THROMBOEMBOLIC AND BLEEDING COMPLICATIONS IN PATIENTS WITH PROSTHETIC HEART VALVES AT THE KENYATTA NATIONAL HOSPITAL

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DISSERTATION SUBMITTED AS PART FULFILMENT OF THE REQUIREMENTS OF THE UNIVERSITY OF NAIROBI FOR AWARD OF THE DEGREE OF MASTER OF MEDICINE (MMED) IN GENERAL SURGERY

A* 2011

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DECLARATION

I hereby declare that this study is my original work and has not been presented at any other university.

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LIST OF ABBREVIATIONS

	Computed Tomography
	Ejection Fraction
JJSJR	International Normalised Ratio
KNH-ERC	Kenyatta National Hospital Ethics Review Committee
j V	Left Ventricle
SVE)	Structural Valve Deterioration

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ABSTRACT

background

The number of patients on warfarin anticoagulation due to prosthetic heart valve insertion is significant. Presence of valves and long term treatment with warfarin has associated hacmatological complications. These patients need constant follow up and monitoring of anticoagulation in order to minimize the occurrence of these complications. However, complications do occur in terms of bleeding or thromboembolic episodes. This study documented the occurrence of such complications in a local population and the associated risk factors.

Objectives

To document the incidence of occurrence of haematological complications and to determine the risk factors for developing the complications.

Study design and setting

Combined prospective and retrospective study at the Cardiothoracic clinic, Kenyatta National Hospital.

Study population

A total of 142 patients were recruited into the study. Thirty nine patients were seen at the cardiothoracic clinic over a period of 6 months for the prospective arm of the study; and records for 103 patients were retrieved for the retrospective arm.

Outcome variables

Outcome measures were: International Normalised Ratio (INR) results during clinic visits; presence of signs and symptoms of bleeding tendencies, neurological deficits, and deep venous thrombosis or valve thrombosis.

F)ata collection and analysis

Thirty eight percent of patients developed haematologic complications, with a significant association with the INR levels. Fourty four patients (3 1%) presented with bleeding tendencies, out of who 28 had grade I bleeding, not requiring admission for further management. Four patients had grade III bleeding which required admission into the hospital for symptomatic management. The most common symptom of thromboembolic complications was occurrence of headaches occurring in 23.2% of patients. The mean duration of anticoagulation for the patients developing complications was 82.9 months (± 64 months), as opposed to those without complications, 60.8 months (± 43.8 rhonths). Nine patients were non compliant with taking their medications, and out of these, 8 developed haematologic complications.

A positive association was established between the development of bleeding and thromboembolic complications INR fluctuations, duration of anticoagulation therapy, non-compliance in taking of medications, and increased duration in between clinic visits.

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Recommendation

The rate of occurrence of bleeding and thromboembolic complications can be reduced by improving patient education so that drug compliance is ensured. Establishment of alternative cardiothoracic centres for easier follow up of patients who have to travel long distances to come for follow up in Kenyatta National Hospital would reduce the cases of missed clinic appointments.

INTRODUCTION

In March 1960, the first successful replacement of an aortic valve was performed by Harken[1]. In the following years, many modifications have been made and new designs introduced to address specific deficiencies in these early devices. Most modern prostheses now offer good durability and hemodynamic characteristics. The main problem still remaining is the thromboembolic potential of these valves. Implantation of an artificial device places a large foreign surface in contact with the bloodstream. Thrombus formation on the valve may be influenced - according to Virchow's triad - by:

- surface characteristics of the prosthesis (material and design);
- blood flow (cardiac output, turbulence, and stagnation); and
- characteristics of the blood constituents of the patient (hypercoagulability).

Clinically, this may result in significant disruption of valve function, a life-threatening event. Likewise, parts of the thrombus may embolise to peripheral arterial sites. These emboli usually involve tfie central nervous system, resulting in a spectrum of effects ranging from transient to sometimes fatal events. To prevent these complications, life-long oral anticoagulation therapy is recommended in all patients[2]. However, this treatment introduces a risk of severe or fatal bleeding".

Thromboembolism and anticoagulation induced bleeding are the most common complications occurring after mechanical heart valve replacement. Various risk factors are implicated in the occurrence of these complications in patients on long term anticoagulation. This, study proposes to document the occurrence of haematological complications -in a local population of patients with mechanical prosthetic heart valves and determine the associated risk factors for developing these complications.

LITERATURE REVIEW

Although numerous mechanical and biologic heart valves are now available after more than 30 years of continual improvement in this field, none of them fulfills all of the demands we make of an ideal replacement for a destroyed human heart valve .

All mechanical valves require long-term anticoagulation. Biological valves are less thrombogenic and do not require long-term anticoagulation unless there are other indications, e.g. persistent atrial fibrillation. However, both biological and mechanical prosthetic heart valves are all subject to structural valve deterioration (SVD) over time.

Two randomized trials in the 1970s, comparing now obsolete models of mechanical and bioprosthetic valves found no significant difference in rates of valve thrombosis and thromboembolism,, im accordance with numerous individual valve series in the literature. Long term survival was also very similar." A recent meta-analysis of mechanical and bioprosthetic valve series found no difference in survival when age and risk factors were taken into account.

Baseline assessment and Modalitiesytff follow-up

A complete baseline assessment should be ideally performed 6-12 weeks after surgery. If for practical reasons this outpatient evaluation cannot be organized, it could be at the end of the postoperative stay. This will include clinical assessment, chest radiography, electrocardiography, transthoracic echocardiography, and blood testing. This reference assessment is of utmost importance to interpret subsequent changes in murmur, prosthetic sounds, as well as ventricular function and transprosthetic gradients as assessed by Doppler echocardiography.

This postoperative visit is also useful to improve patient education on endocarditis prophylaxis and, if needed, on anticoagulant therapy, as well as emphasizing that new symptoms should be reported as soon as they occur.

Antithrom.botic manageinent

General management

Antithrombotic management should encompass the effective management of risk factors for thrombo-embolism in addition to the prescription of antithrombotic drugs.[8,9] Oral anticoagulation is recommended for the following situations:

- Lifelong for all patients with mechanical valves.[9,10,11]
- Lifelong for patients with bioprostheses who have other indications for anticoagulation, e.g. atrial fibrillation, or with a lesser degree of evidence, e.g. heart failure, impaired LV function (EF less than 30%).
- i. For the first 3 months after insertion in all patients with bioprostheses with a target INR of 2.5. However, there is widespread use of aspirin (low dose: 75-100 mg) as an alternative to anticoagulation for the first 3 months, but there are no randomized studies to support the safety of this strategy.[9]

Although there is no consensus regarding the initiation of anticoagulant therapy immediately after valve replacement, oral anticoagulation should be started during the first postoperative days. Intravenous heparin or subcutaneous Enoxaparin enables effective anticoagulation to be obtained before the INR rises.

The first postoperative month is a particularly high-risk period for thrombo-embolism, and anticoagulation should avoid being lower than the target value during this period.[13] In addition, anticoagulation should be monitored more frequently during this period.

Risk of major bleeding rises considerably when the INR exceeds 4.5, and exponentially above an INR of 6.0. An INR of more than 6.0 therefore requires reversal of anticoagulation[1^].

However, in patients with prosthetic valves who are not bleeding, intravenous vitamin K should not be used because of the risk of valve thrombosis if INR falls rapidly. The patient should be admitted to hospital, oral anticoagulant stopped, and the INR allowed to fall gradually.

Spontaneous fall in INR after anticoagulant cessation occurs more slowly in the elderly and in the presence of heart failure.[14] If INR is more than 10.0. consideration should be given to the use of fresh frozen plasma. Reversal of anticoagulation should be more aggressive, using fresh frozen plasma and adapted doses of intravenous vitamin K[1"] if there is active bleeding not amenable to local control. Bleeding with a therapeutic INFf - is "often related to an underlying pathological cause and it is important to identify and treat it.

High variability of the INR is the strongest independent predictor of reduced survival after valve replacement."[1]

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Self-management of anticoagulation has been shown to reduce INR variability and should therefore be recommended in all patients who, after education and training, have the ability to control their own anticoagulation.[17]

Indications for the addition of an antiplatelet agent to an anticoagulant include concomitant arterial disease, in particular, coronary disease and other significant atherosclerotic disease. Antiplatelet agents can also be added after one definite or recurrent embolic episode with adequate INR; there should be full investigation and treatment of identified risk factors, and optimization of anticoagulation management.[18] '

l,.UjX!lEti[t)n <>*'Anticoagulant Theranv

Most instances of short-term anticoagulation interruption do not lead to thromboembolism or valve thrombosis. The finding is that most cases of valve thrombosis occur following a period of anticoagulation interruption for bleeding or another operative procedure.[19]

Anticoagulant management during subsequent non-cardiac surgery therefore requires very careful management after appropriate risk assessment has been conducted.[20, 21, 22] Besides prosthesis- and patient-related prothrombotic factors, surgery for malignant disease or an infective process carries a particular risk, due to the hypercoagulability associated with these conditions. For very high-risk patients, anticoagulation interruption should be avoided if at all possible. Mam- minor surgical procedures (including dental extraction) and those where bleeding is easily controlled do not require anticoagulation interruption. The INR should be lowered to a target of 2.0.[23]

For major surgical procedures, in which anticoagulant interruption is considered essential (INR

more than 1.5), patients should be admitted to hospital in advance and transferred to intravenous unfractionated heparin. Heparin is stopped 6 hours before surgery and resumed 6-12 hours after.

Thromboembolism and anticoagulation induced bleeding are the most common complications alter mechanical heart valve replacement, accounting for 75% of complications[2"].

Risk levels in conjunction with ongoing anticoagulation therapy are considerably higher in cases in which 'international normalised ratio (INR) values fluctuate strongly. When anticoagulant-induced complications occur, as many as 60% of the coagulation values controlled are not within the therapeutic range[26].

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pijjnition of Complications[2]

Thromboembolism

Grade I Questionable events (e.g. dizziness) not requiring medical treatment.

Grade II Complaints presumably connected with the ongoing anticoagulation, requiring outpatient treatment and causing no lasting impediments (including transient ischemic attacks).

Grade III Prosthetic thrombosis, severe thromboembolism requiring inpatient treatment and causing long-term impediments.

Bleeding

Grade I Mild bleeding (e.g. of the gums) not requiring medical treatment.

Grade II Haemorrhage leading to outpatient medical care, not requiring surgical or endoscopic intervention.

Grade III Severe haemorrhage, requiring transfusion, surgical or endoscopic intervention and inpatient care and causing long-term impediments.

In 1990, the British Society of Haematology recommended a target range of 3.0 to 4.5 for the INR, and in 1992 the American College of Chest Physicians recommended that the target range be 2.5 to 3.5~[1].

Previous studies to assess the incidence of haematological complications found that the chance of bleeding in patients receiving anticoagulation was higher than in patients not on any medication. However the incidence of major bleeding was less than 1.4% annually[29]. Batfic,information on the treatment with oral anticoagulant therapy was however lacking with the INR not being stated[29]. Thus the results

could not be related to anticoagulation levels. A study done by Schapkaitz at the Johannesburg General Hospital showed a higher incidence of thromboembolic and bleeding complications in patients who had undergone double valve replacement than in patients who had single valve replacement surgery/[0] Buchanan-Leel et al demonstrated the difficulty of maintaining adequate anticoagulation in a young, impoverished peri-urban community in Cape Town, increasing the incidence of complications in patients with prosthetic valves'[1]. In 2000, a study at the Kenyatta National Hospital Cardiothoracic clinic demonstrated that adequate anticoagulation was maintained for 18% of follow up time, and only 6.9% of patients were able to maintain adequate anticoagulation 50% or more of the follow up time[ji] A study from Pakistan showed a rate of 3.4% per patient years occurrence of complications in patients with prosthetic heart valves , with 2.04% being bleeding events and 1.13% being thromboembolic events. In Kenyatta National Hospital, there was a demonstrated 16% chance of bleeding" and an occurrence rate of 1.04% pet-patient years for thromboembolic incidents[0].

Various studies have identified risk factors for developing complications from anticoagulation therapy as increasing age, duration of therapy, compliance with dosage and administration of drugs and controversially female gender"[5] ' . Other risk factors have been identified ,as presence of other co-morbidities such as hypertension[1]*, interruption of anticoagulation therapy due to admission for other surgeries and the socio-economic status of the patients[19,]

STUDY JUSTIFICATION

The importance of the results of this study in our setup is justified by the findings °1 previous studies that showed inadequate anticoagulation in patients with Prosthetic heart valves and "the occurrence of complications associated with the P°or anticoagulation[32,34"3"] However there have been no local studies to identify

risk factors associated with these haematological complications. Thus the aim of this study was to assess the risk factors for development of haematological implications in a Kenyan population of patients who have undergone mechanical heart valve replacement surgery. Results shall be useful in planning long term follow up of these patients in terms of optimizing the level of INR control and minimizing the occurrence of haematological complications. Thus it is hoped that the study will prove to be a step towards provision of better management of patients with prosthetic heart valves on anticoagulation at Kenyatta National hospital

RESEARCH QUESTION

What are the risk factors associated with the occurrence of thromboembolic and bleeding complications in patients with prosthetic heart valves at Kenyatta National Hospital?

OBJECTIVES

Broad objective

To document occurrence of haematological complications and the association of these complications with predetermined risk factors.

Specific objectives

i. Determine the occurrence of haematological complications;

ii. Determine fluctuations in INR in between clinic visits;

iii. Determine occurrence of predetermined risk factors
   - o Duration of anticoagulation therapy;
   - o Poor compliance in taking of warfarin;

- Interruption of anticoagulation therapy;
- Longer duration between clinic visits.

iv. Determine association of risk factors and INR fluctuations with haematological complications.

STUDY METHODOLOGY

The study type was a combined prospective and retrospective study. The study population was the patients with prosthetic heart valves on follow up in the Cardiothoracic clinic at the KNII. The duration of the prospective arm of the study was from 16th July 2010 to 14th January 2011. For the retrospective arm, records dating back 10 years were retrieved and data collected.

PATIENTS

Inclusion criteria was:

- Patients with mechanical prosthetic heart valves;
- Patients on anticoagulation with INR results readily available;
- Patients giving their informed consent/

Exclusion criteria was:

- Patients with co-morbidities such as hypertension and diabetes with cerebrovascular complications, for instance stroke, which have been determined not to be due to anticoagulant therapy. In such instances, the event shall be excluded but the patient shall be included in the study;

- Trauma patients with head injury and associated neurological deficits shall also be excluded from the study.

Sampling procedure

The patients were identified during the Cardiothoracic clinics and after determining that they met the inclusion criteria, they were recruited into the study.

To prevent double participant recruitment, the files for the patients already recruited and interviewed were identified with a coloured sticker.

Conxcntint; process

Once a patient met the inclusion criteria, the principal investigator and/or the research assistant then elaborated on the study and the role the patient would play. It was emphasized that participation was voluntary and service delivery would not be affected should they decline.

Dat:i collection

For the prospective arm of the study,-'the data collection instrument was a questionnaire and information was gathered through interviews. The questionnaire was administered by the primary investigator and research assistants.

The research assistants were trained on administration of the questionnaire before the study commenced.

Outcome measures of interest for each patient were INR results during clinic visits; presence of signs and symptoms of bleeding tendencies, and neurological deficits suggestive of thromboembolism for instance fainting episodes, headaches, and dizinesss.

The information obtained included INR, duration between clinic visits, occurrencc of complications, age, sex, and socioeconomic status of the patients

Data obtained from both arms of the study were analysed simultaneously.

Follow up

Patients recruited into the prospective arm of the study were followed up via mobile phones in order to ensure no loss to follow up.

SAMPLE SIZE

The sample size was calculated using the formula:

$$n = z^2 \times \frac{p(1-p)}{d^2}$$

where z: score at 95% confidence interval (1.96)

p: proportion of patients with complications (estimated as 16%)

d: margin of error (0.05%)

thus $n = 1.96^2 \times \frac{0.16 \times 0.84}{0.05^2} = 206.52$.

The figure was rounded off to 207 patients.

However, the actual sample size was 142 patients, with the prospective arm having 39 patients and the retrospective having 103. This was attributed to the fact that even with the high number of reviews of patients with prosthetic heart valves in the clinic, some patients would not keep their clinic appointments. There was also the Problem of record keeping whereby records dating past 10 years were no longer available, as were fifes of deceased patients. There were also a number of patients

from other countries who came for surgery but follow up was in their countries of origin.

DATA MANAGEMENT AND ANALYSIS

Data collected was entered and cleaned in Microsoft Excel and data analysis **performed** using STATA version 11.

For categorical variables, the association with bleeding or thromboembolism were **explored** using the Pearson chi squared test or test. The non parametric Kruskal-Wallis test was used test equality of medians for continuous variables.

A p value of 0.05 or less was considered significant.

The results have been presented in the form of tables arjd graphs below

RESULTS

A total of 142 patients were recruited into the study, 39 in the prospective arm, and 103 in the retrospective arm. Sixty one percent of patients seen in the study were female Thirty three percent of the patients had at least a basic education and 21% in formal employment (table 1).

Table 1: Demographic Characteristics

Variable	Frequency/%
Mean Age	29.61
Sex	
Male	55 (38.7)
Female	87(61.3)
Highest Level of Education	
Primary	48 (33.8)
Secondary	62 (43.7)
Tertiary	21 (14.8)
Not documented	11 (7,70->
Occupation	
Formal	31 (21.8) ,
Informal	25 (17.6) '
Student	30.(21.1)
Unemployed	51(35.9)
Not documented	,5(3.5)

The most common surgery performed over the last 10 years in our institution was mitral valve replacement and an almost equal number of aortic and double valve replacement surgeries were done (table 2).

More than half of the patients attended clinic with 3 month intervals between clinic visits. In the prospective arm of the study, 13 patients reported non compliance in taking their medication; four patients reported interruption of their anticoagulation for various reasons (table 3)

Table 2: Clinical Characteristics

Variable	Frequency/ (%)
Type of surgery	
Mitral valve replacement	73 (51.4)
Aortic valve replacement	35 (24.6)
Double valve replacement	34 (23.9)
Intervals between clinic visits (months)	
< 3 months	80 (56.33)
4 - 6 months	56 (39.43)
7 - 12 months	5 (3.52)
Compliance to medication (n=39)	
Yes	30 (76.92)
No	9 (23.07)
Interruption of anticoagulation (n=39)	
Yes	4(10.25)
No	35 (89.75)
Presence of bleeding tendencies (n=142)	
Yes	44 (31)
No	71 AO)
Not documented	27(19)
Grade of bleeding tendency	
I	28 (19.7)
II	,11 (7.7)
.III	'4(2.8)
Missing data	I (69.7)
Thromboembolic incidents	
Dizziness	
Yes	30(21.1)
No	84 (59.2)
Fainting	
Yes	19(13.4)
No	95 (66.9)
Headaches	
Yes	33 (23.2)
No	81 (57)

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Fourty four patients (31%) presented with bleeding tendencies, out of who 28 had grade I bleeding, not requiring admission for further management. Four patients had grade III bleeding which required admission into the hospital for symptomatic management.

Table 3: Reasons for interruption of warfarin

Interrupted treatment (n=39)	4
Dental procedure	1
During menses	1
Elevated INR	1
Pregnancy	1

Of the patients presenting with features of thromboembolic complications, the main symptom was occurrence of headaches (figure 1) occurring in 33 patients (23.2%).

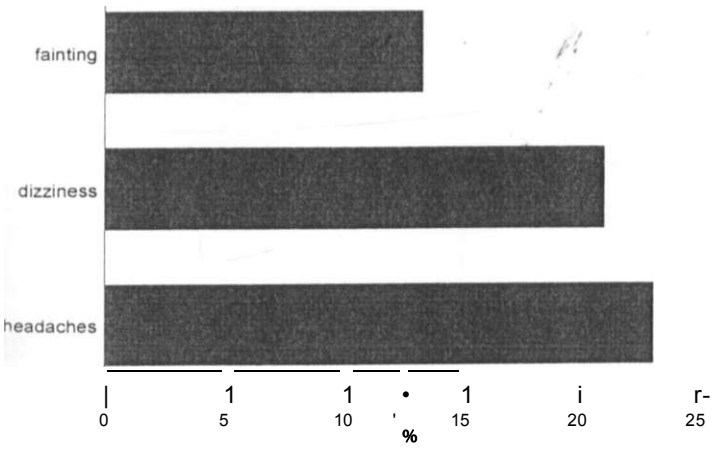

Figure 1: Thromboembolic symptoms

Thirty eight percent of patients developed haematological complications, and there was a significant association with the INR levels (table 4, figure 2).

Table 4: Haematological complications and INR

Variable	Frequency	p value
Haematological complications*(number/ %)		
Yes	54 (38%)	
No	88 (62%)	
INR (mean, SD)	2.3 (0.7)	**0.0165**

* Presence of bleeding or thromboembolism

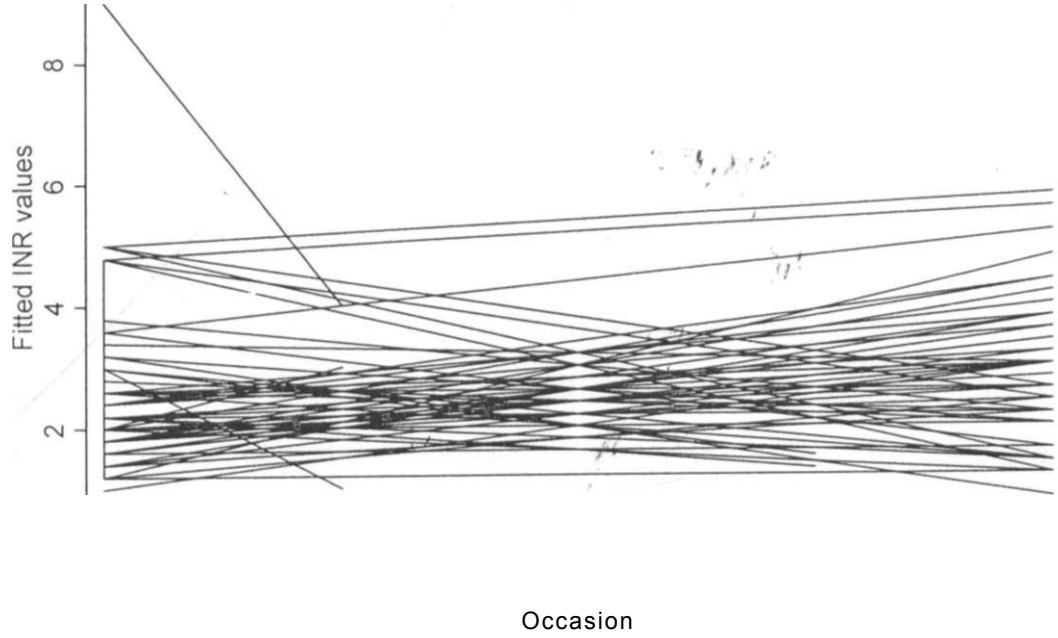

Figure 2: Fluctuation in INR was associated with an increased risk of developing Haematologic complications

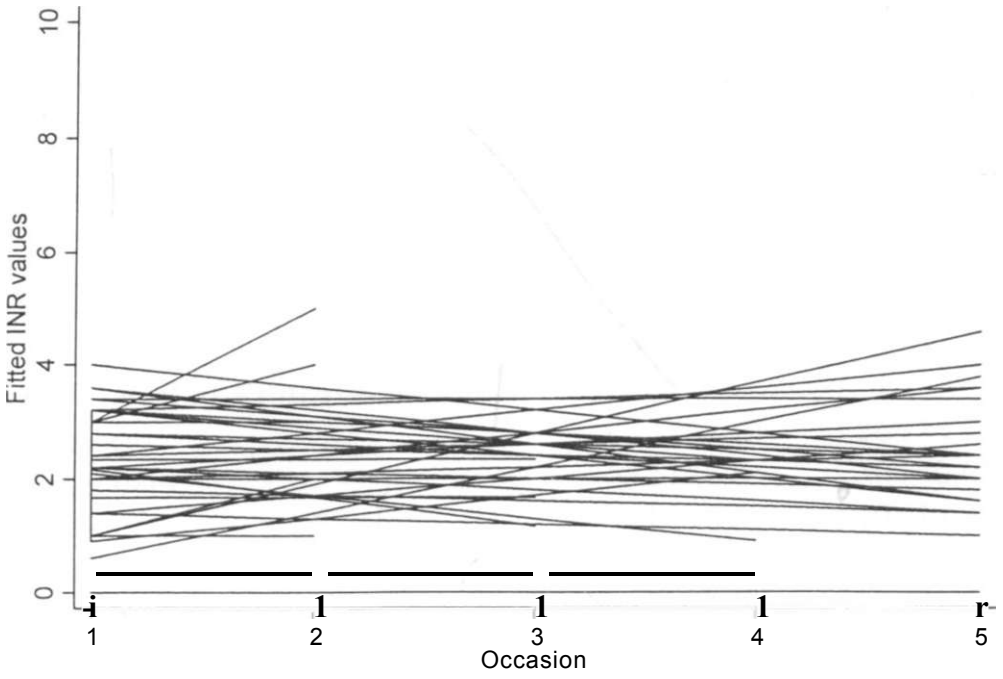

Figure 3: Well controlled INK resulted in occurrence of fewer haeniatoIo°ic complications

Twenty three out of fifty five men developed haematologic complications, while 44 out of 87 women developed complications. Fourty seven percent of patients with haematologic complications had completed their education upto secondary school level. The mean duration of anticoagulation for the patients developing complications was 82.9 months (± 64 months), as opposed to those without complications, 60.8 months (± 43.8 months). Over half of the patients with complications had undergone mitral valve replacement surgery. Of the 9 patients who were non compliant with taking their medications, 8 developed haematologic complications. None of the patients who interrupted taking their anticoagulation drugs reported any complications ('table 5).

[pie 5: Associations between predetermined risk factors and haeinatologic P .(plications

friable	Haematologic complications		p value
	Yes (freq/ %)	No (freq/ %)	
j * Male	23 (34.3)	32 (42.7)	0.308
Female	44 (65.7)	43 (57.3)	
<jjghest Level of Education			0.186
Primary	22 (32.8)	26 (34.7)	
Secondary	32 (47.8)	30 (40.0)	
Tertiary	11 (16.4)	10(13.3)	
[Occupation			0.688
Formal	16(23.9)	15 (20.0)	
Informal	13 (19.4)	12(16.0)	
'jvfean duration of anticoagulation (Months /SD)	82.9(64.0)	60.8 (43.8)	0.0965
Type of surgery			0.668
Mitral valve replacement	41 ***(54.7)***	32 (47.8)	
Aortic valve replacement	18(24.0)	17(25.4)	
Double valve replacement	16(21.3),'	18 (26.9)	
Intervals between clinic visits (months)			**0.052**
1	33 (23.23)	16(11.26)	
2	19(13.38)	21 (14.78)	
3 :/ fi	11 (7.74)	19(13.38)	
4	12(8.45)	10(7.04)	
>4	0(0)	1 (0.7)	
Number of clinic visits/year			**0.046**
1	30(44.8)	50(66.7)	
2	33 (43.93)	23(30.7)	
3	3(4.5)	2(2.7)	
4	1 (1.5)	0	
Compliance to medication			
Ves	14(35.89)	16(41.02)	**0.040**
No	8(20.51)	1 (2.56)	
Jnterruption of anticoagulation			
Ves J	0(0.0)	4(10.25)	**0.041**
No	20 (51.28)	15 (38.46)	

After multivariate regression analysis was performed, it was demonstrated that duration of anticoagulation is strongly related with development of haematologic complications (table 6).

Table 6: Multivariate regression analysis for occurrence of haematologic complications

Label	Estimate	Confidence interval	p value
Ase centred	0.99	0.95,1.02	0.471
Male vs female	0.84	0.33,2.09	0.703
Advanced vs basic education	0.82	0.32,2.12	0.682
Visits:3-4 vs <3	0.47	0.10,2.09	0.319
5-6 vs <3	1.15	0.12,10.86	0.901
7-12 vs <3	0.41	0.04,4.10	0.445
Duration of anticoagulation	14.99	3.90,218.70	**0.005**
SD of INR	1.58	'0.75*3,33	0.229

DISCUSSION

There is a demonstrable association between poor compliance and occurrence of complications. This finding is in keeping with the results of the study done by Buchanan-Leer'[1].

However, from the patients who interrupted taking their warfarin for various reasons it was shown that short term interruption of anticoagulation was not associated with an increased risk of valve thromboembolism or any bleeding tendencies[19].

The interval between clinic visits, and consequently the number of clinic visits in a year, was shown to have a weak association with development of haematologic complications (p value 0.052 and 0.046 respectively) with increasing duration between clinics associated with increased occurrence of complications. This is in keeping with results of an earlier study in this same institution whereby it was found that only 6.9% of patients were able to maintain adequate anticoagulation during their follow up'". The increased occurrence of complications is likely to be due to the fact that during the period when the'patient is not attending the clinic, they are usually not monitoring their INR levels, thus these levels are likely to fluctuate.

These findings are further corroborated by the findings of increased occurrence of complications with INR fluctuations (table 3). Patients with poorly controlled INR are more likely to develop bleeding or thromboembolic complications (p value 0.0165). This tallies with similar results seen when patients have poorly controlled INR[26] (figure 3).

The duration of anticoagulation therapy was demonstrated to have a direct effect on the occurrence of bleeding and thromboembolic complications on multivariate

regression logistics (table 6), with longer duration being an increased risk for development of bleeding and thromboembolic complications. A plausible explanation for this is the fact that it is harder to maintain INR levels within therapeutic levels with a prolonged duration on treatment. Ogendo in a study in Kenyatta National Hospital showed that adequate anticoagulation was maintained for 18% of follow up time [12].

The level of education or socioeconomic status of patients were not risk factors for development of complications in this study (p values 0.186 and 0.688 respectively). This is in contrast to a study by Buchanan-Leel et al in Soweto, South Africa, which had demonstrated a direct association between these factors and the occurrence of bleeding and thromboembolic complications.

The type of surgery performed was also shown in our study not to be a risk factor for the occurrence of haematologic complications (p vklue 0.668), with 54.7% of patients with complications having undergone mitral valve replacement surgery. However, this could be attributed to the imbalance in the type of surgeries performed in our institution, with mitral valve replacement being the most common type of surgery. A South African study,showed a higher incidence of thromboembolic and bleeding complications in patients who had undergone double valve replacement than in patients who had single valve replacement surgery[30].

CONC LUSION AND RECOMMENDATIONS

From these results, it can be shown that risk factors for developing bleeding or thromboembolic complications after, prosthetic heart valve surgery in the Kenyatta National Hospital include: non-compliance with taking of drugs, longer duration of anticoagulation therapy, increasing INR fluctuations, longer duration in between follow up clinic visits and subsequently fewer clinic visits in a year. Some of these

can be remedied by increasing patient education and awareness, for instance ensuring compliance of taking the oral anticoagulant drugs. It should be emphasised to all patients that medication with warfarin after insertion of a mechanical heart valve is lifelong; the patients should fully understand the gravity of complications that can occur with non-compliance.

Another remediable risk factor is the longer duration in between clinic visits. In the developed countries, a system for self management of anticoagulation has been established[17]. However, in a resource poor setting this is not a feasible alternative. One option available would be stricter follow up of the patients who are on anticoagulation therapy. However, this would place a greater financial burden on the patients, most of who have to travel very long distances to come for follow up in Nairobi. It also brings to the fore the lack of reliable facilities outside Kenyatta National Hospital that can conduct INR determinations. Thus a viable alternative would be the establishment of other reliable centres where patients can have their INR monitored on a regular basis, and upon any fluctuation of the levels, they should immediately seek attention in KNH. An eventual long term solution would ultimately be the establishment of other cardiothoracic centres in the country, whereby patients can be followed up, thus decentralizing the provision of services.

STUDY LIMITATIONS

Study limitations included rccall bias, which is the subjectivity of information presented to the interviewer on the complications, with thrombus formation being particularly hard to assess in the absence of laboratory investigations and imaging studies.

Poor documentation of complications in the patients files for the retrospective arm of the study was also a limiting factor in data collection. This is particularly hard to address with regards to the filing procedure.

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Questionnaire

1. How old are you? Age (Years)

2. Gender (Tick next to appropriate response)

   Male . . . . . Female

3. What is your highest level of education?

   Primary School

   Secondary School

   University/College

4. What is your occupation?
5. When was surgery performed on you?

6. What type of surgery was carried out?

   Mitral Valve Replacement

   Aortic Valve Replacement . . . . . •

   Double Valve Replacement . . . . . •

7. How many times a year do you visit the Cardiothoracic Clinic?

8. How long do you stay in between clinic visits?

   (Months)

9. What drugs are you taking?

10. Do you sometimes forget ydur drugs?

11. Have you ever had to interrupt taking your drugs for any reason?

What was the reason?

12. Have you ever noticed any bleeding tendencies?

Yes.....No

Grade I

. Grade II

Grade III

13. Have you ever noticed abnormally heavy menstrual periods?

14. Have you had any episodes of:

Dizziness Yes.....No

Headaches Yes.....No

Fainting spells Yes

Grade I

Grade II

Grade III

15. How often have you had the above symptoms in the last one year

INR VALUES

Current INR

Retrospective data collection sheet **IP** No.

1. Age (Years)
2. Gender

   Male. . . . . Female

3. Educationlevel

   Primary School

   Secondary School

   University/College

4. Occupation
5. Year surgery was performed. . . . . :
6. Type of surgery carried out

   Mitral Valve Replacement

   Aortic Valve Replacement

   Double Valve Replacement

7. Duration of anticoagulation treatment
8. Total number of clinic visits per year

   Duration between clinic visits. . . . . (Months)

9. Medications
10. Bleeding tendencies documented?

    Yes. . . . . No

    Grade I

    Grade II

    Grade III

1 l. Any record of abnormaily heavy menstrual periods?

12. Any documentation of:

Dizziness Yes..... No

Headaches Yes..... No

Fainting spells Yes..... No

Grade I

Grade II

Grade III

13. Frequency of symptoms in the last one year?

INR VALUES