Improving care pathways: Permanent Pacemaker Implantation (PPI) after Transcatheter Aortic Valve Implantation (TAVI)

Wilmington Healthcare

Contents

Acknowledgements

Wilmington Healthcare held an advisory board meeting in March 2020 to evaluate the treatment pathway for transcatheter aortic valve implantation (TAVI) and post-TAVI permanent pacemaker insertion (PPI). Our thanks to the members of the advisory panel for their expert input and contribution to the writing of this report:

- Professor Philip MacCarthy, TAVI operator, King's College Hospital NHS Foundation Trust, Event Chair
- Professor Azfar Zaman, TAVI operator, The Newcastle Upon Tyne Hospitals NHS Foundation Trust
- Professor Neal Uren, TAVI operator, NHS Lothian
- Dr James Cockburn, TAVI operator, Brighton and Sussex University Hospitals NHS Trust
- Dr Stephen Dorman, TAVI operator, University Hospitals Bristol NHS Foundation Trust
- Dr Iqbal Malik, TAVI operator, Imperial College Healthcare NHS Trust
- Dr Douglas Muir, TAVI operator, South Tees Hospital NHS Foundation Trust
- Dr Muhiddin (Mick) Ozkor, TAVI operator, Barts Health NHS Trust
- Dr David Smith, TAVI operator, Swansea Bay University Health Board

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Foreword

As in so many areas of healthcare, increased demand for TAVI procedures for patients with severe aortic stenosis (AS) has not been matched with a proportional increase in available resources in recent years.

Increasing numbers of patients with AS are waiting for TAVI in the UK and this situation will have worsened after the COVID-19 pandemic. A number of these patients will require pacing, but different centres across the UK have different approaches in terms of patient management and technology choices, and there is significant variation in the rate of post-TAVI PPI across centres. A unified strategy is required to ensure that patients receive a consistent level of care, with the aim of reducing waiting times to access TAVI, reducing PPI where possible and optimising patient outcomes.

PPI post-TAVI increases the hospital mean length of stay (LOS), which presents a capacity issue, especially in light of the COVID-19 pandemic, so it is important that a clearly defined and integrated 'best practice TAVI pathway' is developed with a standardised protocol for PPI embedded within it.

This advisory board meeting highlighted that there is much scope to increase the capacity for TAVI procedures within the NHS by the introduction of true integrated care, which could improve the referral pathway for patients and increase the efficiency of tertiary centre multidisciplinary teams.

Prof Phil MacCarthy
Event Chair and TAVI operator,
King's College Hospital NHS Foundation Trust

Executive summary

The demand for TAVI procedures continues to rise as rates of degenerative heart valve disease (HVD) increase, the most common form of which is aortic stenosis (AS).

The complications associated with TAVI have become much rarer since the procedure was introduced over 12 years ago. However, the onset of new atrioventricular conduction disturbance requiring PPI remains a common complication. Data also suggest that the need for pacing is higher with the new generation transcatheter valves.

The expert panel of TAVI operators from tertiary centres highlighted the wide variation in TAVI pathways across the UK, stressing that there is no consistent approach to TAVI care pathways and likewise no consistent approach to PPI protocol following TAVI. Most PPI post-TAVI is associated with longer LOS and potential complications, so the approach to pacing within the TAVI patient journey warrants careful consideration. In addition, the longer-term benefits of TAVI in terms of symptom improvement appear lessened by PPI.

Developing consistent care pathways across geographical areas is challenging. Clinic set-up and procedure days vary, and importantly, bed availability differs between centres, which often drives decisions about immediate post-procedure care.

Equally challenging would be reaching agreement on a standard set of indications for TAVI approved by both NHS England and professional bodies. Guidelines setting out eligibility criteria for TAVI would enable more efficient use of limited multidisciplinary team (MDT) meeting time. Currently, MDTs often discuss all cases, which increases waiting times for patients. Clear eligibility criteria for TAVI would free teams to focus on 'grey-area' patients requiring more detailed discussions whilst "rubber-stamping" more straightforward cases. This approach would help to reduce time to decision and increase access to TAVI procedures by enabling smoother progress through the care pathway.

Different centres have different criteria for PPI following TAVI, both in terms of patient eligibility and timing of the procedure. Both hospital episode statistics (HES) and National Institute for Cardiovascular Outcomes Research (NICOR) data show significant variation in the rate of post-TAVI pacing between centres. A number of factors underlie this variation, including valve choice, patient age, severity of calcification present, comorbid conditions and when the TAVI procedure is completed (e.g. Friday procedures and the lack of weekend provision if a temporary pacemaker needs to be removed and replaced by a PPI).

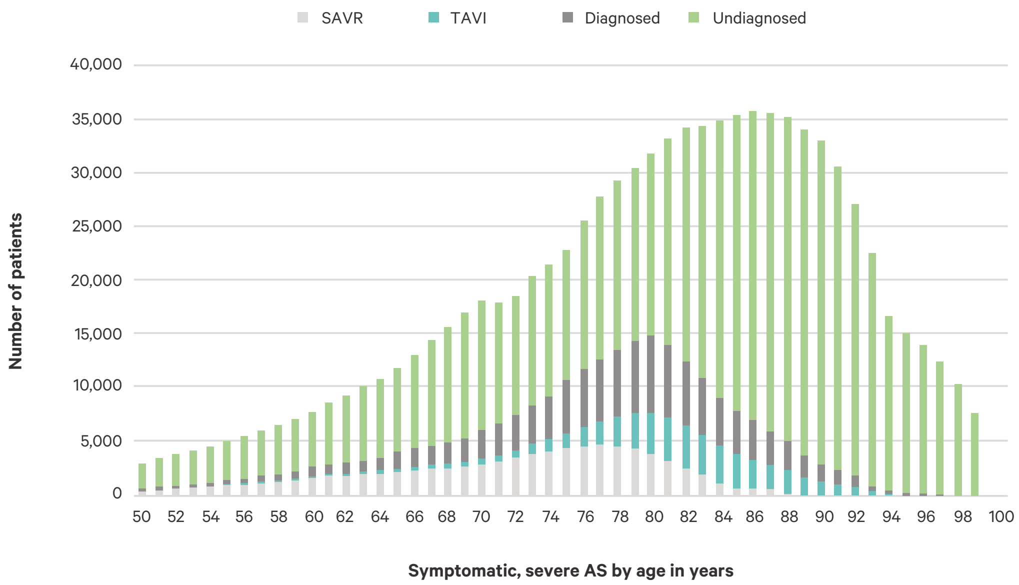
It is essential that an improved TAVI care pathway is developed which avoids patient delays and integrates a clear protocol for PPI. End-to-end integrated care pathways are central to the NHS Long Term Plan (2019)[1], both to enhance patient outcomes and to improve throughput of patients in secondary care. This pathway needs to encompass all aspects of care, including better HVD detection and referral in the community.

Introduction

Around 1.5 million people in the UK currently have moderate to severe HVD and numbers are expected to rise to 2.7 million by 2040[2]. This will present a significant challenge to the NHS and is highlighted in The NHS Long Term Plan (2019)[1] as a priority.

Aortic stenosis is the most common form of heart valve disease[3]. Figure 1 shows the level of severe symptomatic aortic stenosis (ssAS) in the population by age[4]. Note the high level of undiagnosed patients across all age groups, and the significant proportion of patients receiving TAVI who are aged 75 to 90 years.

Figure 1. ssAS population by age[4]



One of the most common issues following TAVI is the onset of new atrioventricular conduction disturbance, which requires the insertion of a permanent pacemaker. Figure 2 shows the rate of new PPI among different patient risk categories, which is higher among patients who have undergone TAVI compared with patients undergoing SAVR[5].

Figure 2. New PPI rate [6, 7, 8, 9]

Procedural complications from TAVI have reduced over time, aside from conduction disturbances that require PPI. Some reports suggest it is an outcome which is more likely with newer-generation transcatheter valves[10]. Conversely, with time, operators have modified deployment techniques to reduce trauma to the AV node and reduce permanent pacemaker rates.

The mortality data associated with PPI after TAVI is controversial. Some data suggest that PPI decreases short-term[11, 12, 13] but not medium-term[10] mortality. In younger patients, TAVI operators are generally reluctant to use PPI as there is concern about PPI reducing the symptom benefit of TAVI, even if mortality is not proven to be altered. TAVI operators are also reluctant to use PPI in younger patients, as the patient's life expectancy may result in the need for further pacemaker replacement.

PPI is associated with worsening left ventricular ejection fraction[11], increased repeat hospitalisation[11, 12] and longer LOS[14] – all of which contribute to worse patient outcomes and increased healthcare costs.

Expert perspectives

1. TAVI care pathways and PPI

1.1 No consistent pathway for TAVI and PPI

TAVI pathways need to be mapped out with PPI built into the patient journey with a consistent approach that optimises patient outcomes and service efficiency.

Care pathways for patients undergoing TAVI involve a number of steps and healthcare professionals and may also require PPI. The advisory panel observed that there is not a consistent TAVI pathway across services, nor a consistent protocol for PPI.

Although PPI post-TAVI increases the complexity of the pathway and results in LOS and increased readmission rates, it is not always factored into the TAVI patient pathway.

When performing TAVI, operators look for rhythm disturbances to assess whether PPI is required during procedure. Post procedure patients continue to be monitored for up to 48 hours, to assess the need for PPI insertion (subsequent to the TAVI procedure but generally within the same spell of care). Other patients will have pacing issues after discharge and be managed in secondary care under a separate spell.

Historically, the major focus in tertiary centres has been on the identification of AS and early referral for treatment. Pacing has not necessarily been considered as something to address during assessment.

1.2 Post-TAVI protocol

There is not a consistent approach to the care of patients immediately following a TAVI procedure. Limited bed availability is a key factor and as a result, some TAVI teams are performing fewer procedures per day.

Care decisions post-TAVI are frequently based on hospital bed capacity. This may also influence decisions on PPI, which is commonly associated with a longer LOS. Importantly, limited bed capacity is leading some TAVI teams to carry out fewer procedures per day.

The protocol post-TAVI varies between centres. Some centres mainly use non-specialist beds and rarely use the coronary care unit (CCU) for TAVI patients. Other centres generally use the CCU to ensure that early complications can be managed promptly and also because this approach ensures better bed availability. Cardiothoracic intensive care units (CICU) are also used for the same reason of bed availability. Some services operate a mixed approach, using a traffic light system to stratify patient risk to determine the level of monitoring required.

Ideally, uncomplicated low-risk TAVI patients would be transferred to an elective ward with 24–48 hours of telemetry and discharged unless PPI is required. A same-day or one night discharge policy is feasible in selected cases.

1.3 Delays in the TAVI pathway

Limited capacity in MDT meetings contribute to extending patient waiting times for TAVI.

Delays in the TAVI pathway increase waiting times for TAVI patients. There are three main issues that cause delay: communication between teams, waiting times for CT scan, echocardiogram, preadmission slots and delays in individual MDTs.

Communication efficiency varies between district general hospital (DGH) cardiology teams, who make TAVI referrals, and the specialist teams at the centres where procedures are performed. For example, in Wales and Scotland the national picture archiving and communications system (PACS) portals enable access to patient imaging, whereas in England the situation is more complicated and reliant on the capabilities of each individual PACS, which often presents a barrier for specialist teams.

Improvements to IT systems would facilitate the TAVI care pathway by providing staff with better communication:

- A template of the referral information required by the specialist centre
- Access for TAVI operators to patient imaging performed elsewhere
- Real-time updates for DGH consultants to appraise them of the treatment decision-making process and clarify care responsibilities.

Real time communication between DGHs and tertiary centres, helps to facilitate a smoother care process for patients.

Among individual MDTs, the MDT meeting is recognised as a bottleneck in the TAVI pathway for patients. Currently, MDT meetings often focus on patient eligibility for TAVI. Development and wide dissemination of a standard approved set of eligibility criteria would allow MDTs to focus on discussing the approach to any particular TAVI procedure. This would ease pressure on MDT time and enable teams to use their time more efficiently and to cover more patients. However, in high risk patients, the use of the MDT is valuable to provide the best evidence-based care and expansion of MDT capacity to more than 1 per week, and addition of the severe symptomatic aortic stenosis (SSAS) surgical case load would be valuable.

Eligibility criteria of the recognised indications for TAVI would need to be endorsed by NHS England and the professional bodies. By establishing a protocol for TAVI approvals, patient waiting times could be significantly reduced.

Develop standard approved eligibility criteria for TAVI to enable MDT time to be reserved for discussion about the TAVI procedure approach in individual cases and whether TAVI or SAVR is more appropriate for certain ‘grey-area’ patients. However, all SSAS cases being discussed at the MDT, including those considered “surgical” would be best practice.

2. Variations in pacing rates post-TAVI

There is no consistent approach to addressing conduction disturbances and PPI, which indicates a wide variation in care across the United Kingdom. It is important that there is a standard protocol for PPI following TAVI.

The panel highlighted the variations in pacing policy between centres, including differing criteria for when pacing is considered following TAVI. Analysis of Hospital Episode Statistics (HES) data by Wilmington Healthcare reveals the extent to which pacing practice post-TAVI varies across England (see Figure 3)[14].

Examples of criteria for pacing in different centres:

- Complete heart block during the case
    - Doubts were raised about whether complete heart block alone was enough to indicate need for PPI immediately following TAVI, which sometimes resolves in the days following the procedure.
- Complete Heart Block after the case has ended
- PR interval greater than 280 milliseconds with broad left bundle branch block and complete heart block.
- QRS duration is considered alongside the PR interval. Complete heart block and left bundle branch block with a PR interval greater than 200 milliseconds and a QRS greater than 160 milliseconds at particular centres, reported by panel clinicians leads to pacing. At this centre, a patient with a PR interval of, for instance, 300 milliseconds but a QRS of 120 milliseconds would not be paced, assuming telemetry showed no issue for 48 hours, as research suggests that there is an increased risk of sudden death if a patient has left bundle branch block and a QRS above 160 milliseconds[15].

Figure 3. TAVI and PPI rate by specialist centre in England[14]

Specialist centre	TAVI whole cohort – 2016/17–2018/19 and ranking	Permanent pacemaker (sub-cohort) 2016/17–2018/19 and ranking
Barts Health NHS Trust	1,110 (9.7%), 1	75 (8.6%), 2
Royal Brompton & Harefield NHS Foundation Trust	795 (6.9%), 2	105 (12.1%), 1
Leeds Teaching Hospitals NHS Trust	755 (6.6%), 3	45 (5.2%), 7
Guy's and St Thomas' NHS Foundation Trust	645 (5.6%), 4	30 (3.4%), 10
Oxford University Hospitals NHS Foundation Trust	515 (4.5%), 5	65 (7.5%), 3
Imperial College Healthcare NHS Trust	510 (4.4%), 6	30 (3.4%), 13
University Hospitals Birmingham NHS Foundation Trust	485 (4.2%), 7	35 (4.0%), 9
Liverpool Heart and Chest Hospital NHS Foundation Trust	475 (4.1%), 8	15 (1.7%), 18
Brighton and Sussex University Hospitals NHS Trust	460 (4.0%), 9	65 (7.5%), 4
The Royal Wolverhampton NHS Trust	430 (3.8%), 10	10 (1.1%), 23
University Hospitals of Leicester NHS Trust	430 (3.8%), 11	55 (6.3%), 5
Royal Papworth Hospital NHS Foundation Trust	400 (3.5%), 12	10 (1.1%), 21
University Hospitals of North Midlands NHS Trust	390 (3.4%), 13	35 (4.0%), 8
University Hospitals Bristol NHS Foundation Trust	355 (3.1%), 14	45 (5.2%), 6
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	330 (2.9%), 15	30 (3.4%), 12
South Tees Hospitals NHS Foundation Trust	325 (2.8%), 16	20 (2.3%), 16
St George's University Hospitals NHS Foundation Trust	320 (2.8%), 17	30 (3.4%), 11
University Hospitals Plymouth NHS Trust	300 (2.6%), 18	15 (1.7%), 19
Blackpool Teaching Hospitals NHS Foundation Trust	300 (2.6%), 19	15 (1.7%), 20
University Hospital Southampton NHS Foundation Trust	295 (2.6%), 20	25 (2.8%), 14
King's College Hospital NHS Foundation Trust	290 (2.5%), 21	20 (2.3%), 15

Figure 3 shows that there is wide variation in the number of TAVI procedures undertaken in the last three years by the specialist centres in England. Possible explanations for this include differing demographics of patients in centres, different care pathways protocols, variability in funding across commissioning organisations, time taken by DGHs to refer patients to specialist centres, and the individual hospital recovery set-up within each specialist centre. The data also point to a very large variation in the PPI rate across England, from 1.1% up to 12.1% of the whole TAVI population over the last three years of HES data in different centres.

Investigating the reasons behind the variation in PPI between centres would help us to understand whether this range is justified or whether it can be reduced.

Meanwhile data from across European registries shown in Figure 4, including the National Institute for Cardiovascular Outcomes Research (NICOR), and NHS HES data in Figure 5, reveal similar pacing variation from country to country, ranging from 7.5% to 18.1%.

There may be underreporting because NICOR data are not always accurately recorded, particularly if the pacemaker is implanted a few days after the TAVI procedure.

Figure 4. European data for PPI rates

Country	STS/EuroScore	PPI rate (baseline)	New PPI rate	Source
Germany	5.6 (STS)	12% (762/6,368)	18.1% (1,014/5,606)	GARY registry[16]
France	18.9 (EuroScore I)	14.3% (2,404/168,000)	16.3% (2,316/14,229)	France TAVI[10]
Sweden	6.6 (EuroScore II)	(total patients: 1,102)	7.5%	SWENTRY registry[17]
NICOR 2017	22.9 (EuroScore)	(total no. TAVI: 3,778)	11.3% (427/3,778)	NICOR[18]

(STS: Society of Thoracic Surgeons Risk Score)

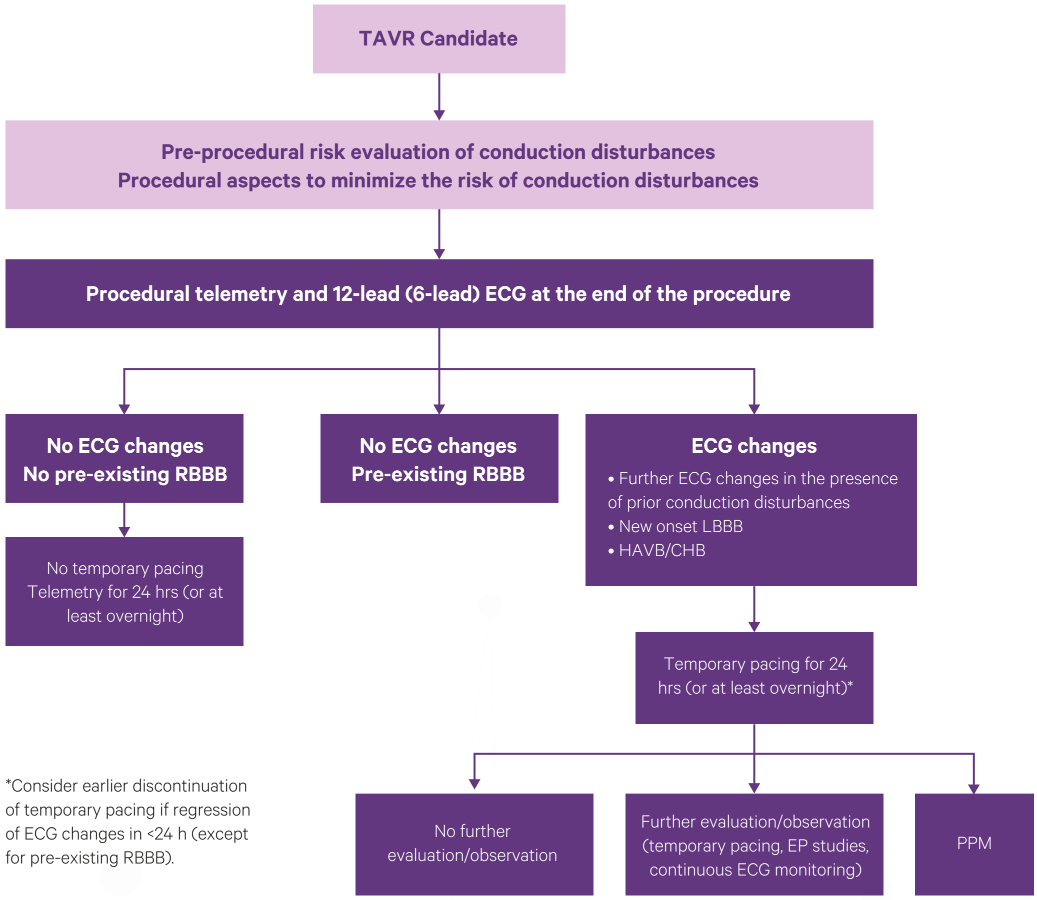
Figure 5. English hospital episode statistics data for Total TAVI and PPI (2016/17–2018/19)[14]

HES data	TAVI whole cohort	Existing pacemaker coded (sub-cohort)	No pacemaker coded (sub-cohort)	Temporary pacemaker (sub-cohort)	Permanent pacemaker (sub-cohort)
Number of spells	10,230	1,250	3,865	4,335	780

There is no single factor underlying this variation in pacing, and it is likely a result of many different variables. Case mix is an important issue, as some centres may be performing TAVI procedures on older, more complex patients who are more likely to require pacing. In addition, deployment height is related to pacing rates, and the newer techniques of high deployment may reduce rates in the future.

Figure 6. Strategy algorithm proposal for management of patients with conduction disturbances post TAVI[19]

Central Illustration: Strategy Algorithm Proposal for the Management of Patients With Conduction DIsturbances Post-Transcatheter Aortic Valve Replacement



EPS = electrophysiologic study; HAVB/CHB = high-degree atrioventricular block/complete heart block; LBBB = left bundle branch block; PPM = permanent pacemaker implantation; RBBB = right bundle branch block.

It should also be noted that different valves are associated with different pacing rates. A meta-analysis[20] including 11,210 patients undergoing TAVI, showed a median PPI rate of 6% following insertion of an Edwards SAPIEN valve and 28% after insertion of a Medtronic CoreValve. While pacing rate is one consideration, it is not the only factor that influences valve choice, and certain valves have useful application for particular patient profiles.

Clinicians take a number of issues into account when choosing a TAVI device; the risk of paravalvular leak (PVL), which if severe is associated with very poor outcomes, the presence and degree of calcification, the risk of annular rupture, and the ability to perform transfemoral TAVI are considered more pressing concerns than pacing rate. Pacing rate is not a major discriminator, especially among older people, whereas for younger people it has more importance. The panel felt there was a limited amount they could do to further influence the risk of PPI following a TAVI procedure.

Clinicians may benefit from the development of an algorithm involving two or three different valves in order to offer best possible care to a TAVI cohort ranging from 65 years of age to over 85.

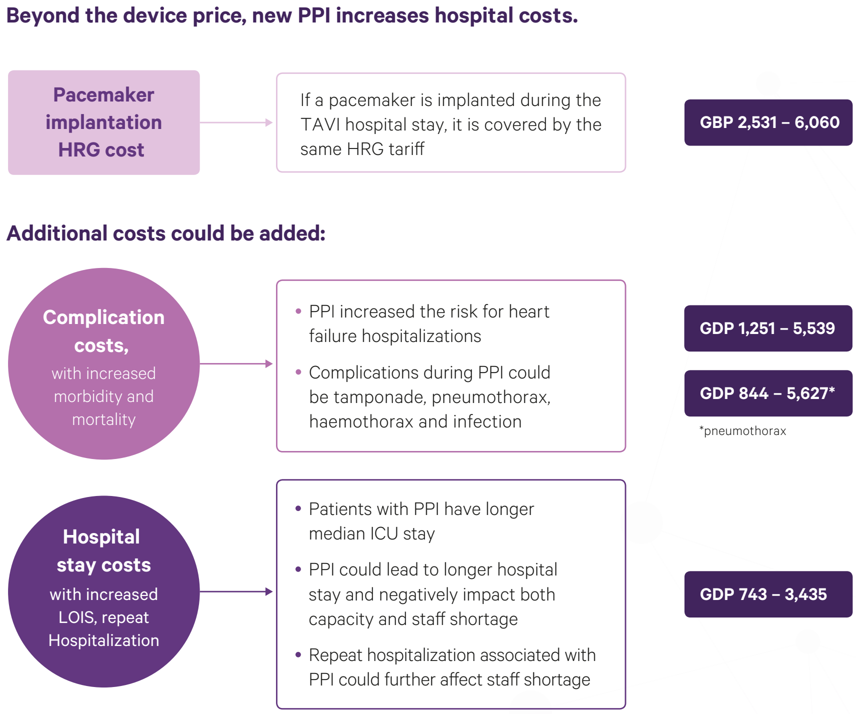
Further research is required to guide clinicians on which patients are likely to need PPI post-TAVI, its likely impact, and the stage at which PPI should be implanted.

3. Clinical and economic impact of PPI

PPI has an impact on complications, survival and cost of treatment.

The high cost of TAVI is offset by service optimisation through shorter mean LOS of the procedure compared to SAVR. However, if pacing is required, this can increase the overall cost of the pathway (see Figure 7[21]).

Figure 7. New PPI has a negative economic and organisational hospital impact[21]



(HRG: healthcare resource group)

It is important to understand the full integrated TAVI care pathway and longer-term associated costs, which are not captured alone by clinicians working in the specialist centre. Some complications may arise sometime later in the context of secondary care. Potential complications associated with PPI post-TAVI:

- Increased mortality and morbidity[22, 11, 12]
- Increased risk for hospitalisation with heart failure[18,19]
- Increased risk of tamponade, pneumothorax, haemothorax and infection[17]
- A longer mean length of stay
- Higher rates of hospital readmission at 30 days

The last two points are reinforced by HES data analysis performed by Wilmington Healthcare and cover the last 3 years of HES data (see Figure 8). This shows that mean LOS is 2.8 days more for patients receiving a PPI. The mean LOS in admissions involving critical care is increased by 3 days, and readmission rate (to any specialty within 30 days) is 7.9% higher, while readmission rate to cardiology in the first year is 7.7% higher.

Figure 8. HES data 2016/17–2018/19[14]

HES data 2016/17–2018/19	TAVI (whole cohort)	Permanent pacemaker (sub-cohort)
Mean length of stay (days)	7.8	10.6
Mean length of stay in admissions involving critical care (days)	9.1	12.1
Patients readmitted to any specialty within 30 days (% of patients)	1,645 (13.6%)	210 (21.3%)
Patients readmitted to cardiology, cardiac surgery or cardiothoracic surgery within 1 year	1,260 (12.3%)	155 (20.0%)

It is worth noting that PPI may be inserted at the same time as the TAVI procedure, or within a couple of days. Both of these scenarios are captured under one spell of care (see definition of 'spell', see definition in box below and therefore may include more than one care episode). In this case, the cost of the PPI procedure is covered by the TAVI procedure tariff and thus will not earn its own tariff. Other patients will receive PPI subsequent to the TAVI spell of care should a conduction disturbance occur sometime later. The cost of the PPI procedure in this case is not covered by the TAVI tariff and is an extra expense for the provider but may allow a separate tariff to be negotiated with commissioners.

It is worth noting that readmission costs are charged to the hospital trust if they occur within 30 days of the procedure; after 30 days the cost is paid by the clinical commissioning group (CCG).

Definition of spell: A hospital provider spell is the total continuous stay of a patient using a hospital bed on premises controlled by a health care provider during which medical care is the responsibility of one or more consultants, or the patient is receiving care under one or more nursing episodes in a ward.

It would be worth understanding if the pacemaker is the cause of the readmission; or an underlying comorbidity that has necessitated the TAVI in the first place. Patients undergoing TAVI are generally higher-risk patients, and it is possible that readmissions are more likely among older, more frail patients who are discharged earlier post-TAVI.

The panel highlighted that PPI can potentially have a psychological impact on patients; learning that a pacemaker is necessary can be difficult even if explained on the consent form.

While installing TAVI and PPI in the same procedure is efficient, this has knock-on effects for the day's procedure list, and it can be beneficial to observe a patient post-TAVI to determine whether PPI is essential, although – however, this clearly then has an impact on LOS.

PPI has an effect on post-TAVI mortality, although predicting the impact in individual cases is challenging. Pacing among younger patients is controversial, since evidence suggests that PPI decreases short-term mortality[11, 12, 13] but increases mortality over the longer term[10]. It is not ethical to carry out a randomised controlled trial on PPI for patients in complete heart block following TAVI as PPI is the only viable treatment option available.

Studies focus on the highest-risk patients who tend to be patients who develop complete heart block and need a pacemaker. This cohort is likely to be older patients with comorbidities (including those that may sometimes emerge once the valve has been replaced), a fragile conducting system, poor left ventricular function and more annular calcification. Furthermore, protocols on when to pace TAVI patients vary between centres. Patient profile may therefore have a large effect on the observed short- and long-term mortality effects of PPI.

Further data is needed to understand the impact of PPI post-TAVI to identify the optimal protocol for patients.

Conclusion

Pacing is recognised as an important issue, particularly in changing the risk profile of TAVI patients. Yet there is wide variation in practice across the UK for many aspects of the TAVI pathway, and no standardised pacing protocol. This is an area which requires further discussion to agree best practice guidelines for clinicians in order to minimise rates of PPI post-TAVI, valve choice should be made by clinicians in an MDT setting and to enable patients to have an informed choice about their treatment plan. There is particular need for more data to understand how PPI impacts patient outcomes over the long term and to help guide both case and device selection, especially among younger patients.

Glossary

AS	Aortic stenosis
CCG	Clinical commissioning group
CCU	Coronary care unit
CICU	Cardiothoracic intensive care unit
DGH	District general hospital
HES	Hospital episode statistics
HRG	Healthcare resource group
HVD	Heart valve disease
LOS	Length of stay
MDT	Multidisciplinary team
NICOR	National Institute for Cardiovascular Outcomes Research
PACS	Picture archiving and communications system
PPI	Permanent pacemaker implantation
PVL	Paravalvular leak
SAVR	Surgical aortic valve replacement
ssAS	Severe symptomatic aortic stenosis
STS	Society of Thoracic Surgeons Risk Score
TAVI	Transcatheter aortic valve implant

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Wilmington Healthcare
5th Floor
10 Whitechapel High Street
London
E1 8QS

T +44 (0)20 7490 0049
E info@wilmingtonhealthcare.com
W www.wilmingtonhealthcare.com