

ORIGINAL ARTICLE

Efficacy of Topical Hemostatic Powder on Hemorrhagic Complications After Transrectal Prostate Biopsy: A Randomized Controlled Trial

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Purpose: Topical hemostatic powders may help limit blood loss when applied to a wound early in the course of bleeding. This study evaluated the effectiveness and safety of a hemostatic powder composed of carboxymethyl starch and calcium ions for reducing hemorrhagic complications (specifically hemoglobin loss) after transrectal prostate biopsy.

Materials and Methods: In this randomized controlled trial, 95 patients undergoing transrectal prostate biopsy received either hemostatic powder with povidone-iodine-soaked gauze or povidone-iodine-soaked gauze alone. The primary outcome was hemoglobin level measured before biopsy and 1 day after biopsy. Secondary outcomes included the incidence of hematuria, hematochezia, infection, and other complications.

Results: Postbiopsy hemoglobin levels did not differ significantly between the control (12.3 ± 1.6 g/dL) and experimental (12.2 ± 1.8 g/dL) groups ($p=0.872$). In both groups, hemoglobin level decreased significantly from 13.1 ± 1.9 g/dL before biopsy to 12.2 ± 1.8 g/dL after biopsy ($p<0.001$). Hematuria occurred in 95.1% of the experimental group and 87.2% of the control group ($p=0.389$). The incidence of hematochezia was significantly lower in the experimental group (18.8%) than in the control group (59.6%) ($p<0.001$). No significant differences were observed in other complications, including infection, urinary retention, and transfusion requirement. No severe adverse events were reported in either group.

Conclusion: Application of the hemostatic powder did not prevent postbiopsy hemoglobin decline; however, it significantly reduced the incidence of hematochezia. The procedure appeared safe in this trial, although further studies are needed to identify more effective strategies to prevent cumulative hemoglobin loss after transrectal prostate biopsy.

Key Words: Biopsy hemorrhage, Complications, Carboxymethyl starch topical powder, Hemostatics

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- **Research Ethics:** The study protocol was reviewed and approved by the institutional review board of Chung-Ang University Hospital (no. 2208-020-520). Informed consent was obtained from all patients upon study enrollment, and this study was conducted in accordance with the Declaration of Helsinki.
- **Conflicts of Interest:** The authors have nothing to disclose.

INTRODUCTION

Prostate cancer is a major health concern and is the second most frequently diagnosed cancer in men, with approximately 1.4 million new cases diagnosed worldwide in 2020 [1]. Although transperineal prostate biopsies have become common, transrectal prostate biopsy remains the most commonly used method for diagnosing prostate cancer [2]. As the number of prostate cancer diagnoses increases each year, the number of prostate biopsies performed is also rising [3]. In the early days of prostate biopsy in the 1920s, the transrectal approach was not favored due to concerns about fecal contamination. However, with the development of transrectal ultrasound (TRUS) in the 1980s, this method has been widely used due to its ease of access [4]. The disadvantages of using the transrectal approach include difficulty in obtaining tissue from the apex and anterior regions of the prostate, concerns about infection, and the potential for severe bleeding if the rectal artery is damaged [5].

Prostate biopsy is generally safe and easy to perform, but complications such as infection, sepsis, hematuria, hematospermia, hematochezia, and acute urinary retention can occur. Various methods have been used to reduce the adverse effects and discomfort associated with transrectal prostate biopsy, including adjustments to the number of biopsy cores, administration of prophylactic antibiotics, performing prebiopsy enemas, and altering techniques to administer local anesthesia, which vary among practitioners [6]. To reduce hemorrhagic complications, techniques such as rectal Foley catheterization or ultrasound-guided compression have been used [7,8]. Hemostatic agents can help prevent blood loss when they are applied to the wound during the early stages of bleeding. In this study, we aimed to assess whether using a hemostatic powder comprising carboxymethyl starch and calcium ions can help reduce bleeding and prevent hemoglobin loss after transrectal prostate biopsy.

MATERIALS AND METHODS

1. Ethics Statement

The study protocol was reviewed and approved by the institutional review board of Chung-Ang University Hospital

(no. 2208-020-520). Informed consent was obtained from all patients upon study enrollment, and this study was conducted in accordance with the Declaration of Helsinki.

2. Study Design

This trial (Clinical Research Information Service, Republic of Korea; approval number KCT0008584) was designed as a prospective, randomized, single-blind, controlled trial to evaluate the efficacy and safety of a hemostatic powder comprising carboxymethyl starch in patients undergoing transrectal prostate biopsy. Written informed consent was obtained from all participants after a detailed discussion about the nature of the procedure and associated risks before the performance of the prostate biopsy. The patients were blinded to allocation, but the urologist was aware of the intervention rendered.

3. Study Population

The study included adult men suspected of having prostate cancer who underwent transrectal biopsy. Enrollment occurred from October 12, 2022, to June 27, 2024. Individuals were excluded if they were deemed unsuitable for prostate biopsy, unable to discontinue anticoagulants before the procedure, had a history of bleeding disorders or thromboembolic conditions, or were unable to comprehend the study or communicate their health status.

4. Study Procedure

After providing informed consent, participants were randomly assigned in a 1:1 ratio to either the experimental or control group. To minimize selection bias, the randomization sequence was generated using a web-based program (www.random.org) by a study coordinator who was not involved in patient recruitment or clinical care. Allocation was concealed using sequentially numbered, opaque, sealed envelopes. These envelopes were opened by the performing urologist only after the patient provided written informed consent and immediately prior to the biopsy procedure. This ensured that the enrolling urologist remained blinded to the treatment assignment during the recruitment phase.

All participants received a laxative and a second-generation cephalosporin and metronidazole prophylactic antibiotic before the biopsy. During the prostate biopsy, patients were positioned in the left lateral decubitus position. The perianal skin was disinfected with 10% povidone-iodine, and the area was covered with a sterile drape. A mixture of 3 mL of 10% povidone-iodine and 7 mL of 2% lidocaine was instilled into the rectum, followed by the administration of 10 mL of 1% lidocaine gel for local pain control. All participants underwent systematic biopsies using a TRUS probe, and some also received targeted biopsies. For each core biopsy, the needle was cleaned with povidone-iodine before use.

After the biopsy, the experimental group received hemostasis with two 4×8 cm sterile gauze pads soaked in povidone-iodine, which were saturated with hemostatic powder containing carboxymethyl starch (OOZFIX, Theracion Biomedical, Korea) and inserted into the rectum at the biopsy site. Hemostasis was achieved by applying finger pressure for 1 minute. In the control group, hemostasis was performed in the same manner but without the use of hemostatic powder, using only povidone-iodine-soaked gauze. The gauze pads were left in place to be expelled naturally with defecation. After the biopsy, a third-generation cephalosporin antibiotic and metronidazole were administered orally for one week.

5. Study Outcomes

The primary outcome was to compare hemoglobin levels between groups on the first day after the biopsy. Blood tests were performed the morning after the biopsy. Secondary outcomes included the incidence of complications such as hematuria, hematochezia, transfusion, infection, acute urinary retention, and readmission. Hematuria was confirmed by a urinalysis on the first day after the biopsy. Hematochezia was operationally defined as any visible bright red blood from the rectum during or after defecation. The patient was monitored for this and other complications through a structured interview until the outpatient visit scheduled one week after the biopsy. To ensure the objectivity of these patient-reported outcomes, all participants remained blinded to their group allocation throughout the 1-week assessment period. The severity of bleeding was classified as mild if it was self-limited and severe if it required transfusion, hospitalization,

or additional interventions.

6. Statistical Analysis

Descriptive variables are expressed as the mean±standard deviation or numbers with percentages. All analyses were performed in the intention-to-treat population. Student's t-test was used for comparing continuous variables between the groups, and the chi-squared test was used for categorical variables. A value of $p < 0.05$ was considered to indicate statistical significance. All statistical analyses were performed with R ver. 4.4.1 (R Project for Statistical Computing, Austria). The sample size was determined using G*Power 3.1.9.7. Assuming an expected difference in hemoglobin change of 0.7 g/dL (based on the typical physiological drop observed in our clinical practice) with a standard deviation of 1.0 g/dL (corresponding to an effect size of 0.7), a sample size of 43 participants per group was required using a 2-tailed Student t-test with a significance level (α) of 0.05 and a power ($1-\beta$) of 0.90. To account for a 10% dropout rate, the final sample size was set at 95 participants.

RESULTS

1. Patient Characteristics

A total of 98 eligible patients were assessed, and 3 patients declined to participate. Subsequently, the patients were randomized to the experimental group ($n=48$) and control group ($n=47$) (Fig. 1). Overall, the groups were balanced for baseline characteristics and biopsy outcomes (Tables 1 and 2). Age, body mass index, smoking history, and prevalence of hypertension, diabetes, and dyslipidemia were similar between the groups. The proportion of patients using antithrombotic agents was 17% in the control group and 29.2% in the experimental group ($p=0.246$). Prostate cancer was detected in 53.2% of the control group and 60.4% of the experimental group. Grade group 4 was the most frequently observed, in 21.7% of the control group and 22.9% of the experimental group. The total number of biopsy cores was 12.4 ± 1.4 in the control group and 12.3 ± 1.2 in the experimental group ($p=0.731$). The positive core count was 2.8 ± 4.0 in the control group and 3.4 ± 3.9 in the

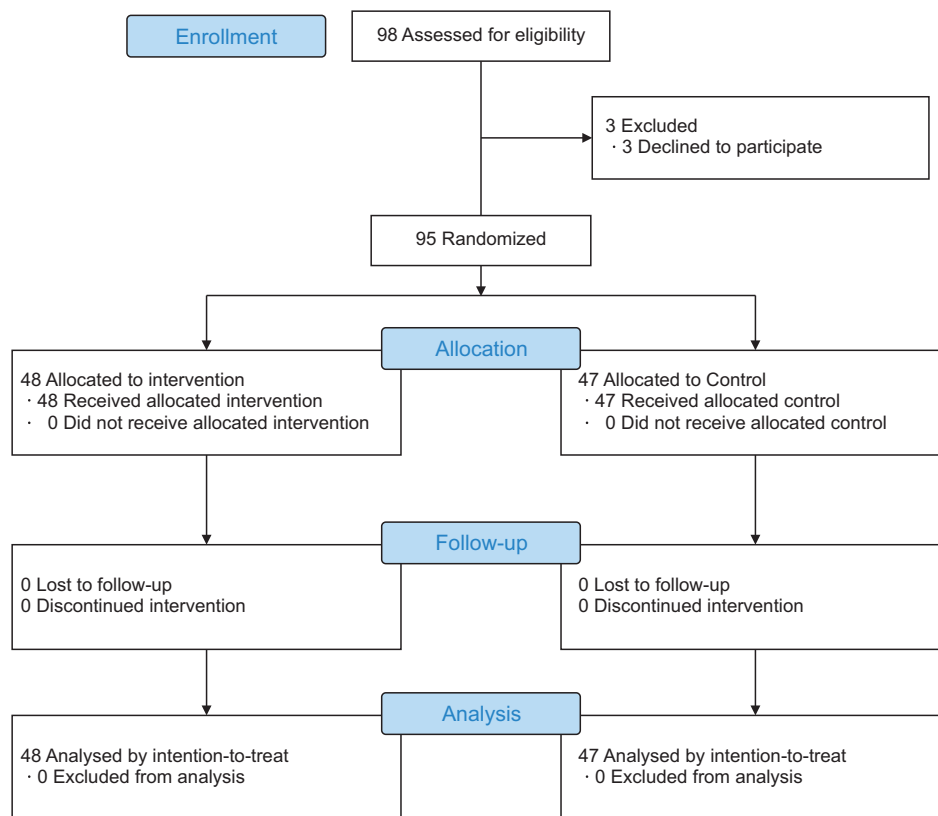


Fig. 1. CONSORT (Consolidated Standard of Reporting Trials) flow diagram.

Table 1. Baseline characteristics

Characteristic	Control group (n=47)	Experimental group (n=48)	p-value
Age (yr)	72.9±8.2	71.0±10.9	0.337
Height (cm)	164.2±14.0	166.5±6.0	0.314
Weight (kg)	67.5±8.7	67.9±8.9	0.848
BMI (kg/m ²)	26.6±5.4	24.5±3.4	0.374
Smoking			0.210
None	30 (63.8)	31 (64.6)	
Yes	8 (17.0)	13 (27.1)	
Previous	9 (19.1)	4 (8.3)	
Hypertension	24 (51.1)	27 (56.2)	0.763
Diabetes	11 (23.4)	14 (29.2)	0.686
Dyslipidemia	9 (19.1)	10 (20.8)	1.000
Antithrombotic agent	8 (17.0)	14 (29.2)	0.246

Values are presented as mean±standard deviation or number (%).
BMI, body mass index.

Table 2. Biopsy outcomes

Outcome	Control group (n=47)	Experimental group (n=48)	p-value
Adenocarcinoma	25 (53.2)	29 (60.4)	0.614
Grade group			0.560
1	3 (6.5)	1 (2.1)	
2	4 (8.7)	7 (14.6)	
3	4 (8.7)	8 (16.7)	
4	10 (21.7)	11 (22.9)	
5	4 (8.7)	2 (4.2)	
Biopsy total core	12.4±1.4	12.3±1.2	0.731
Positive core count	2.8±4.0	3.4±3.9	0.523
Maximal tumor length (%)	27.1±35.0	36.2±39.2	0.235
Atypical small acinar proliferation	3 (6.4)	9 (18.8)	0.132

Values are presented as number (%) or mean±standard deviation.

experimental group (p=0.523). The maximal tumor length in the positive cores was 27.1%±35.0% in the control group and 36.2%±39.2% in the experimental group (p=0.235).

2. Outcomes

The primary outcome was the difference in hemoglobin levels between the groups on the first day after biopsy, with

no significant difference observed between the control (12.3±1.6 g/dL) and experimental groups (12.2±1.8 g/dL) (p=0.872) (Fig. 2). Prebiopsy hemoglobin levels were also similar between the control (13.0±1.7 g/dL) and experimental groups (13.2±2.0 g/dL) (p=0.708). In the overall study population, the hemoglobin level significantly decreased from 13.1±1.9 g/dL before biopsy to 12.2±1.8 g/dL after biopsy (p<0.001). Platelet counts were similar between the groups before biopsy (control: 215.5±84.8, experimental: 212.8±63.2 ×10⁹/L;

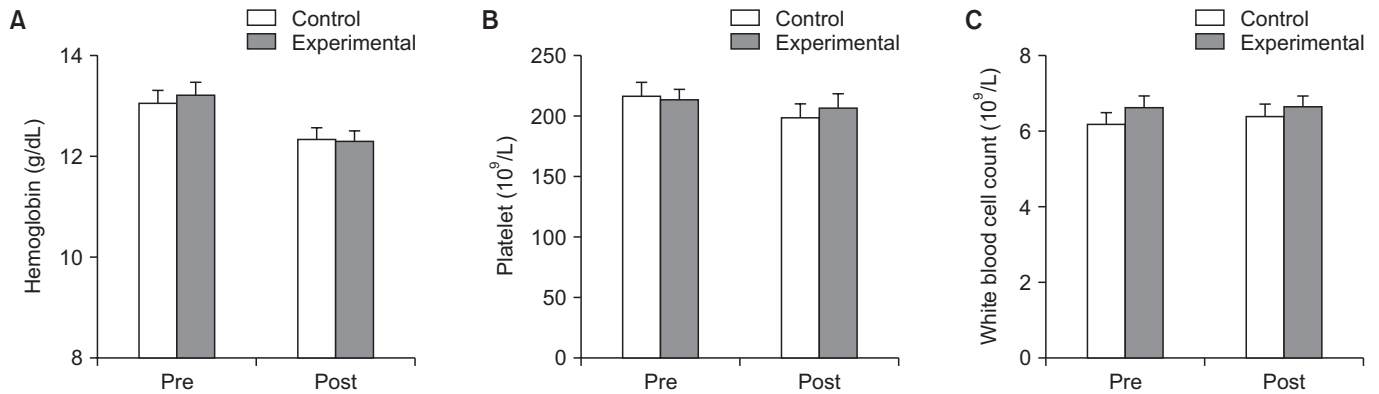


Fig. 2. Changes after transrectal prostate biopsy in hemoglobin level (A), platelet count (B), and white blood cell count (C).

Table 3. Secondary outcomes

Outcome	Control group (n=47)	Experimental group (n=48)	p-value
Hematuria	34/39 (87.2)	39/41 (95.1)	0.389
Pyuria	9/39 (23.1)	11/41 (26.8)	0.897
Bacteriuria	2/39 (5.1)	2/41 (4.9)	1.000
Hematochezia	28/47 (59.6)	9/48 (18.8)	<0.001
Transfusion	0/47 (0)	0/48 (0)	-
Fever	0/47 (0)	0/48 (0)	-
Readmission	0/47 (0)	0/48 (0)	-
Acute urinary retention	0/47 (0)	0/48 (0)	-

Values are presented as number (%).

$p=0.863$) and after biopsy (control: $197.4 \pm 83.8 \times 10^9/L$, experimental: $205.4 \pm 89.8 \times 10^9/L$; $p=0.660$). White blood cell counts were also comparable between the groups before biopsy (control: $6.1 \pm 2.3 \times 10^9/L$, experimental: $6.6 \pm 2.3 \times 10^9/L$; $p=0.365$) and after biopsy (control: $6.4 \pm 2.4 \times 10^9/L$, experimental: $6.6 \pm 2.2 \times 10^9/L$; $p=0.614$).

Other biopsy-related adverse events were assessed as secondary outcomes (Table 3). In the control group and experimental group, hematuria was observed in 87.2% and 95.1% of the patients, respectively ($p=0.389$), pyuria in 23.1% and 26.8% ($p=0.897$), and bacteriuria (postbiopsy urinalysis) in 5.1% and 4.9%, respectively ($p=1.000$). Hematochezia was significantly more frequent in the control group (59.6%) than in the experimental group (18.8%) ($p<0.001$). *Post hoc* analysis of the hematochezia revealed a power of 1.0 and an effect size of 0.831. Importantly, all cases were classified as mild and self-limited, with no clinically significant bleeding requiring intervention or readmission in either group. There were no cases of transfusion, fever, readmission, or acute urinary retention. No severe adverse events were observed.

DISCUSSION

To our knowledge, this is the first study to use a hemostatic powder comprising carboxymethyl starch and calcium ions for preventing bleeding after TRUS-guided prostate biopsy. Through this study, we found that placing the hemostatic powder, together with gauze soaked in povidone-iodine, into the rectum did not significantly reduce hemoglobin levels compared to the control group. However, it was effective in significantly reducing rectal bleeding. Moreover, use of the hemostatic powder was safe and without severe adverse effects.

Our study failed to demonstrate a significant reduction in hemoglobin loss, thus the primary endpoint was not met. Several factors may explain why systemic hemoglobin changes did not reflect the localized hemostatic effect observed in the rectum. First, periprocedural intravenous fluid administration can lead to hemodilution, potentially masking minor differences in actual blood loss between groups. Second, while the hemostatic powder effectively reduced hematochezia, it had no effect on hematuria, which occurred in over 85% of patients in both groups. Since postbiopsy hemoglobin decline is a cumulative result of both rectal and urinary tract bleeding, the localized control of only one bleeding source may be insufficient to impact overall hemoglobin levels. Furthermore, hemoglobin levels are sensitive to individual hydration status and baseline cardiovascular health, which may have introduced variability that exceeded the specific effect of the intervention.

Although major complications following transrectal prostate biopsy occur in approximately 1% of the cases, the

risk of complications has been reported to be higher when the number of biopsy cores is more than 6 than with the earlier 6-core technique [9]. Hematuria and rectal bleeding are common after biopsies, with reported rates of up to 84% for hematuria and 51% for rectal bleeding [10,11]. These are usually self-limiting within a few days, but patients on anticoagulant therapy may experience more severe bleeding [12]. To mitigate this risk, anticoagulants are typically discontinued for several days to a week before the biopsy, depending on the type of medication. Performing multiple biopsies through the rectal mucosa can also increase the risk of infection, which could be a concern in the context of rising antibiotic resistance. The increased risk of infections could also translate to increased risk of sepsis and hospitalizations [13]. As an alternative, transperineal biopsy has gained popularity, offering a comparable cancer detection rate with fewer rectal bleeding and infection risks [12]. Additionally, transperineal biopsy is better for detecting cancers in the anterior and apex regions of the prostate [14]. However, it has been associated with a higher prevalence of postprocedural pain and, while it can be performed under local anesthesia in an office-based setting, it is more commonly performed under general anesthesia [12,13]. In a recent randomized controlled trial (RCT), there were no significant differences in infectious complications, urinary retention, or bleeding requiring intervention when comparing transrectal biopsy with targeted prophylaxis with appropriate antibiotics based on rectal cultures and transperineal biopsy without antibiotic prophylaxis [15].

To reduce unnecessary biopsies and their associated complications, several studies have focused on minimizing the number of biopsy cores through the use of targeted biopsy techniques, which have been advanced by the development of multiparametric magnetic resonance imaging (MRI) and the Prostate Imaging-Reporting and Data System (PI-RADS) scoring system [16]. The PRECISION trial showed that targeted biopsy guided by multiparametric MRI was more effective at detecting clinically significant cancer (grade group 2 or higher) than systematic biopsy without MRI guidance [17]. In the PROMIS (Patient-Reported Outcomes Measurement Information System) study, multiparametric MRI demonstrated a high negative predictive value (89%) for significant cancer defined as grade group 3 or higher, or

a maximum cancer core length of ≥ 6 mm, though the negative predictive value was lower for grade group 2 cancers (76%), indicating that some significant cancers might be missed with targeted biopsy alone [18]. In the MRI-FIRST study, both systematic and targeted biopsies were performed after multiparametric MRI, and the combination of the 2 biopsy techniques yielded the highest detection rate for significant cancer (grade group 2 or higher) [19]. Based on these findings, it appears that targeted biopsy alone may not completely replace systematic biopsy, and efforts to reduce the number of biopsy cores may be limited. In fact, combining systematic biopsy with targeted biopsy could increase the total number of cores. Thus, minimizing biopsy-related complications remains an important goal.

Several strategies have been developed to reduce bleeding complications during transrectal biopsy. In patients on anti-coagulant therapy, an RCT showed that oral administration of 500-mg tranexamic acid, an antifibrinolytic agent that inhibits the activation of plasminogen to plasmin, 1 hour before biopsy significantly reduced hematuria and rectal bleeding compared to that in the control group [20]. Mechanical compression techniques have also been studied. In one study, ultrasound-guided compression was used with a transducer for 5 minutes to compress the site of active bleeding identified by power Doppler, resulting in a reduction of rectal bleeding from 44% to 20% compared to that in the control group [8]. In another study, an 18F Foley catheter was inserted into the rectum and inflated with 50 mL of saline for 30 minutes after biopsy. Although this method did not significantly reduce hematuria or hemospermia, it significantly reduced rectal bleeding [7]. The use of hemostatic agents in the rectum has also been studied. In one study, a 3×8 cm absorbable hemostatic gelatin sponge was inserted into the rectum immediately after biopsy, and this significantly reduced rectal bleeding without causing pain or discomfort [21]. The authors of that article suggested that the hemostatic effect was likely due to direct compression from the anal canal's shape, as well as the sponge's facilitation of platelet aggregation and fibrin clot formation [21]. In another study, the use of an oxidized regenerated cellulose patch in the rectum reduced rectal bleeding and alleviated patient anxiety, but it did not reduce other types of bleeding [22]. We used a powder-form hemostatic agent containing blood

coagulation factors that is known for its high absorbability [23]. The selection of a powder-form hemostatic agent was based on the fact that as a powder it can be used in confined spaces without causing significant discomfort. Although it did not improve hemoglobin levels or reduce other types of bleeding, a reduction in rectal bleeding was observed.

Our study has several limitations. While we initially hypothesized that the primary outcome would be a reduction in hemoglobin loss, we were unable to meet this endpoint. We anticipated that the hemostatic powder's superior absorbability would help improve overall bleeding complications and yield significant results in preventing hemoglobin reduction, but this was not achieved. The hemoglobin levels decreased by approximately 1 g/dL before and after the biopsy. Additionally, our study showed a higher incidence of hematuria and rectal bleeding in the overall population compared to other studies. This may be because all patients underwent urinalysis the day after the biopsy, which could have increased the detection rate of hematuria. Rectal bleeding was assessed only during follow-up visits in the outpatient clinic, which may have introduced recall bias. However, the patients were blinded to whether they were in the experimental or control group. Furthermore, unlike other studies, which typically included patients in their 60s, our study population was slightly older, with a mean age in their 70s. Moreover, the detection rate of prostate cancer was higher at approximately 60%, which may have influenced the results. A strength of this study is the objective assessment of hemoglobin changes through direct measurement, providing concrete and quantifiable data.

CONCLUSION

The application of a hemostatic powder comprising carboxymethyl starch and calcium ions did not significantly prevent systemic hemoglobin reduction after transrectal prostate biopsy. However, it was associated with a significant decrease in the incidence of hematochezia. These findings suggest that while the powder is safe and effective for managing localized rectal bleeding, it may not be sufficient to mitigate cumulative postprocedural hemoglobin loss. Given the significant reduction in hemoglobin levels observed after transrectal prostate biopsy in either group, further research is

needed to explore more effective methods for preventing this complication.

NOTES

• **Author Contribution:** Conceptualization: JHK, SYC; Data curation: SYC; Formal analysis: SYC; Funding acquisition: SYC; Methodology: SYC; Project administration: SYC; Visualization: SYC; Writing - original draft: JHK, SYC; Writing - review & editing: YSL, IHC, TTN.

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