

بسم الله الرحمن الرحيم



HOSSAM MAGHRABY



شبكة المعلومات الجامعية التوثيق الالكتروني والميكروفيلم



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جامعة عين شمس

التوثيق الإلكتروني والميكروفيلم

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Comparing planned surgical versus percutaneous access vascular outcomes and complications in patients undergoing transcatheter aortic valve implantation

Thesis

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Cardiology*

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List of Abbreviations

Abb.	Full term
AF	Atrial fibrillation
AS	Aortic stenosis
AVC	Aortic valve calcification
BMI	Body mass index
CABG	Coronary artery bypass graft
CLD	Chronic liver disease
Crcl	Creatinine clearance
CT	Computed tomography
CVS	Cerebro-vascular stroke
DM	Diabetes mellitus
ECG	Electrocardiogram
EF	Ejection fraction
EVAR	Endo-vascular aneurysm reapi
FDA	Food and drug administration
Fr	French (0.33 mm)
HGB	Haemoglobin
HTN	Hypertension
IHD	Ischaemic heart disease
LV	Left ventricle
LVOT	Left ventricular outflow tract
MSCT	Multi-slice computed tomography
PLT	Platelets
RCTs	Randomised controlled trials
TAVI	Transcatheter aortic valve implantation
TF	Trans-femoral
TF-TAVI	Transfemoral-transcatheter aortic valve implantation
THV	Transcatheter heart valve
VARC	Valve Academic Research Consortium

ABSTRACT

Background: Increased expertise and technical advancements lead to a significant reduction of major access site-related vascular complications that occur, nowadays Post and intra-procedural in <10% of cases. Due to its wide diffusion and feasibility, the trans-femoral access is the preferred route in the majority of the clinical trials and is recommended as first choice by all guidelines and consensus documents, as vascular complications are a non-comparable factor to traditional SAVR so it is a new side effect that has emerged with TAVI that is in need to be minimized

Aim: The aim of this work is to compare surgical versus percutaneous access peripheral vascular outcomes in TAVI procedure during hospital stay.

Patients and Methods: This was a Comparative cross-sectional study that was conducted at Ain Shams university hospitals & Helwan university hospital this study included 68 retrospective and prospective patients that were scheduled for TAVI 29 with percutaneous access followed by device closure (Proglide) and 37 surgical cut-down patients followed by surgical closure.

Result: A total of 68 patients were enrolled, 34 patients were females (50 %) and 34 patients were males (50 %). Their age ranged from 65-97 years with mean age (75.12) years. Patients in this study are classified into 2 groups: Group I: included patients who did the procedure with percutaneous vascular approach followed by device closure. Group II: included patients included patients who did the procedure with surgical cutdown vascular approach.

Conclusion: There is no significant difference in vascular complications between the 2 approaches indicating that whenever closure devices (Proglide) are available it can be used safely on patients undergoing TAVI, a more dedicated closure device to larger puncture sites such as MANTA should be properly studied as a promising step..

Recommendation: Larger studies with increased sample size are recommended for proper evaluation of intra and post procedural predictors of vascular complications. Further studies on the new MANTA device as it is a dedicated device to larger puncture sites. Long-term follow up.

Keywords: TAVI, VCs, Echocardiographic predictors

INTRODUCTION

Aortic stenosis (AS) is one of the most common valvular diseases in developed countries and its prevalence is projected to increase over the next decade as the population ages. Recently, as a start TAVI has emerged a valid alternative to surgery for treatment of elderly patients with symptomatic, severe AS. However, recently, two prospective industry-sponsored trials (Evolut Low-risk, PARTNER 3) demonstrated at least non-inferiority of the TAVI approach in low-risk patients (*Nkomo et al., 2006; Otto et al., 2014; Mack et al., 2019*).

In 2002, Cribier reported the first TAVI in a human subject for treatment of calcific aortic stenosis. Since then, another era has opened for patients with critical calcific aortic stenosis (AS) who had been considered too ill for conventional surgical AVR. Now, there is good evidence that TAVI represents a true treatment advance not only for AS patients who are considered too ill to undergo AVR but also it became FDA approved in august 2019 for low-risk patients after studies showed at least non-inferiority of the TAVI approach in low-risk patients. In these patients, TAVI has produced a markedly improved survival and relief of symptoms. In the United States, TAVI using a *Sapien 3*, *Sapien 3Ultra*, the *CoreValve Evolut R* and *CoreValve Evolut PRO* devices are now approved by the FDA for use in patients considered low-risk. Throughout its

history, however, TAVI has been associated with common complications:

- 1) Aortic regurge.
- 2) Stroke
- 3) Coronary artery occlusion
- 4) Vascular access complications.
- 5) Conduction disturbance

Additionally, the long-term natural history after TAVI of the progressive proliferative disease that causes calcific AS is unknown (***Cribier et al., 2002***).

The objective of this study is to assess vascular complications and vascular adverse events according to VARC 2 definition in patients undergoing TF-TAVI via surgical cut-down versus percutaneous trans-femoral occlusion device (Proglide) which is the only approved device in Egypt till now.

AIM OF THE WORK

The aim of this work is to compare surgical versus percutaneous access outcomes in patients undergoing TAVI procedure.

Chapter 1

AORTIC STENOSIS AND TREATMENT MODALITIES

Aortic stenosis is the most common primary valve disease leading to surgery or catheter intervention in Europe and North America, with a growing prevalence due to the ageing population (*Baumgartner et al., 2017*).

Echocardiography is the key diagnostic tool. It confirms the presence of aortic stenosis; assesses the degree of valve calcification, LV function and wall thickness; detects the presence of other associated valve disease or aortic pathology and provides prognostic information (*Baumgartner et al., 2017*) as seen in Figure 1.