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Evaluating fondaparinux vs bovine-derived enoxaparin as halal anticoagulants in East Java Provincial Haji Hospital

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ABSTRACT

This study evaluated the effectiveness of two halal anti-coagulant therapies used in patients at East Java Provincial Haji Hospital. The research design was a retrospective, comparative, observational study spanning the last three years. The study population consisted of patients assigned to anti-coagulant therapy, divided into two groups based on the use of two halal anti-coagulants: bovine enoxaparin and fondaparinux. Participation in this study is voluntary, and all patient data will be kept confidential in accordance with data protection laws. Inclusion criteria were patients with diagnoses requiring anticoagulants, such as atrial fibrillation, while exclusion criteria included patients with conditions that could affect drug metabolism or response to therapy. The main variables to be assessed in this study were length of stay, which is one of the key indicators of anticoagulant effectiveness. In addition, this study also compared the cost-effectiveness of hospital care. This data will be collected through electronic medical records, followed by rigorous statistical analysis. Independent t-test and chi-square by which quantitative data, while multivariate analysis was applied to control potential confounding variables. Two anticoagulant groups were used as samples containing fondaparinux and bovine enoxaparin, respectively. Based on the observational results showed that the average length of stay for patients using the group fondaparinux was shorter than bovine enoxaparin. The bovine enoxaparin group has a lower price per dose, but based on the LOS, the fondaparinux group can reduce total hospital costs, because it has a shorter length of stay. The expectation of this research will provide insight into the effectiveness of halal anti-coagulant drugs in muslim patients, which will also assist in clinical decision making. Hopefully, the results of this research will be useful in Indonesia and other countries with large muslim populations, and can provide the scientific confirmation needed to validate the use of halal medicines.

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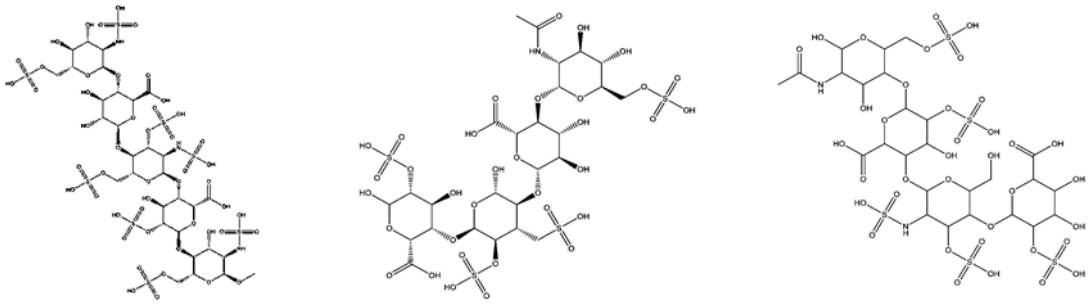
INTRODUCTION

The need for halal products in Indonesia is not only limited to food and drinks, but also in the realm of pharmaceuticals or medicines (Qur'an Surah 2: 168 and 172). The dominant muslim population in this country demands clarity on the halal status of the medicinal products consumed, including anti-coagulants in the treatment of cardiovascular therapy.

The National Food and Drug Agency (BPOM) Regulation No. HK.03.1.23.06.10.5166 of 2010 concerning manufacturers' obligations to include the words "contains pork, by which is not enough to guarantee the halalness of medicinal products that do not bear this label. As halal critical point for pharmaceuticals not only determined by the halal status of raw materials ingredients but preparing and processing them is also a critical point (Nekha, 2024).

According to BPOM, there were only 3 medicines containing pork (Kementerian Kesehatan Republik Indonesia, 2014), including the porcine enoxaparin class of anticoagulants used at a lot of hospitals. Enoxaparin itself is a low molecular weight heparin-based anticoagulant; it is typically produced using heparin extracted from porcine intestinal mucosa. However, enoxaparin can also be produced from bovine, including the generic one used at East Java Provincial Haji Hospital, produced by Biofarma, which is produced through a depolymerization process catalyzed by bovine enzymes, offering an alternative for Muslim individuals (Oliveira et al., 2024)

Another anticoagulant drug used at East Java Provincial Haji Hospital is fondaparinux, a synthetic drug whose molecular structure contains the active group of the heparin molecule (Figure 1). These two classes of drugs have different targets and mechanisms of action (Figure 2), so their effectiveness and side effects are also different. The use of anticoagulants in certain cases, fondaparinux is more effective than enoxaparin, as are the side effects (Dong et al., 2016)



A B C

Figure 1. Molecular structure of: (A) Fondaparinux, (B) Heparin, (C) Enoxaparin.

Herdiana et al. (2024) found that understanding about halal medicines is still limited among Muslim communities, especially regarding their effectiveness and safety compared to non-halal medicines. Research on direct comparisons of clinical effectiveness between halal anticoagulant drugs is still rare. Hopefully, this research will fill this gap by evaluating the clinical effectiveness of halal anti-coagulant drugs in patient therapy at East Java Provincial Haji Hospital. The large and diverse patient population at this institution can be generalized to be a wider population. This research will use a retrospective comparative observational design for the last 3 years, with a quantitative approach to measure length of stay and cost-effectiveness parameters.

The existence of doubts among muslim patients about using non-halal medicines may affect therapy compliance and clinical outcomes (Ang et al., 2024). Recent studies highlighting the halal status and production processes of these medications address important religious and ethical considerations, particularly regarding the use of animal-derived catalysts. By ensuring that the sources and processes comply with Islamic guidelines, muslim patients can have increased confidence in selecting anticoagulant medications that align with their religious beliefs, ultimately promoting better adherence to prescribed therapies and improving overall treatment outcomes (Tumiran et al., 2020)

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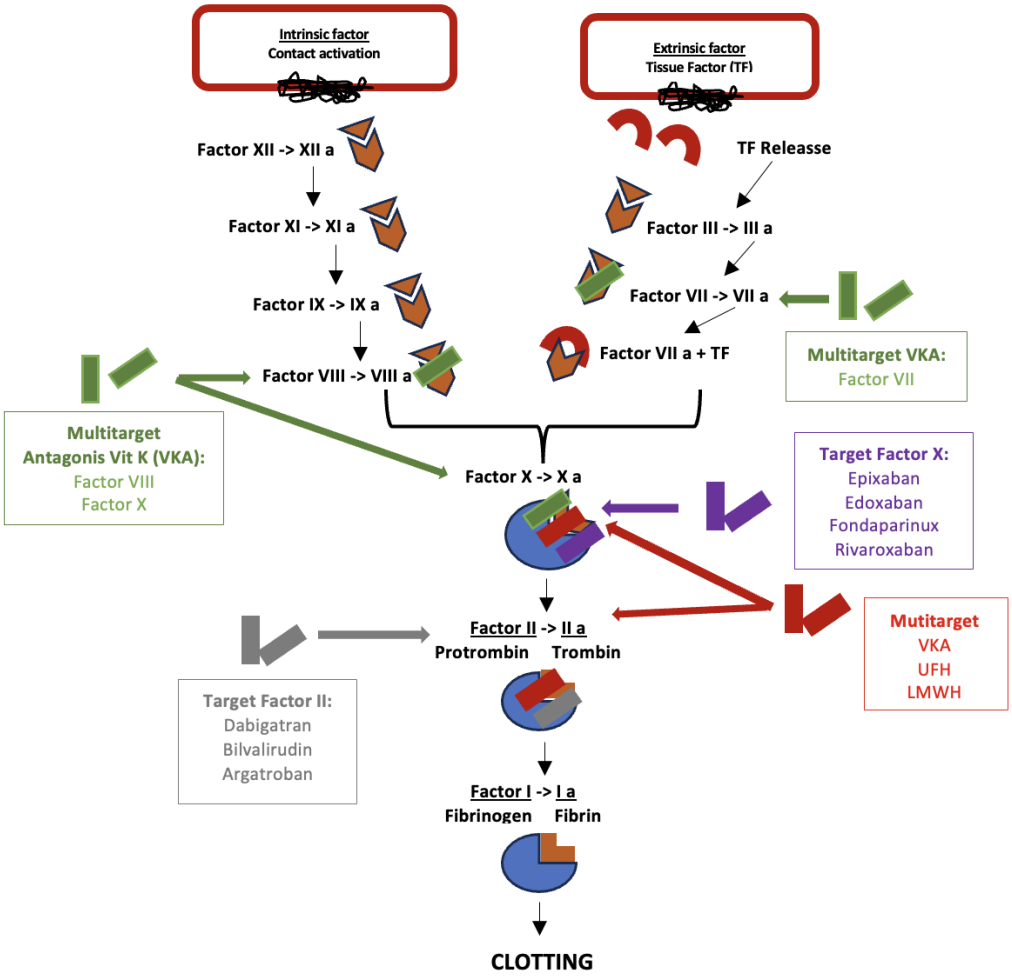

Figure 2. Mechanism of action and target of anticoagulants.

RESEARCH METHOD

This research is a descriptive observational study that collected retrospectively using medical records from hospitalized patients at East Java Provincial Haji Hospital, who met the inclusion criteria. The study focuses on patients with Acute Coronary Syndrome (ACS), including NSTEMI (Non-ST-Elevation Myocardial Infarction), STEMI (ST-Elevation Myocardial Infarction), and unstable angina (UA), who were treated with either bovine enoxaparin or fondaparinux. Key patient details, such as age, gender, side effects, and clinical parameters such as hemoglobin, troponin, and platelet counts, were recorded upon admission.

Statistical Method

The primary endpoint of this study is the total length of stay as a parameter. Descriptive statistics were used to summarize the data, and group comparisons were performed using the Chi-Square test for categorical variables. For continuous variables, the Kolmogorov-Smirnov test was applied to assess normality. Normally distributed data were compared using t-tests, while non-normally distributed data were analyzed using the Mann-Whitney U test. A multivariate logistic regression analysis was conducted to determine predictors of outcomes, with statistical significance set at $p < 0.05$.

Data Analysis

The analysis was conducted using SPSS 26, a comprehensive statistical software for data analysis. The dataset was first prepared by ensuring proper labeling and handling of missing data. Descriptive statistics, including means, medians, and standard deviations, were used to summarize patient characteristics and clinical variables like Length of Stay (LOS). The normality of the data was

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tested using the Shapiro-Wilk test, and either Independent t-tests or Mann-Whitney U tests were applied based on data distribution to compare LOS between the enoxaparin and fondaparinux groups. Categorical variables, such as gender and bleeding risks, were analyzed using Chi-square tests. A multivariate regression analysis was then performed to identify significant predictors of LOS, accounting for factors such as gender, age, and platelet count, while binary logistic regression was used to assess the likelihood of prolonged hospital stay or bleeding events. Results were considered statistically significant at a p-value less than 0.05, and findings were presented in tables showing means, standard deviations, and regression coefficients for interpretation.

RESULT AND DISCUSSION

Patients treated with fondaparinux (mean LOS: 5.77 ± 1.79 days) had shorter hospital stays than those receiving bovine enoxaparin (mean LOS: 6.73 ± 2.66 days) (Table 1). This suggests that fondaparinux may promote quicker recovery and earlier discharge, particularly relevant for acute coronary syndromes. This finding is consistent with studies like the Fifth Organization to Assess Strategies in Ischemic Syndromes (OASIS-5) trial, which indicated that fondaparinux is linked to lower bleeding risks, facilitating faster recovery and reduced hospital resource utilization (Bundhun et al., 2017). Additionally, research published in the European Heart Journal confirmed that fondaparinux enhances clinical outcomes by decreasing major bleeding events, a critical factor in shortening hospital stays (Puymirat et al., 2015)

Table 1. Length of Stay (LOS) Comparison Between Bovine Enoxaparin and Fondaparinux.

Statistical Measure	LOS of Bovine Enoxaparin (Days)	LOS of Fondaparinux (Days)
Mean LOS	6.73 ± 2.66	5.77 ± 1.79
Median	6.00	5.00
Min LOS	4.00	3.00
Max LOS	16.00	13.00

Gender and platelet count play a significant role in determining the Length of Stay (LOS) among patients treated with bovine enoxaparin. Male patients and those with higher platelet counts have been associated with longer hospital stays, likely due to the complexity of their conditions and increased bleeding risk. This suggests that bovine enoxaparin's effects on LOS are influenced by patient-specific factors, which necessitate careful consideration in clinical decision-making. These findings highlight the importance of personalized therapy in optimizing treatment outcomes. Additionally, patients with elevated platelet counts at admission may require more careful monitoring due to the increased risk of thrombotic complications (Karcutskie et al., 2018; Suprapti et al., 2023)

Recent studies have shown that in patients treated with fondaparinux, clinical variables such as gender or platelet count do not significantly influence Length of Stay (LOS). This consistency may be attributed to the predictable pharmacokinetic profile of fondaparinux and its lower associated bleeding risks. A retrospective review of patients with renal failure, for instance, found that fondaparinux achieved effective anticoagulation with stable platelet counts and without considerable variation in LOS across different patient demographics (Karcutskie et al., 2018; Suprapti et al., 2023). Fondaparinux is also associated with a lower rate of reinfarction (6.1% compared to 10.5% for enoxaparin) and fewer bleeding complications (2.3% vs. 5.2%). This highlights fondaparinux's potential as a safer alternative in high-risk ACS patients (Soeiro et al., 2016).

Although fondaparinux is more expensive, its association with shorter LOS and fewer complications makes it more cost-effective in the long term (Table 2). A Canadian cost-effectiveness analysis showed that fondaparinux led to significant cost savings due to fewer adverse events and reduced hospital stays (Bundhun et al., 2017). Similarly, the OASIS-5 trial highlighted the economic advantages of Fondaparinux in reducing the need for blood transfusions and other costly interventions (Terres et al., 2015). The 2015 ESC guidelines emphasize the importance of combining anticoagulation with antiplatelet therapy for the management of ACS. They recommend fondaparinux as a first-line option when available, especially for patients undergoing percutaneous coronary intervention (PCI).

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Enoxaparin remains a viable alternative but requires careful monitoring due to its associated bleeding risks and contraindications in patients with renal impairment (Damman et al., 2017).

Table 2. Multivariate regression analysis of predictors of length of stay (LOS) for Enoxaparin and Fondaparinux.

Variable	Enoxaparin Coef.	Enoxaparin P-value	Fondaparinux Coef.	Fondaparinux P-value
Age	0.024	0.049	0.027	0.202
Gender	11,219	0.033	-0.221	0.635
Troponin	-0.033	0.751	-0.012	0.805
Platelet Counts	$1.508e^{-5}$	0.001	$1.963e^{-6}$	0.524
Hemoglobin	-0.278	0.173	0.158	0.214

From a halal perspective, bovine enoxaparin could be recommended, especially for halal perspective, presents significant concerns for muslim patients, as the use of porcine-derived products is strictly prohibited under Islamic law. However, some variations of enoxaparin use bovine-derived catalysts, which may offer a more acceptable option. The principle of darurah (necessity) allows for exceptions when no alternative treatments are available, especially in life-threatening situations. Wan Ismail and Mahamad Maifiah emphasize that wherever possible, healthcare providers should prioritize halal-compliant alternatives to align medical treatment with religious values. In this regard, bovine enoxaparin provides a suitable alternative that avoids the ethical dilemmas posed by porcine enoxaparin. Bovine enoxaparin is depolymerized using bovine enzymes to create an anticoagulant with similar pharmacological efficacy to traditional porcine-based enoxaparin. This alternative enables muslim patients to receive effective treatment without compromising their religious beliefs (Ismail & Maifiah, 2023).

Adverse effects were more frequently reported in patients treated with Enoxaparin compared to those treated with Fondaparinux. Specifically, nine patients in the bovine enoxaparin group experienced side effects, including hematuria, nausea, vomiting, elevated serum creatinine levels, and hemorrhoids. These findings are consistent with the known safety profile of Enoxaparin, which has been associated with a higher incidence of bleeding (Bundhun et al., 2017; Khan et al., 2022) and renal complications, especially in patients with impaired kidney function (Karcutskie et al., 2018; Suprapti et al., 2023). Additionally, the lower bleeding risk of fondaparinux was highlighted in both OASIS-5 and real-world Brazilian data in Soeiro et al. (2016) It is particularly advantageous in patients with renal impairment. Its selective factor Xa inhibition and synthetic nature contribute to its stable and safe profile (Liu et al., 2017).

In contrast, only four patients in the fondaparinux group reported adverse effects, such as hematuria, dizziness, chest pain, mucous diarrhea, catheter pain, and nausea. Previous research suggests that fondaparinux generally has a lower overall risk of bleeding complications compared to enoxaparin, particularly in patients with renal impairment (Ghaziri et al., 2023; Zufferey et al., 2018), which may explain the reduced frequency of adverse events observed in this group.

Fondaparinux-treated patients had shorter hospital stays (mean 5.77 ± 1.79 days) than those receiving bovine enoxaparin (6.73 ± 2.66 days). These findings align with international studies such as OASIS-5, which demonstrated significantly lower major bleeding in fondaparinux vs enoxaparin (2.2% vs 4.1%), contributing to reduced resource utilization and early discharge (Ray et al., 2023; Soeiro et al., 2016). Cost-effectiveness models in Brazil and Thailand also reported that fondaparinux was a dominant strategy in NSTEMI/UA treatment, offering lower costs and higher QALYs (Pepe et al., 2012; Permsuwan et al., 2015). Thus, despite the lack of statistical significance in this study, the trend observed aligns with international evidence.

The synthetic origin of fondaparinux eliminates concerns related to the use of animal-derived products. This makes it the preferred anticoagulant for Muslim patients (Bokek-Cohen et al., 2023; Ulah & Jiwa, 2024). While bovine enoxaparin is a halal-compliant alternative to porcine enoxaparin, Liu et al. (2017) note that production methods and bioactivity can vary depending on tissue source and

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manufacturer, which may affect transparency and confidence in its use. Ethical frameworks in Islamic jurisprudence support using haram products only when no alternatives exist, further reinforcing fondaparinux as the primary option when available (Almarzouqi et al., 2018; Attum et al., 2025; Wijaya & Riskah, 2022; Yassin et al., 2024).

Although, bioactivities of Bovine enoxaparin were about 70% of Porcine enoxaparin based on anti-factor IIa and Xa chromogenic assays, bovine lung heparin has been used as a clinical anticoagulant drug for a long period. Its efficacy and safety had been approved and would be subject to future approval. Bovine lung-derived enoxaparin has the potential to be developed as an analogue of porcine intestine-derived enoxaparin (Guan et al., 2016). Moreover, Tovar et al. (2013) demonstrated that bovine and porcine heparins exhibit similar anticoagulant effects in hemodialysis patients, suggesting comparable efficacy in clinical settings. Recent findings by Suprapti et al. (2023) also revealed that enoxaparin, regardless of source, significantly impacts coagulation and inflammation markers with a low risk of adverse effects in hospitalized patients. These findings support the potential utility of bovine

CONCLUSION

In conclusion, bovine enoxaparin is recommended as a halal alternative anticoagulant for porcine enoxaparin, especially in muslim patient populations. Fondaparinux provides a halal and safer alternative, contributing to shorter hospital stays and fewer complications. Its synthetic composition also makes it a more favorable option for muslim patients, as it does not involve the ethical concerns linked to porcine-derived medications, ensuring compliance with halal guidelines. Overall, fondaparinux and enoxaparin offer both clinical, ethical advantages and cost effectiveness in managing cardiac patients.

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