

Market Analysis of Thrombectomy Devices Used for Dialysis Access

By

Amit Modi

*Dissertation submitted in partial fulfillment of the requirements of the degree
MBA Hospital and Health Management*

Academic year, 2017-2019



The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Sanganer, Airport
Jaipur 302029, Rajasthan
Ph: 0141 3924700, Fax: 3924738
Website: www.iihmr.edu.in

Market Analysis of Thrombectomy Devices Used for Dialysis Access

By

Amit Modi

*Dissertation submitted in partial fulfillment of award of
MBA Hospital and Health Management*

Academic year, 2017-2019

Decision Resources Group (DRG), Bangalore



The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Sanganer, Airport
Jaipur 302029, Rajasthan
Ph: 0141 3924700, Fax: 3924738
Website: www.iihmr.edu.in

TO WHOMSOEVER MAY CONCERN

This is to certify that **Dr.Amit Modi**, student of MBA Hospital and Health Management from The IIHMR University, Jaipur has undergone internship training at **Decision Resources Group(DRG), Bangalore** from **4thFebruary to 3rdMay 2019**.

The Candidate has successfully carried out the study assigned to him during internship training and his approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all his future endeavors.

A handwritten signature in blue ink, likely belonging to the Dean.

Dean, Academics and Student Affairs
The IIHMR University, Jaipur

A handwritten signature in blue ink, likely belonging to a Professor.

Professor
The IIHMR University, Jaipur

14 May 19

May 8, 2019

To Whom It May Concern

Amit Modi
Emp Code - 102100

This is to certify that Amit Modi has completed his dissertation project "Study on Market Analysis of Thrombectomy Devices used for Dialysis Access in European Union" with DRG Analytics and Insights Private Limited from 4th February 2019 to 3rd May, 2019.

We wish him all the best for his future endeavours.

Yours Sincerely,

K. Aswini

Aswini Konda
Associate Manager - HR

DRG Analytics & Insights Private Limited

Registered Office

1st Floor, Tower B, Prestige Shantiniketan, Krishnarajapuram Hobli,
Bangalore South Taluk, Bangalore - 560048. Karnataka, INDIA.
T : +91 80 4656 0000, www.decisionresourcesgroup.com
CIN-U74900KA2015FTC080238

Gurgaon Office

12th Floor, Tower B, DLF Building No. 10,
DLF Cyber City, DLF Phase-II, Gurgaon - 122002, Haryana, INDIA.
T : +91 124 4111741, www.decisionresourcesgroup.com

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **Market Analysis of Thrombectomy Devices Used for Dialysis access** and submitted by Amit Modi Enrolment No **534** under the supervision of **Dr. Ashok Kaushik** for award of MBA in Hospital and Health in Health carried out during the period from **4th April to 3rd May** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Signature

A handwritten signature in blue ink, appearing to read 'Amit', is written below the 'Signature' label.

Acknowledgement

The satisfaction and euphoria that accompany the successful completion of the project would be incomplete without the mention of the people who made it possible.

Firstly, I would like to express my sage sense of gratitude and indebtedness to our President Pankaj Gupta, The IIHMR University.

I would also like to thank to my guide at The IIHMR University, Dr. Ashok Kaushik for being available whenever I needed for guidance and support.

I would also like to extend my sincere thanks to my analyst Bishwjit Ghoshal at DRG for providing his valuable guidance at all stages of the study, his advice, constructive suggestions, positive and supportive attitude and continuous encouragement, without which it would not have been possible to complete the project.

The compilation of this undertaking would not have been possible without the wholehearted support of the all the people in MedTech team at DRG, Bangalore for being a constant source of knowledge, support and guidance throughout the span of time.

I hope that I can build upon the experience and knowledge that I have gained and make a valuable contribution towards the industry in coming future.

Table of Contents

Abbreviations:	5
Abstract:	7
Introduction	7
Rationale	7
Research Question	10
Objectives	10
Methodology	10
Research Design	10
Data Collection:	10
DATA ANALYSIS:(Findings and Forecast)	13
Conclusion	25
Bibliography	Error! Bookmark not defined.
Table 1	8
Table 2	9
Table 3	13
Table 4	13
Table 5	13
Table 6	13
Table 7	14
Table 8	14
Table 9	18
Table 10	22
Table 11	23
Table 12	Error! Bookmark not defined.
Table 13	25
Table 14	26

ABBREVIATIONS:

Acronym/Initialism	Definition
AV	Arteriovenous
AVF	Arteriovenous Fistula
AVG	Arteriovenous Graft
BD	Becton, Dickinson and Company
CDT	Catheter-Directed Thrombolysis
CVC	Central Venous Catheter
ePTFE	Expanded Polytetrafluoroethylene
ESRD	End-Stage Renal Disease
HeRO	Hemodialysis Reliable Outflow
IV	Intravenous
KDOQI	Kidney Disease Outcomes Quality Initiative
PD	Peritoneal Dialysis
POBA	Plain Old Balloon Angioplasty
PTA	Percutaneous Transluminal Angioplasty
RAS	Renal Artery Stenosis
RRT	Renal Replacement Therapy

ABSTRACT

There is global burden of chronic kidney disease in the world. The growing patient population of ESRD, followed by the aging population supports dialysis access treatment device market. The study aims to understand the Thrombectomy device market used for dialysis access in European Union which includes (France, Germany, Italy, Spain and the United Kingdom). The competitive landscape of the major players in the device segment, the products offered by them, the major challenges, drivers and limiting factors of the market were identified. The study included 50 vascular surgeons from European Union. The information about the major acquisitions, mergers, clinical trials, FDA approvals, product coverage, emerging products were gathered through secondary research which was verified and supplemented by industry experts and key opinion leaders. Hence the forecast was given for the period of five years about the market.

INTRODUCTION¹

Chronic kidney disease (CKD) is a growing health problem with an estimated prevalence of 11.5 per cent worldwide. Kidney disease is associated with a tremendous economic burden. High-income countries typically spend more than around 3% of their annual healthcare budget on the treatment of end-stage kidney disease, even though those receiving such treatment represent under 0.03% of the total population. In 2010, around 2 million people received dialysis worldwide and the need for dialysis was projected to double by 2030(as projected by WHO). Globally, the total cost of the treatment of the milder forms of chronic kidney disease appears to be much greater than the total cost of treating end-stage kidney disease. One of the most common causes of ESRD is type 2 diabetes; however, ESRD is also linked to glomerulonephritis, hypertension/large-vessel disease (which includes RAS and occlusion), and cystic, hereditary, and congenital diseases. The three different RRT options for ESRD are hemodialysis, PD, and kidney transplants. Dialysis makes it possible to continue living with end-stage kidney disease for many years or even decades. Others may prefer a method which they can use at home. A kidney transplant is often the best option for people who have end-stage kidney disease, but it's not always possible. In that case, and while waiting for a donor kidney, it's necessary to have renal (kidney) replacement therapy with dialysis. The patients with Stage-5 chronic Kidney disease go for Dialysis. The patients going for Hemodialysis, in order to start the process, have to undergo dialysis access procedures for which initially an access is created and during the time the passage is maintained by using maintenance procedures which are used whenever there is stenosis and obstruction of the vasculature.

The figure below illustrates treatment algorithms for ESRD in the prevalent populations.

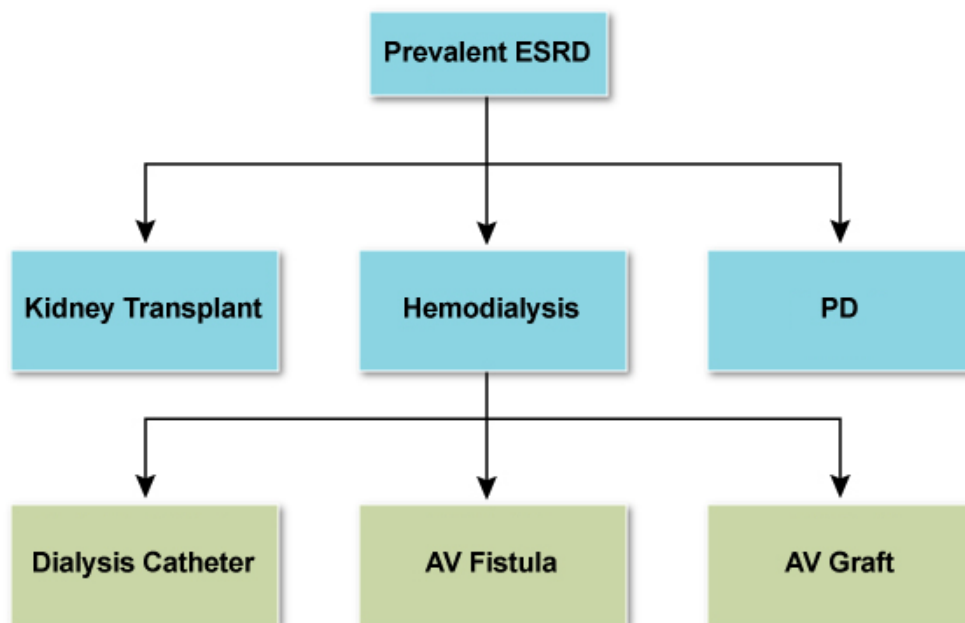


Figure 1

List of procedures and Products covered under Dialysis Access:

Procedures Covered Under Dialysis Access		
Access Creation	Technique	
	Surgical	Product Type
		AVF
		AVG
		Dialysis Catheter
		HeRO Graft
	Endovascular	pAVF
Maintenance	Technique	
	Endovascular	Procedure Type
		POBA (Plain old Balloon Angioplasty)
		PTA-with-Stent (Percutaneous Trans-luminal Angioplasty)
		Percutaneous Thrombectomy
		Procedure Type
		PTA-with-Thrombectomy
		Stent-with-Thrombectomy
		Stand-alone-Thrombectomy
		CDT (Catheter directed Thrombectomy)
		Embolectomy balloon catheter
	Surgical	Embolectomy balloon catheter

Table 1

Products Covered Under Dialysis Access

Access Creation	Technique				
	Surgical	Product Type			
		AVGs	Material		
			ePTFE	Product Feature	
				Early Cannulation	
				Standard	
			Biologic		
		Dialysis Catheters	Product Type		
			Acute	Product Feature	
				Standard	
Coated					
Tunneled	Product Feature				
	Standard				
	Coated				
HeRO Graft					
Endovascular	pAVF				
Maintenance	Endovascular	Product Type			
		PV Stents	BMS SX		
			Covered SX		
			PTA Balloon Catheters	Standard	
		Large			
		High Pressure			
		Specialty			
		Drug-Coated			
		Percutaneous Thrombectomy Devices	Mechanical		
			Aspiration		
		CDT Devices			
		Embolectomy Balloon Catheters			
		Accessory Devices	Guidewires		
			Diagnostic Catheters		
			Sheaths		
			Guiding Catheters		
		Surgical	Embolectomy Balloon Catheters		

Table 2

RATIONALE

There is a growing patient population of ESRD which is followed by aging population that supports dialysis access treatment device market. As the geriatric population is increasing, there is a corresponding rise in number of patients suffering from chronic kidney diseases which require treatment. Hemodialysis is the most commonly performed RRT, exceeding kidney transplants and PD. Because hemodialysis involves the use of dialysis access creation and maintenance devices, hemodialysis procedures fuel unit sales for these devices. Prevalent use of AVFs and AVGs will support the dialysis access maintenance device market, particularly as patients remain longer on dialysis. During the long process various thrombi hinder the procedure and stenosis occurs. Multiple products (Thrombectomy devices) are often used in dialysis maintenance procedures to treat both the stenosis and thrombosis.

This Report provides information on:

- Thrombectomy device market estimates and forecasts.
- Factors driving the growth of its market.
- Geographically, the potential of thrombectomy devices market in the regions of European Union (France, Germany, Italy, Spain and the United Kingdom)

RESEARCH QUESTION

What is the market of key players of Thrombectomy devices segment used in Dialysis Access devices in European Union (France, Germany, Italy, Spain and the United Kingdom)?

OBJECTIVES

- To Analyse and estimate the market of Thrombectomy devices used for Dialysis Access of European Union region.
- To understand the competitive landscape associated with thrombectomy devices market used for Dialysis Access.
- To find out the drivers and challenges of the market.

METHODOLOGY

- Research Design- Market research study (Descriptive Study)
- Type of Data- A combination of Primary and Secondary data
- Data collection tool-Questionnaire, Telephonic Interviews
- Data Analysis tool- MS Excel

Inclusion criteria: Thrombectomy devices covered under Dialysis Access

Exclusion criteria: Thrombectomy Devices covered under other procedures such as in treatment of acute ischemic stroke, pulmonary embolism (PE), venous thromboembolism (VTE) and deep vein thrombosis (DVT)

DATA COLLECTION:

Sample Size: 50 Vascular surgeons of European region contacted via LinkedIn

Sampling Technique: Purposive Sampling

Mode of Survey administration: LinkedIn

1.Primary Data:

- Since the lowest sample size is 120 and considering the non-response rate to be 10%, around 150 vascular surgeons were approached.
- Out of 150 vascular surgeons approached through LinkedIn from European Union who were having the therapy knowledge about the procedures happening in Thrombectomy market, 45 replied to the questionnaire which was sent to them.
- Along with it, 5 in-depth Telephonic interviewers of Vascular surgeons (The key opinion Leaders) from these countries were conducted through a guided questionnaire for which they were also paid honorarium from the organization and hence the sample size was chosen to be 50.

2.Secondary Data:

- Secondary research using journals, articles, company websites, annual reports, product brochures, and corporate profiles, Government registries, general Internet searches, medical literature, and newspaper and magazine searches to identify various centres of specialization and articles that might provide leads for primary research.
- The information about the major mergers, acquisitions, clinical trials, new product launches which we will have an impact on the market obtained from the secondary research stage builds the foundation for the primary research.

LITERATURE REVIEW

Authors (year)	Study	Sample size	Sampling techniques	Salient features
Canadian Society of Nephrology Vascular Access Work Group, Jennifer M. MacRae, Christine Dipchand	Canada			Vascular access–related complications can lead to patient morbidity and reduced patient quality of life. Some of the common arteriovenous access complications include failure to mature, stenosis formation, and thrombosis
Aalpen A. Patel, December 2005	USA			In this article, the authors present approaches they use in performing dialysis access intervention—clotted access
Carol C. Steenson (Department of Radiology, VA Medical Center, Minneapolis, MN), Renan Uflacker (Interventional Radiology, Medical University of South Carolina, Charleston, SC)	USA	The study population consisted of 174 DAG, 109 of which were randomized to mechanical thrombectomy using the ATD and 65 of which were randomized to conventional surgical thromboembolism		The results of the trial comparing the Amplatz thrombectomy device (ATD) with surgical thromboembolism (ST) to de clot thrombosed dialysis access grafts (DAG). The results of the performance of both methods were comparable. No statistically significant differences were seen
Keith Bertram Quencer, Rahmi Oklu	USA			For the over 400,000 patients in the United States dependent on hemodialysis, arteriovenous (AV) access thrombosis may lead to missed dialysis sessions, inpatient admissions and the need for placement of temporary dialysis catheters

DATA ANALYSIS:(Findings and Forecast)

1. The below data is taken from Registry of European Renal Association^{11,12}, the total Dialysis Patient

Dialysis Patients	2015	2016	(Growth/yoy%)
France	42706	43680	2.3%
Spain	21709	22401	3.2%
UK	24661	25069	1.7%
Italy	19010	20020	5.3%
Germany	94237	97318	3.3%

Table 3

2. From this data, year on year growth was calculated and forecasting was done for year 2018-2022.

Dialysis Patients	2018	2019	2020	2021	2022
France	45695	46737	47803	48894	50009
Spain	23852	24612	25397	26206	27042
UK	25905	26334	26770	27213	27663
Italy	22204	23384	24626	25934	27312
Germany	103785	107179	110683	114301	118038

Table 4

3. The percentage of patients going for AVF and AV Grafts were taken from the DOPPS country report⁷ about vascular access and based on that forecasting was done.

Dialysis Patients going for AVF	2018	2019	2020	2021	2022
France	31712	31641	31550	31439	31305
Spain	17054	16662	16762	16851	16928
UK	25050	17828	17668	17498	17317
Italy	18118	15831	16253	16676	17097
Germany	95068	72560	73051	73496	73892

Table 5

Dialysis Patients going for AV Graft	2018	2019	2020	2021	2022
France	2467	3131	3824	4547	5301
Spain	1288	1649	2032	2437	2866
UK	1399	1764	2142	2531	2932
Italy	1199	1567	1970	2412	2895
Germany	5604	7181	8855	10630	12512

Table 6

4. From Primary data we got the information about the percentage split in both AVF and AV Graft patients in which thrombosis occurs.

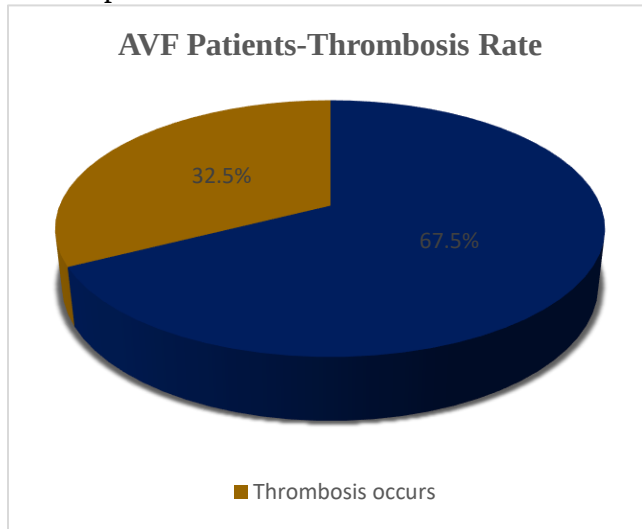


FIGURE-2

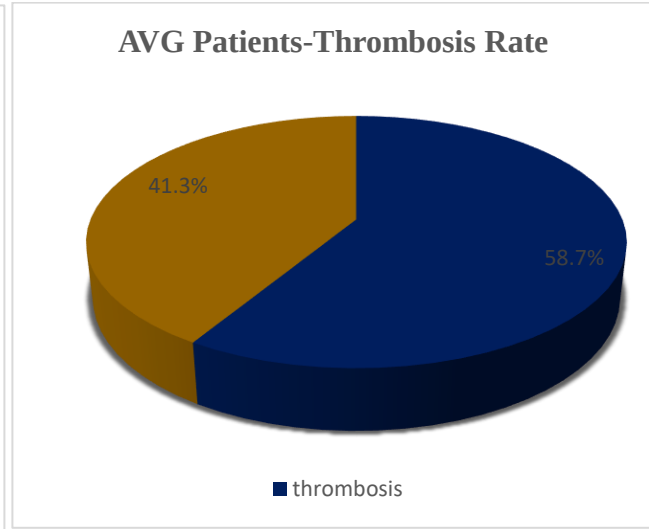


FIGURE-3

5. Based on the above information, the forecasting was done for years (2018-2022)

AVF Patients in which thrombosis occurs	2018	2019	2020	2021	2022
France	10307	10283	10254	10218	10174
Spain	5543	5415	5448	5476	5502
UK	8141	5794	5742	5687	5628
Italy	5888	5145	5282	5420	5557
Germany	30897	23582	23741	23886	24015

AV Graft patients in which thrombosis occurs	2018	2019	2020	2021	2022
France	1448	1838	2245	2669	3112
Spain	756	968	1193	1431	1683
UK	821	1036	1257	1486	1721
Italy	704	920	1156	1416	1699
Germany	3290	4215	5198	6240	7345

Table 7

Table 8

6. Now since most of the patients are covered under AVF and AV Graft in which thrombosis occurs, total patients going for thrombectomy were forecasted for European Union for years 2018-2022.s

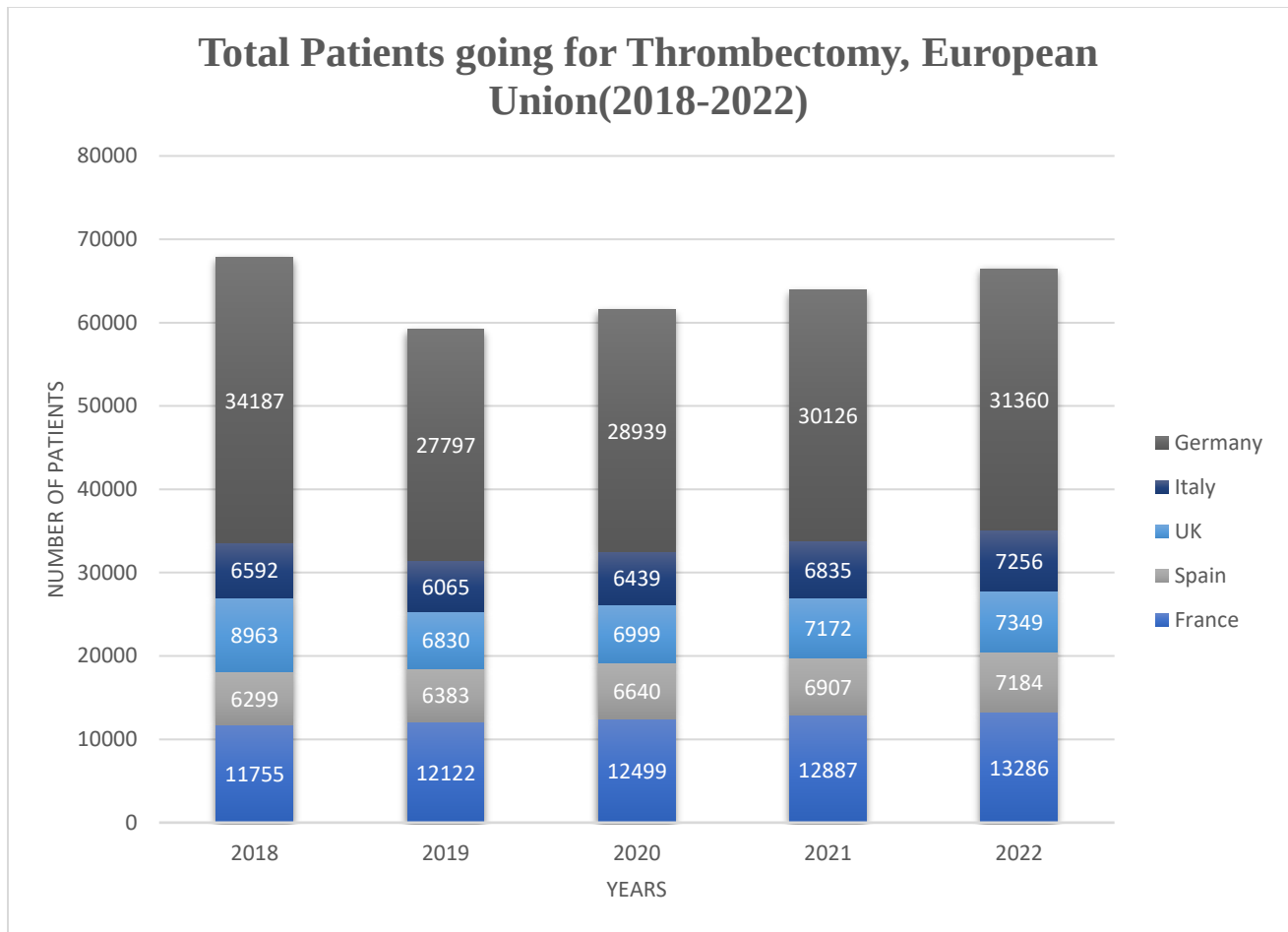


FIGURE-4

7. The below insight was obtained from the Primary data that was taken from key opinion leader i.e. vascular surgeons.

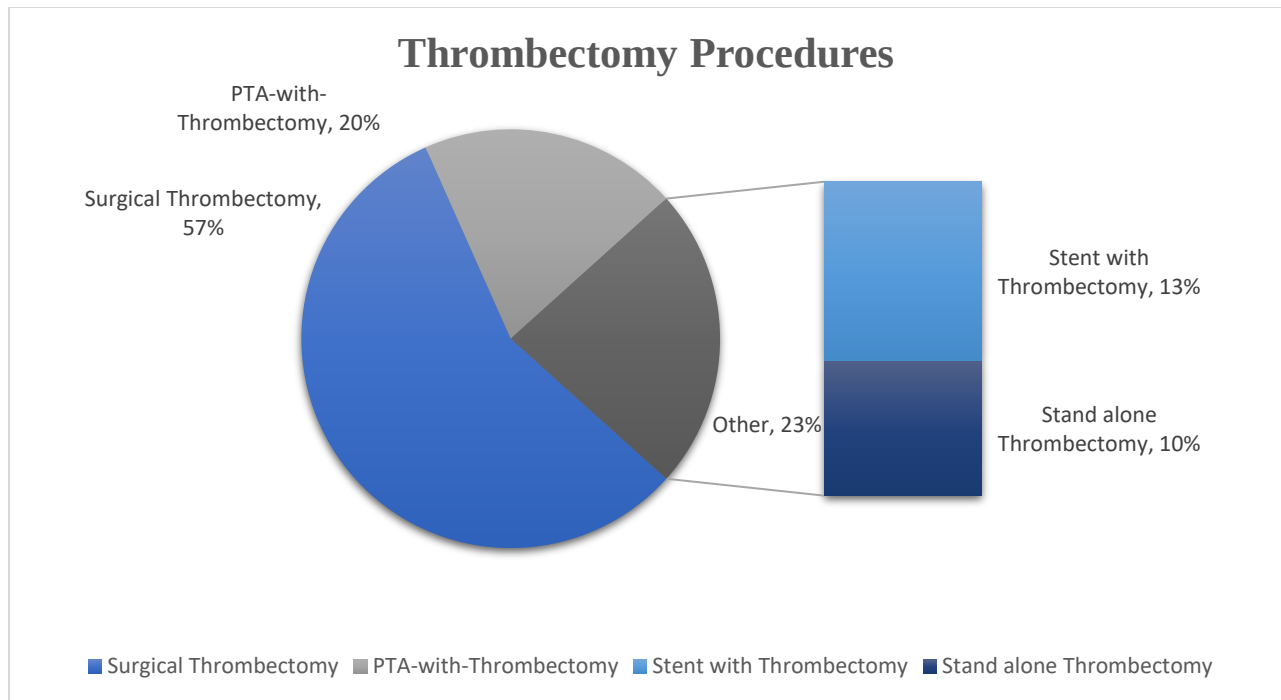


FIGURE-5

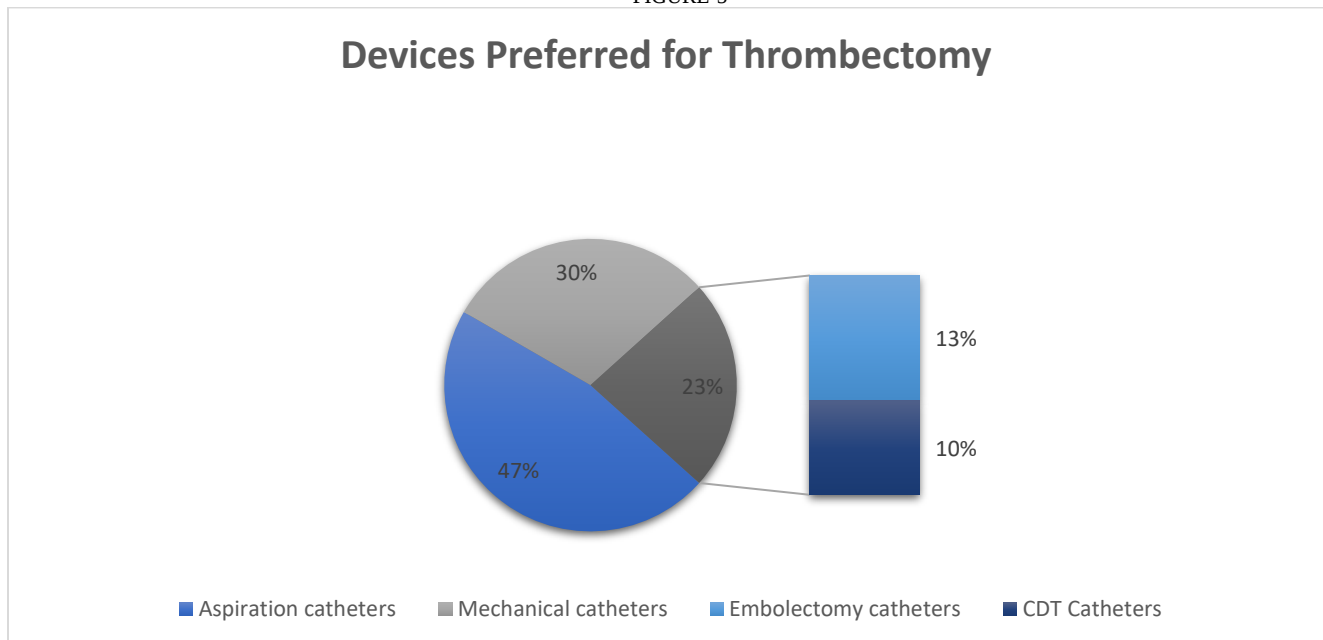


FIGURE-6

8. Based on the above insight from key opinion leaders and industry experts the data was forecasted for European Union for years 2018-2022, with respect to the procedures preferred by the surgeons and the devices used to do those procedures.

a. Forecasting of Procedures Performed for thrombectomy.

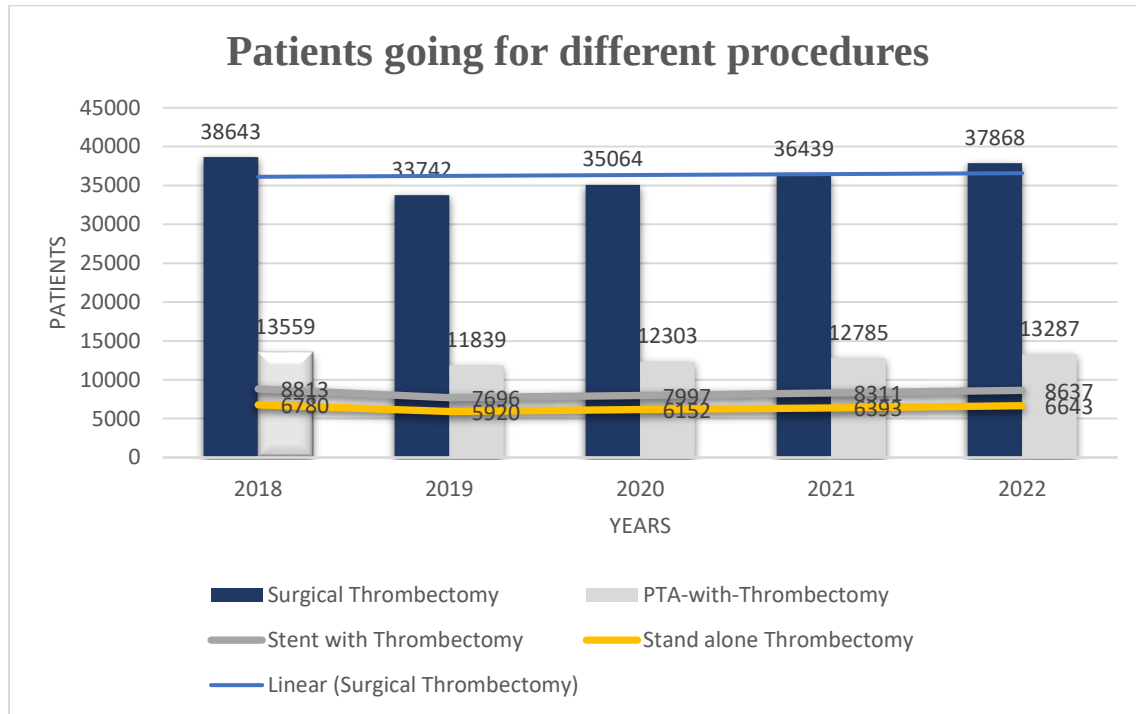


FIGURE-7

The above graph shows, that Surgical Thrombectomy is the most preferred procedure performed by vascular surgeons throughout the European Union whereas stent with thrombectomy and stand-alone thrombectomy are the least preferred ones.

b. Forecasting for Devices used to perform Thrombectomy procedures:

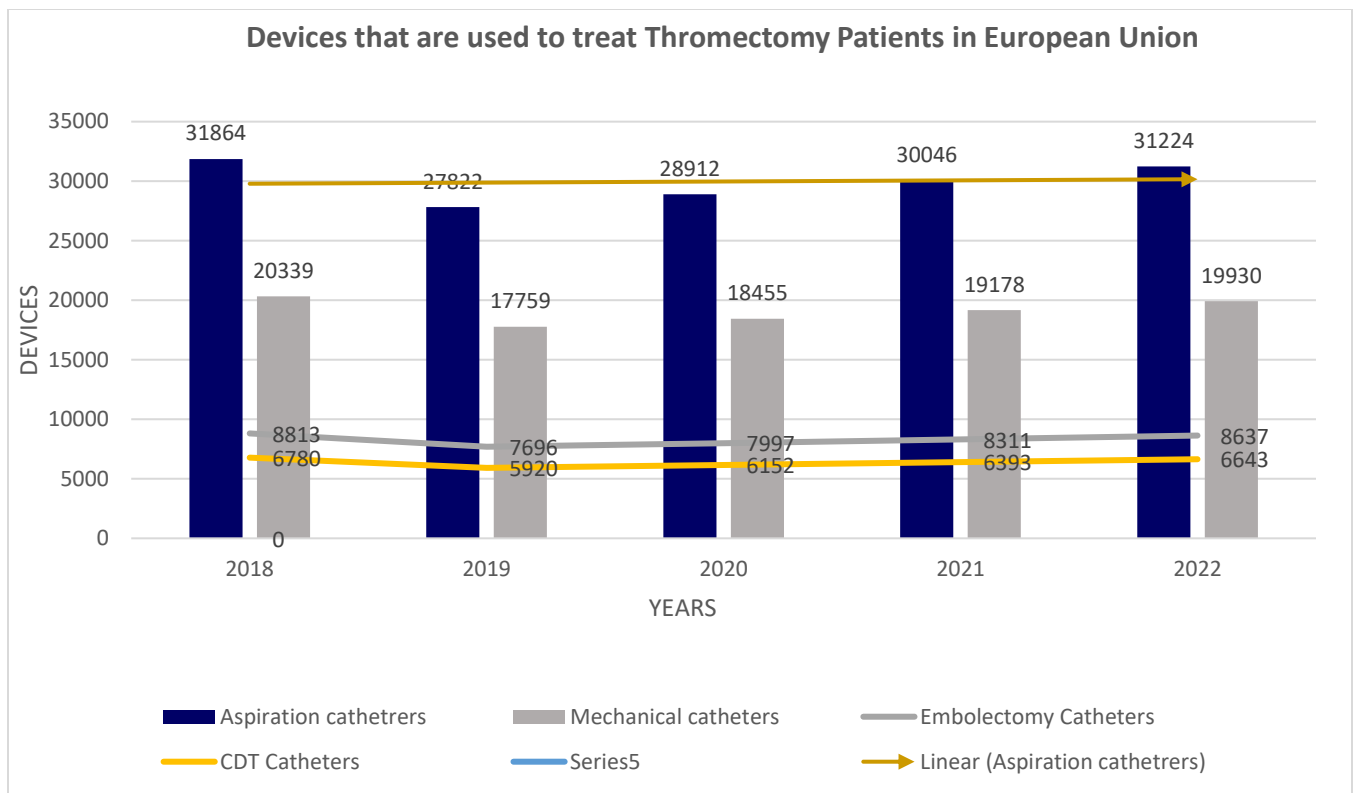


FIGURE-8

The above graph shows, that Aspiration catheter is the most preferred device used by vascular surgeons throughout the European Union whereas CDT catheters are the least preferred.

THROMBECTOMY DEVICES MARKET: COMPETITIVE LANDSCAPE:

- In 2017, Medtronic continued to lead the thrombectomy device market in Europe through its strong performance in the large percutaneous thrombectomy device segments. Furthermore, whereas many other competitors are present in only one or two segments, Medtronic also competes in most of other clot management device segments, bolstering its overall market share. However, the company's percutaneous thrombectomy device revenues are largely derived from sales in the manual aspiration thrombectomy device space, which is contracting rapidly.
- Stryker and Penumbra also held strong positions in the European thrombectomy device market through their sizable shares in the percutaneous thrombectomy device space; Stryker continues to enjoy success in that space due to the positive clinical results that support the adoption and reimbursement of its Trevo stent retriever, while Penumbra continues to benefit from being the only competitor in the US to offer both aspiration thrombectomy devices and stent retrievers. In addition, Penumbra has gained significant share in the percutaneous thrombectomy device market through the strong performance of its Indigo system, which is priced at a premium and has been aggressively marketed by the company.
- Boston Scientific is still among the top clot management device competitors in Europe due to its strong performance in the percutaneous thrombectomy device market in 2017, where the company benefits from offering a portfolio of products in both mechanical and manual aspiration thrombectomy device segments, as well as a strong sales and physician network.
- As the health care system in Europe shifts toward functional centers geared to treatment of specific indications, manufacturers with strong indication-specific product portfolios will benefit across several medical device market segments. This is most significant in the thrombectomy device market. For example, Penumbra offers several aspiration-based thrombectomy devices, but its strong AIS-specific aspiration device has allowed it to be one of the leaders in the thrombectomy device market.
- The thrombectomy device market in Europe is relatively fragmented; this is partly due to the high pace of innovation in this space, which attracts both small and large companies with novel technologies. Additionally, the lucrative nature of certain market segments, such as the percutaneous thrombectomy device space, appeals to companies seeking to capitalize on the substantial size of the market, resulting in a large number of competitors holding a significant portion of overall market shares.

1. Percutaneous Thrombectomy Device Revenue Market Shares, Europe, 2018

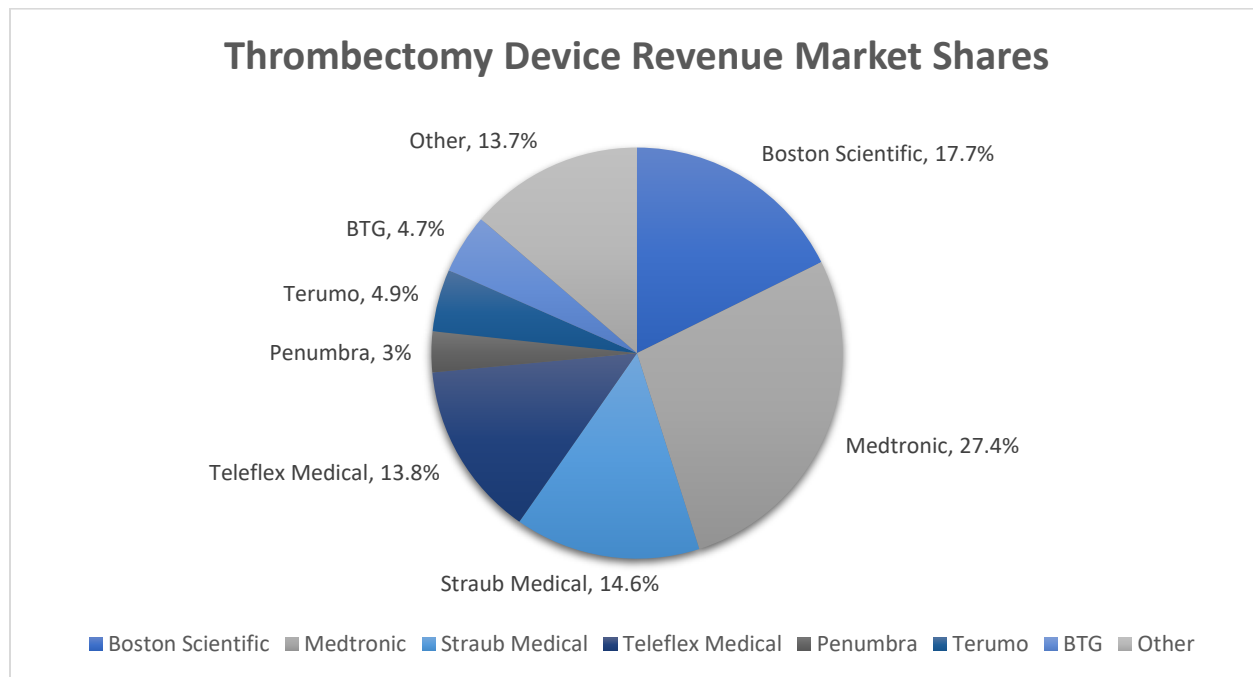


FIGURE-9

The Major Companies in the Percutaneous Thrombectomy device segment was calculated by taking the market revenue of the companies from their quarterly and annual reports

- Medtronic
- Boston Scientific
- Staub Medical
- Teleflex Medical
- Terumo
- Penumbra
- BT

The Products offered by some of them and other companies in the device segment are given below:

COMPANY NAME	PRODUCT NAME	DEVICE CATEGORY
Acandis GmbH & Co. KG	Aperio 1.9 F Thrombectomy Device	Mechanical thrombectomy devices
Argon Medical Devices, Inc.	Cleaner 15,XT	Mechanical thrombectomy devices
Boston Scientific Corporation	AngioJet AVX Thrombectomy Set	Mechanical thrombectomy devices
BTG Vascular	EkoSonic Endovascular System	Mechanical thrombectomy devices
Codman Neuro (Johnson & Johnson)	ReVive SE Thrombectomy Device	Mechanical thrombectomy devices
Control Medical Technology	Aspire Aspirator	Mechanical thrombectomy devices
Invamed	Mantis,Viper	Mechanical thrombectomy devices
MicroVention Terumo	Eric Retrieval Device,Sofia Plus Aspiration Catheter	Mechanical thrombectomy devices
Penumbra, Inc. (Neuro	3D Revascularization Device,Penumbra System Reperfusion Catheter ACE, 5MAX, 4MAX, 3MAX, 026	Mechanical thrombectomy devices
Penumbra, Inc. (Peripheral Vascular)	Indigo System Catheter CATD, CAT8, CAT6, CAT5, and CAT3	Mechanical thrombectomy devices
phenox GmbH	Preset Lite Thrombectomy Device	Mechanical thrombectomy devices
Straub Medical AG	Aspirex S	Mechanical thrombectomy devices
Stryker	Trevo ProVue,	Mechanical thrombectomy devices
Teleflex	Arrow-Trerotola OTW PTD	Mechanical thrombectomy devices

Vesalio	NeVa M1 - Vesalio NeVa Mechanical Thrombectomy System	Mechanical thrombectomy devices
Walk Vascular, LLC	Jeti	Mechanical thrombectomy device

Table 9

COMPANY NAME	PRODUCT NAME	DEVICE CATEGORY
Amg International GmbH	Isolv Aspiration Catheter	Aspiration thrombectomy devices
Arthesys	Pegase	Aspiration thrombectomy devices
Control Medical Technology	Aspire Aspirator,Max 5,6	Aspiration thrombectomy devices
Eucatech AG	Euca AC	Aspiration thrombectomy devices
Invamed	Dovi	Aspiration thrombectomy devices
iVascular	Capturer 6F,7F,Nautilus	Aspiration thrombectomy devices
Medtronic	Diver CE Aspiration Catheter,Export Catheter	Aspiration thrombectomy devices
Meril Life Sciences Pvt. Ltd.	Aspiron-Aspiration Catheter	Aspiration thrombectomy devices
Merit Medical Systems, Inc.	ASAP Aspiration Catheter Kit	Aspiration thrombectomy devices
MicroVention Terumo	Sofia Plus Aspiration Catheter	Aspiration thrombectomy devices
Natec Medical Ltd	Dyson	Aspiration thrombectomy devices
Optimed Medizinische Instrumente GmbH	BigLumen Aspiration Catheter	Aspiration thrombectomy devices
QualiMed Innovative Medizinprodukte GmbH	Aspiration Catheter (VX)	Aspiration thrombectomy devices
Terumo Europe	Eliminate	Aspiration thrombectomy devices

Table 10

2. Embolectomy Balloon Catheter Revenue Market Shares, Europe, 2018

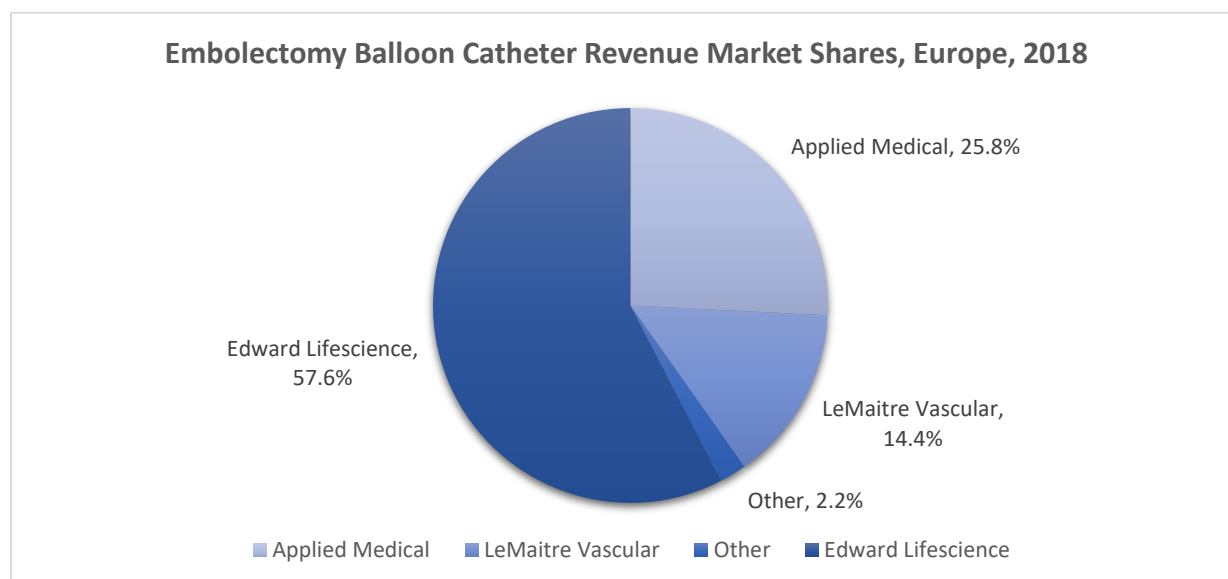


FIGURE-10

The Major Companies in the Embolectomy Balloon Catheter device segment holding the maximum shares are:

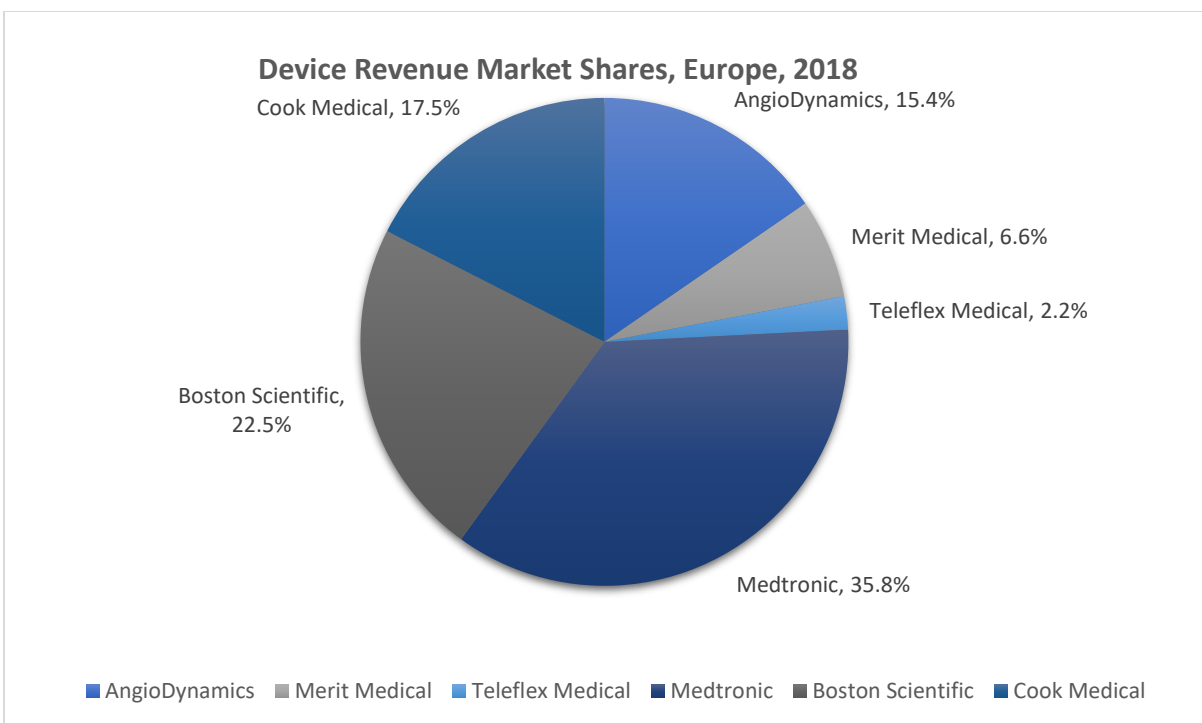
- Applied Medical
- Edward Lifescience
- LeMaitre Vascular

The Products offered by some of them and other companies in the device segment are given below:

COMPANY NAME	PRODUCT NAME	DEVICE CATEGORY
Balton	Embolectomy Catheter	EMBOLECTOMY BALLOON CATHETERS
Edwards Lifesciences	Fogarty Adherent Clot Catheter, Latex Free Embolectomy Catheter, Over-the-Wire Fogarty Embolectomy Catheter	EMBOLECTOMY BALLOON CATHETERS
LeMaitre Vascular, Inc.	LeMaitre Over-the-Wire Embolectomy Catheter, NovaSil Latex Free Single Lumen Embolectomy Catheter	EMBOLECTOMY BALLOON CATHETERS

Table 11

3.CDT Device Revenue Market Shares, Europe, 2018



The Major Companies in the Catheter Directed Thrombectomy (CDT) device segment holding the maximum shares are:

- Medtronic
- Boston Scientific
- Cook Medical
- AngioDynamics
- Merit Medical
- Teleflex Medical

The Products offered by some of them and other companies in the device segment are given below:

COMPANY NAME	PRODUCT NAME	DEVICE CATEGORY
Merit Medical Systems	Mistique® Infusion Catheters	CDT DEVICES
AngioDynamics	Uni*Fuse,Pulse*Spray catheters	CDT DEVICES
Medtronic	CRAGG-MCNAMARA VALVED,MICROMEVI INFUSION CATHETER	CDT DEVICES

Table 12

NEWS AND EVENTS:

Here are some news and Events about the therapy area which may impact the Thrombectomy market. The list includes the major acquisitions, FDA clearance, new product launches, clinical trials, approvals.

	EVENT	PRODUCT CATEGORY	DESCRIPTION
1	Percutaneous AV Fistula Creation Systems Gain FDA Marketing Authorization	PAVF	The Ellipsys Vascular Access System (Avenu Medical) and the everlinQ endoAVF System (TVA Medical) are poised to enter the US market after having been reviewed via the FDA's De Novo premarket review pathway.
2	Penumbra's Indigo Thrombectomy Aspiration System Studied in Acutely Thrombosed Dialysis Arteriovenous Fistulas and Grafts	Aspiration Thrombectomy	It was concluded that Percutaneous mechanical thrombectomy aspiration of thrombosed dialysis AVFs and/or AVGs with a vacuum-assisted thrombectomy catheter is a safe procedure with a low complication rate and an effective method for restoring patency before hemodialysis.
3	BD's WavelinQ 4-F endoAVF System Receives FDA 510(k) Clearance	Creation of AVF	The WavelinQ 4-F endoAVF system provides a minimally invasive option for AV fistula creation due to its low profile and allows more options for AVF anatomic location with additional venous wrist access points (ulnar vein or radial vein).
4	Merit Medical's Prelude Ideal Hydrophilic Sheath Introducer Launched in EMEA Markets	Accessory Devices	Merit Medical Systems, Inc. announced the launch of the Prelude Ideal hydrophilic sheath introducer in European, Middle Eastern, and African markets.

Table 13

CLINICAL TRIALS ^{2,3,4,5}			
S o r t	Product Type	Title	Status
	EUROPE		
1	Arteriovenous fistula	Primary Patency in Post-angioplasty Dysfunctional Arteriovenous Fistula in Renal Dialysis: Paclitaxel-releasing PTA Balloon Catheter vs PTA Balloon (FISBAL)	Completed
2	POBA	A Randomized Trial of Aperto Paclitaxel Eluting Dilatation Catheter Compared to POBA in Dialysis Fistula	Completed
3	Tunnelled Catheter	Evaluation of the Efficacy of an interdialytic "Ethanol 40% v/v - enoxaparin 1000 U/ml" Lock solution to Prevent Tunnelled Catheter Infections in Chronic Hemodialysis Patients (ETERNITY)	Completed
4	Arteriovenous fistula	Primary Patency in Post-angioplasty Dysfunctional Arteriovenous Fistula in Renal Dialysis: Paclitaxel-releasing PTA Balloon Catheter vs PTA Balloon (FISBAL)	Completed
5	ePTFE Grafts	Evaluation of stargraft AV for Hemodialysis Access	Enrolling/Ongoing
6	Tunnelled Dialysis Catheter	Tunneled Dialysis Catheters Versus Non-tunneled Dialysis Catheters as First-line for Renal Replacement Therapy in the ICU (BACKDOOR)	Ongoing
7	AV fistula, Tunnelled dialysis catheter	Comparison of Tunneled Cuffed Dialysis Catheters Versus Arteriovenous Fistulae in Elderly or Multimorbid Patients	Ongoing
US			
1	Hero Graft	Data Collection Registry of the hero Graft for End Stage Renal Disease Patients Receiving Hemodialysis	Recruiting
2	AV STENT graft	Clinical Study of the BARD® COVERA™ Arteriovenous (AV) Stent Graft (avenew)	Ongoing

Table 14

DISCUSSION

In Europe mostly surgical AVF creation is the preferred option for dialysis access whereas in countries where Interventional Radiologist and Cardiologist have more power, there the trend is in the favor of percutaneous creation of AVF. There were also some insights about the reimbursement when it comes to these procedures. Most of the vascular surgeons say that the Reimbursement of surgical procedures is about 3500Euros and for endovascular procedures it is about 4000 Euros which covers overall reimbursement.

Germany will account for around over one third of all percutaneous thrombectomy procedures performed in Europe over the forecasted period. According to the industry sources, Germany has higher

reimbursement for percutaneous thrombectomy, particularly for AV fistula than other countries. The greater use of mechanical thrombectomy devices in that country which represents nearly 60% of all mechanical thrombectomy procedures in Europe is mitigating the impact of declining manual aspiration volumes. As a result, Germany will be the only country to see positive percutaneous thrombectomy device market growth over the forecasted period.

According to industry sources, despite also having a Diagnosis Related Group reimbursement system, France's reimbursement for percutaneous thrombectomy procedures is lower compared to that of Germany; as a result, the use of mechanical thrombectomy devices in that country has been limited. However, reimbursement is expected to improve for mechanical thrombectomy devices in France, given that the Ministry of Health has considered implementing a device-specific reimbursement system akin to Germany's.

In Italy and Spain, reimbursement for percutaneous thrombectomy is available, but the lingering effects of the economic crisis and ongoing budgetary concerns are prompting physicians to keep overall procedural costs down.

While UK physicians are generally conservative in adopting new technologies, positive clinical data and adequate reimbursement will encourage adoption and drive procedure volumes.

CONCLUSION

There are several competitors in this market and a few others are still attempting to gather safety and efficacy data to bring their products in the market. Medtronic and Boston Scientific are leading the market of percutaneous thrombectomy and that of Catheter directed thrombolysis (CDT) in European region whereas in Embolectomy balloon catheter Applied Medical, Edward Lifescience and LeMaitre Vascular have captured the overall market.

From the overall patients going for dialysis, in around 32% AVfistula cases and in around 58% AV Graft cases thrombosis occurs. It was found out that out of all the patients going for thrombectomy, around 57% patients go for surgical thrombectomy procedures and mechanical catheters and aspiration are preferred devices while doing these procedures.

Germany is the most penetrated market in Europe and is responsible for most of the unit sales. Advancements in technology drive continuous improvements in thrombectomy techniques. Higher adoption rates of thrombectomy devices will depend on clinical evidence of superiority, technological advancements and the new players on the market.

Several factors such as rising target patient population, ongoing technological advancements, favourable medical device reimbursements, increasing demand for minimally invasive thrombectomy procedures, and increasing expenditure on healthcare across emerging markets like Europe are making an impact on the growth of the thrombectomy device market.

However, the stringent regulatory scenario, limited patient awareness resulting in delayed treatment for chronic kidney diseases, and dearth of skilled and well -trained surgeons to perform thrombectomy procedures are the key challenges faced by majority of the thrombectomy device manufacturers across the globe and in the European market.

BIBLIOGRAPHY

1. Levin A, Hemmelgarn B, Culleton B, Tobe S, McFarlane P, Ruzicka M, Burns K, Manns B, White C, Madore F, Moist L. Guidelines for the management of chronic kidney disease. *Cmaj*. 2008 Nov 18;179(11):1154-62.
2. Uflacker R, Rajagopalan PR, Vujic I, Stutley JE. Treatment of thrombosed dialysis access grafts: randomized trial of surgical thrombectomy versus mechanical thrombectomy with the Amplatz device. *Journal of vascular and interventional radiology*. 1996 Mar 1;7(2):185-92.
3. Turmel-Rodrigues L, Sapoval M, Pengloan J, Billaux L, Testou D, Hauss S, Mouton A, Blanchard D. Manual thromboaspiration and dilation of thrombosed dialysis access: mid-term results of a simple concept. *Journal of vascular and interventional radiology*. 1997 Sep 1;8(5):813-24.
4. Gray RJ, Chair S, Sacks D, Chair C, Martin LG, Trerotola SO, members of the Technology Assessment Committee. Reporting standards for percutaneous interventions in dialysis access. *Journal of vascular and interventional radiology*. 1999 Nov 1;10(10):1405-15.
5. Haage P, Vorwerk D, Wildberger JE, Piroth W, Schürmann K, Günther RW. Percutaneous treatment of thrombosed primary arteriovenous hemodialysis access fistulae. *Kidney international*. 2000 Mar 1;57(3):1169-75.
6. Tordoir JH, Bode AS, Peppelenbosch N, van der Sande FM, de Haan MW. Surgical or endovascular repair of thrombosed dialysis vascular access: is there any evidence?. *Journal of vascular surgery*. 2009 Oct 1;50(4):953-6.
7. Vesely TM, Idso MC, Audrain J, Windus DW, Lowell JA. Thrombolysis versus surgical thrombectomy for the treatment of dialysis graft thrombosis: pilot study comparing costs. *Journal of Vascular and Interventional Radiology*. 1996 Jul 1;7(4):507-12.