FEDERAZIONE
CENTRI PER LA DIAGNOSI
DELLA TROMBOSI E LA
SORVEGLIANZA DELLE TERAPIE
ANTITROMBOTICHE (FCSA)

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XXVIII CONGRESSO NAZIONALE FCSA
BOLOGNA, 5-7 OTTOBRE 2017

GESTIONE E FOLLOW UP DI PAZIENTI IN TAO (AVK) IN UN CONTESTO DI ALTA COMPLESSITÀ. DIECI ANNI DI ESPERIENZA AL SALAM CENTRE DI EMERGENCY DI KHARTOUM, SUDAN

DOTT. ALESSANDRO MOCINI

EFFICIENCY COMBINED WITH BEAUTY

SALAM CENTRE ENTRANCE

PAZIENTI OPERATI CON PATOLOGIA VALVOLARE TRA IL 19/04/2007 ED IL 31/07/2017

TIPO DI CHIRURGIA	NUMERO (%)
MITRAL VALVE	2429 (44.73)
MITRAL VALVE + AORTIC VALVE	1055 (19.42)
MITRAL + TRICUSPID VALVE	970 (18.86)
AORTIC VALVE	631 (11.62)
MITRAL + AORTIC + TRICUSPID VALVE	337 (6.20)
TRICUSPID VALVE	5 (0.09)
AORTIC + TRICUSPID VALVE	3 (0.05)
TOTAL	**5430**

ATTIVITÀ E STAFF

LA CLINICA DI INR HA CIRCA 300 ACCESSI AL GIORNO:

- 200 CONTROLLI CLINICI
- 100 PRESCRIZIONI TELEFONICHE
- 15 PRESCRIZIONI MAIL

STAFF

- 2 receptionists
- 3 INFERMIERI
- 2 MEDICI
- 3 - 4 FARMACISTI
- 2 TECNICI DI LABORATORIO
- 3 PERSONALE PER LE PULIZIE

ORGANIZZAZIONE DEL LAVORO

Flusso di lavoro dalla domenica al giovedì

- 8:00 I pazienti iniziano ad entrare con un numero progressivo loro assegnato
- 8:30 due infermiere iniziano a fare i prelievi che vengono inviati al Lab a gruppi di 20
- 10:00 arrivano i primi risultati e vengono inseriti nel programma PARMA e valutati dai medici
- A seguire i farmacisti preparano le dosi prescritte e le consegnano ai pazienti
- 10.30 -11.00 I primi pazienti lasciano l'Ospedale

PROTOCOLLO TAO

Pathology or Type of Surgery	Therapy	INR range	Duration
Mechanical AVR (bileaflet or current-generation single tilting disk) and no risk factors for thromboembolism	Warfarin +	2,0 - 3,0 (target 2.5)	Life long
	Aspirin 100 mg OD		Life long
AVR and additional risk factors for thromboembolic events (AF, previous TE or hypercoagulable conditions) or an older-generation mechanical AVR (such as ball-in-cage)	Warfarin +	2,5 - 3,5 (target 3)	Life long
	Aspirin 100 mg OD		Life long
Mechanical MVR	Warfarin +	2,5 - 3,5 (target 3)	Life long
	Aspirin 100 mg OD		Life long
MVR repair with ring	Warfarin	2,0 - 3,0 (target 2.5)	3 months
	Aspirin 100 mg OD		Life long after stopping AOC
MVR repair without ring (pledgets, pericardial strip, etc)	Aspirin 100 mg OD		Life long
Bioprosthetic aortic or mitral valve	Warfarin	2,0 - 3,0 (target 2.5)	6 months
	Aspirin 100 mg OD		Life long after stopping AOC

2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

Developed in Collaboration With the American Association for Thoracic Surgery, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons

WRITING GROUP MEMBERS*

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Catherine M. Otto, MD, FACC, FAHA, *Co-Chair*

PROTOCOLLI DI AGGIUSTAMENTO DOSAGGIO - 1

	RANGE 2.5-3.5	RANGE 2-3
INR 2-2,5	Increase the usual daily dose of warfarin by 5-10% Check INR in 5-7 days	
INR 1,5-2	Double the usual daily dose of Warfarin ONLY on the same day, then 1.25 x usual daily dose Add sc fraxiparine 90 IU/Kg BID for 2 days Check INR in 3-5 days	Increase the usual daily dose of warfarin by 5-10% Check INR in 5-7 days
INR < 1,5	Double the usual daily dose of Warfarin ONLY on the same day, then 1.5 x usual daily dose Add sc fraxiparine 90 IU/kg BID for 2 days Check INR in 3-5 days	Double the usual daily dose of Warfarin ONLY on the same day, then 1.25 x usual daily dose Add sc NADROPARIN 90 IU/Kg BID for 2 days Check INR in 3-5 days

PROTOCOLLI DI AGGIUSTAMENTO DOSAGGIO - 2

INR<5 with no severe bleeding*	Decrease the usual daily dose of Warfarin by 5-10% and check INR in 7-14 days; resume therapy at an appropriately adjusted dose when the INR is in range.
5<INR<9 and no severe bleeding	Omit the next 1 or 2 doses, check INR after 3-7 days, resume therapy at an appropriately adjusted dose when the INR is in range.
INR>9 and no severe bleeding	**Inform the OPD/Triage responsible** Hold the therapy with Warfarin for 2 days, check INR in 3 days; resume therapy at an appropriately adjusted dose when the INR is in range. In case of active bleeding, consider vitamin K**
Severe bleeding and elevated INR	Urgent admission (see protocol for inpatients)

BRIDGING THERAPY

Pathology or Type of Surgery	Therapy	What to do	How to do
Mechanical MVR undergoing minor procedure (such as dental extraction or cataract removal) where bleeding is easily controlled	Warfarin	No need Bridging Therapy	Do not stop (As per physician preference consider bridging therapy).
	Aspirin	Stop	5 days before surgery
Bileaflet mechanical aortic valve and no other risk factors for thromboembolism	Warfarin	No need Bridging Therapy	Stop 2 to 4 days before the procedure (so the INR falls to <1.5 for major surgical procedures) and restarted as soon as bleeding risk allows, typically 12 to 24 hours after surgery.
	Aspirin	Stop	5 days before surgery
Mechanical AVR plus any tromboembolic risk factor Mechanical MVR undergoing major surgery	Warfarin	Bridging Therapy See below**	Resuming warfarin approximately 12 to 24 h after surgery (evening of or next morning)
	Aspirin	Do not Stop	

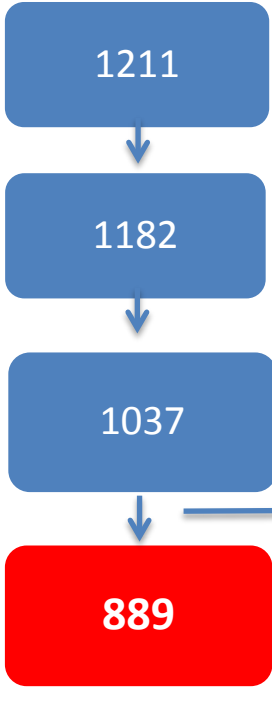
Nodraparin 0.9 UI/Kg bid, Enoxaparin 1 mg/kg bid or 1.5 mg/kg daily, Dalteparin 100 International Units/kg bid or 200 International Units/kg daily, tinzaparin 175 International Units/kg daily, IV UFH to attain an activated partial thromboplastin time [aPTT] 1.5 to 2 times the control aPTT).

NUMERO TOTALE DI PAZIENTI (PRE E POST-CHIRURGICI) PRESI IN CARICO DALLA CLINICA INR DAL 01/01/2010 AL 31/12/2016

YEARS	2010	2011	2012	2013	2014	2015	2016
N° TEST	19676	37350	45478	55270	63468	73258	85020
PAZIENTI	1621	2466	2884	3122	3353	3669	3982

METODO

Pazienti operati per sostituzione valvolare meccanica
2014- 2015 - 2016



Pazienti operati (mortalità ospedaliera : 1 intervento 3,2 %; Redo 9,4 %)

Pazienti seguiti per INR presso in nostro centro

Pazienti arruolati per la valutazione TTR sono stati inclusi solo i pt con almeno una determinazione entro i primi 90 gg dopo l'intervento

148 Drop-out

Totale pazienti inclusi nell'analisi.

Età mediana 24 anni (IQ 16 - 33) 466 (52.4%) Femmine

PROVENIENZA DEI PAZIENTI

STATO	N° PAZIENTI
Sudan	827
South Sudan	20
Chad	11
Sierra Leone	9
Burundi	4
Ethiopia	4
Zimbabwe	3
Eritrea	2
Somalia	2
Afghanistan	1
Central African Republic	1
Iraq	1
Kenya	1
Philippines	1
Rwanda	1
Uganda	1

MAPPA DEL SUDAN

UN ESEMPIO DELLE DISTANZE IN SUDAN

TIPO DI INTERVENTO

853 prima chirurgia; 36 REDO

TIPO DI CHIRURGIA	N° (%)	PROGRAMMA REGIONALE	REDO	FA PRIMA DELLA CHIRURGIA N (%)
V. MITRALE	309 (34.76)	26	16	94 (30.42)
V. MITRALE + V.AORTA	233 (26.21)	10	1	56 (24.03)
V. MITRALE + V. TRICUSPIDE	135 (15.19)	14	7	75 (55.55)
V. AORTA	116 (13.05)	8	7	2 (1.72)
MITRALE + AORTA+ TRICUSPIDE	85 (9.56)	3	4	32 (37.64)
MALATTIA VALVOLARE CONGENITA	8 (0.90)	0	1	2 (25.00)
V.AORTA + V. TRICUSPIDE	2 (0.11)	0	-	-
V. MITRALE + V. AORTA	1 (0.11)	1	-	-

RISULTATI - 1

Misurazione TTR (metodo Rosendaal)
Numero totale di determinazioni INR nella popolazione: 38753

Valore mediano TTR nella popolazione totale= 52.58 (IQR= 40.4- 65.8)

ANNO	% GIORNI IN RANGE	% NUMERO TEST IN RANGE
2014	53,4 (41,4-66,7)	43,6 (31,91-54,84)
2015	52,7 (43,2-64,7)	44,3 (32,90-55,0)
2016	52,38 (38,2-66,8)	43,90 (33,33- 57,2)

RISULTATI - 2

TTR	2014 N° (%)	2015 N° (%)	2016 N° (%)	Totale N° (%)
>70	43 (18,8)	47 (16,9)	82 (21,4)	172 (19,34)
<50-70>	84 (36,8)	114 (41,0)	121 (31,6)	319 (35,88)
< 50	101 (44,3)	117 (42,1)	180 (46,99)	398 (44,76)

RISULTATI - 3

TTR	Maschi (%)	Femmine(%)
>70	97 (22.9)	75 (16.1)
<50-70>	149 (35.2)	170 (36.5)
< 50	177 (41.8)	221 (47.4)

Original Article

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Pharmacology Section

Evaluation of Time in Therapeutic Range (TTR) in Patients with Non-Valvular Atrial Fibrillation Receiving Treatment with Warfarin in Tehran, Iran: A Cross-Sectional Study

Bahram-FariBorz FarSad[1], mohammad aBBaSinazari[2], atouSa daBagh[3], hooman BakShandeh[4]

ABstrAct

Introduction: Anticoagulant control is assessed by Time in Therapeutic Range (TTR). For a given patient, TTR is defined as the duration of time in which the patient's International Normalized Ratio (INR) values were within a desired range.

Aim: To assess TTR in patients receiving treatment with warfarin for non-valvular atrial fibrillation at a referral center for cardiovascular diseases in Tehran, Iran.

Materials and Method: Over 6 months, we enrolled eligible patients presenting to Shaheed Rajaie Hospital in Tehran for regular INR testing. Demographic data, medical history, and current medications were determined for all participants. TTR was assessed by the Rosendaal method.

results: A total of 470 patients (mean age 58.0±14.2 years, 60.2% women) underwent 1450 INR measurements. The mean TTR was calculated as 54.9±11.9%. Of the sample patients, 37.3% were in the good control category (TTR > 70%), 24.6% were in the intermediate category (50% < TTR < 70%), and 38.1% were in the poor control category (TTR < 50%). The number of current medications above four was a significant predictor of poor control (OR = 2.06; 95% CI, 1.87, 2.23). The mean TTR of the studied patients (54.9%) was below the good control range.

conclusion: The quality of anticoagulant therapy with warfarin in Iranian patients was poorer than that reported in European countries. Based on these results, research considering the causes of poor TTR among Iranian patients is recommended.

Keywords: Anticoagulant, Iranian patients, International Normalized Ratio

IntrOductIOn

Warfarin is now the most widely-used anticoagulant in the world. In the United Kingdon (UK), it has been estimated that at least 1% of the whole population is taking warfarin [1]. Although new oral anticoagulants are available, warfarin remains a viable oral anticoagulant for many patients because of its availability and cost [2]. The risk of warfarin-induced bleeding complications is well-known and is typically managed with vitamin K, which restores the production of vitamin K–dependent coagulation factors within 12–24 hour [3]. The therapeutic range for warfarin therapy is defined in terms of the International Normalized Ratio (INR). The INR is calculated as the prothrombin time ratio (patient prothrombin time/mean of normal prothrombin time for laboratory)^{ISI}, which uses the International Sensitivity Index (ISI) for an exponent, and is dependent on the specific reagents and instruments used in the measurement. For most reagent and instrument combinations in current use, the ISI is close to 1, making the INR roughly the ratio of the patient prothrombin time to the mean normal prothrombin time [4]. Obtaining exact and consistent INR levels maximizes the desired benefits and safety of warfarin [5]. The Time in Therapeutic Range (TTR) estimates the percentage of time a patient's INR is within the desired treatment range or goal and is widely-used as an indicator of anticoagulation control. TTR is commonly used to evaluate the quality of warfarin therapy and is an important tool for assessing the risks versus benefits of warfarin therapy [6]. There are 3 methods for assessing TTR in patients taking warfarin: 1) Calculating the fraction of INRs that are in range, which is the conventional method; 2) Evaluating a cross-section of the patient's files; and 3) using the Rosendaal method [7,8]. Assessing TTR allow physicians to estimate the success of warfarin therapy in patients, because it is a major determinant of warfarin's efficacy and safety, with the maximum benefits evident when TTR is >70% [6,9]. The aim of the present study was to evaluate TTR in patients with non-valvular atrial fibrillation who were receiving warfarin therapy at a referral hospital for cardiovascular diseases in Tehran, Iran.

MAterIAls And MethOds

This cross-sectional study was done during six months (between September 2014 to March 2015) at outpatient anticoagulant clinic of Shaheed Rajaie Hospital, Tehran, Iran. This is a well-known center for the treatment of cardiovascular diseases in Iran. Patients diagnosed with non-valvular atrial fibrillation were included in the study if they were between 30-85-years-old and had been taking warfarin for >3 months. Patients who did not want to participate in the study were excluded. All study participants signed consent forms after the study procedures were explained. Demographic data such as age, sex, educational level, medical history and current medications were determined for all participants. The INRs of patients were collected during their referral to the clinic where every patient had at least 3 INR measurements taken in total. Each patient's TTR was calculated using the Rosendaal method. The Rosendaal linear interpolation methodology is based on the INR-DAY software program (Dr. F.R. Rosendaal, Leiden, The Netherlands) that assumes a linear relationship exists between two INR values and allows the researcher to allocate a specific INR value to each day for each patient [8].

stAtIstIcAl AnAlysIs

Results are reported as mean ± SD. Data were analysed using the Statistical Package for the Social Sciences version 20 (SPSS-20), and p-values less than 0.05 were considered statistically significant. The continuous data obtained in this study were analysed using Chi-square test. Significant univariate predictors were subsequently assessed in the multivariate logistic regression

Follow Up

Pazienti	MORTI/100 PTS/ ANNO
889	1,70

COMPLICANZE POTENZIALMENTE CORRELATE A TERAPIA ANTICOAGULANTE

25/889 Pazienti (2.81%) hanno avuto una complicanza potenzialmente correlata all'assunzione di terapia anticoagulante.

7/25 pazienti sono deceduti verosimilmente in relazione alla complicanza

.

COMPLICANZE	PAZIENTI	MORTI RELATI A COMPLICANZE TAO
Valvole Bloccate	16	3
Stroke Emorragico	3	2
Stroke Ischemico	2	1
Sanguinamenti maggiori	3	1

	Mediana (IQ)	Min	Max
TTR (%)	43,3 (34,0- 52,6)	8,3	63,7

PROBLEMATICHE RELATIVE ALLA POPOLAZIONE (DIETA, LIVELLO DI COMPRENSIONE DEL PROBLEMA SCOAGULAZIONE)

Problemi	Possibili Soluzioni
Difficoltà nei trasporti sprattutto dalle zone rurali al Salam Center per i follow up	Usiamo già il telefono e le email per poter ricevere risultati da altri centri e comunicare le variazioni di dosaggio.
Difficoltà nella comprensione delle terapie, dei dosaggi, degli orari, ecc.	Intensificare il lavoro di informazione (counseling)
Difficoltà a comprendere e accettare le restrizioni dietetiche	Intensificare il lavoro di informazione (counseling)
Difficoltà a seguire la terapia in caso di viaggi, malattia, gravidanza e durante il Ramadan	La religione mussulmana consente deroghe alle donne gravide, e ai malati che devono assumere terapie.

POSSIBILI SOLUZIONI IN COLLABORAZIONE CON FCSA

1. IMPLEMENTAZIONE DI PROCEDURE INFORMATIZZATE DEDICATE
2. POSSIBILITÀ DI FORMAZIONE DEL PERSONALE SANITARIO COINVOLTO NELLA GESTIONE TAO TRAMITE SPECIALISTI FCSA
3. PARTECIPAZIONE AI CONTROLLI QUALITÀ FCSA

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Grazie dell’attenzione