the median initial dose of term neonates that did not achieve therapeutic concentrations was 1.67 mg/kg. This value is lower than what the protocol recommends, which is consistent with non-therapeutic anti-FXa concentrations.

The discrepancy in therapeutic anti-FXa concentrations achieved between term and preterm neonates may result from differences in the development of the coagulation cascade and resulting clotting factors that enoxaparin inhibits (factor Xa and factor IIa). With having a smaller sample size included in this statistic, this value may not reflect the efficacy of the guideline.

Lastly, it was noted that 77% of the patients requiring dose titrations fell into the "increase by 10%" category while only 23% of the patients required a higher dose titration of 25%. This may suggest that higher dose titrations may only be required for select patients with certain conditions. Determining which patient characteristics necessitate higher dose titrations may be an area for further research.

One strength of this study includes the consistent manner which data extraction was performed using a protocol outlined by the data collection form. Additionally, the results demonstrated a potential negative correlation between preterm neonates and their initial post-titration anti-FXa concentration, which may be useful in clinical practice once further research with a larger sample size is conducted.

Limitations include a limited sample size in addition to a greater percentage of the patient population being male (62%) vs. female (38%). This may lead to increased variability due to differences in metabolism of anti-FXa between male and female neonates thus providing an area for future research in neonates. Moreover, during the process of data collection, an extended time frame of 30 minutes before and after anti-FXa concentrations were drawn was not applied which led us to exclude more patients, further limiting our patient population. Conversely, although our inclusion/exclusion criteria may have led to a small patient population, exclusion of such patients increased generalizability to the general population and decreased outlier data.

CONCLUSION

Due to the small sample size, it is unclear whether current enoxaparin dosing titration recommendations are adequate to achieve therapeutic anti-FXa concentrations after the first dose titration in neonates. It would be beneficial to conduct this same research on a larger scale of participants to have a better understanding of the findings.

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TABLES AND FIGURES

Table 1. Baseline Characteristics of Study Participants

Total # of patients N = 26	**Preterm (<37 weeks gestation) N = 6 (23.1%)**	**Term (≥37 weeks gestation) N = 20 (76.9%)**
Age in days at first dose, mean ± SD	16.67 ± 3.67	14.7 ± 6.94
Sex, N (%)		
Male	5 (83.3%)	11 (55%)
Race, N (%)		
White	5 (83.3%)	7 (35%)
Hispanic	1 (16.7%)	11 (55%)
Other	0 (0%)	2 (10%)
Weight (kg), mean ± SD	2.67 ± 0.64	3.20 ± 0.51
SCr (mg/dL) at baseline, mean ± SD	0.33 ± 0.11	0.34 ± 0.14
CrCl (mL/min), mean ± SD (calculated via the bedside Schwartz equation)	64.13 ± 19.93	68.17 ± 25.01
Urine output over 24 hours (mL) at baseline, median (IQR)	153.10 (88.5-166.2)	96.74 (19.9-151.2)
Baseline PT, mean ± SD (seconds)	15.03 ± 0.50	14.75 ± 1.47
Baseline INR, mean ± SD	1.17 ± 0.06	1.16 ± 0.13
Baseline platelet count (per mcL), mean ± SD	257.83 ± 151.95	259.47 ± 131.68

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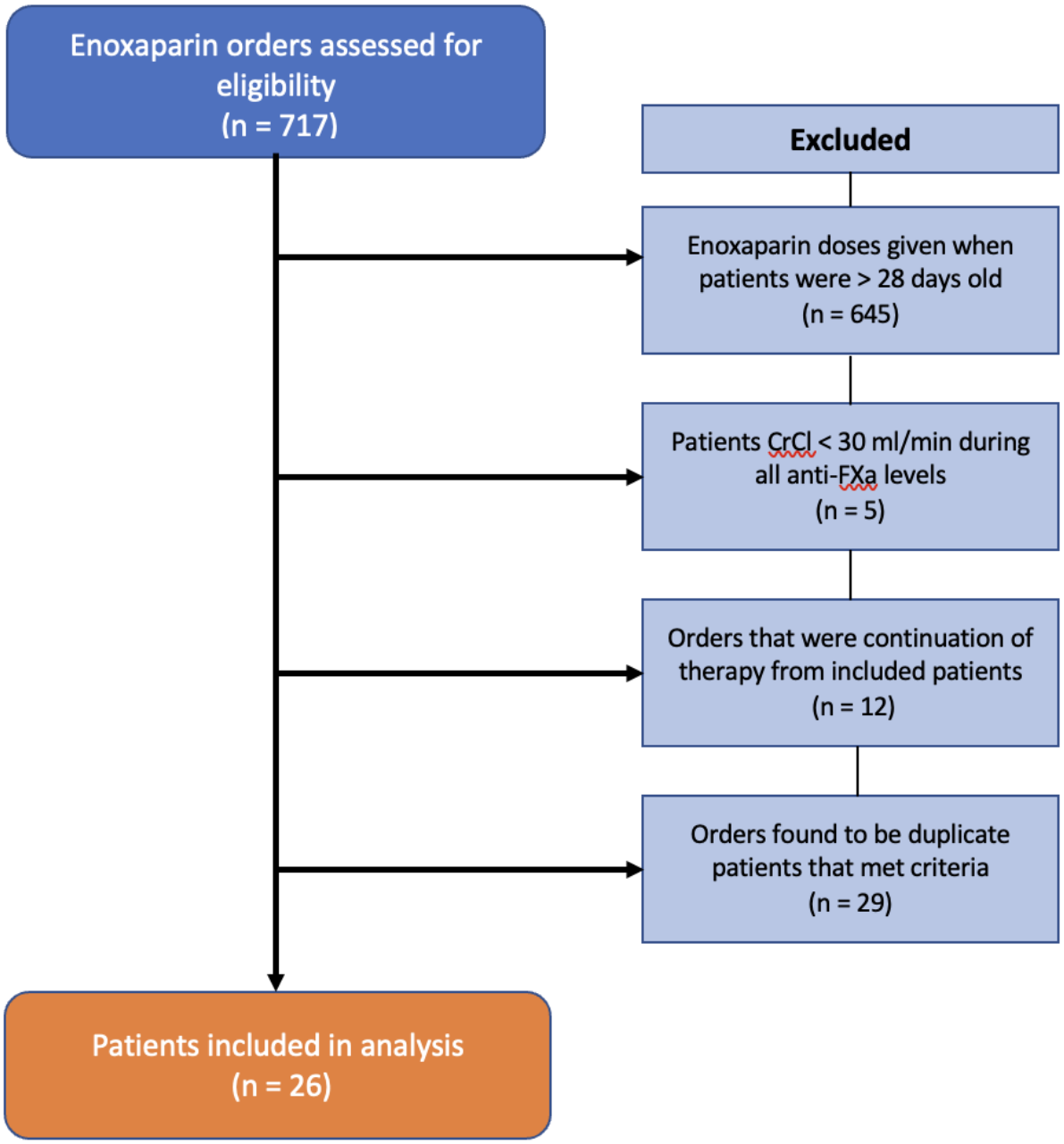
Figure 1: Flowchart of Orders and Patients Included and Excluded



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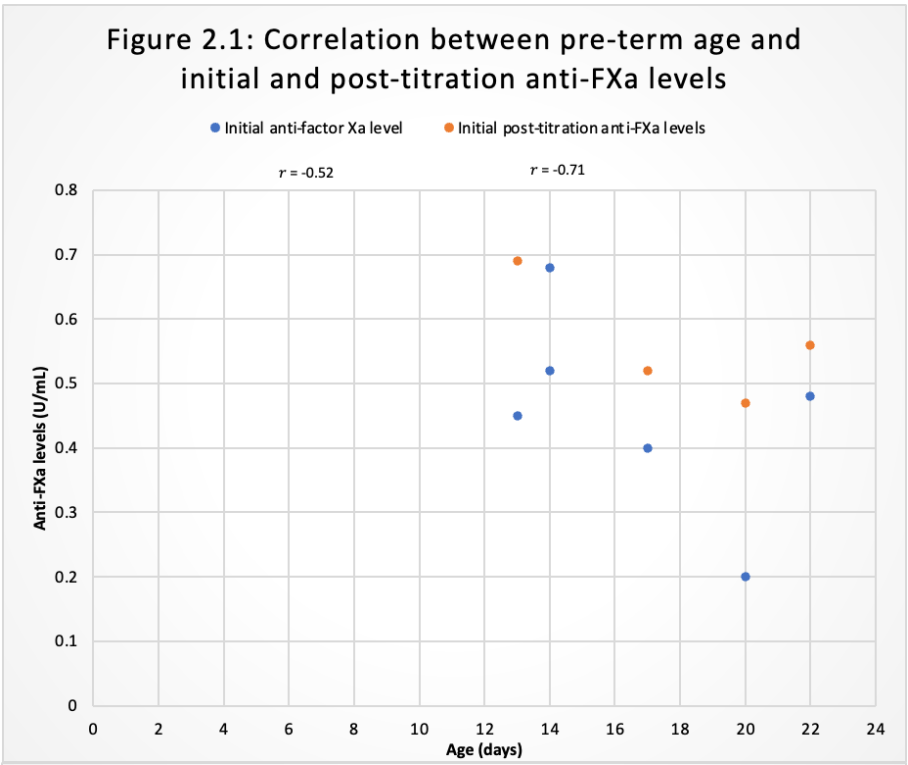

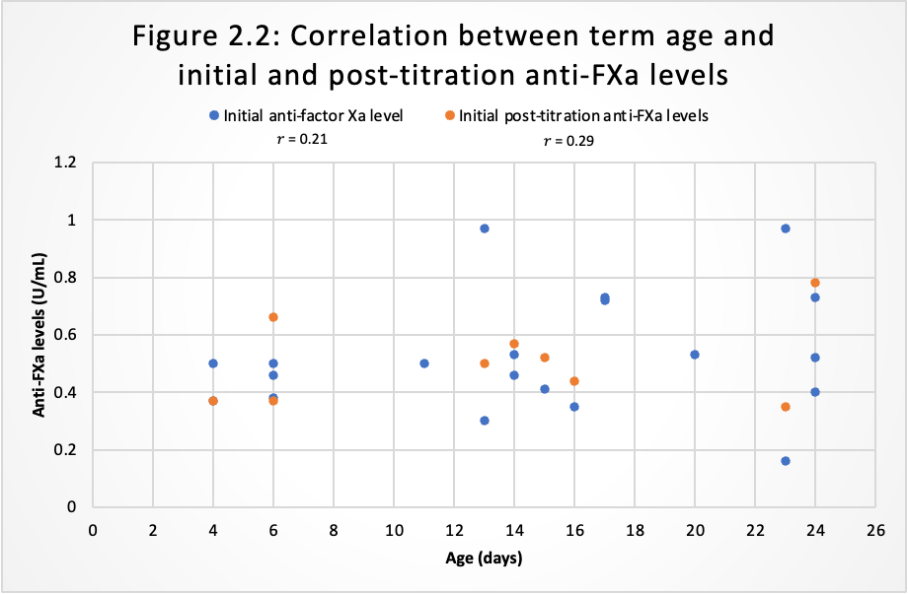

Figure 2: Correlation between age in days and both initial anti-FX concentrations before and after titration. Correlation coefficient can be found under the corresponding legend.

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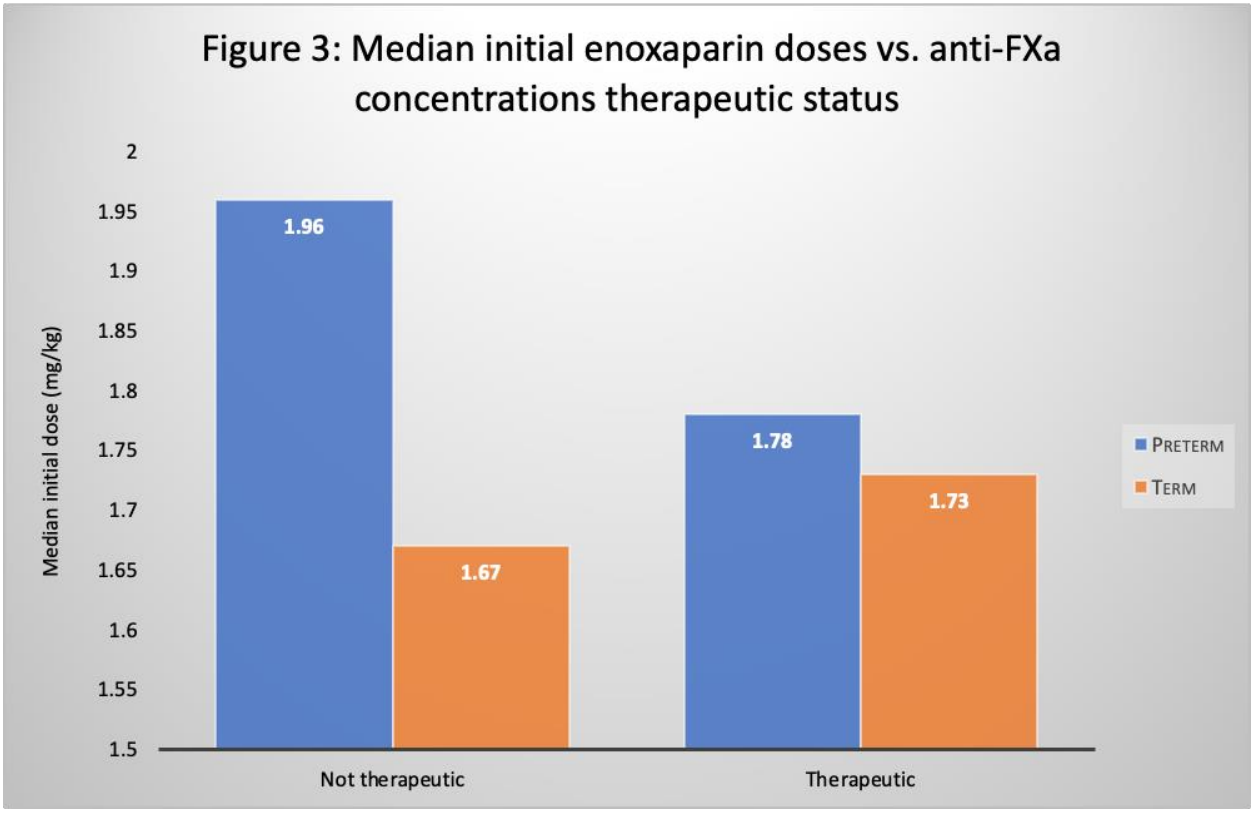

Figure 3: This figure shows the median initial enoxaparin doses of both preterm and term neonates categorized by therapeutic status.

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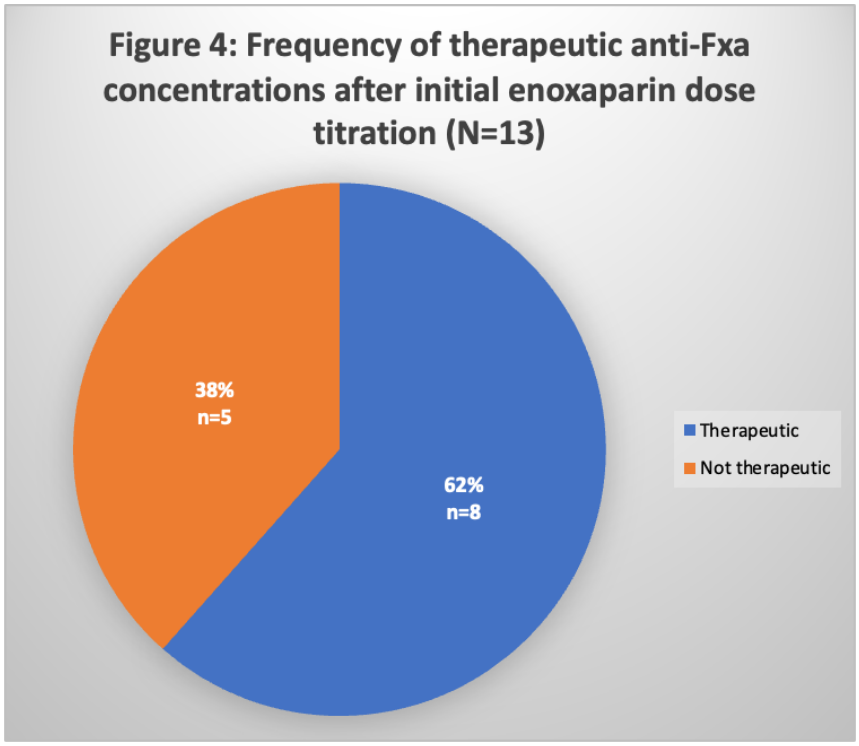

Figure 4: This graph demonstrates the percentage of subjects that achieved therapeutic and non-therapeutic anti-FXa concentrations. It includes a combination of both preterm and term neonates that underwent dose titration according to the published guidelines.

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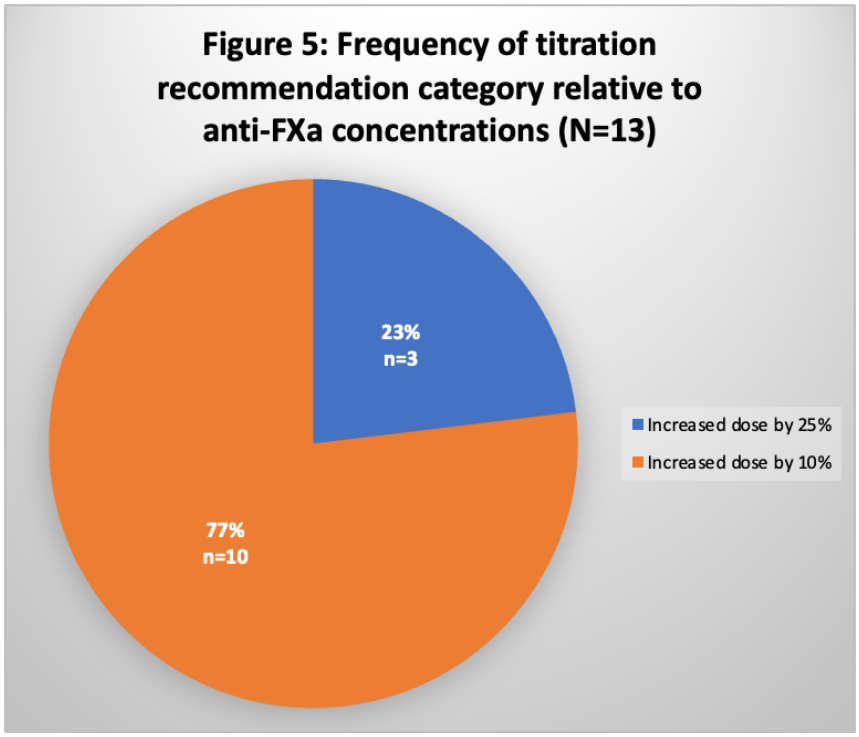

Figure 5: This figure represents the frequency of patients that fell into the corresponding published titration recommendation category based on their previous anti-FXa concentrations.

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APPENDICES

Data Collection Form

Form 1

Record ID	_____
Admission diagnosis	_____
Indication for enoxaparin	_____
Date of admission [MM/DD/YYYY]	_____
Date of Birth [MM/DD/YYYY]	_____
Term	◯ Term [≥ 37 weeks gestation] ◯ Preterm [< 37 weeks gestation]
Sex	◯ Male ◯ Female
Ethnicity	◯ White ◯ Black ◯ Asian ◯ Hispanic ◯ Other
Weight (kg)	_____
How many doses were given before first anti-factor Xa level was obtained?	_____
Initial enoxaparin dose (mg)	_____
Is initial dose appropriate as per guidelines?	◯ Yes ◯ No
Date and time of first enoxaparin dose (mm/dd/yy and 24hr clock)	_____
2nd enoxaparin dose given before first anti-factor Xa level obtained (mg)	_____
Date and time of 2nd enoxaparin dose given before first anti-factor Xa level was drawn (mm/dd/yy and 24hr clock)	_____
3rd enoxaparin dose given before first anti-factor Xa level obtained (mg)	_____

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Date and time of 3rd enoxaparin dose given before first anti-factor Xa level was drawn (mm/dd/yy and 24hr clock)	
4th enoxaparin dose given before first anti-factor Xa level obtained (mg)	
Date and time of 4th enoxaparin dose given before first anti-factor Xa level was drawn (mm/dd/yy and 24hr clock)	
5th enoxaparin dose given before first anti-factor Xa level obtained (mg)	
Date and time of 5th enoxaparin dose given before first anti-factor Xa level was drawn (mm/dd/yy and 24hr clock)	
6th enoxaparin dose given before first anti-factor Xa level obtained (mg)	
Date and time of 6th enoxaparin dose given before first anti-factor Xa level was drawn (mm/dd/yy and 24hr clock)	
7th enoxaparin dose given before first anti-factor Xa level obtained (mg)	
Date and time of 7th enoxaparin dose given before first anti-factor Xa level was drawn (mm/dd/yy and 24hr clock)	
8th enoxaparin dose given before first anti-factor Xa level obtained (mg)	
Date and time of 8th enoxaparin dose given before first anti-factor Xa level was drawn (mm/dd/yy and 24hr clock)	
9th enoxaparin dose given before first anti-factor Xa level obtained (mg)	
Date and time of 9th enoxaparin dose given before first anti-factor Xa level was drawn (mm/dd/yy and 24hr clock)	
10th enoxaparin dose given before first anti-factor Xa level obtained (mg)	
Date and time of 10th enoxaparin dose given before first anti-factor Xa level was drawn (mm/dd/yy and 24hr clock)	
Initial anti-factor Xa level	

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Date and time of initial anti-factor Xa level (mm/dd and 24hr clock)	_____
Calculate time between most recent dose given and initial level measured (hh:mm)	_____
Was this anti-factor Xa level drawn at appropriate time? (4-6 hours)	○ Yes ○ No
Therapeutic initial anti-factor Xa level?	○ Yes ○ No
Was the enoxaparin dose titrated?	○ Yes ○ No
Was the enoxaparin dose titrated based off an inappropriate drawn level?	○ Yes ○ No
If enoxaparin dose was NOT titrated based off and incorrect level drawn, what was the first appropriate anti-factor Xa level.	_____
If enoxaparin dose was NOT titrated based off and incorrect level drawn, date/time of the first appropriate anti-factor Xa level.	_____
Were additional enoxaparin doses given between initial incorrect level drawn and appropriate level drawn?	○ Yes ○ No
How many additional enoxaparin doses were given between inappropriate level drawn and appropriate level drawn.	_____
List all additional enoxaparin doses (mg) with the date and time (mm/dd/yy and 24hr clock).	_____
New titrated enoxaparin dose (mg)	_____
Dose adjusted according to current guideline?	○ Yes ○ No
How many doses of enoxaparin were given after first titration before the next anti-factor Xa level was obtained?	_____
1st enoxaparin dose given following dose titration before anti-factor Xa level is obtained (mg)	_____
Date and time of 1st dose given post-titration (mm/dd and 24hr clock)	_____
2nd enoxaparin dose given following dose titration before anti-factor Xa level is obtained (mg)	_____

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Date and time of 2nd dose given post-titration (mm/dd and 24hr clock)	
3rd enoxaparin dose given following dose titration before anti-factor Xa level is obtained (mg)	
Date and time of 3rd dose given post-titration (mm/dd and 24hr clock)	
4th enoxaparin dose given following dose titration before anti-factor Xa level is obtained (mg)	
Date and time of 4th dose given post-titration (mm/dd and 24hr clock)	
5th enoxaparin dose given following dose titration before anti-factor Xa level is obtained (mg)	
Date and time of 5th dose given post-titration (mm/dd and 24hr clock)	
6th enoxaparin dose given following dose titration before anti-factor Xa level is obtained (mg)	
Date and time of 6th dose given post-titration (mm/dd and 24hr clock)	
7th enoxaparin dose given following dose titration before anti-factor Xa level is obtained (mg)	
Date and time of 7th dose given post-titration (mm/dd and 24hr clock)	
8th enoxaparin dose given following dose titration before anti-factor Xa level is obtained (mg)	
Date and time of 8th dose given post-titration (mm/dd and 24hr clock)	
9th enoxaparin dose given following dose titration before anti-factor Xa level is obtained (mg)	
Date and time of 9th dose given post-titration (mm/dd and 24hr clock)	
10th enoxaparin dose given following dose titration before anti-factor Xa level is obtained (mg)	
Date and time of 10th dose given post-titration (mm/dd and 24hr clock)	
Initial anti-FXa level post-titration	

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Date and time of initial anti-factor Xa level post titration (mm/dd and 24hr clock)	_____
Calculate time between most recent dose given and the initial anti-factor Xa level post-titration measured (hh:mm)	_____
Was this post-titration anti-factor Xa level drawn at an appropriate time? (4-6 hours)	◯ Yes ◯ No
Therapeutic post-titration anti-factor Xa level?	◯ Yes ◯ No
If anti-factor Xa level was drawn incorrectly, was a new level done at an appropriate time?	◯ Yes ◯ No
Was there any additional dose changes before the appropriate anti-factor Xa level was drawn?	◯ Yes ◯ No
If no, what was the first appropriate anti-factor Xa level?	_____
What was the date/time of the first appropriate anti-factor Xa level.	_____
Were additional enoxaparin doses given between initial incorrect level drawn and appropriate level drawn?	◯ Yes ◯ No
How many additional enoxaparin doses were given between inappropriate level drawn and appropriate level drawn.	_____
List all additional enoxaparin doses (mg) with the date and time (mm/dd/yy and 24hr clock).	_____
Was this appropriately drawn post-titration anti-factor Xa level therapeutic?	◯ Yes ◯ No
Enoxaparin dose once therapeutic (mg/kg and total mg dose)	_____
SCr levels (baseline, at time of initial anti-factor Xa level, at time of post-titration anti-factor Xa level)	_____
Calculate CrCl (ml/min) at baseline	_____
Urine output over 24 hours at baseline? [mL]	_____
List urine output over 24 hours (mL) for subsequent days anti-factor Xa level was drawn.	_____
Is patient on or has been on MCS/RRT within the last 48 hours?	◯ Yes ◯ No

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Has patient experienced any bleeding complications? [GI bleed, hemorrhaging, intracranial bleeds, peritoneal bleeds, etc]	○ Yes ○ No
If yes to bleeding complication, indicate type of bleed.	_____
Baseline PT/INR? [seconds/N/A]	_____
Baseline platelet count? [platelets/mcL]	_____

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Enoxaparin Dosage Titration[7]

Antifactor Xa	Dose Titration	Time to Repeat Antifactor Xa Level
<0.35 units/mL	Increase dose by 25%	4 h after next dose
0.35-0.49 units/mL	Increase dose by 10%	4 h after next dose
0.5-1 unit/mL	Keep same dosage	Next day, then 1 wk later, then monthly (4 h after dose)
1.1-1.5 units/mL	Decrease dose by 20%	Before next dose
1.6-2 units/mL	Hold dose for 3 h and decrease dose by 30%	Before next dose, then 4 h after next dose
>2 units/mL	Hold all doses until antifactor Xa is 0.5 units/mL, then decrease dose by 40%	Before next dose and every 12 h until antifactor Xa <0.5 units/mL