Transcatheter aortic valve replacement in Europe: adoption trends and factors influencing device utilization

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ABSTRACT

Objectives

The authors sought to examine the adoption of transcatheter aortic valve replacement (TAVR) in Western Europe and investigate factors that may influence the heterogeneous use of this therapy.

Background

Since its commercialization in 2007, the number of TAVR procedures has grown exponentially.

Methods

The adoption of TAVR was investigated in 11 European countries: Germany, France, Italy, United Kingdom, Spain, the Netherlands, Switzerland, Belgium, Portugal, Denmark, and Ireland. Data were collected from 2 sources: 1) lead physicians submitted nation-specific registry data; and 2) an implantation-based TAVR market tracker. Economic indexes such as healthcare expenditure per capita, sources of healthcare funding, and reimbursement strategies were correlated to TAVR use. Furthermore, we assessed the extent to which TAVR has penetrated its potential patient population.

Results

Between 2007 and 2011, 34,317 patients underwent TAVR. Considerable variation in TAVR use existed across nations. In 2011, the number of TAVR implants per million individuals ranged from 6.1 in Portugal to 88.7 in Germany (33 ± 25). The annual number of TAVR implants performed per center across nations also varied widely (range 10 to 89). The weighted average TAVR penetration rate was low: 17.9%. Significant correlation was found between TAVR use and healthcare spending per capita ($r = 0.80$; $p = 0.005$). TAVR-specific reimbursement systems were associated with higher TAVR use than restricted systems (698 ± 232 vs. 213 ± 112 implants/million individuals ≥75 years; $p = 0.002$).

Conclusions

The authors' findings indicate that TAVR is underutilized in high and prohibitive surgical risk patients with severe aortic stenosis. National economic indexes and reimbursement strategies are closely linked with TAVR use and help explain the inequitable adoption of this therapy.

Keywords: aortic stenosis, transcatheter aortic valve implantation, transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) gained Conformité Européenne (CE) mark approval in 2007, and the number of patients undergoing TAVR in Europe has increased exponentially in subsequent years. Despite the encouraging results from randomized, controlled trials and registries (1–4), there is anecdotal evidence that the use of TAVR varies markedly across European nations. Disparate adoption of medical technology is pervasive and results in inequitable patient access (5). Adoption kinetics of a novel medical technology such as TAVR and the factors influencing these variables have not been previously described. Regional differences in TAVR adoption are likely to have emerged because of variations in social, regulatory, economic, and political circumstances, as well as disease prevalence and longevity. This information may be of interest to patients, healthcare professionals, regulatory authorities, the medical device industry, and healthcare payers. In addition, these data may have implications for healthcare resource allocation, service development planning, assessment of equitable patient access, and physician training.

We sought to address this information gap by examining the trends in both the number of TAVR implants and number of centers across 11 European countries since CE mark approval. In addition, we investigated factors that may influence the heterogeneous adoption of this novel technology across nations.

METHODS

Data sourcing

We investigated TAVR use in 11 European countries: Germany, France, Italy, United Kingdom (including Northern Ireland), Spain, the Netherlands, Switzerland, Belgium, Portugal, Denmark, and Ireland. Data were collected from 2 distinct sources. First we identified data from published national registries and large databases in countries in which reimbursement is linked to registry inclusion (3,4,6–8). Lead physicians from each nation submitted data from national registries regarding the annual number of patients treated with TAVR and the annual number of implanting centers from 2007 to 2011. Lead physicians take responsibility for the integrity of the data (Online Table 1).

Secondly, we present data from BIBA MedTech (London, United Kingdom), a cardiovascular market analysis group tracking TAVR use since mid-2009. These data were gathered through specifically designed questionnaires and prearranged telephone interviews with an extensive research panel comprising interventional cardiologists, cardiac surgeons, and administrators from a large number of TAVR centers throughout Europe. National implant estimates were extrapolated using an algorithm that incorporated the following variables: device pricing, national guidelines, national reimbursement policies, portfolio, spread, and trend. This final data set was cross-referenced with published registries.

Table 1 TAVR Implants in Each Nation

	TAVR Implants per Annum, % increase					Cumulative TAVR	Cumulative TAVR, %
	2007	2008	2009	2010	2011		
Germany	157	921 (487)	2,566 (179)	4,859 (89)	7,252 (49)	15,755	45.9
France	58	82 (41)	320 (290)	1,523 (376)	2,447 (61)	4,430	12.9
Italy	71	450 (534)	1,138 (153)	1,581 (39)	1,879 (19)	5,119	14.9
United Kingdom	66	295 (347)	561 (90)	778 (39)	1,037 (33)	2,737	8.0
Spain	12	151 (1,158)	426 (182)	655 (54)	770 (18)	2,014	5.9
the Netherlands*	40	123 (208)	226 (84)	329 (46)	438 (33)	1,156	3.4
Switzerland	18	127 (606)	277 (118)	382 (38)	501 (31)	1,305	3.8
Belgium*	10	100 (900)	163 (63)	257 (58)	289 (12)	819	2.4
Portugal	4	13 (225)	52 (300)	67 (29)	65 (-3)	201	0.6
Denmark	9	81 (800)	126 (56)	190 (51)	239 (26)	645	1.9
Ireland	0	12	61 (408)	34 (−44)	29 (−15)	136	0.4
Total (% increase)	445	2,355 (429)	5,916 (151)	10,655 (81)	14,946 (40)	34,317	100

Values are n (%).

* Excludes 1 low-implant volume center (<30 TAVR implants per annum) in both the Netherlands and Belgium. TAVR = transcatheter aortic valve replacement.

Nation-specific data were combined with European Union– derived year-end population estimates (9) to calculate the: 1) annual and cumulative number of TAVRs performed in each nation; 2) annual number of TAVR implants per million population and TAVR implants per million population of age ≥75 years; 3) annual and cumulative number of TAVR centers in each nation; 4) number of TAVR centers per million population; and 5) mean number of TAVR implants per center for each nation.

TAVR penetration

The penetration rate of a therapy is a descriptor of the use of that therapy among eligible patients. Thus, TAVR penetration in each nation was determined as a measure of actual TAVR use relative to potential use. The numerator for calculating penetration was the number of living TAVR recipients at year end in each country. This was calculated as the sum of patients receiving TAVR in that calendar year and the number of living TAVR recipients from previous years. Annual mortality rates at 1, 2, 3, and 4 years following TAVR were assumed to be 24%, 33%, 49%, and 57%, respectively (10). The denominator was an estimate of the prevalence of patients with symptomatic severe aortic stenosis at high or excessive surgical risk that could potentially be treated with TAVR (11). Briefly, the proportion of elderly inhabitants of each country of age ≥75 years with severe aortic stenosis (3.4%) was determined by a random-effects meta-analysis. Among these patients, 75.6% were estimated to be symptomatic, 40.5% were deemed to be inoperable due to excessive surgical risk, and 5.2% were determined to be at high operative risk among the patients who received surgical aortic valve replacement

(Society of Thoracic Surgeons risk of mortality ≥10%). Finally, 40.3% of inoperable patients and 80.0% of the high-risk patients were deemed to be potential TAVR candidates.

Economic indexes

National economic indexes and healthcare parameters for 2011 were obtained from European Union and Organisation for Economic Co-operation and Development databases (12). To establish economic factors associated with TAVR use, we correlated the number of TAVR implants per million population (age ≥75 years) to the volume indexed gross domestic product (GDP) per capita in purchasing power standards. GDP per capita in purchasing power standards is obtained by converting GDP per capita to a fictive currency using purchasing power parities that eliminate differences in currency and price levels between countries, thereby allowing meaningful volume comparisons of GDP. In addition, we correlated the number of TAVR implants per million population (age ≥75 years) with the percentage of GDP spent on health care and the purchasing power parities–adjusted total healthcare expenditure per capita (U.S.$). In Europe, health care is funded either by taxation or by social insurance institutions, which are largely outside the commercial marketplace. We classified healthcare financing in each country according to the principal source of funding and compared TAVR use between these systems.

TAVR reimbursement

Medical device reimbursement in Europe is inconsistent because healthcare regulators with diverse policies dictate the method of reimbursement (12). We divided existing 2011 TAVR reimbursement into 2 categories and compared TAVR use between these schemes: 1) "TAVR-specific" systems, in which TAVR is completely reimbursed via a therapy-specific national diagnosis-related group (DRG) tariff; and 2) "constrained" systems, in which TAVR reimbursement is only partially funded by an existing national DRG tariff or the cost is borne by a local healthcare trust or hospital budget.

Statistics

Continuous variables are presented as mean ± SD or median with interquartile range according to distribution. Normally distributed variables were compared with the Student *t* test and non-normally distributed variables compared with the Wilcoxon rank-sum test. Categorical variables are presented as numbers and percentages. Bland-Altman plots were used to graphically compare the 2 sources of TAVR implant data. Correlation between economic indexes and TAVR implants per million population (age ≥75 years) was assessed using the Pearson or Spearman correlation according to distribution. A probability value <0.05 was considered to indicate statistical significance. Analyses were performed using SPSS version 17.0 (SPSS Inc., Chicago, Illinois).

RESULTS

Data sourcing

With the exception of 1 small center (<30 TAVR implants per annum) in both the Netherlands and Belgium, complete data were available from the 11 study nations. Herein, we report the results from the national databases which include TAVR implant data since CE mark approval in 2007. The BIBA MedTech data set includes data from 2009 to 2011 and is presented in the Online Appendix.

Implantation rates

Between January 2007 and December 2011, 34,317 patients underwent TAVR in the 11 study nations (Fig. 1A). Almost half of all implants were performed in Germany (45.9%), with Italy (14.9%) and France (12.9%) the next most frequent implanters (Table 1). Ireland accounted for

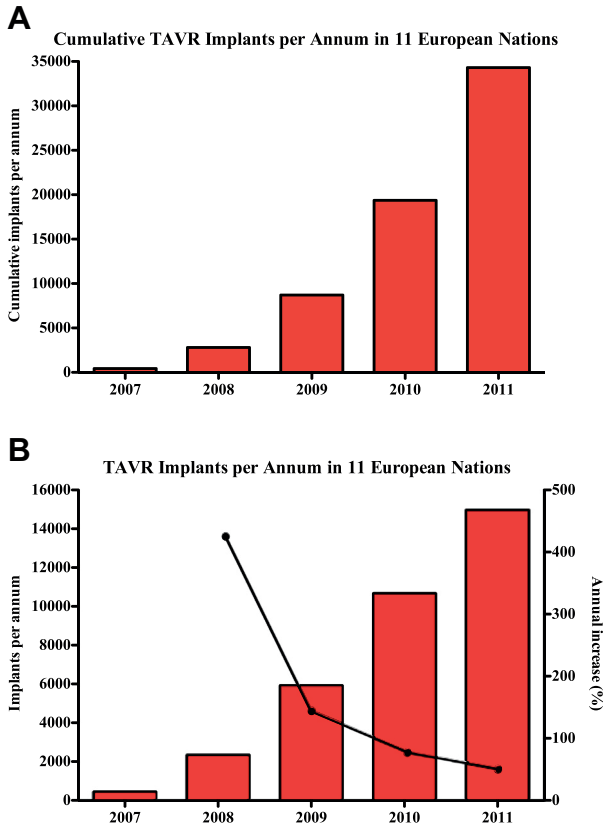

Figure 1 TAVR Adoption in Europe
(A) Cumulative transcatheter aortic value replacement (TAVR) implants in 11 Western European nations between 2007 and 2011. **(B)** TAVR implants per annum and percentage annual increase **(solid line)**.

the smallest proportion of implants (0.4%). In 2011, the highest annual increases in procedural volume were observed in France (61%) and Germany (49%), whereas Ireland (−15%) and Portugal (−3%) were the only nations to experience declines. The annual number of implants increased 33-fold from 455 in 2007 to 14,946 in 2011 (Fig. 1B). Although the annual procedural volume growth rate decreased from 429% in 2008 to 40% in 2011, it remained positive.

We observed a wide variation in the number of TAVR implants per million population (Figs. 2A and 2B). Germany (88.7) and Portugal (6.1) accounted for the highest and lowest

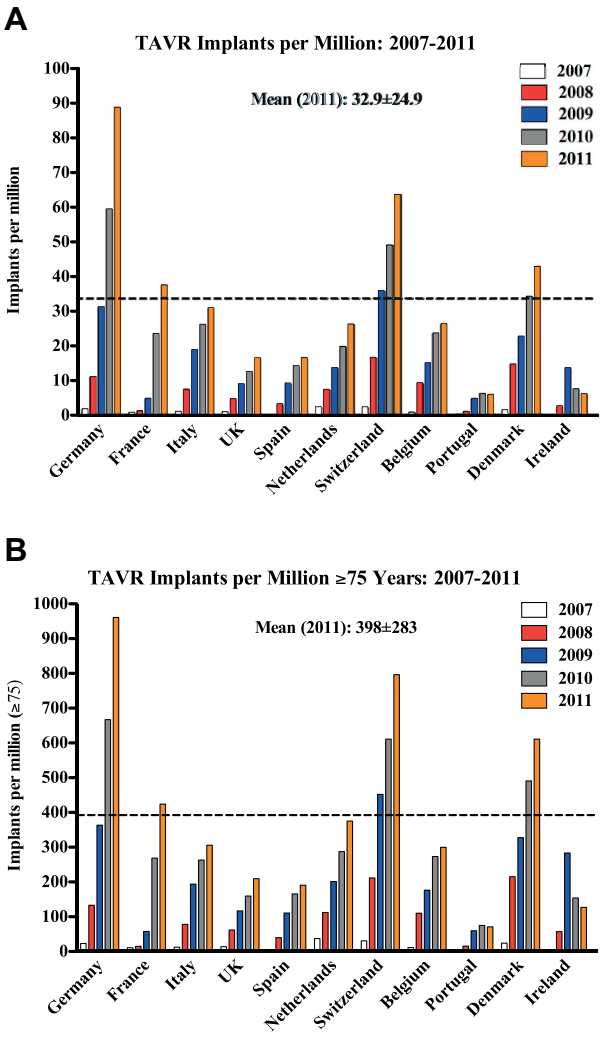

Figure 2 TAVR Implants per Million Population in the Study Nations

TAVR implant dynamics in the study nations between 2007 and 2011. **(A)** TAVR implants per million population. **(B)** TAVR implants per million population age ≥75 years. **Broken line** represents mean. Abbreviation as in Figure 1.

number of TAVR implants per million population in 2011, respectively. Among the 11 study nations, the mean number of TAVR implants per million population was 32.9 ± 24.9 and the mean number of TAVR implants per million population age ≥75 years was 398 ± 283.

Implanting centers

The number of centers performing TAVR increased approximately 9-fold from 37 in 2007 to 342 in 2011 (Fig. 3A). In 2011, Germany (90) and Italy (87) had the highest number of TAVR centers, whereas Portugal, Denmark, and Ireland (3 each) had the lowest (Table 2). Belgium had the highest number of TAVR centers per million population (2.1) and Portugal (0.3) the lowest (Fig. 3B). On average, there were 0.9 ± 0.6 TAVR centers per million population. These numbers led to an average of 41 ± 28 TAVR implants per center in 2011, with estimates in individual countries ranging from 10 in Ireland to 89 in Germany (Fig. 3C). On account of the high number of TAVR centers per million population, Belgium had the second lowest number of TAVR implants per center (13).

Table 2 Implant Centers

	Cumulative TAVR Centers					TAVR Centers, 2011, %	TAVR Centers per Million Population, 2011	TAVR Implants per Center, 2011
	2007	2008	2009	2010	2011			
Germany	6	36	61	80	90	26.3	1.1	81
France	6	12	16	33	33	9.6	0.5	74
Italy	8	21	50	75	87	25.4	1.4	22
United Kingdom	6	19	26	31	33	9.6	0.5	31
Spain	2	10	20	39	48	14.0	1.0	16
the Netherlands	3	6	7	7	7	2.0	0.4	63
Switzerland	1	7	8	11	12	3.5	1.5	42
Belgium	2	7	13	20	23	6.7	2.1	13
Portugal	1	2	3	3	3	0.9	0.3	22
Denmark	2	3	3	3	3	0.9	0.5	80
Ireland	0	1	3	3	3	0.9	0.7	10
Total	37	124	210	305	342	100	0.9 ± 0.6	41 ± 28

TAVR penetration

In 2011, we estimated that there were 28,400 living TAVR recipients and 158,371 potential TAVR candidates in the 11 study nations (Table 3). Thus, the calculated weighted average TAVR penetration rate in 2011 was 17.9%. The estimated collective and nation-specific TAVR penetration rates are presented in Figures 4A and 4B. Germany (36.2%) and Switzerland (34.5%) had the highest TAVR penetration rates; Portugal (3.4%) and Spain (8.4%) had the lowest penetration rates.

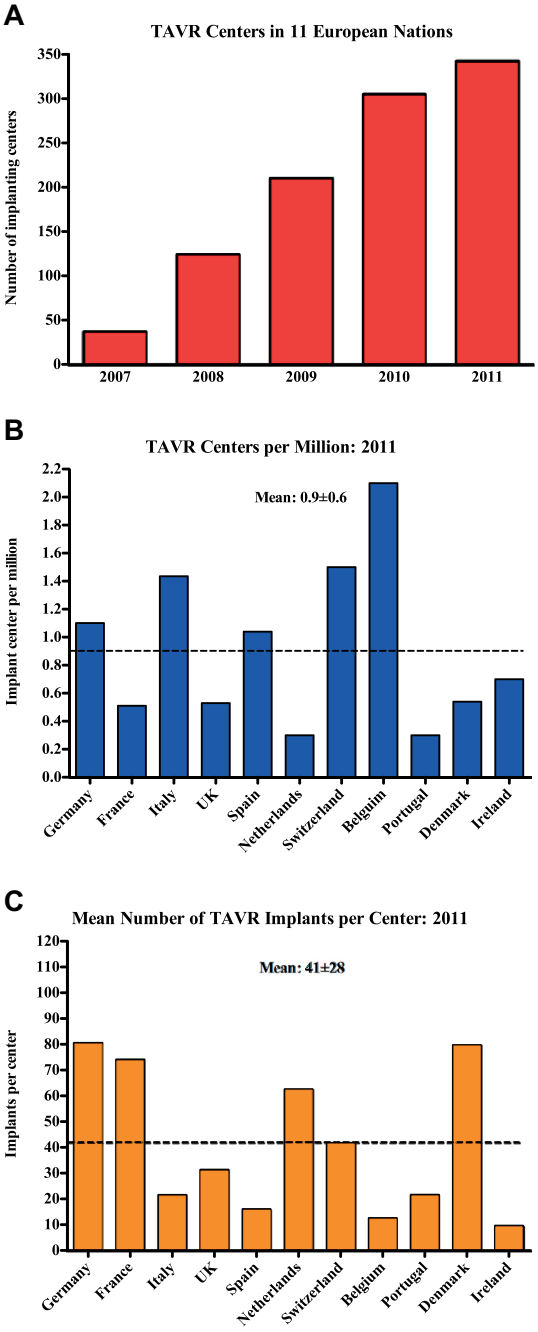

Figure 3 TAVR Centers in Europe
(A) Cumulative TAVR centers in 11 Western European nations from 2007 to 2011. **(B)** TAVR centers per million population in 2011. **(C)** Mean number of TAVR implants per center in each nation in 2011. **Broken line** represents mean. Abbreviation as in Figure 1.

Table 3 TAVR Penetration, 2011

	Total Population, 2011	Population Age > 75 years, 2011	Severe AS (3.4%)	Symptomatic Severe AS (75.6%)	Ineligible for SAVR		Eligible for SAVR			Total TAVR Eligible	TAVR Penetration, 2011, %
					Ineligible for SAVR (40.5%)	TAVR Eligible (40.3%)	Eligible for SAVR (59.5%)	High Risk (5.2%)	TAVR Eligible (80%)		
Germany	81,751,602	7,546,760	256,590	193,982	78,563	31,661	115,419	6,002	4,801	36,462	36.2
France	65,048,412	5,771,830	196,242	148,359	60,085	24,214	88,274	4,590	3,672	27,887	13.9
Italy	60,626,442	6,147,116	209,002	158,005	63,992	25,789	94,013	4,889	3,911	29,700	13.8
United Kingdom	62,498,612	4,947,416	168,212	127,168	51,503	20,756	75,665	3,935	3,148	23,903	9.1
Spain	46,152,926	4,031,995	137,088	103,638	41,947	16,915	61,665	3,207	2,565	19,481	8.4
the Netherlands	16,655,799	1,166,868	39,647	29,993	12,147	4,895	17,846	928	742	5,638	16.3
Switzerland	7,870,134	629,004	21,386	16,168	6,548	2,639	9,620	500	400	3,039	34.5
Belgium	10,951,266	954,607	32,457	24,537	9,938	4,005	14,600	759	607	4,612	14.1
Portugal	10,529,255	964,125	32,780	24,782	10.037	4,045	14,745	767	613	4,658	3.4
Denmark	5,560,628	391,138	13,299	10,054	4,072	1,641	5,982	311	249	1,890	27.1
Ireland	4,569,864	227,917	7,749	5,858	2,373	956	3,486	181	145	1,101	9.2
Total	376,049,328	32,778,776	1,114,478	842,546	341,230	137,516	501,315	26,068	20,855	145,962	Weighted average: 17.9

Population data derived from EU sources (9). Estimates of TAVR-eligible patients derived from Osnabrugge (11).
AS = aortic stenosis; SAVR = surgical aortic valve replacement; other abbreviation as in Table 1.

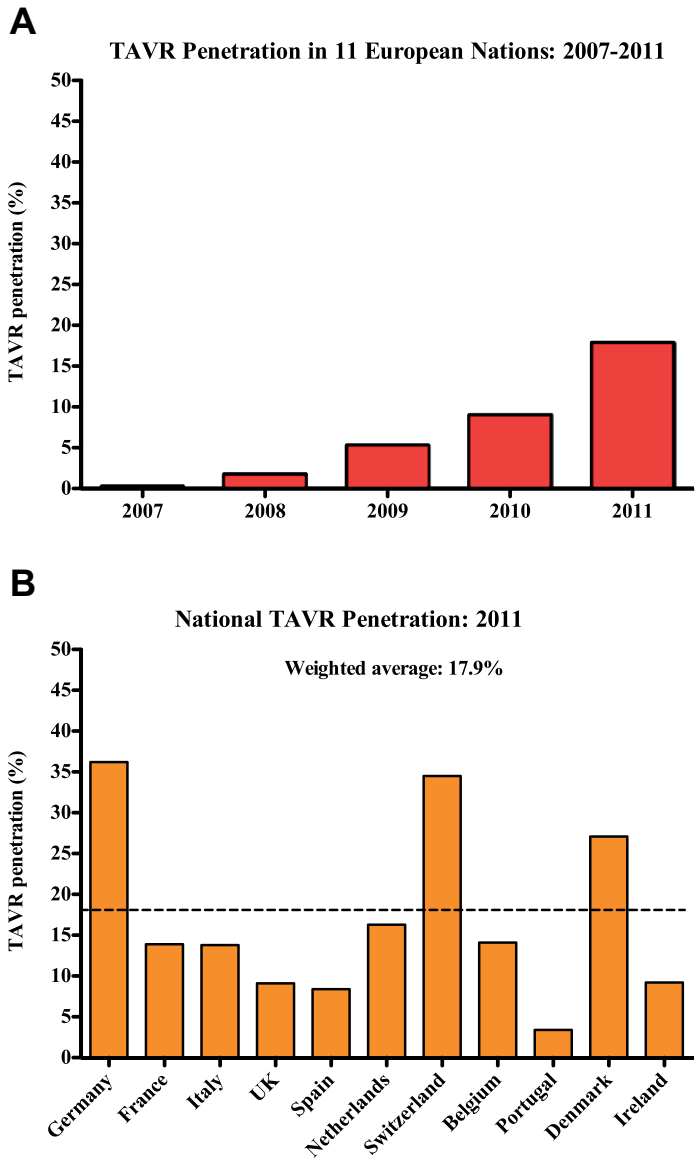

Figure 4 TAVR Penetration in Europe
(A) Estimated TAVR penetration among the 11 study nations from 2007 to 2011. **(B)** TAVR penetration in each nation in 2011. Broken line represents weighted average. Abbreviation as in Figure 1.

Economic indexes

We assessed the association between several economic indexes and TAVR use (Table 4). The volume-indexed GDP per capita, which is considered to be a reliable indicator of a country's standard of living, was not associated with TAVR use (r = 0.53; p = 0.10) (Fig. 5A). In contrast,

Table 4 Economic Indexes and Reimbursement Schemes

	Volume Indexed GDP per Capita (PPP)	Healthcare Spend, % of GDP	Healthcare Spend per Capita, 2010, US$ (PPP)	Principle Source of Healthcare Funding	TAVR Reimbursement
Germany	120	11.6	4,338	Social insurance	National TAVR DRG
France	107	11.6	3,974	Taxation	National TAVR DRG
Italy	101	9.3	2,964	Taxation	Region dependent
United Kingdom	108	9.6	3,433	Taxation	Cost borne by local trust
Spain	99	9.6	3,056	Taxation	Cost borne by hospital
the Netherlands	131	12.0	5,056	Social insurance	Cost borne by hospital
Switzerland	151	11.5	5,270	Social insurance	National TAVR DRG
Belgium	118	10.5	3,969	Social insurance	Cost borne by hospital
Portugal	77	10.7	2,728	Taxation	National SAVR DRG.; remainder of cost borne by hospital
Denmark	125	11.1	4,464	Taxation	National TAVR DRG
Ireland	127	9.2	3,718	Taxation	Cost borne by hospital

Values are actual numbers.
DRG = diagnosis-related group; GDP = gross domestic product; PPP = purchasing power parity; other abbreviations as in Tables 1 and 3.

a significant linear correlation was found between the number of TAVR implants per million population (age ≥75 years) and healthcare spending as a percentage of GDP (r = 0.68; p = 0.025) (Fig. 5B) and healthcare spending per capita (r = 0.80; p = 0.005) (Fig. 5C). We also found an association between the principal source of healthcare funding and the number of TAVR implants per million population (Fig. 5D). Although not statistically significant, there was a trend toward increased TAVR use in those nations in which healthcare was funded principally by social insurance (Germany, France, the Netherlands, Switzerland, and Belgium) than those principally funded by taxation (Italy, United Kingdom, Spain, Portugal, Denmark, and Ireland) (571 ± 290 vs. 252 ± 192 implants per million population age ≥75 years; p = 0.056).

TAVR reimbursement

TAVR reimbursement strategies across the study nations were heterogeneous (Fig. 6, Table 4). TAVR-specific national DRG-based reimbursement occurs in Germany, France, Switzerland, and Denmark. Constrained reimbursement systems were noted for the United Kingdom, Spain, the Netherlands, Belgium, Portugal, and Ireland, where the cost of TAVR is borne by a local healthcare trust (United Kingdom) or by the hospital budget. Reimbursement systems

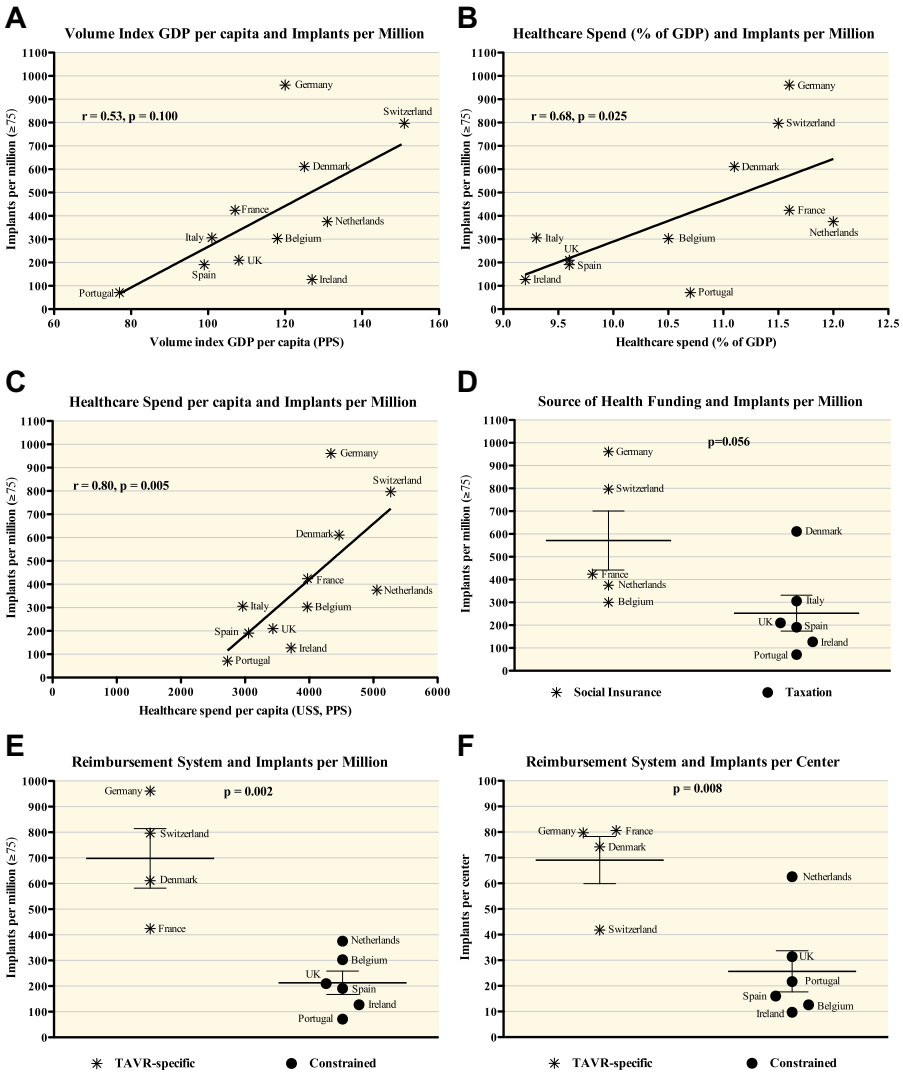

Figure 5 Factors Influencing TAVR Adoption in Europe

Correlation between TAVR implants per million population (age ≥75 years) and **(A)** volume-indexed gross domestic product (GDP); **(B)** healthcare expenditure (% of GDP); and **(C)** annual healthcare spend per capita (U.S.$). Number of TAVR implants per million population (age ≥75 years) according to **(D)** the principal source of healthcare funding (social insurance or taxation) and **(E)** the system of reimbursement (TAVR specific or constrained). **(F)** The average number of TAVR implants per center in 2011 and the system of reimbursement. DRG = diagnosis-related group; PPS = purchasing power standards; other abbreviation as in Figure 1.

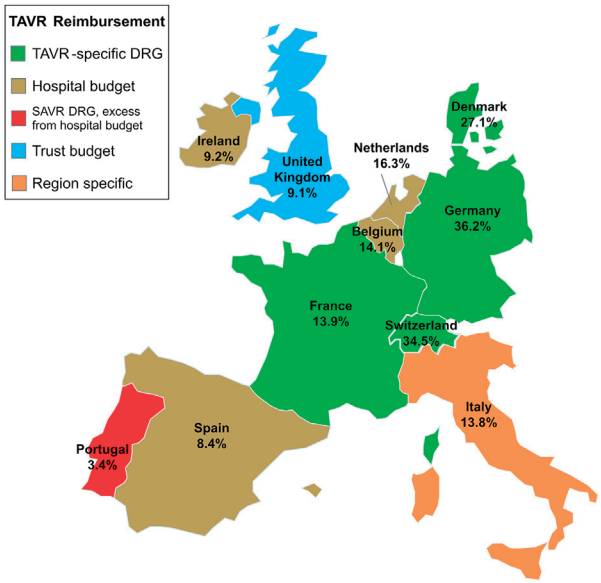

Figure 6 Reimbursement Systems and TAVR Penetration Across Europe
Map of the 11 study nations depicting estimated TAVR penetration rate and the 2011 TAVR reimbursement systems. SAVR = surgical aortic valve replacement; other abbreviations as in Figures 1 and 5.

evolved over the course of the study. For example, a TAVR-specific DRG was introduced in Germany in January 2008 as opposed to France, where it was introduced in December 2009.

We investigated the association between reimbursement system and both TAVR use (implants per million population age ≥75 years) and the number of TAVR implants per center. Italy was excluded from the analysis because reimbursement strategies varied across provinces. TAVR-specific reimbursement systems were associated with a 3.3-fold higher number of TAVR implants per million population (age ≥75 years) than constrained systems (698 ± 232 vs. 213 ± 112; p = 0.002) (Fig. 5E). Furthermore, TAVR-specific reimbursement systems were associated with 2.5 times more TAVR implants per center than constrained systems (69 ± 18 vs. 26 ± 20 implants per center; p = 0.008) (Fig. 5F).

Comparison between registry and BIBA data sets

The correlation between national registry and BIBA MedTech data sets for TAVR implant numbers is presented in a Bland-Altman plot (Online Fig. 1). There was satisfactory agreement between the 2 sources of information, and both provided similar results and conclusions (Online Figs. 2 to 6, Tables 2 to 4).

Values are n or mean ± SD, unless otherwise indicated. Abbreviation as in Table 1.

DISCUSSION

This study described the adoption of TAVR in 11 Western European nations since the 2007 CE mark approval of the Edwards Sapien (Edwards Lifesciences Inc., Irvine, California) and Medtronic CoreValve (Medtronic Inc., Minneapolis, Minnesota) systems. The main findings are: 1) more than 34,000 patients received TAVR between 2007 and 2011; 2) there is substantial variation in the adoption of TAVR across nations; 3) there is disparity in the annual number of TAVR implants per center across nations (mean 41 ± 28); 4) TAVR remains greatly underutilized, with an estimated weighted penetration rate of 17.9%; and 5) economic and reimbursement indexes may help explain the variability in TAVR adoption across nations.

We found considerable variation in TAVR use across nations. Germany had more than 2 times the implant rate of all other nations except Switzerland and 14 times the implant rate of Ireland and Portugal. Regional variation in the adoption of medical technology is not unique to TAVR. In Europe, disparate use of drug-eluting stents and implantable cardioverter-defibrillators (ICDs) has previously been described (5,14,15). The identification of inequitable access to medical technologies is important because it generates discussion and initiatives to address inequalities and the corresponding impact on patient outcomes through payer- and physician-led programs (e.g., Stent for Life initiative [16]).

Explanations for the divergence in TAVR adoption among countries are numerous and varied. The economic challenge of providing progressive care for an aging population has mandated that the use of new medical device technologies be not only determined by the expectation of improved clinical outcomes but also by cost effectiveness. It is axiomatic, therefore, that the magnitude of healthcare resources influences the adoption of new medical device technology. Consistent with our findings that healthcare expenditure correlated with TAVR use, the use of ICDs in Europe has also been associated with national economic performance (5,14). Not surprisingly, the lowest TAVR implantation rates were found in Spain, Portugal, and Ireland, who are currently experiencing substantial economic hardship. In these nations, the medical device industry could provide additional support to develop and maintain TAVR programs. As was the case with drug-eluting stents and ICDs, the introduction of competitive TAVR systems should decrease procedural costs and consequently increase TAVR adoption.

Procedural reimbursement and healthcare funding are critical factors in determining the adoption of new medical device technology. Previously, these factors were shown to influence the use of ICDs and coronary stents. In the current study, TAVR use and the number of TAVR implants per center were found to be higher in the presence of nationwide TAVR-specific reimbursement schemes than restrictive reimbursement schemes. The impact of restrictive reimbursement systems was evident in the United Kingdom, Spain, the Netherlands, Belgium, Portugal, and Ireland. We also observed a trend toward increased TAVR use in nations in which social insurance rather than taxation was the principal source of healthcare funding ($p = 0.056$).

Our estimates of TAVR penetration suggest that TAVR remains underutilized in Western Europe. Although the TAVR penetration rate in 2011 was >30% in Germany and Switzerland, the weighted average penetration among the 11 nations studied was 17.9%, and penetration rates were <15% in two-thirds of countries. The adoption of new technology can be a slow process. It requires a threshold of robust clinical evidence, device iteration, physician training, and clinical and financial planning. Moreover, the cultural change required to embrace new therapies often evolves gradually. Given the therapeutic benefit associated with TAVR in inoperable patients (number needed to treat = 5) (1), the demonstrable cost effectiveness in both excessive and high-risk cohorts (17–19), and the less invasive nature of TAVR procedures, the protracted uptake of TAVR technology may have negative consequences for patients, physicians, and administrators. Although TAVR penetration is not necessarily a surrogate for quality of medical care, it may suggest the need for enhanced patient access to novel and potentially life-saving therapies. Indeed, it is interesting to speculate that in nations with higher TAVR penetration rates, a move toward treating patients at less extreme surgical risk may be emerging (20).

The impressive clinical trial outcomes with TAVR are attributable, in part, to the participation of experienced physicians and institutions. These outcomes are not necessarily reproducible in lower-volume settings (21–23). For these reasons, volume-based guidelines for catheter-based and surgical procedures exist (24,25). The recommended centralization of TAVR procedures in high-volume tertiary referral centers aims to ensure adequate operator and center volume for these complex procedures (26–28). National health technology assessments and position papers have suggested that each center perform a minimum of 24 TAVR procedures per annum (27,29,30). We observed centers with low procedural volume and therefore nonadherence to these criteria in several nations. In particular, centers in Ireland, Belgium, and Spain performed on average less than 20 implants in 2011. Two distinct observations explain the low procedural volume: 1) low number of TAVR implants per million population (Ireland); and 2) excessive number of TAVR centers (Belgium and Spain). The reasons for the variation in the number of TAVR centers per million population and center volume across nations are unclear. National political and financial concerns, healthcare policy, population density and profile, reimbursement strategy, and cultural factors may be important in determining the number of centers in each nation.

The way complex medical technology is disseminated has been revolutionized by TAVR. Clinical site selection, mandatory physician and team training, and detailed algorithms outlining patient selection have become the standard of care. Nevertheless, the variation in the adoption of TAVR in Western Europe is clear. Physicians, medical societies, the medical device industry, and other stakeholders have a responsibility to ensure the appropriate use and sensible dispersion of this innovative technology.

Study limitations

Several limitations are of note. First, although every attempt was made to ensure the validity of the implant data, both data sources should be considered to be estimates. Registry data may underestimate the true scale of TAVR use because some cases or small implant centers may not have been included. Secondly, the estimates of TAVR use are likely to have included patients treated for off-label indications, such as patients at lower surgical risk, which may have affected the estimates of TAVR penetration.

CONCLUSIONS

Despite the rapid adoption of TAVR across Europe, our findings indicate that a sizeable treatment gap remains for high/prohibitive surgical risk patients with severe aortic stenosis. National economic indexes and reimbursement strategies are closely linked with TAVR use and may explain the inequitable adoption of TAVR across nations.

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ABBREVIATIONS AND ACRONYMS

CE = Conformité Européenne
DRG = diagnosis-related group
GDP = gross domestic product
TAVR = transcatheter aortic valve replacement

APPENDIX

For supplemental tables and figures, please see the online version of this article.

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