



# Impact of pharmacist educational interventions on patients with anticoagulants

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## Main Information

**Primary registry identifying number**

LBCTR2020033424

**Protocol number**

LAU.SOP.LK2.11/Jul/2017

**MOH registration number**

**Study registered at the country of origin**

Yes

**Study registered at the country of origin: Specify**

**Type of registration**

Retrospective

**Type of registration: Justify**

LBCTR did not exist/was available at the start of the study

**Date of registration in national regulatory agency**

06/03/2020

**Primary sponsor**

Lebanese American University

**Primary sponsor: Country of origin**

Lebanon

**Date of registration in primary registry**

16/03/2020

**Date of registration in national regulatory agency**

06/03/2020

**Public title**

Impact of pharmacist educational interventions on patients with anticoagulants

**Acronym**

N/A

**Scientific title**

Impact of pharmacist-conducted anticoagulation patient education and telephone follow-up on transitions of care: A randomized controlled trial

**Acronym**

N/A

**Brief summary of the study: English**

This was a randomized, non-blinded interventional study conducted at a tertiary care teaching hospital in Beirut, Lebanon. Participants were inpatients  $\geq 18$  years, discharged on a therapeutic dose of anticoagulant.

Patients were randomized by block randomization. The control group received the standard anticoagulant discharge counseling provided by nurses. The intervention group was counseled by a pharmacist. All patients received a phone call from the study investigators at day at day 30 post-discharge. Patients counseled by pharmacists received an additional phone call at day 2 to 3. Primary outcome measures included readmission rates within 30 days post-discharge and bleeding events. Secondary outcomes included unplanned patient contact with prescribers post-discharge.

**Brief summary of the study: Arabic**

إن المعيار المعتمد حالياً في المستشفى يقضي بتوفير المرضى وعائلاتهم بالمعلومات اللازمة عن الأدوية الموصوفة بعد خروجهم من المستشفى. كل مقدمي الرعاية الصحية بما في ذلك الممرضين والأطباء والصيادلة متمرسون في توفير المعلومات المطلوبة عن الأدوية. نحن إلى 2 نرغب في تقييم أثر المعلومات الموفرة من قبل الصيادلة قبل مغادرة المرضى المستشفى حول الأدوية المسببة للدم وخلال فترة المتابعة من 30 يوم بعد مغادرة المستشفى خصوصاً بما يخص مخرجات السلامة كالنزيف 30 أيام بعد مغادرة المستشفى وفي اليوم 3.

**Health conditions/problem studied: Specify**

The most common indication for anticoagulation was atrial fibrillation, venous thromboembolism, aortic valve replacement, and mitral valve





replacement

**Interventions: Specify**

Patients were randomized by block randomization. The control group received the standard anticoagulant discharge counseling provided by nurses. The intervention group was counseled by a pharmacist. All patients received a phone call from the study investigators at day at day 30 post-discharge. Patients counseled by pharmacists received an additional phone call at day 2 to 3.

**Key inclusion and exclusion criteria: Inclusion criteria**

Participants were inpatients  $\geq 18$  years discharged on an oral anticoagulant for treatment

**Key inclusion and exclusion criteria: Gender**

Both

**Key inclusion and exclusion criteria: Specify gender**

**Key inclusion and exclusion criteria: Age minimum**

58

**Key inclusion and exclusion criteria: Age maximum**

86

**Key inclusion and exclusion criteria: Exclusion criteria**

Excluded were those with severe cognitive impairment, inability to communicate or to be followed-up, discharged on an anticoagulant for prophylaxis.

**Type of study**

Interventional

**Type of intervention**

Educations programs

**Type of intervention: Specify type**

N/A

**Trial scope**

Safety

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

Randomized controlled trial

**Study design: Masking**

Open (masking not used)

**Study design: Control**

Active

**Study phase**

N/A

**Study design: Purpose**

Health services research

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Parallel

**Study design: Specify assignment**

N/A

**IMP has market authorization**

**IMP has market authorization: Specify**

**Name of IMP**

**Year of authorization**

**Month of authorization**

**Type of IMP**

**Pharmaceutical class**

Anticoagulants

**Therapeutic indication**

The most common indication for anticoagulation was atrial fibrillation, venous thromboembolism, aortic valve replacement, and mitral valve replacement

**Therapeutic benefit**

N/A - studied readmission rates



**Study model**

N/A

**Study model: Explain model**

N/A

**Study model: Specify model**

N/A

**Time perspective**

N/A

**Time perspective: Explain time perspective**

N/A

**Time perspective: Specify perspective**

N/A

**Target follow-up duration**

**Target follow-up duration: Unit**

**Number of groups/cohorts**

**Biospecimen retention**

None retained

**Biospecimen description**

N/A

**Target sample size**

200

**Actual enrollment target size**

200

**Date of first enrollment: Type**

Actual

**Date of first enrollment: Date**

01/08/2017

**Date of study closure: Type**

Actual

**Date of study closure: Date**

31/07/2019

**Recruitment status**

Complete

**Recruitment status: Specify**

**Date of completion**

31/07/2019

**IPD sharing statement plan**

No

**IPD sharing statement description**

N/A

**Additional data URL**

None

**Admin comments**

**Trial status**

Approved

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
N/A	N/A

## Sources of Monetary or Material Support

Name
N/A

## Secondary Sponsors

Name
N/A

## Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Lamis Karaoui	Lebanese American University - School of Pharmacy, Byblos	Lebanon	+961-354-7254 ext 2318	lamis.karaoui@lau.edu.lb	Lebanese American University
Scientific	Nibal Chamoun	Lebanese American University - School of Pharmacy, Byblos	Lebanon	+961-345-7254 ext 24017	nibal.chamoun@lau.edu.lb	Lebanese American University

## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Lebanese American University - Medical Center Rizk Hospital	Lamis R. Karaoui	Pharmacist/Clinical Associate Professor	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Lebanese American University- University Medical Center Rizk Hospital	11/07/2017	Christine Chalhoub	christine.chalhoub@lau.edu.lb	+961 9 547254 ext. 2340



## Countries of Recruitment

Name
Lebanon

## Health Conditions or Problems Studied

Condition	Code	Keyword
Anticoagulation	2-Propanol (T51.2)	Anticoagulation

## Interventions

Intervention	Description	Keyword
Patients were randomized into 2 groups.	The control group received the standard anticoagulant discharge counseling provided by nurses. The intervention group was counseled by a pharmacist. All patients received a phone call from the study investigators at day at day 30 post-discharge. Patients counseled by pharmacists received an additional phone call at day 2 to 3.	postdischarge counseling

## Primary Outcomes

Name	Time Points	Measure
Readmission rates and any bleeding event	day 3 and day 30 post-discharge	Number of patients readmitted at day 3 and day 30 post discharge

## Key Secondary Outcomes

Name	Time Points	Measure
Documented elements of education in the medical record and reported mortality	30 days post-discharge follow-up	number of patients receiving elements of education



## Trial Results

### Summary results

200 patients were included with 100 patients in each group. Baseline characteristics were similar between the two groups ( $p > 0.05$ ). More patients in the pharmacist-counseled group contacted their physician within 3 days (14% versus 4%;  $p=0.010$ ). No statistically significant difference in bleeding rates at day 3 and day 30 post-discharge between the two groups was observed. The documentation in the pharmacist-counseled group was better ( $p < 0.05$ ), and more explicit education documents were provided by the pharmacist-counseled group ( $p < 0.001$ ). Patients in the standard of care group were more aware of their next appointment date with the physician compared to the pharmacist-counseled group (52% versus 31%,  $p < 0.001$ ).

### Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files