Original Article

Cost-Effectiveness Analysis of Hemoptysis Therapies Among Hospitalized Patients at Persahabatan Hospital

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Abstract

Background: Carbazochrome has not been included in the Indonesian National Formulary (FORNAS), which serves as a prescribing guideline for patients covered by the National Health Insurance program (JKN). However, Persahabatan Hospital issued a Director's Decree on January 18, 2024, permitting the use of carbazochrome for patients with massive hemoptysis or for those who did not respond to tranexamic acid after three days of treatment. This study aimed to analyze the cost-effectiveness of hemoptysis therapy in hospitalized patients at Persahabatan Hospital. A retrospective cohort study was conducted using medical records of hospitalized patients with hemoptysis from January to June 2024.

Methods: Therapeutic effectiveness was assessed based on the time to bleeding cessation (days), while costs were calculated from total direct medical costs. Cost-effectiveness analysis was subsequently performed. The non-parametric Kruskal–Wallis test was used to compare therapeutic effectiveness and total direct medical costs among the three treatment groups.

Results: The results showed no significant differences in sex, age, diagnosis, therapeutic effectiveness, or total direct medical costs among the treatment groups. However, there was a significant difference in the proportion of patients with massive hemoptysis among the three groups (p=0.040), indicating differences in baseline disease severity.

Conclusion: There were no significant differences in sociodemographic profiles, therapeutic effectiveness, or total direct medical costs among the three treatment groups.

Keywords: Cost-effectiveness analysis, hemoptysis therapy, tranexamic acid, vitamin K, carbazochrome

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INTRODUCTION

Hemoptysis is a common clinical symptom encountered in respiratory practice and may become life-threatening, particularly in cases of massive hemoptysis[1]. Hemoptysis refers to the coughing up of blood from the lower respiratory tract, which may present as blood-tinged sputum or pure blood without mucus[2,3]. The clinical presentation of hemoptysis ranges from self-limiting blood expectoration to massive hemoptysis, which may result in airway obstruction, respiratory failure, and death[4]. Massive hemoptysis was defined as hemoptysis exceeding 500 mL within 24 hours or according to institutional clinical assessment documented in the medical records[5]. No consensus has been determined, but in general, bleeding rates more than 100 mL per hour or total volumes more than 500 mL in 24 hours are considered life-threatening hemoptysis[7].

The etiology of hemoptysis is diverse, including parenchymal disease, respiratory tract disease, and vascular disease[1]. Previous studies have reported that the etiology remains unidentified in approximately 3–42% of hemoptysis cases, which are classified as cryptogenic hemoptysis[6]. Another study reported the most common causes of life-threatening hemoptysis include bronchiectasis from infectious and non-infectious etiologies, bronchogenic carcinoma, and depending on geographical location, various lung infections such as tuberculosis (TB)[7].

The management of hemoptysis according to the General Guidelines for Clinical Practice of Pulmonary and Respiratory Diseases is by therapeutic bronchoscopy or with non-bronchoscopic therapy, namely with drugs such as intravenous vasopressins, tranexamic acid (anti-fibrinolytic), systemic corticosteroids, administration of GnRH in catamenial hemoptysis, administration of antituberculosis drugs, antibiotics, antifungals in other infectious diseases[2]. Drug interventions are usually used for non-massive hemoptysis. The applicable drugs can be further divided into local lavage of ice-cold physiological saline, local vasoconstrictors (e.g.,epinephrine and vasopressin), and clotting agents (e.g., thrombin or a fibrinogen-thrombin combination)[8].

Tranexamic acid is commonly used as an antifibrinolytic agent that can control menstrual bleeding, postpartum hemorrhaging, bleeding during trauma and surgery, and gum bleeding. According to Tsai YS et al, tranexamic acid was found to effectively enable shorter bleeding duration and earlier discharge in hemoptysis patients. Another commonly used drug for hemoptysis is Vitamin K. The classical role of Vitamin K is as an antihemorrhagic dietary factor that is essential for the synthesis in the liver of four procoagulant proteins (factors II, VII, IX, and X). After secretion in the blood, these four vitamin K–dependent (VKD) proteins become available to participate in blood coagulation, the complex series of events that, once initiated, culminates in the conversion of fibrinogen to fibrin and the formation of a hemostatic plug[9]. An average daily dose of 10 mg of vitamin K for an average duration of approximately 5 days is given to cystic fibrosis patients with hemoptysis. Carbazochrome is a hemostatic agent that reduces capillary permeability and increases capillary resistance, resulting in shortened bleeding time. It has been used to treat bleeding of the gastrointestinal and respiratory tracts[10].

Persahabatan Hospital serves as the national referral center for respiratory diseases in Indonesia. The hospital manages a wide spectrum of pulmonary conditions, including tuberculosis, asthma, chronic obstructive pulmonary disease (COPD), and pneumonia. In addition, it frequently treats patients presenting with hemoptysis associated with various underlying respiratory disorders. The prevalence of hemoptysis in

hospitalized patients at Persahabatan Hospital in 2007 and 2008 was 30.99% and 34.68%[6].

In routine clinical practice at Persahabatan Hospital, carbazochrome has been used as an adjunctive therapy for the management of hemoptysis. The effectiveness of carbazochrome in patients with hemoptysis was evaluated in a 2014 study, which showed that the administration of carbazochrome (cromeR) 3x50 mg iv plus vitamin K 3x10 mg iv and vitamin C 3x200 mg iv was more effective in controlling hemoptysis compared to vitamin K 3x10 mg iv plus vitamin C 3x200 mg iv[3].

The use of carbazochrome as a therapy in hemoptysis has not been included in the National Formulary (FORNAS) which is a guideline for the use of drugs in National Health Insurance (JKN) patients. This causes the use of carbazochrome to be considered non-compliant with Fornas guidelines. At the Persahabatan Hospital itself, a Circular Decree has been issued Number: HK. O2. O3/DXX/2386.3/2024 dated January 18, 2024 concerning the List of Approved Drug Prescriptions Without management approval. Patients at the Persahabatan Hospital who approve the administration of carbazochrome injection to inpatients with indications: 1. Hemoptysis, 2. Patients who do not respond to Tranexamic acid after 3 days of use[4]. Evidence regarding the cost-effectiveness of carbazochrome for the management of hemoptysis remains limited. Therefore, an economic evaluation is needed to support evidence-based decision making regarding its use in clinical practice.

This study aimed to evaluate the cost-effectiveness of three hemoptysis treatment regimens among hospitalized patients at Persahabatan Hospital, including tranexamic acid therapy, a combination of tranexamic acid and vitamin K, as well as a combination of tranexamic acid, vitamin K, and Carbazochrome. In addition, this study also aims to evaluate the sociodemographic profile of patients, the prevalence of diseases that cause hemoptysis, differences in therapy effectiveness, differences in direct medical costs, and incremental ratios of cost-effectiveness between therapy regimens.

METHODS

This retrospective cohort study utilized secondary data obtained from the medical records of hospitalized patients with hemoptysis at Persahabatan Hospital, Jakarta, for the period January–June 2024. The subjects of the study included patients who received tranexamic acid therapy, a combination of tranexamic acid and vitamin K, or a combination of tranexamic acid, vitamin K, and Carbazochrome., and had complete medical record data. Massive hemoptysis was defined according to the criteria documented in the medical records and institutional clinical practice guidelines. Patients who died, were referred before hemoptysis was resolved, or had incomplete data were excluded from the study.

The data collected included sociodemographic characteristics, diagnosis, therapy regimen, time to cessation of hemoptysis, and direct medical costs from the hospital's perspective, including drug costs, laboratory tests, hospitalizations, doctor services, and other medical services. Therapeutic effectiveness was defined as the duration from treatment initiation to complete cessation of hemoptysis, measured in days. Economic evaluation was performed by calculating the Average Cost-Effectiveness Ratio (ACER) for each treatment regimen.

Data processing is carried out using Microsoft Excel and IBM SPSS version 25.0. Descriptive analysis is presented according to the distribution of data. The difference in therapy effectiveness and total direct medical costs between therapy groups was analyzed using the Kruskal-Wallis nonparametric test. This research has obtained

ethical approval from the Ethics Committee of the Persahabatan Hospital and all confidentiality of patient data is maintained during the study. Categorical variables were analyzed using the Chi-square test or Fisher's exact test when appropriate. Continuous variables were analyzed using the Kruskal–Wallis test because the data were not normally distributed. Statistical significance was defined as $p < 0.05$.

RESULTS

A total of 155 patients with hemoptysis were identified during the study period. The patient screening process can be seen in Figure 1.

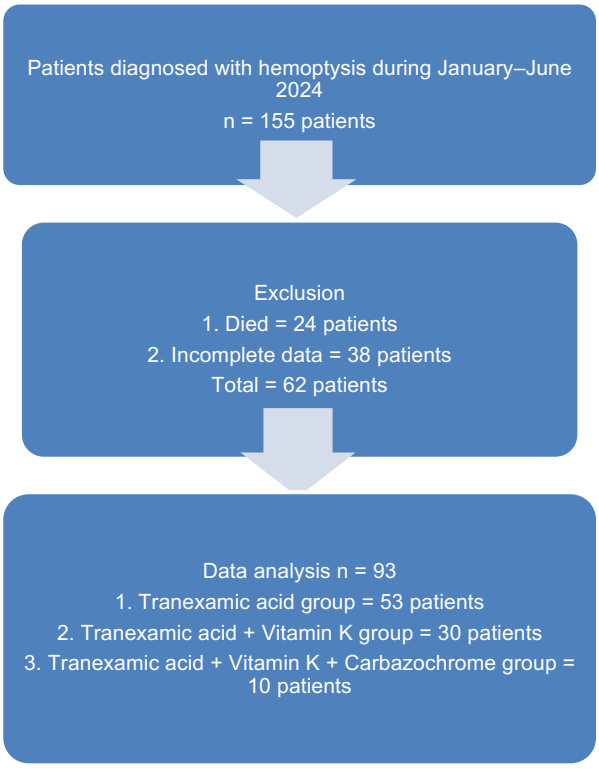

Figure 1. Patient Data Screening Process Flow Diagram

Patient characteristics data

The patient characteristics data in Table 1 show that male patients were more numerous in all three therapy groups (79.2%–80.0%). The mean age of patients was 51.2 years in the Tranexamic acid group, 55.3 years in the Tranexamic acid + Vit group. K and 51.6 years in the Tranexamic acid + Vit group. K + Carbazochrome. The most common diagnosis in patients with hemoptysis is cancer, followed by TB/BE/CAP (infection), then aspergilloma/mycosis, and COPD.

Baseline characteristics were compared among treatment groups to assess potential differences that might influence treatment outcomes. This analysis is done to avoid bias in interpreting cost and effectiveness. The results of the analysis of patient characteristics showed that there was no significant difference in terms of sex comparison, average age and patient diagnosis. These findings indicate that sex distribution, age, and diagnosis were comparable among groups. However, a significant difference was observed in disease severity among the treatment groups ($p = 0.040$).

Table 1. Patient characteristics data

		Group 1	Group 2	Group 3	P-value
Gender					
•	Male	42 (79,2%)	24 (80%)	8 (80%)	0,901
•	Female	11 (20,7%)	6 (20%)	2 (20%)	
Age (mean)					
•	Mean	51,2	55,3	51,6	0,662
•	SD	15,133	14,568	14,323	0,067
Diagnosis					
1	TB/BE/ CAP (Infection)	13 (24,5%)	13 (43,3%)	4 (40%)	
2	COPD	2 (3,8%)			
3	Cancer	33 (62,3%)	9 (30%)	6 (60%)	
4	Aspergiloma/mikosis	5 (9,4%)	8 (26,7%)		
Severity					**0,040***
1	Non massive	50 (94,3%)	24 (80%)	7 (70%)	
2	Massive	3 (5,7%)	6 (20%)	3 (30%)	

Effectiveness of Hemoptysis Therapy

The effectiveness of hemoptysis therapy is seen from the average number of days bleeding

stops. The Tranexamic acid group was the fastest to stop bleeding, which was 3.6 days, followed by the Tranexamic acid + Vit group. K 4.3 days, and the Tranexamic acid + Vit K + Carbazochrome group was 7 days.

Although the tranexamic acid group showed a shorter mean time to bleeding cessation, the difference did not reach statistical significance (p=0.055) (Table 2).

Table 2. Effectiveness of Hemoptysis therapy

Effectiveness Time to bleeding resolution (days)	Group 1	Group 2	Group 3	p-value P = 95%
Mean (days)	3,51	4,3	6,3	
Minimum	1	1	0	0,055
Maximum	12	13	15	
Standard deviation	2,826	2,855	4,692	

Direct Medical Expenses

The largest component of the average direct medical costs of a hemoptysis patient is other costs that include the cost of non-surgical procedures or surgical procedures. Non-surgical procedures included in-room procedures such as injections, intravenous catheter insertion, ECG, oxygen therapy, nebulization, bronchoscopy, mechanical ventilation, intubation, and extubation.

The highest cost of hemoptysis drugs was in the Tranexamic acid + Vit K + Carbazochrome group, which was Rp. 497,880, followed by the Tranexamic acid + Vit K group, which was Rp. 193,859, then the lowest was the Tranexamic acid group, which was Rp. 59,588 (appendix 2).

The proportion of hemoptysis drugs to the total cost in each therapy group was as follows: 0.25%; 0,8%; and 2.2 %. The average total direct medical costs of each therapy group did not differ significantly (p value 0.838) as shown in Table 3.

Table 3. Average Total Medical Direct Costs per hemoptysis patient

Total Average Cost per Group	Group 1	Group 2	Group 3	p-value
Average Total Cost	Rp23.619.398	Rp24.036.285	Rp22.133.317	0,838

Cost-effectiveness analysis

Table 4. Comparison of the effectiveness of therapy against the average of total direct medical costs

	Comparison			
	Group 1	Group 2	Group 3	p - value
Effectiveness Time to bleeding resolution (days)	3,51	4,3	6,3	0,055
Average Total Direct Medical Costs	Rp23.619.398	Rp24.036.285	Rp22.133.317	0,838

Table 4 shows that there was no significant difference in therapeutic effectiveness and average total direct medical costs among the three therapy groups (p values 0.055 and 0.838).

Although the carbazochrome group showed the lowest ACER value, interpretation of this result should be made cautiously because the effectiveness outcome was defined as time to bleeding cessation, where a shorter duration indicates better clinical effectiveness.

Table 5 Average Cost-Effectiveness Ratio (ACER)

Cost-effectiveness ratio	Effectiveness (Length of time to stop bleeding)	Average Total Direct Medical Costs	CER
Group 1 (n = 53)	3,51	Rp23.619.398	Rp6.597.597,2
Group 2 (n = 30)	4,3	Rp24.036.285	Rp5.589.833,7
Group 3 (n = 10)	6,3	Rp22.133.317	Rp3.161.902

Based on the statistical analysis, no significant differences were observed in either therapeutic effectiveness or total direct medical costs among the three treatment groups. Therefore, calculation of the Incremental Cost-Effectiveness Ratio (ICER) was not considered necessary. Although the Average Cost-Effectiveness Ratio (ACER) was calculated and presented descriptively, these results should not be interpreted as evidence of superiority of any treatment regimen because no statistically significant differences in effectiveness or costs were identified among the groups.

DISCUSSION

The results of this study show that in the period January – June 2024 the number of male patients was higher in the three hemoptysis therapy groups (79-80%). This finding is consistent with the study by Mufrodi et al. conducted in 2014. where the number of hemoptysis patients was 72.4% male, 27.6% female. The average age of patients in all three therapy groups was 51.2 years, 55.3 years and 51.6 years. This is different from the research of Mufrodi et al, namely the average age of patients is 45 years. The most common diagnoses in patients with hemoptysis were cancer (48/93 = 51.6%), followed by TB/BE/CAP infection (30/93 = 32.3%), aspergilloma/mycosis fungal infection (13/93 = 14%), and COPD (2/93 = 2.1%). This differs from the study by Mufrodi et al., where pulmonary tuberculosis was the most common diagnosis (58%), followed by patients classified as post-tuberculosis (25%)[15].

In this study, hemoptysis therapy is grouped into 3, namely Tranexamic Acid; Tranexamic acid + vitamin K; and Tranexamic Acid + Vitamin K + Carbazochrome (AC Adona). In terms of severity, patients are grouped into 2, namely Nonmassive and Massive. The proportion of patients with massive hemoptysis differed significantly among treatment groups, suggesting that treatment allocation may have been influenced by disease severity, namely in the Tranexamic Acid + Vitamin K + carbazochrome group 30%, the Tranexamic Acid + Vitamin K group 20%, and the Tranexamic Acid group 5.7% (p value = 0.040). This finding is consistent with the hospital policy permitting carbazochrome administration in patients with massive hemoptysis or inadequate response to tranexamic acid. Consequently, the observed outcomes may have been affected by confounding by indication.

The effectiveness of hemoptysis therapy is seen from the average number of days bleeding stops. The Tranexamic acid group was the fastest to stop bleeding, which was 3.5 days, followed by the Tranexamic acid + Vit group. K 4.3 days, and the Tranexamic acid + Vit K + Carbazochrome group was 6.3 days. Although at first glance there is a difference in effectiveness, because the variability within groups was substantial, there is no significant difference in the effectiveness of therapy between groups in statistical analysis (Table 2). This result is different from previous research by Mufrodi et al which compared the effectiveness of two groups of therapy, namely Vitamin K + Vitamin C versus Vitamin K + Vitamin C + Carbosomes. Previous studies did not use tranexamic acid therapy.

The present study demonstrated that the addition of vitamin K and carbazochrome to tranexamic acid did not result in a statistically significant reduction in the time required for bleeding cessation. This finding is in line with current evidence suggesting that tranexamic acid remains one of the most widely studied pharmacological agents for the management of hemoptysis. A systematic review and meta-analysis by Tsai et al. reported that tranexamic acid was associated with a shorter duration of bleeding and reduced length of hospitalization compared with standard care. However, the available evidence remains limited by small sample sizes and heterogeneity among

studies, making it difficult to establish clear superiority over other adjunctive hemostatic therapies[8].

Although the cost of hemoptysis drugs in the Tranexamic Acid + Vitamin K + Carbazochrome group is larger, no significant difference was observed in total direct medical costs among treatment groups. Therefore, statistical analysis was not carried out to find differences in each component of the cost.

Economic evaluation demonstrated comparable effectiveness and direct medical costs among the three treatment regimens. Despite comparable baseline demographic characteristics, no significant differences were observed in therapeutic effectiveness or total direct medical costs among treatment groups in the effectiveness of the length of the bleeding stop day and the total immediate medical cost.

Like other retrospective research, this study also has several limitations, including: an imbalance in the number of samples, namely the limited number of samples of the Carbazochrome group (10 people). This is because carbazochrome does not enter Fornas so initially if doctors want to prescribe this drug, they must apply to management approval. Although in January 2024, a Director's Decree has been issued that allows the use of carbazochrome drugs in patients with massive cough without having to go through an approval process to Komdik, KFT, and Dirmed. However, doctors may still not be socialized about this circular. Prospective follow-up research may be able to obtain better data with a more balanced number of samples between groups.

The significantly higher proportion of massive hemoptysis in the carbazochrome group suggests that physicians tended to prescribe carbazochrome to patients with more severe clinical presentations. This prescribing pattern was consistent with the hospital policy allowing carbazochrome use in patients with massive hemoptysis or inadequate response to tranexamic acid. Therefore, direct comparison of effectiveness between groups should be interpreted cautiously due to potential confounding by indication.

Massive hemoptysis is recognized as a life-threatening emergency that requires rapid evaluation and management. Therefore, physicians may be more likely to use additional hemostatic agents in patients with severe presentations, which may explain the higher proportion of massive hemoptysis in the carbazochrome group[12].

Massive hemoptysis is also associated with substantial morbidity and mortality and requires prompt multidisciplinary management. Current evidence suggests that airway protection, localization of the bleeding source, and definitive hemorrhage control are the primary determinants of patient outcomes. Therefore, pharmacological hemostatic agents should be considered as adjunctive therapies rather than the sole intervention in the management of severe hemoptysis[13].

Previous studies have demonstrated that underlying diseases such as lung cancer and aspergillosis are independent predictors of poor outcomes in patients with hemoptysis. In the present study, malignancy was the most common underlying diagnosis, followed by infectious diseases and aspergilloma/mycosis. Consequently, treatment outcomes may have been influenced not only by the hemostatic regimen administered but also by the severity of the underlying disease process[14].

Recent reviews have emphasized that pharmacological hemostatic agents represent only one component of hemoptysis management. In patients with severe or life-threatening hemoptysis, clinical outcomes are also influenced by airway stabilization, bronchoscopic interventions, bronchial artery embolization, and treatment of the underlying disease. Furthermore, mortality is frequently related to airway obstruction and respiratory compromise rather than blood loss itself. Therefore, the absence

of significant differences in effectiveness among treatment groups in the present study may reflect the multifactorial nature of hemoptysis management rather than the comparative efficacy of the hemostatic agents alone[15].

LIMITATION

This study has several limitations. Firstly, the sample size of the carbazochrome group was relatively small compared with the other treatment groups, which may have reduced statistical power. Another limitation is a significant difference in disease severity observed between groups, potentially introducing confounding by indication. Additionally, the retrospective design relied on the completeness and accuracy of medical records. Moreover, this study was conducted in a single tertiary referral hospital, which may limit the extent to which the findings can be generalized to other healthcare settings.

CONCLUSION

Among hospitalized patients with hemoptysis, tranexamic acid alone, tranexamic acid plus vitamin K, and tranexamic acid plus vitamin K plus carbazochrome demonstrated comparable therapeutic effectiveness and total direct medical costs. However, interpretation of these findings should be made with caution because baseline disease severity differed significantly among treatment groups. Further prospective studies with larger and more balanced sample sizes are warranted.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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