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### RESEARCH ARTICLE

#### INCIDENCE OF MAJOR BLEEDING IN PATIENTS WITH MECHANICAL HEART VALVE AND WARFARIN; A ONE YEAR STUDY.

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#### Abstract

**Introduction:** Valve replacement surgery has dramatically improved the outcomes of the patients with valvular heart disease. In the last few years it has been estimated that about 280 000 valve substitutes are annually implanted worldwide <sup>1</sup>. nevertheless prosthetic valve complications are many, including valve thrombosis and subsequently systemic embolism, these two main impacts of the prosthetic valves can be minimized by using oral anticoagulant therapy and the main antithrombotic treatment used is coumarin derivatives, commonly warfarin, which can reduce the risk of the thromboembolic events to approximately 1 in 100 patients <sup>2</sup>. Despite this significant effect of warfarin, it has serious side effect especially in prosthetic valve patients, as they may develop major bleeding which can be fatal if it is not managed accordingly.

**Methods:** This study tried to focus on the incidence of the bleeding in one of Iraqi specialized cardiac centres and finding out what are the major sites of bleeding with the outcomes of each one, comparing it to the previously conducted studies.

**Results:** 25% of mortalities was due to intracranial bleeding in spite of admission and intensive care.

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#### Introduction:-

It cannot be denied that valve replacement surgery has dramatically improved the outcomes of the patients with valvular heart disease. In the last few years it has been estimated that about 280 000 valve substitutes are annually implanted worldwide <sup>1</sup>. Nevertheless, the complications of these prosthetic valves are many, including valve thrombosis and subsequently systemic embolism, these two main impacts of the prosthetic valves can be minimized by using oral anticoagulant therapy and the main antithrombotic treatment used is coumarin derivatives, commonly warfarin, which can reduce the risk of the thromboembolic events to approximately 1 in 100 patients <sup>2</sup>. Despite this significant effect of warfarin, it has serious side effect especially in prosthetic valve patients, as they may develop major bleeding which can be fatal if it is not managed accordingly. According to the International Society on Thrombosis and Hemostasis major bleeding was defined as: (1) fatal bleeding; and/or (2) symptomatic bleeding in a critical area or organ, such as intracranial, intraspinal, intraocular, retroperitoneal, intra-articular or pericardial, or intramuscular (iliopsoas) with compartment syndrome; and/or (3) bleeding causing a fall in hemoglobin level of 2 gm% or more, or leading to transfusion of two or more units of whole blood or red cells<sup>3</sup>.

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Major bleeding is 50% of bleedings related to warfarin all over the body .Gastrointestinal tract is most common site (40-60%),Genitourinary tract (15%),followed by intracranial and retroperitoneal bleeding.

Significant morbidity results from warfarin related to transfusion and hospital managements .10% of warfarin related major bleeding are fatal ,and a slight less percent will re-bleed after warfarin re-use <sup>4,5</sup>.

The bleeding events are most often due to excessive anticoagulation, which can be managed mostly by withholding warfarin and monitoring the level of anticoagulation with serial INR determinations, that is why INR is essential in all patients kept on warfarin and high variability of the INR is considered the strongest independent predictor of reduced survival after mechanical valve replacement. A study was found that the incidence of major bleeding in patients treated with coumarin derivatives is 1.4 per 100 patients per year which was considered significant <sup>6</sup>. This study tried to focus on the incidence of the bleeding in one of Iraqi specialized cardiac centres and finding out what are the major sites of bleeding with the outcomes of each one, comparing it to the previously conducted studies.

### Methods:-

This is a retrospective study. The study population included all patients enrolled in outpatient cardiac surgery clinic associated with IbnAlbitar specialized cardiac center in Baghdad .Iraq . The number of patients attained this clinic ranged from 50-100 patients per a day with different cardiac surgical problems . Patients surgeries majorly performed in the hospital, other cases referred from other centers in the country or patients whom their heart valves replaced outside the country. Patients are referred to the clinic for initiation, continuation or follow up of oral anticoagulant therapy, and dosing and monitoring of anticoagulant therapy is accomplished by specialist cardiac surgeons .

Rates of bleeding complications were expressed as percent complications per patient-year of therapy.

During a 12-month period from January to December 2014 , 459 patients newly received prescriptions for warfarin after sustaining valve replacement and were monitored in a variety of settings.288 (62.7%)were females and other 171(32.25% )were males .Other 6300 cases attained this clinic with previous surgeries before the year of this study .These numbers obtained according to hospital archives and laboratory number of (PT and INR) tests performed by this lab .

Complications classified using published guidelines, were considered to be major if they were intracranial or retroperitoneal or resulted in hospital admission or transfusion

### Results:-

It was appeared that the majority of patients with warfarin induced major bleeding were admitted to hospital 38 (43%) for conservative medical treatment and follow up mostly due to severe anemia for blood , fresh frozen plasma and vitamin K administration .Four of those patients were died . Intracranial and retroperitoneal bleeding manifested in 8 and 3 patients successively . Massive hemothorax that had demanded admission and drainage by insertion of intercostal drain was manifested in 13 patients .Lastly,26 patients were presented pericardial effusion and tamponade , and most of them treated by aspiration under imaging guide and some cases needed open surgical technique by creation of pericardial window .

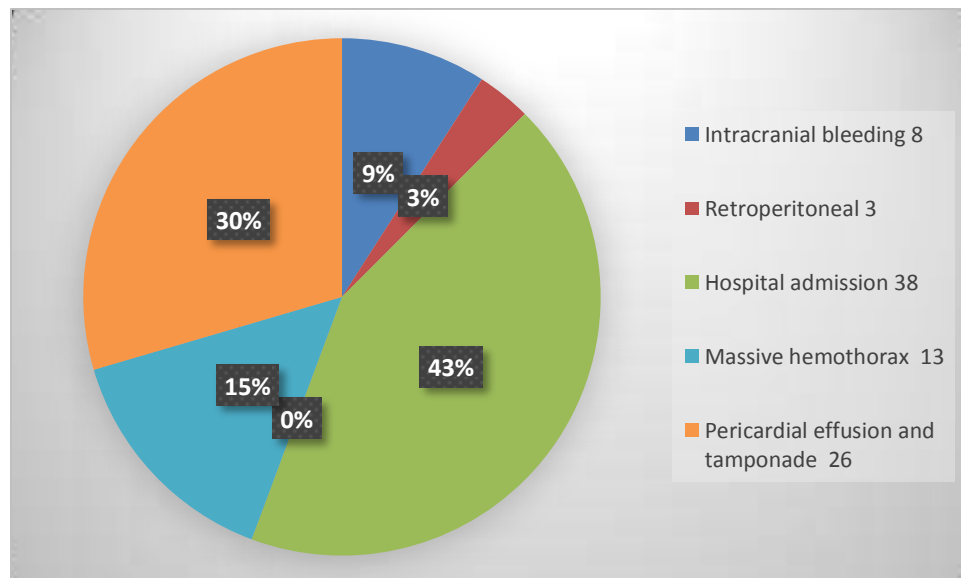
25% of mortalities was due to intracranial bleeding in spite of admission and intensive care . 37.5% of deaths were a result of pericardial tamponade and 33.3% of deaths occurred after admission for severe anemia . and from the given results it was clear that most dangerous complication of warfarin therapy is intracranial bleeding (37.5% of total cases (8)) .

Most of cases were treated conservatively (62.5%) . Multiple modalities of treatment were used . Fresh frozen plasma and vitamin K under medical supervision were administered to control bleeding and elevation of level of INR .and it was successful so far in most of patients .Surgery as a treatment is practiced for (37.5%) of patients , and again multiple modalities from minimal invasive and minor procedures to open major surgery were carried out .

Major bleeding complications are listed in Table

	Treatment	
	surgery	conservative
Intracranial bleeding	-	8
Retroperitoneal	1	2
Hospital admission / Blood transfusion (severe anemia )		38
Massive hemothorax	13	-
Pericardial effusion and tamponade	19	7
Total	33 (37.5%)	55 (62.5%)

	Number of patients	Mortality
Intracranial bleeding	8 (9%)	3
Retroperitoneal	3 (3%)	-
Hospital admission / Blood transfusion (severe anemia )	38(total) (43%)	4
Massive hemothorax	13 (15%)	-
Pericardial effusion and tamponade	26 (30%)	5
	88	12



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