Coagulative Complication Patterns in Patients on Chronic Hemodialysis: A Longitudinal, Multicenter, Observational Study in Thailand

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Objective: *To characterize in real-life the clinical patterns in terms of coagulative complications in end-stage renal disease (ESRD) patients undergoing hemodialysis in Thailand.*

Material and Method: *The study was multicenter, observational in design, comprising 9-month prospective cohort, and 3-month retrospective data collection at baseline. Data related to patient profiles, hemodialysis managements, and coagulative complications were collected. Analyzes were done by means of descriptive statistics.*

Results: *Five hundred ninety eight patients [male 55.7%, mean age 55.4 (SD 14.7) years] with chronic hemodialysis were enrolled. Mean hemodialysis life-time was 7.1 (SD 4.3) years. Two most common ESRD etiologies were diabetes (26.6%) and hypertension (23.5%). The majority of patients (68.4%) had hemodialysis twice-a-week, rather than three times per week. Fifty-seven coagulative complications were reported over one year, of which 24 (4.0%, 95% confidence interval (CI) 0 to 8.95) were bleeding, 24 (4.0%, 95% CI 0 to 8.95) were thrombosis, seven (1.2%) were thrombocytopenia, and one (0.1%) was coagulopathy. Twelve events were considered serious (eight bleedings, two of which were fatal cerebrovascular accidents, two thrombocytopenia, and two thrombosis events).*

Conclusion: *Patient and treatment profiles, including complications, among ESRD patients undergoing chronic hemodialysis in real life were characterized in current study. The incidence profiles of coagulative complications reported in the present study would add a clearer image of safety on anticoagulative agent usage in this group of Thai patients.*

Keywords: *Hemodialysis, Management, Complication, Anticoagulant, Observation study*

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Several clinical aspects are to be taken into consideration when caring for patients undergoing hemodialysis[1], such as nutrition status, volume status, infection, anemia, medications, mineral, and bone disorder, including the use of anticoagulation therapy to prevent thrombosis formation in the extracorporeal blood circuit during the dialysis session. Although it is just one part among other treatments, importance of the anticoagulant use cannot be neglected. When there is imbalance in coagulation homeostasis, the complications of the anticoagulant uses are hemorrhage[2], thrombocytopenia[3,4], or, if there is inadequacy in anticoagulation, clots in dialyzer[5]. Other long-term complications are osteoporosis[6], hypertriglyceridemia[7], and hyperkalemia[8]. Given with a lack of data in terms of coagulation complications in Thai patients, we conducted a multicenter, prospective, non-interventional, observational study in end-stage renal disease (ESRD) patients undergoing hemodialysis to evaluate the pattern of coagulative complications in these patients.

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Material and Method

Study design

The Thai Hemodialysis Registry (THEORY) was a prospective, longitudinal, multicenter, observational study conducted in Thailand. Study objectives were to describe patient profiles and treatments, to determine coagulative complications during the study period. There were three study visits at day 0 (baseline visit, V1), at 3-month ± 2 weeks (V2), and at 9-months ± 2 weeks (end of the study visit, V3). Participating investigators were nephrologists from 13 hemodialysis centers, which were selected based on their feasibilities by the study committees. The participating physicians were free to prescribe any treatment according to their clinical practices.

Patients

Patients eligible for inclusion were out-patients, aged 18 to 90 years, having ESRD, receiving hemodialysis regularly (two to three times/week) for at least three months, receiving low-molecular-weight

heparin (LMWH) or unfractionated heparin (UFH) as anticoagulants during hemodialysis, and signed informed consent. The exclusion criteria comprised of participation in other clinical studies, patients with life-expectancy of less than 12 months, patients with contraindication to UFH or LMWH, and patients who could not adhere with the same investigator throughout the complete study period.

Study assessment

Data collected at baseline included patient demographics, histories of hemodialysis, recent (within three months before enrollment) treatment complications, hemodialysis prescriptions, medical history, and concomitant medications. For the 9-month study cohort, data regarding new coagulative complications or any other new adverse events were prospectively collected. Since the data for complications were captured both in a retrospective manner (backward for three months) and in prospective manner (up to nine months), the overall coagulative complications were reported as one-year incidence. A serious complication was pre-defined as having any one of the following conditions: 1) resulting in death, 2) requiring/prolonging hospitalization, 3) persistent/significant disability/incapability, and 4) life-threatening. It should be noted that the study did not design to investigate at the certainty level the causal-effect relationships between the complications and the anticogulative agents or any other reason; therefore, the study could not conclude that the observed coagulative and non-coagulative complications were merely of causation from any agent or from any reason.

The present study was conducted in accordance with the Declaration of Helsinki[9] and the Guidelines for Good Epidemiological Practice[10,11]. The protocol was approved by the local Ethics Committees.

Statistical analysis

Descriptive statistics including mean, SD, and percentages were used in majority of the study result presentation. Given that the prevalence of bleeding complication was around 10 to 15%[12], and the confidence interval (CI) of estimation was set at 95%, to have a precision rate of ±6%, the target sample size was 500 patients.

Results

Baseline characteristics and demographics

Between October 2008 and June 2010, 597 patients were enrolled from 13 study centers. The baseline demographics and etiological causes of ESRD were presented in Table 1. The mean age ± SD of the patients was 55.4±14.7 years. Fifty-six percent (55.7%) of the patients were men. The three most common etiologies for the ESRD were diabetes mellitus (26.6%), hypertension alone (23.4%), and unknown causes (18.7%). Miscellaneous causes (such as obstructive nephropathy, Table 1) were described in 14.5%. Presumed or biopsy-proven glomerulonephritis (GN) was described in 13.4%, and the most common identifiable GN was the IgA nephropathy, described in 4.2% of patients by overall.

Mean (SD) lifetime of hemodialysis was 7.1 (4.3) years. The majority of patients (409 patients or 68.4%) received hemodialysis twice a week, whereas the rest 31.6% received three times a week. The most common vascular access types were arteriovenous (AV) fistula, used in 418 patients (69.9%), followed by AV graft (94 patients, 15.7%), tunnelled cuffed venous catheter (65 patients, 10.9%), and non-cuff double lumen catheter (20 patients, 3.3%). The most common vascular access sites were forearm (54.8%),

Table 1. Baseline characteristics and etiologies of ESRD

Characteristics	n = 598
Male, n (%)	333 (55.7)
Mean age (year), (SD)	55.4 (14.7)
Mean weight (kg), (SD)	56.4 (12.2)
Mean height (cm), (SD)	160.5 (8.8)
Etiologies of ESRD	n (%)
Diabetes	159 (26.6)
Hypertension alone	140 (23.4)
Unknown	112 (18.7)
Miscellaneous	87 (14.5)
Obstructive nephropathy	43
Gouty acid nephropathy	23
Other etiologies	15
Allograft dysfunction	6
Presumed GN	46 (7.7)
Biopsy-proven GN	34 (5.7)
IgA nephropathy	25 (4.2)
Focal segmental glomerulosclerosis	2 (0.3)
Membranous nephropathy	2
Crescentic GN (rapidly progressive GN)	2
Membranoproliferative GN	1
Other	2
Cystic kidney disease	14 (2.3)
Lupus nephritis	6 (1.0)

ESRD = end-stage renal disease; GN = glomerulonephritis

upper arm (29.9%), jugular (8.2%), subclavian (4.2%), and femoral (2.7%), respectively.

Details in hemodialysis parameters and concomitant treatments at baseline were shown in Table 2. The majority of patients (81.8%) could tolerate high flux rate. The most common dialyzer membrane used was polysulfone (48.2%). UFH was the most widely used anticoagulant in 83.3% of patients. Most of patients (90.1%) received at least one or more antihypertensive agents. Erythropoietin was used in 88.5%. It should be noted that these data may not be relevant to the present time, given the study period of 2008 to 2010.

Prospective follow-up

On the prospective follow-up, 64 patients did not complete the study. Reasons included 17 deaths, 15 lost to follow-up, six switched to another renal replacement mode (five renal transplantations and one peritoneal dialysis), and 26 patients left for unidentified reasons. Causes for the 17 deaths were cardiac (six myocardial infarctions and two cardiac arrests), infections (two septic shocks, two pneumonias, one bacterial endocarditis, and one acute bronchiolitis), fatal hemorrhage (two intra-cranial hemorrhages), and uremia (one patient).

Table 2. Hemodialysis details, anticoagulants, and concomitant medications

Hemodialysis details	n = 598
Dialyzer surface area (m^2), mean (SD)	1.89 (0.29)
Blood flow rate (ml/hour), mean (SD)	330.4 (56.2)
Dialysate flow rate (ml/hour), mean (SD)	572.3 (127.5)
Dialysis flux rate, n (%)	
High	489 (81.8)
Low	108 (18.1)
Missing data	1 (0.2)
Type of dialyzer membrane, n (%)	
Polysulfone	288 (48.2)
Cellulose triacetate	229 (38.3)
Other	61 (10.2)
Cellulose or celloboise	8 (1.3)
Cellulose	6 (1.0)
Polyacrylonitrile and methyl sulfonate	4 (0.7)
Ployethylene polyvinyl alcohol	1 (0.2)
Data missing	1 (0.2)
Anticoagulant agent, n (%)	
UFH	496 (83.3)
Tinzaparin sodium	45 (7.5)
Nadroparin calcium	30 (5.0)
Enoxaparin sodium	26 (4.3)
Other	2 (0.3)
Concomitant medications*, n (%)	
Anti-hypertensive agents	525 (90.1)
Erythropoietin	516 (88.5)
Vitamins and supplements	275 (47.2)
Anti-hyperlipidemic agents	235 (40.4)
Anti-diabetic agents	78 (13.4)
Cardiovascular agents	23 (4.0)
Other	269 (46.1)

UFH = unfractionated heparin
* Non-mutually exclusive data

Coagulative complications and adverse events

Over one year of data collection (3-month retrospective and 9-month prospective), 56 coagulative complications were reported in 56 patients (9.4% over 1 year, Table 3), of which 12 were reported as serious events. Among the 56 complications, bleeding was reported in 24 patients (4.0% by overall over one year, 95% CI 0 to 8.95), of which eight were serious (two patients died of intracranial hemorrhage); thrombocytopenia and/or coagulopathy was reported in eight patients (1.3% by overall over one year), of which two were serious; and thrombosis was reported in 24 patients (4.0% by overall over one year, 95% CI 0 to 8.95), of which two were serious.

Discussion

In current study, we assessed three aspects of coagulative complications in patients on hemodialysis, which were categorized into bleeding, thrombocytopenia/coagulopathy, and thrombosis. Of the first aspect, we are reporting herewith a 4% rate of bleeding complications. Comparing with other literature, this 4% bleeding rate is considerably lower than the rate of 10 to 15%, as that was reviewed from western country data by Özkan and Ulusoy (2011)[12]. Whether or not ethnic factor and treatment difference are contributable to this discrepancy is to be investigated. Consideration on bleeding sites, Lohr and Schwab (1991)[13] described that bleeding complications on a dialysis could be any one of the following sites: pericardium, gastrointestinal (GI) tract, intracranial, retroperitoneal, subcapsular liver, ocular, uterine, and surgical wound. In accordance, bleeding sites reported in current study shared some sites in common with them; of note, two fatal intracranial hemorrhages were reported in current study. With regard to thrombosis complication as the second aspect of coagulative complications, van de Wetering et al (1996)[5] reported an average rate of filter coagulation at 13.5 per 1,000 hours of dialysis. In order to make this data comparable to our data (unit of percentage per year),

Table 3. Coagulative complications during 1-year period

Type of complication	Number (%)	Description	Number of serious cases (%) and details
Bleeding	24 (4.0)	Bleeding (unspecified): 10 Petechiae/ecchymosis: 5 Prolonged bleeding at puncture site: 3 Fatal intracranial hemorrhage: 2 Melena: 1 Hematuria: 1 Bleeding from surgical site: 1 Prolonged bleeding from unspecified site: 1	8 (1.3%) (among them: 2 were reported as death, 3 as prolonged hospitalization, 1 as life-threatening, and 2 as unspecified details)
Thrombocytopenia/coagulopathy	8 (1.3)	Thrombocytopenia: 7 (1.2%) Coagulopathy: 1	2 (0.3%), both were reported as prolonged hospitalization
Thrombosis	24 (4.0)	Clot in dialyzer: 11 (1.8%) Clot in a blood line: 9 AV graft thrombosis: 2 Fistula thrombosis: 1 Thrombosis (unspecified): 1	2 (0.3%), both were reported as prolonged hospitalization
Overall coagulative complication	56 (9.4)		
Overall serious coagulative complication	12 (2.0)		

AV = arteriovenous

a rough estimation was applied via a calculation assuming four hours per dialysis session and 2.2 sessions per week. The resultant calculation gave an 8.9% rate of filter coagulation per year, for which this number was quite high when compared to 1.8% rate of dialyzer clot in the current study. Since the study was not designed to address further details about this finding, reasons for the relative low dialyzer clot in current study remain unknown. Nevertheless, it should be noted that the thrombosis in central catheter is the matter of multifactor in etiology, which is not only attributable to anti-coagulations used, but also to a variety of factors such as formation of a fibrin sheath, venous stasis, catheter malposition, a patient-related predisposing factors that creates tendency towards thrombosis, and failure to make sufficient heparinization during the hemodialysis[12]. Many of factors mentioned in the latter statement are reflecting the quality of hemodialysis management and thus this entity should not be overlooked. Of the third aspect, a serious coagulative complication that might occur to a patient using heparin or other related products is the heparin-induced thrombocytopenia (HIT), or heparin-related product-induced thrombocytopenia. Incidence of this disorder has been reported at low rate (to rare) among patients undergoing chronic hemodialysis, varying from 0 to 0.1%[4]. This small value was quite different from the thrombocytopenia rate of 1.2% in the current study. However, it should be noted that the thrombocytopenia in the current study was not always the HIT, as the majority of the cases were not severe and that definite diagnosis for the presence of PF4-Heparin antibodies was not assessed. However, there was one patient with thrombocytopenia classified as serious. If the suspected case was presumed for this patient, one possible incidence for the suspected HIT should be around 0.2%.

Strengths and limitations

The longitudinal nature of the study allowed collecting data on complications and management with minimal recall biases. However, for a larger number of complications to be observed, a longer duration of studies or otherwise a larger sample size may be required. Some limitations should be mentioned, in particular, the clinical end-points of the study were not clearly defined in advance, thus, resulting in a lack of clinical data in details; for example, many cases of the bleeding complications were reported with unspecified characteristics (Table 3), and there was the other complication of coagulopathy, in which its clinical details were lacking. Lack of the conclusion whether the complications observed were merely of causation from any agent or any reason is another limitation of the present study. However, given that all patients used one of the anticoagulative agents, and the coagulative complications, either bleeding or thrombosis, were pharmacologically related, the causality assessment should be ranked at the "possible" in at least. In addition, the study centers were not randomly selected,

hence, generalizability of the study results was limited. The data have given a broad but clearer image of coagulative complication incidences in hemodialysis patients in Thailand.

Conclusion

The study has highlighted the incidence of coagulative complications in patients on hemodialysis. These data would reflect a clearer image on safety profiles of anticoagulative agents in the present group of patients.

What is already known on this topic?

Prevalence of ESRD patients undergoing hemodialysis is increasing. Some health information aspects related to Thai patients have been explored[14-16], for example the health-related quality of life and economic evaluation[17], however, safety aspect regarding coagulative complications remain lacking. The current study was conducted to evaluate the patient profiles, dialysis management, and coagulative complications in this group of patients in Thailand.

What this study adds?

This study has characterized the patients and the treatment profiles of ESRD patients undergoing chronic hemodialysis in real life. The incidence profiles of coagulative complications reported in the study would provide a clearer image of safety on anticoagulative agent usage in this group of Thai patients.

The THEORY investigators

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Potential conflicts of interest

None.

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รูปแบบภาวะแทรกซ้อนด้านการแข็งตัวของเลือดในผู้ป่วยที่รับการบำบัดด้วยการฟอกเลือดเรื้อรังในประเทศไทย: การศึกษาการขึ้นทะเบียนโรคจากหลายสถาบันแบบการศึกษาเชิงสังเกตตามแนวยาวของช่วงเวลา ในประเทศไทย

เกรียงศักดิ์ วารีแสงทิพย์, สำหรับคณะวิจัยโครงการ THEORY

วัตถุประสงค์: *เพื่อประเมินรูปแบบภาวะแทรกซ้อนที่เกี่ยวข้องกับการแข็งตัวของเลือด ในผู้ป่วยไตวายระยะสุดท้ายที่กำลังได้รับการบำบัดด้วยการฟอกเลือดของการดูแลทางการแพทย์ในชีวิตจริงในประเทศไทย*

วัสดุและวิธีการ: *เป็นการศึกษาเชิงสังเกตในหลายสถาบัน ที่ประกอบด้วยส่วนของการศึกษาแบบไปข้างหน้า 9 เดือน และเก็บข้อมูลย้อนหลัง 3 เดือน นับจากวันแรกของฐานการศึกษา ข้อมูลต่าง ๆ ที่เกี่ยวข้องกับผู้ป่วย การบริหารจัดการของการรักษาฟอกเลือดและภาวะแทรกซ้อนเกี่ยวข้องกับการแข็งตัวของเลือด ถูกรวบรวมและวิเคราะห์ด้วยสถิติเชิงพรรณนา*

ผลการศึกษา: *มีผู้ป่วยที่ฟอกเลือดเรื้อรังที่เข้าการศึกษาทั้งสิ้น 598 ราย เป็นชาย 55.7% อายุเฉลี่ย 55.4 ปี (ค่าเบี่ยงเบน 14.7 ปี) ช่วงเวลาเฉลี่ยประวัติการฟอกเลือด 7.1 ปี (ค่าเบี่ยงเบน 4.3 ปี) สาเหตุหลักที่ทำให้เป็นไตวายระยะสุดท้าย สองสาเหตุคือ โรคเบาหวาน (26.6%) และความดันโลหิตสูง (23.5%) ผู้ป่วยส่วนใหญ่ (68.4%) ได้รับการฟอกเลือดแบบสัปดาห์ละ 2 ครั้ง มากกว่าแบบสัปดาห์ละ 3 ครั้ง ภาวะแทรกซ้อนที่เกี่ยวข้องกับการแข็งตัวของเลือดถูกรายงานจำนวน 57 ครั้ง ในช่วงเวลา 1 ปี โดยเป็นจากภาวะเลือดออก 24 ครั้ง (4.0% ช่วงความมั่นใจ 95% ตั้งแต่ 0 ถึง 8.95%) เป็นจากลิ่มเลือดอุดกั้น (thrombosis) 24 ครั้ง (4.0% ช่วงความมั่นใจ 95% ตั้งแต่ 0 ถึง 8.95%) เป็นจากภาวะเกล็ดเลือดต่ำ (thrombocytopenia) 7 ครั้ง (1.2%) และเป็นการรายงานถึงภาวะเลือดแข็งตัวผิดปกติ (coagulopathy) อีก 1 ครั้ง (0.1%) มีภาวะแทรกซ้อน 12 ครั้ง ที่ถูกจัดว่าอยู่ในระดับรุนแรง (ภาวะเลือดออกรุนแรง 8 ครั้ง โดยมี 2 ครั้ง ที่ทำให้เสียชีวิตจากภาวะเลือดออกในสมอง ภาวะเกล็ดเลือดต่ำรุนแรง 2 ครั้ง และภาวะหลอดเลือดอุดกั้น 2 ครั้ง)*

สรุป: *ข้อมูลผู้ป่วยและการรักษาต่าง ๆ ที่รวมไปถึงข้อมูลด้านภาวะแทรกซ้อนในผู้ป่วยโรคไตวายระยะสุดท้ายที่กำลังได้รับการบำบัดด้วยการฟอกเลือดในชีวิตจริงได้ถูกนำเสนอในการศึกษานี้ ตัวเลขของอุบัติการณ์ของภาวะแทรกซ้อน coagulation ที่รายงานในการศึกษานี้จะช่วยให้ข้อมูลด้านความปลอดภัยจากการใช้ยาต้านการแข็งตัวของเลือดในผู้ป่วยคนไทยกลุ่มนี้ มีความชัดเจนยิ่งขึ้น*